WEARABLE eHEALTH SYSTEMS FOR PERSONALISED HEALTH MANAGEMENT

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Wearable eHealth Systems for Personalised Health Management

State of the Art and Future Challenges

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PREFACE

The first International Workshop on *New Generation of Wearable Systems for eHealth* took place in Lucca, Italy, 11–14 December 2003. It is a significant milestone in the dissemination and promotion of this new multidisciplinary area which is expected to play an important role in the evolving health care and health delivery sector, in Europe and world-wide.

The management and coordination of healthcare throughout the entire range of services, from primary to tertiary care, are undergoing fundamental changes such as, more emphasis on prevention and education of users, new ways of delivering care, integrated disease management, empowerment of individuals to manage their own health and overall provision of efficient and cost-effective services. The incentives arising from the need to optimise the use of healthcare budgets and provide quality services and equal access, contributed to the significant development of health telematics, telemedicine and eHealth during the last 15 years.

Extraordinary achievements in science and technology e.g. genomics-proteomics, micro- and nanotechnology, mobile communications, human-computer interface and knowledge management offer for the first time the possibility for new approaches in health, healthcare management and services provision. This includes solutions to support personal health monitoring, early warning and timely intervention, lifestyle management and remote collaboration with health professionals. Daily life activities support and risk management for elderly people and chronic patients can also benefit by these ongoing technological developments.

The new generation of wearable personal eHealth systems has to be affordable, user-friendly, "invisible", autonomous in terms of power consumption and able to assist individuals in their own health management. Major challenges are ahead such as further research and development, user acceptance and trust, cost effectiveness and business models. Intelligent Biomedical Clothing and biomedical sensors are becoming major driving forces for cutting edge developments. The synergy and close collaboration of all involved disciplines and sectors is of paramount importance.

The workshop on *New Generation of Wearable Systems for eHealth* was designed to fit the need of the international research community to share advances and brainstorm on future activities in the field. This book has its background in the workshop, and includes full papers describing developments and trends all over the world in the areas of smart wearable monitoring and diagnostic systems, smart treatment systems, biomedical clothing and smart fibres and fabrics. It also covers non-research aspects such as citizens' and patients' needs, interoperability, risk management and market perspectives. The chapters mirror the workshop and are preceded by a short executive summary which highlights the main issues, findings and conclusions for the convenience of the reader.

The participation of the major actors involved in research, development, decision making and business should make this book unique and a pioneer in the field.

The Editors
Dr. Andreas Lymberis
Prof. Danilo De Rossi

Message from the organizers

The 1st International Workshop on "New Generation of Wearable Systems for eHealth" is a unique event focusing on smart personal health management through synergies among diverse engineering and research fields e.g. biomedical, telecommunications, software, and textile.

It follows up and consolidates the workshop organised in Brussels in April 2002 by the European Commission, to brainstorm on the thematic area of Intelligent Biomedical Clothing for preparation of the 6th R&D Framework Programme of the EC.

The main goal of the workshop is to report and promote progress in cutting-edge research, disseminate information and facilitate cross-fertilization and collaborations.

The second goal is to provide awareness to users, health providers and other stakeholders. The programme emphasises the immense progress of technologies and their contribution to reconfigure health provision in individual and community level. Great constraints in healthcare budgets, needs for patient consent, acceptance and privacy, major breakthrough in user-friendly, fault tolerant and cost-appropriate technologies are also key factors that necessitate in-depth analysis. The sessions and the round table are build in a way that major problems relating to smart wearable and implantable health systems are presented and discussed in order to seek solutions by involving researchers, industrials and decision makers from several specialities and sectors.

On behalf of the organising team I would like to thank all those who worked so hard to make this event successful. Special thanks are addressed to the workshop collaborators, the European Commission, IEEE-EMB, IEE and AIIMB, as well as to the sponsors, Philips Research Medical Division, M-Wear Team, CSEM and Messe Frankfurt.

Prof. Danilo de Rossi
On behalf of the organisers

Acknowledgments

The Editors want to thank all authors for their contribution to this book, and Stavroula Maglavera and Andriana Prentza for drafting the minutes from the various sessions which were helpful for producing the sessions' executive summaries. The Editors are grateful to Francoise Hannecart for the support in the editing of the papers. Special acknowledgment is addressed to Silas Olsson for his continuous support and advice for the improvement of the book.

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Health in the Information and Knowledge Economy Age – A European Perspective

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Abstract. The health sector today faces great challenges. Health is an information-intensive sector where Information and Communication Technologies (ICTs) could significantly contribute to efficiency and productivity gains. European Union is looking at the different facets of eHealth and mainly at the following three:
a) Research and development, in particular to support the development of several regional health information networks, telemedicine services, and personal health systems for patients and citizens.
b) Regulatory framework and standardisation, which ensure competition, interoperability and, at the same time, the confidentiality of personal data.
c) Promotion of eHealth best practices through various eEurope 2002 and 2005 initiatives.
After the pharmaceutical and radiology industry, eHealth is now the third industrial pillar for health. This emerging sector forms the backbone for the reengineering of health systems. It actually improves the access to and quality of care and places citizens at the very centre of its concern.

1. Challenges of the Health Sector

All European countries are currently trying to find ways to sufficiently address the challenges the health sector faces. The citizens demand more efficient and responsive health care services. However, this can not be easily done without significant increases in operational costs.

The recent economic slowdown in conjunction with the ageing problem does not leave enough space to the policy makers for significant increases of the health budgets. With a considerable rise in average life expectancy gains[2] and with more citizens passing this critical age threshold the required public finances for covering healthcare costs have been in steady increase.

The problems, thus, is how to improve the quality of the provided healthcare services without increasing the costs in a challenging social and economic environment. Infor-

[1] The views developed in this paper are that of the author and do not reflect necessarily the position of the European Commission

[2] According to the projections of the United Nations, OECD countries are likely to experience increases of between 3 and 4 years in the life expectancy of their populations up to 2030 (OECD, 1998). It is anticipated that rates of growth in numbers of people passing the age of 80 across OECD countries average to 70 per cent (OECD, 1995). In addition, persons aged 80 and over are the heaviest users of medical care.

mation and Communication Technologies (ICT) have proven to contribute to the productivity gains of institutions and the consequent reduction of the related costs. ICTs are used already with great success for administrative and healthcare purposes. However, as the ICTs are becoming smaller, faster, wireless and remotely controlled, new opportunities are being created for new medical tools and systems. Recently, the Internet and the web have opened up new opportunities for improving the response time of health care services and simultaneously reducing the costs (e.g. through telediagnosis).

As the penetration of PCs and the Internet in Europe is increasing, a critical mass of general practitioners and users for the provision of online health care services is being created. Eurobarometer surveys have showed a steady rise in the rate of Internet connections by general medical practitioners. The 2002 survey showed that, on average, 78% of EU medical general practitioners were connected to the Internet, with 100% connected in the UK and 98% in the Nordic countries. The use of the Internet to deliver patient care is also growing. On average, 48% of medical practitioners use Electronic Health Care Records and 46% use the Internet to transmit patient data to other care providers for the purposes of continuity of care. However, a fully interactive use of the Internet to deliver care to patients through the provision of, for example, e-mail consultation (12%) or allowing patients to book appointments on line (2%) appear to be in its early stages.

It becomes evident that we are at the early stages of a new era that will completely change the way the healthcare services are/will be offered. Significant efforts should be devoted to the research, development, promotion, and diffusion of new eHealth services and technologies. According to a study realised by Deloitte & Touche, the eHealth or Health Telematics sector is becoming the third industrial pillar of healthcare area after the pharmaceutical and the medical (imaging) devices industries. It is estimated that the health expenditure on ICT systems and services would rise from 1 % in 2000 to 5% by 2010, and that the market would offer reliable and affordable personal health systems assisting citizens to manage their lifestyle.

2. The eHealth RTD Activities

The last ten years the eHealth[3] activities of the Directorate General, Information Society at the European Commission have funded through several Framework programs (e.g. Telematics and Information Society Technologies) innovative research and development actions in several areas. The final goal of these activities is to contribute to the Lisbon Strategy through RTD in intelligent environments that enable ubiquitous management of citizens' health status and assist health professionals in coping with major health challenges.

2.1. Vision

The main vision behind these activities is to improve access, quality and cost efficiency of health care services through innovative ICTs by

- delivering health care services online to reduce unnecessary duplicate examinations and waiting queues,

[3]Official Web Site of the *e*Health Unit: http://www.cordis.lu/ist/directorate_c/ehealth/index.html

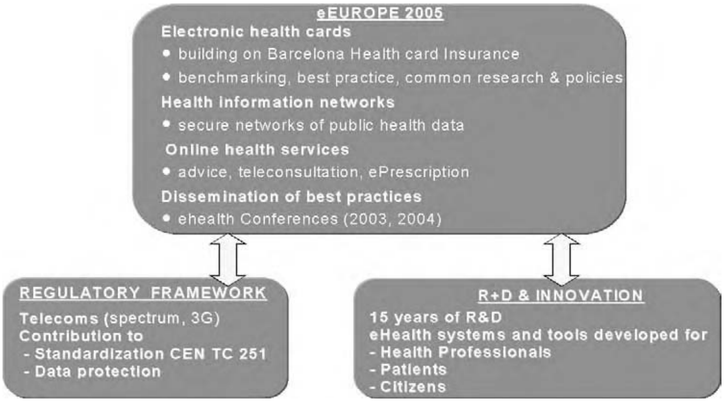

Figure 1. Overall Activities of the eHealth Unit.

- enabling patients to participate, with better knowledge and responsibility, in the processes of care and rehabilitation, through intelligent monitoring systems as well as through relevant and personalised health information,
- developing an intelligent environment that enables citizens to manage their well-being through access to qualified sources of health information and active participation in illness prevention,
- providing health professionals with access to timely relevant information at the point of need, new tools for better management of risk and systems to acquire up-to-date biomedical knowledge and facilitating health authorities to manage properly the on going reorganisation of health delivery systems.
- fostering co-operation of health care providers at regional, national, and European level

2.2. *Research and Innovation Activities*

The focus of research and innovation activities of the *e*Health activities is the implementation of the 6th RTD Framework programme and more specifically to develop, contribute and promote to the following activities:

- smart and wearable biosensor technology (intelligent clothing and textiles) and implants that interact and communicate with other systems and health points of care for the ubiquitous monitoring of health status leading to better management of well being and improved disease prevention and treatment of patients,
- ICT systems supporting health knowledge management, interoperability of health information sources, medical ontology, clinical guidelines development, and method for decision support and risk analysis, evidence based medicine and risk management,
- knowledge in the areas of medical informatics, bioinformatics and neuro-informatics that enable disease prevention and therapy and tools enabling the individualisation of diagnoses and treatment,
- initiatives that help create the European Research Area (ERA) in the field of *e*Health by co-operating with related initiatives, programs and policies of Member States

In addition to the above, dissemination of best practices and implementation issues are also being supported through:

- active contributions to major non-research policies such as *e*Europe and regional policies, such as supporting the *e*Health action plan for *e*Europe 2005
- implementation of FP5 activities by exploiting synergies between projects and external activities, by disseminating achievements and by maximising impact.
- co-ordination and interaction with other European Commission services involved in activities related to *e*Health
- promoting international collaboration both with developed countries in order to support standardisation, assessment and market creation as well as with developing countries to best benefit from the proven technology.

2.3. eHealth activities within the eEurope Action Plan

The focus of the eHealth activities within the eEurope Action Plan focus on:

- Electronic health card: to replace the paper-based health insurance card by an electronic one and support common approach to patient identifiers and electronic health records through standardisation,
- Health Information Networks: to develop health information networks between points of care (e.g. hospitals, labs, homes) with broadband connectivity,
- Online health services: to promote the high penetration and diffusion of online health services provided to the citizens.

2.4. Regulatory Activities

Major contributions to regulatory issues are being done through the research results of several R&D projects as well as special accompanying measures. In some cases, these R&D projects have significantly contributed to standards worked out at different international standardisation bodies.

Recently, the co-ordination of the activities related to the potential impact on health from the non-ionising radiation/electromagnetic fields (mobile phones) has been done by our Directorate.

3. Conclusions

The Health sector faces great challenges that need to be urgently addressed at different levels. In that respect, ICTs are critical enabling technologies that could improve access, quality and cost efficiency of health care systems.

eHealth is already a key component of the existing Health Care delivery systems and contributes to substantial productivity gains. However, more Research and Development in eHealth technologies is needed for facing the increasing demands. In particular the ambient intelligence systems for supporting disease management, prevention and well being offer numerous possibilities for cost-effective individualised health management.

The significant results of the European projects achieved in the last 10 years and the impact of them demonstrate that *e*Health could be the answer to the health sector problems.

I. Introduction to User Needs, Technological Concepts and Market Trends

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Executive Summary

This section introduces the global picture and future trends of eHealth, major issues relating to users' needs and expectations, new concepts and technologies and business opportunities in the domain of personal computerised health management. In particular, some major issues highlighted in the workshop session and not submitted as contribution to the book are summarized below.

The healthcare reform agenda is accelerating, virtually in all developed countries, and is being powered by a series of eHealth applications which started from hospital information systems and have now extended into homecare, eNursing, ePrescribing and eBooking. The paradigm shift in the eHealth sector resulted from the following main driving forces for change:

- Mandatory search for cost containment
- Changing demographics
- Decentralisation of healthcare delivery
- Changing disease patterns
- Impact of Information and Communication Technology (ICT) including IT support for clinical decisions, telemedicine and eHealth
- More informed and demanding patients
- Well-being factor and responsibility shift into patient hand
- Knowledge management

The focus of the future health services will be more in prevention than cure and this may happen with the wide spread use of vital signs monitoring of several user groups e.g. patients with chronic disease and elderly people. Therefore, the integration of monitoring capability into smart clothing seems to be one of the most promising user friendly and affordable solutions.

eHealth is a large scale multi disciplined area which corresponds to a broad field of applications spanning from clinical applications, (e.g. teleconsultation, clinical decision support, vital signs monitoring, home telecare, ambulatory eHealth, and ePrescribing) to personalized health professional continuing education and ePrevention through longitudinal healthcare event recording and lifetime health care records. eHealth must be human centred and requirement driven.

The impact of globalisation on healthcare delivery can be seen at several levels of society. Individuals' mobility creates new delivery paths and requirements for continuity and quality of care. To support "anywhere, anytime, always on" information access, an overall strategy for mobile access provision has to be carefully defined and regularly updated, for every users group, taking into account the locations in which the healthcare professional will be required to operate e.g. in the hospital, at home, on a patient visit (urban, rural), community centres, and GP's practices.

The full integration of ICT into health businesses, including organizational and legal aspects, is a very long process and requires re-engineering of the whole health delivery system.

The mission statement of eHealth in the EU is to make medical services – wherever sourced – ubiquitously available across Europe, to promote eHealth & Telemedicine across Europe at all levels, to identify barriers to eHealth & Telemedicine and use all means to overcome them, and to identify and promote eHealth technologies and solutions to achieve this aim.

Progress in science and technology offers many new possibilities and solutions that bring intelligence, speed, miniaturisation, sophistication and new materials at lower cost. The new possibilities for home care and ambulatory monitoring are provided through several technological platforms e.g. microsensors, wearable devices, smart devices and smart homes.

The current trends in healthcare and wellbeing lead to the development of a new market of personal healthcare that can be defined as “products and services to improve the health status and the personal performance outside institutional points-of-care”. Today products range from dedicated technical solutions for disease management over medical call centres to consumer offers for life critical situations, to home rehabilitation programs and fitness optimisation. The future outlook for wearable computing and Smart Fabrics and Interactive Textile (SFIT) for biophysical monitoring and position location applications is extremely strong.

However, the market of personal wearable healthcare is only at the early stage. Research and development faces several challenges such as the activity effects, the posture effects, the sensor placement effects, the baseline drift and the signal integrity. In addition, the time to market of the newly developed systems/prototypes is still long. Validation, compliance with regulations, property rights, the still high cost of technology and market opportunity assessment, slow down the commercialization process and reduce the chances for sustainable business cases. Several business models and reimbursement schemes are under consideration from manufactures and service providers, but also from national authorities and health insurances. Not to mention, of course, the education, the user acceptance, the ethical and social issues (e.g. resistance to new technologies) implied by the use of such systems.

The success of personal health and lifestyle management systems and services, possibly the next mass market after communication, will depend strongly on the positive positioning of the consumers.

Wearable eHealth Systems for Personalised Health Management
A. Lymberis and D. de Rossi (Eds.)
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New Concepts and Technologies in Home Care and Ambulatory Monitoring

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Abstract. The world is becoming more and more health conscious. Society, health policy and patients' needs are all changing dramatically. The challenges society is currently facing are related to the increase in the aging population, changes in lifestyle**,** the need for healthcare cost containment and the need for improvement and monitoring of healthcare quality. The emphasis is put on prevention rather than on treatment. In addition, patients and health consumers are waiting for non-invasive or minimally-invasive diagnosis and treatment methods, for home care, short stays in hospital, enhancement of rehabilitation, information and involvement in their own treatment. Progress in science and technology offers, today, miniaturization, speed, intelligence, sophistication and new materials at lower cost. In this new landscape, microtechnologies, information technologies and telecommunications are key factors. Telemedicine has also evolved. Used initially to exchange patients' files, radiographic data and other information between health providers, today telemedicine contributes to new trends in "hospital extension" through all-day monitoring of vital signs, professional activities, entertainment and home-based activities.

The new possibilities for home care and ambulatory monitoring are provided at 4 levels:

a) *Microsensors*. Microtechnologies offer the possibility of small size, but also of intelligent, active devices, working with low energy, wireless and non-invasive or minimally-invasive;

b) *Wrist devices* are particularly user friendly and combine sensors, circuits, supply, display and wireless transmission in a single box, very convenient for common physical activities;

c) *Health smart clothes* make contact with 90 % of the skin and offer many possibilities for the location of sensors. These sensors have to be thin, flexible and compatible with textiles, or made using textile technologies, such as new fibers with specific (mechanical, electrical and optical) properties;

c) *Health smart home*s. The aim of this method is to improve the patient's living conditions and to avoid the cost of long hospitalization. "Exosensors" are used for measurement of the activity and behavior of the patient. The field of applications is very large, e.g. continuous monitoring of elderly populations, professional and military activities, athletes performance and condition, and people with disabilities. This new healthcare approach has to take into account lifestyle for improving prevention. For the patient to be more and more involved in his/her own therapy, new responsibilities and ethics have to be defined. A "societal health education" has to be provided to physicians and to patients to get all the benefits of this new context.

Introduction

At the beginning of this new millennium, the world is becoming more and more health conscious and health care is evolving in many ways.

The patient's needs are evolving with the increase in information available and the new offerings of medical technology:

- Non-invasive or minimally-invasive methods for diagnosis and treatment;
- Home care, ambulatory methods, short stays in the hospital, telemedicine;
- Enhancement of rehabilitation engineering;
- Information and involvement of the patient in their treatment.

Health policy and society are changing:

- Limited health care budget and managed care;
- Improvement and control of healthcare quality;
- Prevention rather than treatment; prediction rather than response;
- Changes in society such as increase in aging population and lifestyle changes.

In the face of these changes, progress in science and technology offer, for the first time, many new possibilities and solutions, bringing miniaturization, intelligence, speed, full integration and functionality at low cost.

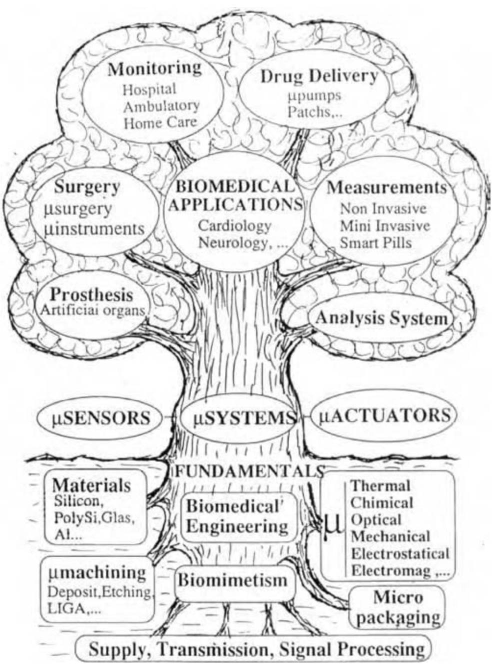


Figure 1. Microtechnology is a key factor for the development of biomedical wearable devices.
The tree of microtechnology is growing fast and its fruit are already numerous. As the root becomes stronger through the joint effort of researchers across disciplines, the tree will continue to grow and produce new and better-tasting fruits!

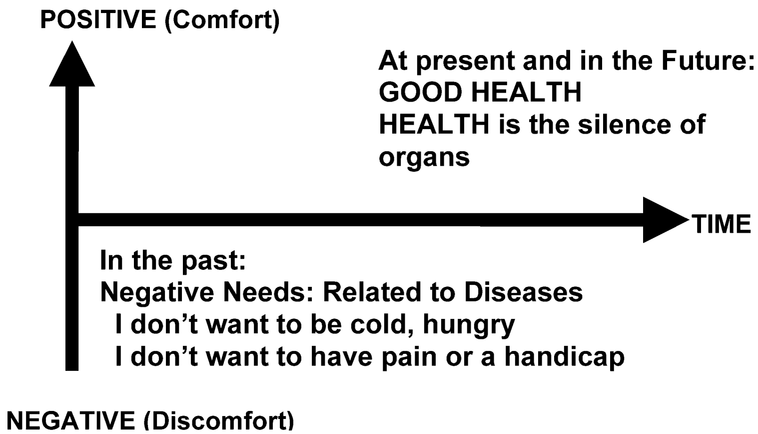


Figure 2. The basic needs of the people of industrial countries are evolving: at one moment a fact can be considered as a component of comfort and 10 years later it has become a basic requirement for quality of life.

In this new landscape of health and technology, microtechnologies, telecommunications and software engineering are key factors in attempts to meet the changing needs in medicine and biology and particularly in ambulatory monitoring and home care.

The basic fundamental needs (Figure 2) of human beings have existed for a long time and can be considered intrinsically "negative needs"; that is, people have sought to avoid cold, heat, hunger and thirst. Now, improvements in the standard of living have changed these needs, which are becoming more and more "positive" - citizens' needs are now related to comfort, pleasure and, more recently, to health and quality of life. In Western society in particular, there is a fundamental shift taking place from a concentration on basic, human needs to a more positive involvement with the citizens' quality of life and health.

Significant scientific progress in the fields of chemistry, physics, and genetics enable this development. Wearable health devices are becoming more sophisticated, and the care they provide is increasingly individualized. But do the risks counterbalance the benefits?

The future scientific direction – and policy direction in terms of health care monitoring and provision – is surely to encourage more sophisticated wearable devices, that are well and appropriately designed, simple and easy to use, but that also minimize risk.

1. The Need for Wearable devices and biomedical smart clothes [2, 13, 14, 16, 17, 29, 38, 39]

Intelligent biomedical clothes will act preliminarily as a source of patient data on his/her behavioral profile as it affects the cardiovascular risk profile, such as activity, stress, sleep and nutrition. Intelligent context-aware personalized algorithms will not only determine the situation but also provide adequate feedback for the user on how to change his/her behavior across all possible disease states.

Intelligent biomedical clothes act as a human interface for the ever increasing knowledge about health and translate this knowledge into personalized feedback for the user in any situation and with any disease status:

For healthy subjects

Interactive gaming and other self-motivational programs will help the user to enjoy a healthier lifestyle. The system will not only help the user to adopt a healthier lifestyle but will also effectively improve personal performance due to better fitness and more effective ways of coping with stress.

For citizens at risk

The system will provide adequate information on how to deal with individual risk factors and give advice on how to improve risks, like hypertension, being overweight, diabetes, physical inactivity and stress, through personalized training plans and motivation to change behavior. Early detection through long-term trend analysis will reduce the damage due to severe events dramatically. For example it will reduce the time to needle for myocardial infarction and stroke.

For post-event patients

These kinds of system can significantly improve the rehabilitation process and detect any complications at an early stage. Daily monitoring will enable new forms of personalized drug treatment and the self-administration of drug medication according to the specific behavior and circumstances of each individual.

For chronic patients

Intelligent biomedical clothes empower the user to better understand and self-manage the disease state. Early detection will limit acute events and complications that may lead to hospitalization and extended hospital treatment. The rehabilitation process will become a lifelong process in which patients and family are also actively involved.

The use of intelligent biomedical clothes will not only improve the situation for the user but will also enable medical professionals to react timely and specifically to the disease of an individual through significantly improved timely diagnosis and new forms of therapy and personalized treatment. It will help to improve the effectiveness of the healthcare system through cost-efficient access to the best care and it will empower each individual to have a longer and healthier life with increased personal performance. Intelligent biomedical clothes and wearable devices can act as a key enabler for a lifelong continuous health improvement process for all individuals.

The vision of continuity of care, integrating prevention, lifestyle and treatment of disease, was also adopted in ancient Greece. Asclepios, the father of medicine, was also the father of two daughters: Panakea, whose pitcher contained a universal drug for the treatment of all disease, and Hugieinon, who worne fruits, olive oil and vegetables for quality of life and prevention of disease (Figure 3).

Until recently, a problem with medicine was that it was almost completely oriented towards treatment using molecules, drugs, mechanics, prosthesis and surgery. More recently, advances have been oriented in a complementary fashion, toward dietetics, quality of life, hygiene, early detection of diseases and continuous monitoring. The concept of ambient intelligence is at last applied for health.

Non-invasive measurements on humans are particularly suitable for several reasons (Figure 4). They are painless, they preserve the capability of the skin to protect against infection, they allow easy access to the medical devices and they are user-friendly.

The flip side of these large advantages is usually a high complexity in principle and design of the devices. It is clear that it is difficult to measure deep phenomena from

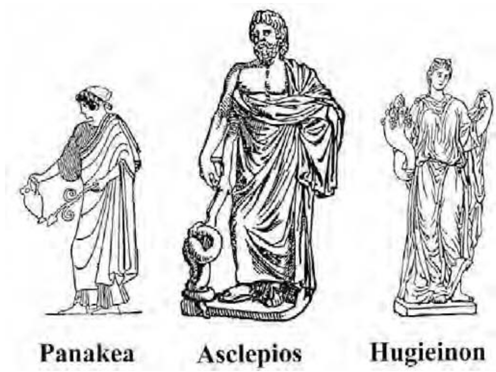


Figure 3. Asclepios and his two daughters, Panakea, symbol of medicine, and Hugieinon, symbol of prevention.

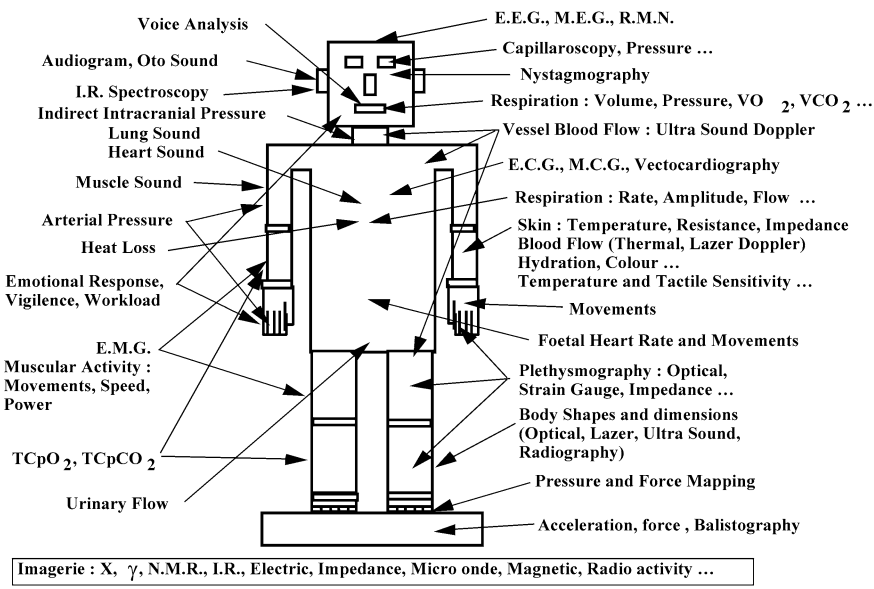


Figure 4. Non-invasive measurements on Man.

the surface of the skin. The measurement principles are indirect and necessarily more complicated. There are dozens of non-invasive measurements on the human body but less than ten basic parameters are currently measured and recorded with ambulatory methods. The choice of placement of non-invasive devices (Figure 5) has to satisfy several criteria and limitations, e.g. obtaining the best signal/noise ratio, the best fixing and the best ergonomics, while also remaining unobtrusive and painless.

Several solutions are available:

- Independent sensors and devices (used in laboratories);
- Perimetric fixing using the body segments and the circular body part (e.g. head, neck, trunk, arm, wrist, leg and ankle);

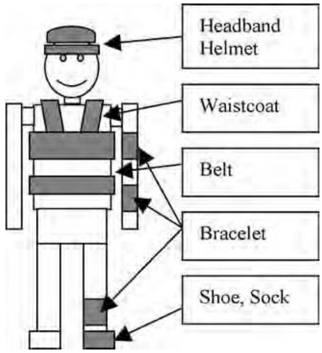


Figure 5. Main placement of biomedical sensors and devices for ambulatory uses.

- Hat, belt, bracelets, socks, shoes, headband, smart clothes.

Of these possibilities, smart clothes, belts and wrist devices are frequently used.

2. Wrist-Wearable Medical Devices

One of the best places to wear an ambulatory device is the wrist. The wrist is a very common place to wear a watch or other devices and nowadays most of the ambulatory devices for sport are worn on the wrist [24].

Wrist devices are readily accepted by anybody. Moreover, as the skin of the hand has the greatest density of sensors and actuators of the body, the wrist and the hand represent a privileged place for physiological measurement, including skin temperature, skin electrical conductance and potential, actimetry, blood oximetry and heart rate. However, wrist devices also have constraints:

- They have to be light and small, in order to not disturb the user. This implies sophisticated power management, wireless data transmission and enhanced miniaturization.
- Sensors have specific locations and wrist devices should be designed according to them.
- They have to be user-friendly and safe. This implies intelligent ergonomics.

Progress in informatics, signal processing, microelectronics, battery technology, and telecommunications is the key to opening up all the possibilities of wrist devices, through enhancing autonomy, low weight, user-friendly interaction and wireless networking.

The wrist has been used for a long time to wear watches, bracelets, jewels etc. because fixing something on the wrist is easy and the mobility of the wrist allows for good ergonomics and easy reading. Three examples of specific uses and a corresponding device are actimetry (“Vivago”), vital signs (“Amon”) and sensorial reactivity and vigilance (“Marsian”).

2.1. Vivago WristCare [34]

The Vivago WristCare (Figure 6) is a device that automatically monitors a person’s well-being 24 hours a day (Figure 7) and transmits automatically to a station called a Multi-

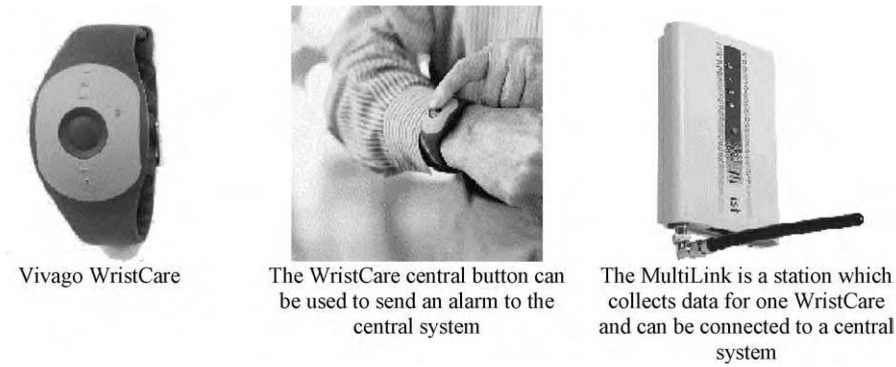


Figure 6. The Vivago WristCare System.

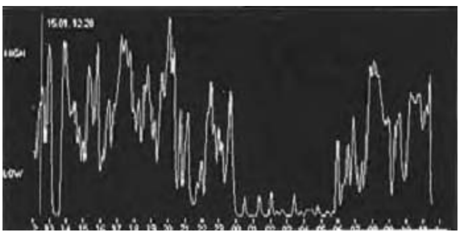


Figure 7a. Vivago's activity record for a normal aged person. During the day activity is high and during the night the activity is very low. This patient sleeps well.

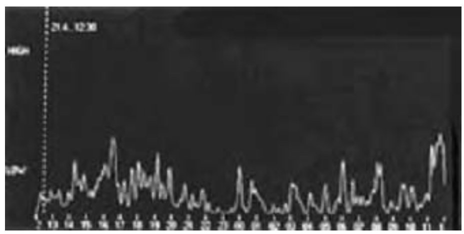


Figure 7b. Vivago's activity record for an aged person with low-level activity. Activity day and night is low and there is almost no difference between the two.

Link within a maximum range of 20 meters. The Vivago wrist device has about 6 months of battery life, but the battery should be replaced by a specialist. During the first four days of use, the unit adapts to the user's normal activity level by measuring micro and macro movement, skin temperature and skin conductivity. If the Vivago WristCare registers a significant change in the user's activity level, it automatically sends an alarm to the alarm recipient.

The Vivago WristCare is able to detect hypothermia, activity of the patient and whether the WristCare is being worn or not. Those three parameters can determine if the situation of the patient is normal and, if they are not, trigger an alarm. The Vivago WristCare can also determine the location of the patient in an institution in order to provide access control or to check if the patient has exited a door or not. This last feature has been designed particularly for users with dementia or mental health problem.

In addition to the wrist unit, the Vivago home system includes a base unit that is connected to the telephone network and an electrical outlet. The base unit wirelessly receives the data from the wrist unit and transmits alarms and notifications to the alarm recipient. The alarm can be routed to any telephone and enable a conversation through the base station. The Vivago system offers benefits beyond the traditional push-button alarm. If desired, the wrist unit can transmit notifications when it is removed or reattached.

This ensures that the unit is in use and that the user is supported by the unit's security features. The wrist unit continuously monitors its own operation, providing notifications on low batteries and connection problems. The wrist unit can trigger an alarm when the

Figure 8. Wrist Monitoring Device from the AMON Project.

user is unable to do so. Such a situation could be the immobility resulting from a bad fall or loss of consciousness. All of the above functions can be switched on or off by remote programming depending on care needs and the user's health.

2.2. Advanced care alert portable telemedical MONitor (AMON) [30]

AMON is a terminated European-Commission-funded project which performed research, development and validation for an advanced wrist personal health system. The system is designed to monitor and to evaluate human vital signs using advanced biosensors (Figure 8). The Wrist Monitoring Device (WMD), the wearable component of AMON, gathers vital information from the sensors, analyzing it using a built-in expert system. The WMD transmits the data to a remote telemedicine centre, for further analysis and emergency care, using GSM or GPRS cellular infrastructure. The device includes sensors for key parameters such as heart rate, heart rhythm, I-lead ECG, blood pressure, O2 blood saturation and skin temperature. Future optional sensors could include 12 lead ECG, EEG, a non-invasive glucose meter and respiratory peak flow sensors.

AMON will enable European patients, who are not confined to a hospital, to monitor and continuously analyze their vital signs. This will help them to participate actively in their on-going care. AMON will provide monitoring of health status at the point and time of need, which will give patients freedom of movement and will enhance their quality of life. AMON will ensure continuity of patient care by providing continuous medical monitoring.

The main benefit is that the European user will be able to have medical monitoring or an emergency alert any time of the day, while having a normal life at home, at work and at leisure places.

2.3. MARSIAN : Modular Autonomous Recorder System for measurement of Autonomic Nervous system activity

The autonomic nervous system activities (non-conscious) in real and ambulatory conditions are related to emotional, sensorial and cognitive responses and activities [12].

MARSIAN (Figure 9) is a hybrid device associating the advantages and the specificity of smart clothes and of wrist devices. Research is now focusing on smart clothing solutions to enhance the use and the reliability of sensors [10]. The MARSIAN smart

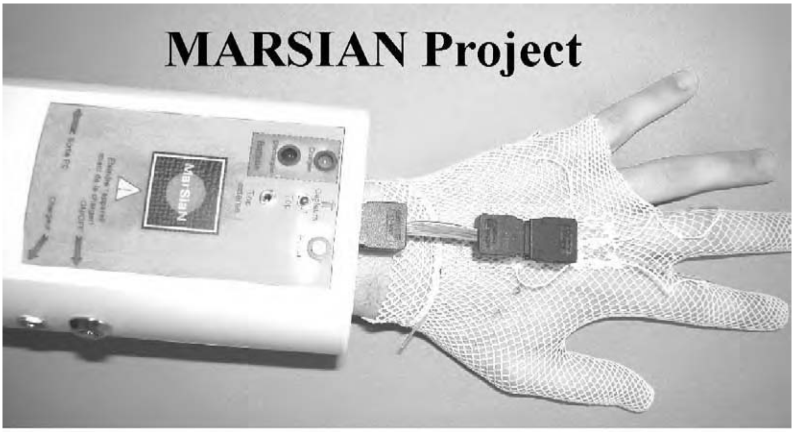


Figure 9. MARSIAN, Modular Autonomous Recorder System for measurement of Autonomic Nervous system activity, is an ambulatory micro central composed of smart clothing and gloves and a wrist device.

glove has a specific design to ensure both a good contact from skin to electrodes whatever the hand's motion and a correct furtivity of the glove so as not to modify the typical physiology of the hand's skin.

The MARSIAN wrist device ensures real-time physiological data acquisition, treatment and wireless transmission in a minimum size. Remote software displays and stores data and provides a semi-automatic analysis in order to facilitate the expert's conclusions. This wrist device has 6 hours autonomy at full utilization.

Experimentation with MARSIAN has been already done. The results have the same quality as a laboratory standard device already developed and tested by A. Dittmar and G. Delhomme (CNRS LPM, INSA Lyon, France) [7,22]. The ergonomics of the software has also been enhanced to enable user-friendly applications and experiments.

The non-invasive multiparametric measurements carried out by MARSIAN have a large field of applications and research uses [4,6,23]. Main research topics are:

- Vigilance level and task-related response (cognitive and physical),
- Response to odor, taste, touch, vision (e.g. shape and color), sound (e.g. speech),
- Research on thermal and environmental comfort responses and states,
- Comparison with conscious and verbal indications,
- Study in real conditions of action programming in sport,
- Mental imagery training and study for sport,
- Study of behavior and stress.

Moreover, in order to get an index or a decision tree to determine ANS responses to thermal comfort, research is also focused on subject responses in comfortable and uncomfortable levels of various environmental factors, such as temperature, humidity and air velocity.

MARSIAN is fitted both to analyze instantaneous emotional responses which occur almost immediately after the stimulation (for example after odor stimulation) and to analyze longer responses which characterize a state change (for example, thermal comfort or discomfort). Figures 10 and 11 show two types of analysis [1].

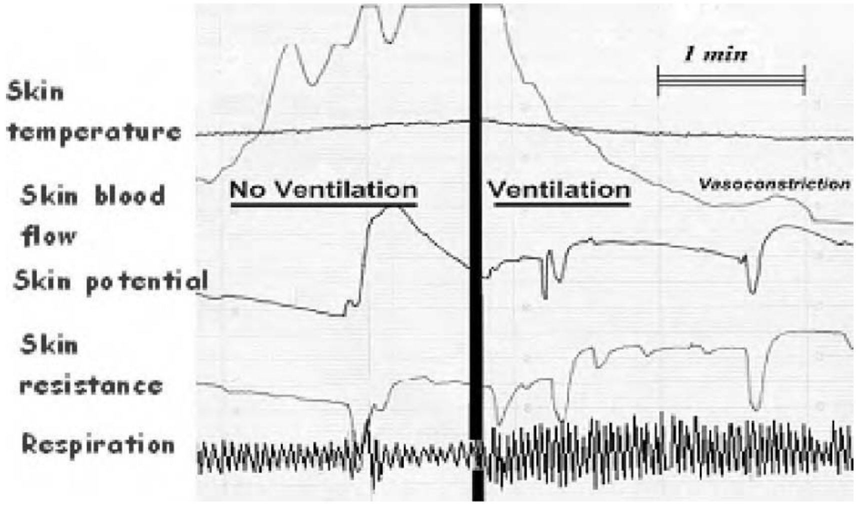


Figure 10. ANS parameter variations for ventilation stimulation. Skin temperature decreases and respiration increases. Skin blood flow also shows vasoconstriction. ANS parameters should be analyzed with a 10 minute time scale for thermal comfort analysis.

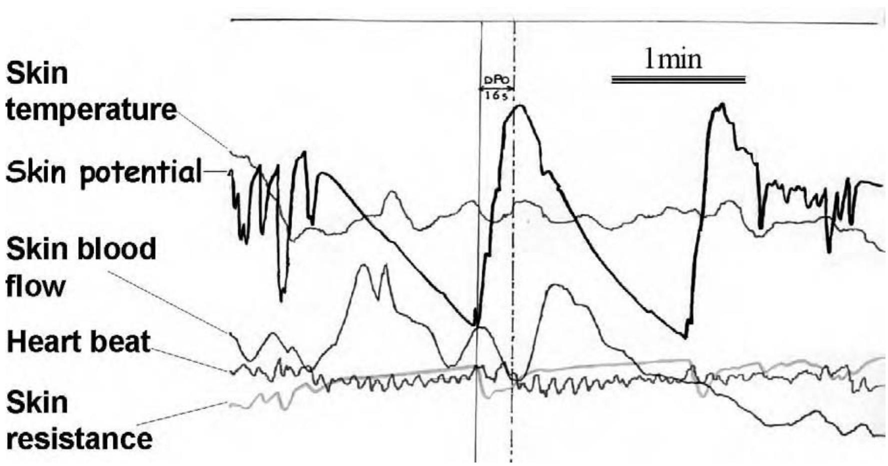


Figure 11. ANS parameter variations for odor stimulation. SP and SC (here shown as skin resistance) modification are particularly visible. Just after stimulation SC increases (resistance decreases) as SP. Thermovascular parameters also show typical reactions. ANS parameters should be analyzed with a time scale of less than 1 minute for emotional responses.

3. Ambulatory Devices

3.1. Enhanced Personal, Intelligent and Mobile system for Early Detection and Interpretation of Cardiological Syndromes (EPI-MEDICS) [31]

In Western countries heart disease is the main cause of early disability and premature death. Moreover, because of the ageing of the population, the number of cardiac deaths is steadily increasing, and almost two thirds of them occur before arriving at the hospital.

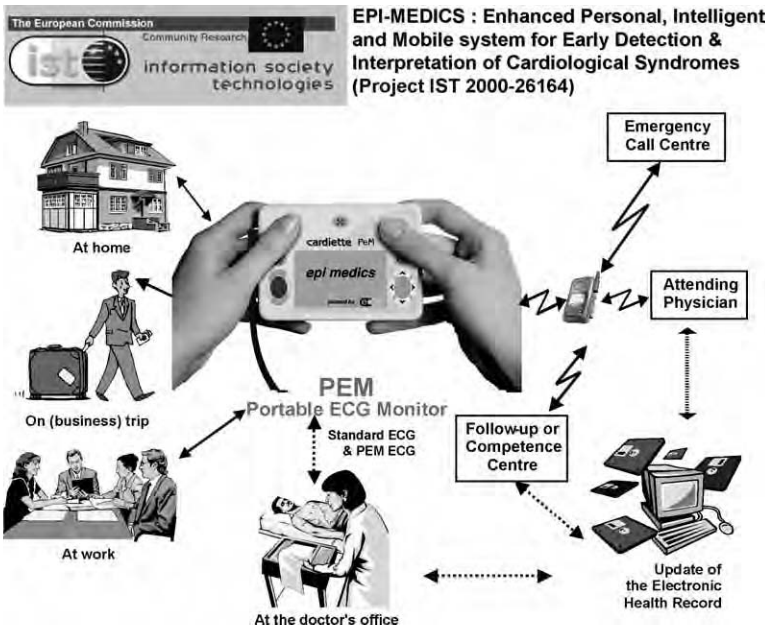


Figure 12. Enhanced Personal, Intelligent and Mobile system for Early Detection and Interpretation of Cardiological Syndromes (EPI-MEDICS).

But despite many attempts to improve the management of cardiac care, only small trends to shorter time intervals before treatment have been reported. Symptoms are often interpreted incorrectly.

Event and transtelephonic ECG (electrocardiogram) recorders are increasingly used to improve decision making, but this approach requires setting up new medical services that would be very expensive if adopted for every cardiac-diseased citizen.

The solution adopted by the EPI-MEDICS project is to develop and experiment with a novel "intelligent" Personal ECG Monitor (PEM) for the early detection and management of cardiac events (Figure 12).

The objective is to design a very affordable, easy-to-use but powerful, professional-quality level embedded device that is able to record, store and synthesize standard 12-lead ECGs, incorporate intelligent self-adaptive data processing and decision-making techniques, generate different levels of alarms, and forward without delay, but only if necessary, the alarm messages with the recorded signals and the patient's electronic health record (HER) to the relevant health care providers by means of new generation wireless communication techniques (Bluetooth and GSM/GPRS). Major alarm message are automatically transmitted to the nearest emergency call centre by means of GSM or GPRS. Data leading to medium or minor alarms are temporarily stored on a central alarm web server and the health professionals are informed by an SMS. The PEM embeds itself in a web server to facilitate the reviewing and/or update of the HER during a routine visit at the GP's or cardiologist's office.

Figure 13. Mélodie®, a multi-channel ambulatory, programmable infusion pump for use by out-patients.

3.2. MELODIE : Programmable and portable Pump [32]

Mélodie® allows the physician to program the order, frequency and timing of administration of drugs, in exact accordance with the prescribed regimen (continuous, simultaneous and/or intermittent infusion). It ensures all the basic requirements for monitoring treatment by producing two documents for inclusion in the patient's medical records. While the protocol is being set up, a program report is produced which ensures that the infusion can be checked at a later stage. Similarly, at the end of treatment, an infusion record is produced which documents all events occurring during treatment.

As far as patients are concerned, the Mélodie® pump (Figure 13) offers them the chance of returning home sooner, greater independence in their daily lives and the security of knowing that their treatments are being given according to the established protocol, without any need for repeated procedures performed by nursing staff.

Mélodie® is a multi-channel chrono-programmable pump offering:

- The ability to administer more than one drug (up to 4) as required by anti-cancer treatment protocols,
- Centralized control of the entire infusion procedure in the patient's own home,
- "Chrono-adapted" administration of drugs,
- Standard administration of drugs.

The Mélodie® pump makes chrono-adapted administration of drugs possible in order to optimize cancer treatment. The concept of chronotherapy is based on evidence of biological rhythms that change over a 24-hour period (circadian rhythms). The fate of a drug in the body and its pharmacological effect are affected by these rhythms so that its toxicity and efficacy can vary up to 5-fold depending on the administration schedule.

Antibiotic therapy is a major indication for Mélodie®. The main benefits are that it:

- Complies with the dosing schedule for each drug,
- Avoids procedures associated with a risk of sepsis,
- Avoids drug interactions (rinsing after each antibiotic),
- Allows treatment traceability (during and after infusion).

The main indications are:

- Cystic fibrosis: Mélodie® permits continuous 24h administration or intermittent administration, given during the "long night" period from 18.00 to 8.00,
- Osteo-articular infections, e.g. osteitis and prosthesis infections,
- Superinfections, e.g. bronchial,
- Conditions requiring long-term antibiotic therapy.

The use of the Mélodie® pump for the management of pain control is directly due to its four channels as well as its PCA (Patient Controlled Analgesia) function, which allows the patients to manage these painful episodes themselves.

In this way, one can combine classical analgesic treatment, often based on morphine, with other drugs allowing each patient's pain to be targeted in a more specific fashion (concomitant administration of anti-inflammatory, anti-depressant and analgesic drugs).

4. Biomedical Smart Clothes

Smart biocommunicative clothes and textiles are playing an active role in ambulatory measurements and monitoring. Textiles have a key role in such developments. Firstly, about 90% of the skin can be in contact with a textile, which is the main interface to body. Additionally, fabrics are flexible and fit well with human body; they are also cheap and disposable. Figure 14 shows the main components in biomedical "intelligent wear".

Lastly, integration of systems into textiles is now possible. Chemistry provides new fibers with new mechanical, optical, or electrical properties. Microtechnologies enable the integration of sensors and actuators in the fabric frame and provide light and user-friendly electronic systems.

Fibers can also have an active role in sensing or communicating. Almost every kind of fiber can be woven or embroidered, such as optical fibers, carbon fibers or polymer fibers [3,25,33]. Woven sensors, microsensors and microsystems can be easily included in textiles due to their small size or their flexibility. Communication can be provided by GPS, radio, screen, keyboard, camera, speaker or phone integrated in the cloth. Biomed-

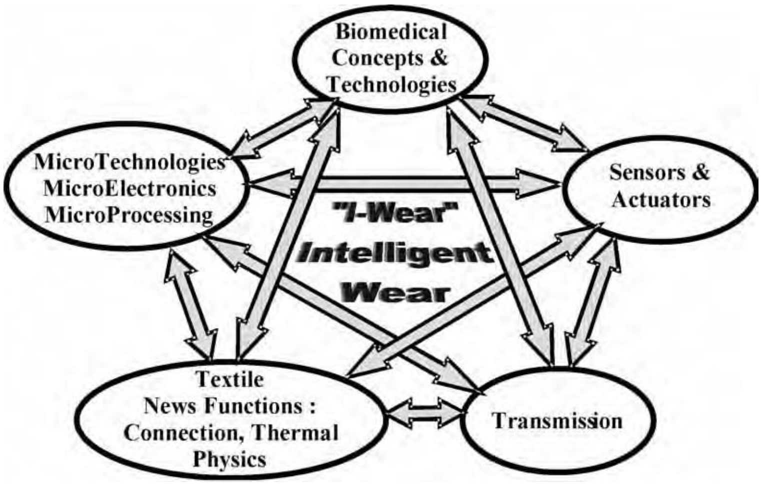


Figure 14. Main Components in biomedical "intelligent wear".

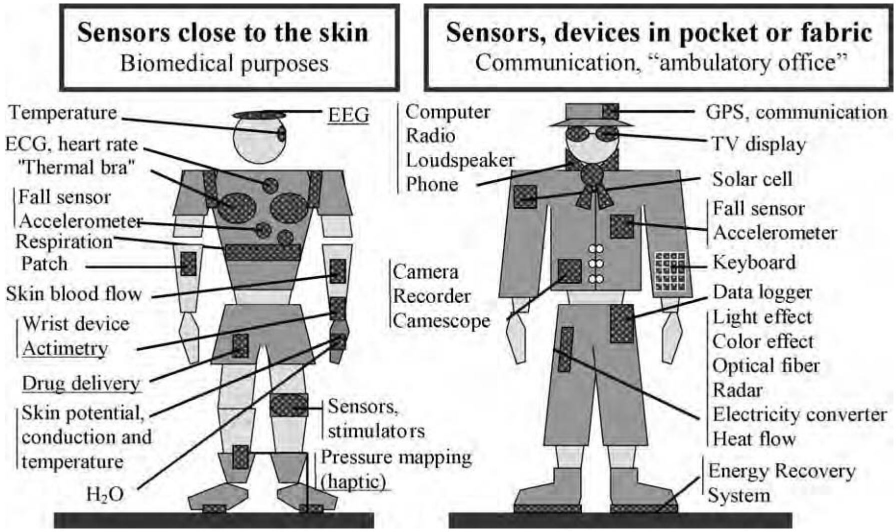


Figure 15. Two main kinds of smart clothes.

ical smart clothes use those facilities with a network of embedded sensors to measure and monitor vital and behavioral human parameters.

There are 2 main kinds of smart clothes (Figure 15):

- Smart clothes with sensors close to the skin, which are used for biomedical purposes. The sensors are enclosed in the layers of fabric or at its surface, or it is the fabric itself which constitutes the sensors [5]. Such sensors can be piezoresistive yarns, optic fibers, and colored multilayers. Biomedical smart clothes have several advantages, starting with removal of the task of placing the sensors by a nurse or a physician. In addition, the sensors are placed at the right place; they are protected, invisible, user-friendly and particularly adapted for monitoring of chronic patients, of handicapped people, elderly people and people performing professional, sport and military activities.
- Smart clothes with sensors or devices in pockets or in the fabric. A lot of new functions can be added to clothes using microtechnologies, microradios, microcomputers, flexible TV screens, microcellular phones, but also solar cells, energy recovery systems (in shoes generally) and flexible keyboards. These devices are used mainly for communication, displaying colors, pictures, indications of mood, messages etc.

However, some devices or sensors used for monitoring, e.g. GPS devices, fall detectors, data loggers, accelerometers and activity detectors can be placed in the clothes in special pockets.

These two approaches are compatible and complementary. Three examples of prototype systems are provided here: VTAMN, WEALTHY and LifeShirt.

4.1. VTAMN, Project of the French ministry of research RNTS 2001 [35]

The VTAM (Clothes for Tele-Assistance in Medicine) project began in January 2001. It aims at developing generic clothing technology which integrates biosensors and bioac-

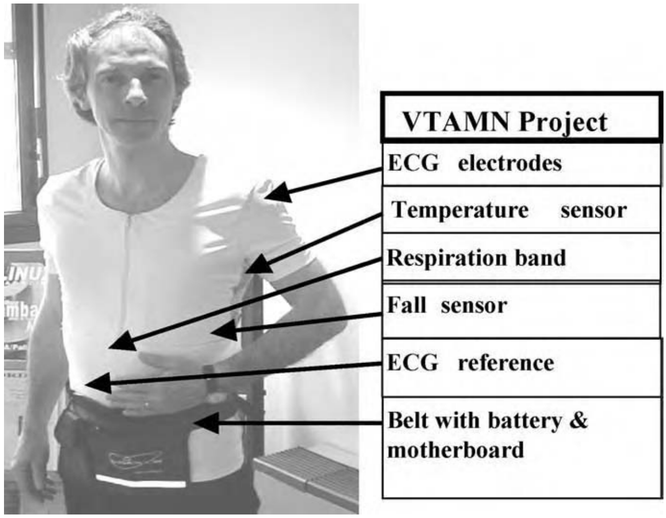


Figure 16. VTAMN prototype.

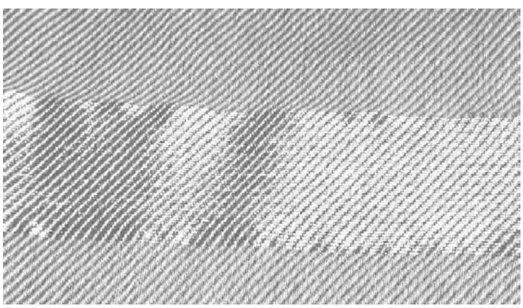


Figure 17. Stainless steel wires woven into the fabric and used as a bus for the electronic system.

tuactors woven into the fabric. The T-shirt incorporates smooth dry ECG electrodes, a shock/fall sensor, a breath rate sensor, two temperature sensors and a GPS receiver (Figure 16). A GSM/GPRS module is connected to the T-shirt and is used for data transmission and hands-free communication [27].

The VTAM attempts to reach a higher level of electronic integration in clothing than previous projects like the LifeShirt USA or the Smart-Shirt USA. The objective is to obtain bioclothing, or a second skin, both comfortable and hygienic (washable), which incorporates connections, wires and microsensors. The leads and treatment modules are flexible and incorporated into the textile itself. The electronic I2C bus is also part of the textile (Figure 17).

The motherboard, the transmission module and power supply are kept on a belt and connected to the VTAM T-shirt through a microconnector. Data is transmitted through a GSM module to a central PC station. A medical protocol is applied to process the biomedical data, which include ECG readings, a pneumogram, temperature, and fall detection in mobile situations.

4.2. Wearable Health Care System (WEALTHY project) [37]

A new concept in health care, aimed at providing continuous remote monitoring of patient vital signs, is now emerging. This paradigm shift is both socially-driven, due to the rising cost of assistance and the need to improve early illness detection and medical intervention, as well as technologically-driven [15,21].

In particular, the advances in sensor technology, as well as in communication technology and data treatment, constitute the basis on which this new generation of health care system can consolidate. At the same time systems designed to be minimally invasive for health status monitoring, based on flexible and smart technologies conformable to the human body, will help to improve the autonomy and the quality of life of patients. They are also cost-effective in providing around-the-clock assistance, for example in rehabilitation from cardiac disease or for monitoring of workers engaged in extreme environmental conditions. Finally, by providing direct feedback to the users, they improve their awareness and potentially allow better control of their own condition.

In these systems smart materials in fiber and yarn form endowed with a wide range of electrophysical properties (e.g. conductive, semiconductive, electroresistive and piezoresistive) will be integrated and used as basic elements to fabricate woven or knitted fabrics posessing distributed sensors and logic functions. The simultaneous recording of vital signs will allow parameter extrapolation and inter-signal elaboration that contribute to making alert messages and personalized synoptic tables of a patient's health.

WEALTHY (Figure 18), a research project funded by the European Commission's IST programme, develops smart fabrics for personal health monitoring. The system will :

- Assist the patient during rehabilitation,
- Assist professional workers during risk activity,
- Ensure intelligent monitoring of the users during, for instance, everyday tasks and physical exercise. Such feedback can include alerts and warnings or, conversely, to provide reassurance over a situation,
- Trigger automatic transmission of physiological or clinical sensitive parameters,
- Alert emergency services if the situation turns critical, e.g. absence of patient response and alarming vital signs,
- Allow the interpretation and extrapolation of an index related to physiological conditions by considering all simultaneous data,
- Guarantee a friendly interface for professionals,
- Ensure a high degree of freedom and let the user perform his/her normal activities.

4.3. LifeShirt : smart shirt for continuous ambulatory monitoring, Vivometrics Inc. [36]

Since 2002, Vivometrics has been producing and testing a smart shirt called LifeShirt (Figure 19) which records physiological parameters such as electrocardiogram, rib cage and abdominal respiration, body posture and blood oxygen saturation.

The LifeShirt is a Lycra (elastic and adaptable) shirt which includes embedded textile sensors such as plethysmographic sensors for respiration. It also provides locations for external sensors such as electrocardiogram electrodes, accelerometers or commercial sensors for blood oxygen saturation. To record physiological data, the LifeShirt integrates a data logger such as a Palm^{TM}, which is able to record raw data and a user diary

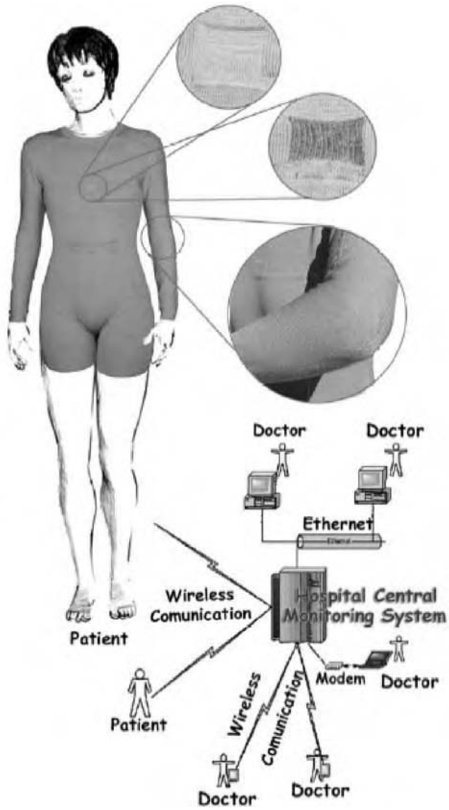


Figure 18. Wearable Health Care System (WEALTHY).

for more than 24 hours. Raw data can be sent to a remote expert center which analyses them and performs diagnostics.

Main research topics explored with LifeShirt are cough measurement, respiration analysis and ambulatory monitoring. It can also provide monitoring of EEG/EOG, leg activity, pulse oximetry, capnography, blood pressure, temperature and 12-lead ECG. After the data are analyzed using VivoLogic software, researchers receive a comprehensive report that correlates the data collected by the optional device(s) with the cardiopulmonary data and electronic patient diary data currently collected by the LifeShirt system

5. Exosensing

Exosensors are not fixed directly on the subject but generally in his/her close environment such as an apartment, place of work, vehicle, sports hall and sports ground. A very important advantage is the lack of constraints for the subject as there are no sensors on the skin and no wires. However there are also limitations and disadvantages: generally only one subject can be monitored by a specific monitoring site and the information collected needs to be supplemented by an ambulatory device or devices for external monitoring.

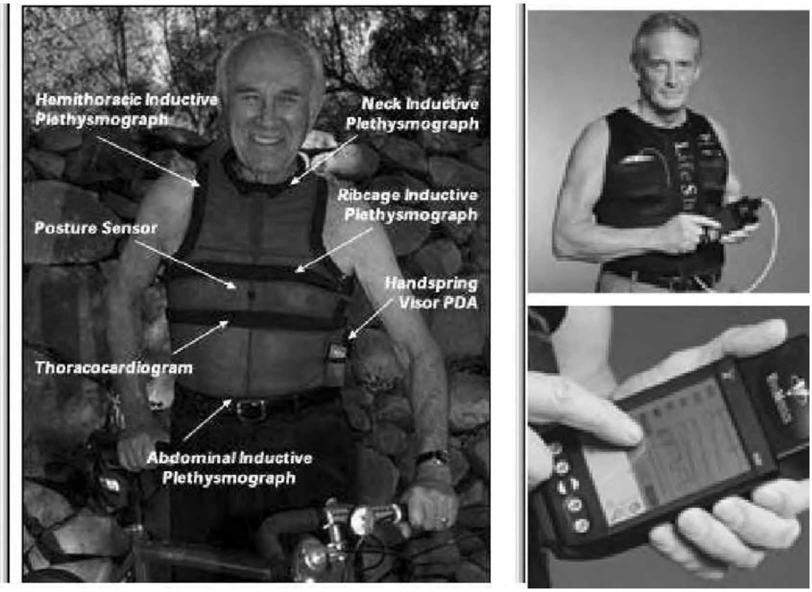


Figure 19. Vivometric's LifeShirt.

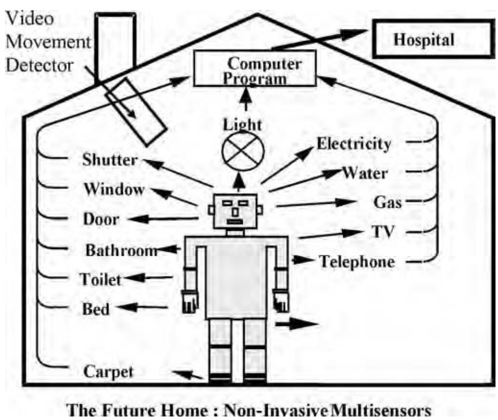


Figure 20. Smart home. Measurements are taken by exosensors not fixed to the subject.

5.1. Exosensors, Smart Homes

Smart homes exist in limited numbers and in are experimental. The first achievements were based on numerous biochemical sensors. The current trends are based on the use of a limited number of highly relevant parameters [9,28]. The smart home is based on the integration of sensors into the house (Figure 20). These sensors, e.g. a sensor array in the carpet for the detection of walking, activity sensors on the taps, shutters, doors, sensors on seats, in beds and bathrooms, measure the activity and the state of a person mainly alone at home. Data processing with neural networks can analyses the activity of the inhabitant and provide early detection of functional disorders and alert a nurse or physician.

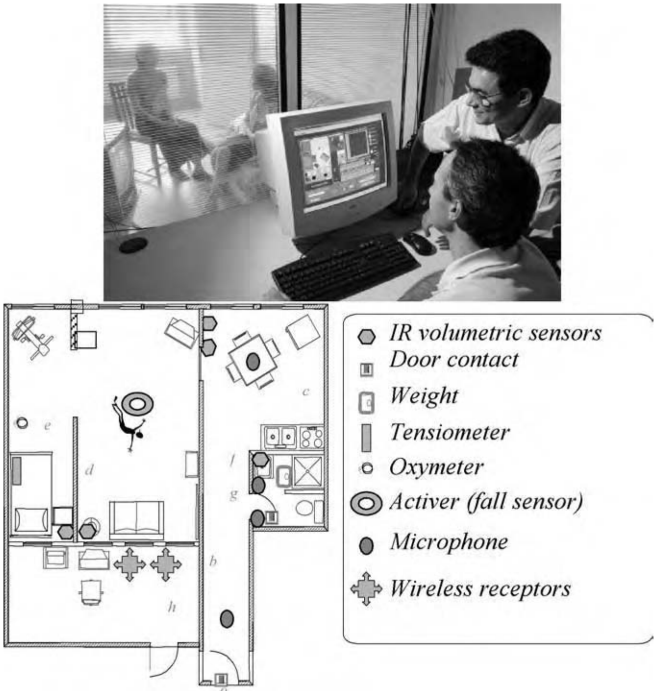


Figure 21. Experimental platform for telemonitoring the health status of the elderly at home.

The Health Integrated Smart Home Information System (HIS^2) is an example of a smart home. It has been developed for remote monitoring of the health status of the elderly at home (Figure 21).

It aims at improving patients' living conditions and avoiding long hospitalization costs. The design is based on a CAN network linked to volumetric, physiological and environment sensors [18-20,26].

The video camera, unacceptable to patients for obvious privacy reasons, was replaced by a system based on Multichannel Sound Acquisition. The coupling of both systems will enable them to detect if a person is in distress or not. Both systems locally process in real time the incoming data and communicate using a CAN network to display the health status.

The experimental platform is a 30m^2 flat (two rooms plus a kitchen) with a technical area for the evaluation and the development of technologies in order to ensure the security and quality of life for patients who need home-based medical monitoring [4]. It integrates smart sensors (e.g. volumetric, audio, physiologic and environmental) linked to a master PC via a CAN bus. The eight microphones for audio surveillance are linked to a slave PC and can be interpreted as a single smart audio sensor. Location and audio sensors are placed in each room of the HIS^2, allowing monitoring of the patient's successive positions and sound activity within the home environment.

Alert-triggering procedures are divided into two types: short- and long-term alerts. Short-term alerts are instantaneously triggered after the reception of a message coming from either the HIS^2 or the sound system. Long-term alerts are obtained after an analysis period. This last type uses a buffer to extract some pathological disease scenarios from

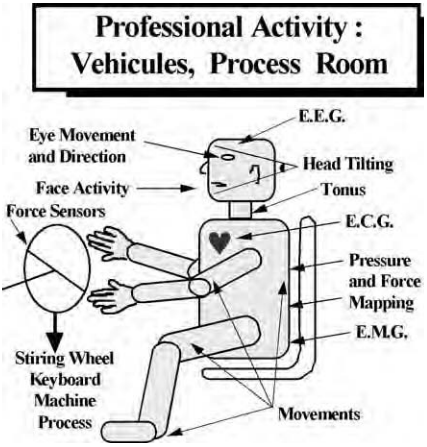


Figure 22. Measure and control of an operator by sensors monitoring his state of vigilance during a cognitive or physical task.

the database. These scenarios have been analyzed following all possible combinations. At present, the system contains “anuria” (not urinating during the night), “nycturia” (urinating during the night) and “pollakiuria” (urinating more than 3 times per day) and some basic scenarios. For instance, if the underlined scenario occurs one time during the same night, then the scenario “nycturia” is detected. If it occurs more than 3 times during the same day, then “pollakiuria” is detected. In the future, these alerts will be sent to the healthcare provider.

5.2. Exosensors in Professional activities

An extension of biomedical instrumentation relates to the control of the capability of a subject for carrying out a task correctly. This is particularly important when the subject has to perform a high-responsibility task. It is the case for car, bus, truck and train drivers, but also pilots, air traffic controllers and controllers of nuclear reactors (Figure 22).

The arousal and vigilance levels and time course is particularly useful for the control and safety of these professional tasks. Usually, the multiparametric approach is used for increasing the reliability of decisions taking account of the basis of the measurements. The detection in public areas of unusual or potentially dangerous behavior is carried out by image analysis of body movements and facial expressions. High-sensitivity and high-resolution thermography of the face is used also for the detection of the emotional state of people at distance.

This total behavior control has to be limited and controlled by an ethical approach and individual acceptance of citizens.

6. Citizen Medicine

This paragraph describes systems and tools enabling citizens by providing self-management of their health and healthcare.

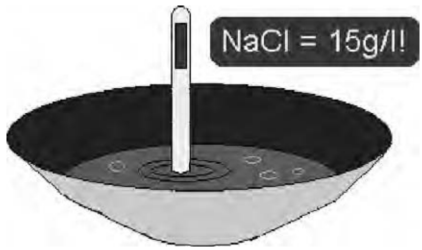


Figure 23. The "salt pencil" can be used by patients to control by themselves the salt content in foods such as soup.

6.1. The "pencil analyzer" for domestic control of meals

An example of such key enabling tools lies in the control of meals and diet.

For the control of the amount of sodium chloride in soups and meals, patients and people on diet can rely on the "salt pencil", a small and autonomous pen (Figure 23). It is the first member of a family of domestic quality detectors for food. It is followed by the odor detectors used in Japan to control the freshness of fish. The probable evolution of this device will be a "multi-sensor pen" capable of detecting the amount of sugar, fat, glucose and other ingredients.

It is possible also to add a code detector to this pen that reads the content of a menu or a plate (by means of a tag on a sticker on each plate in the restaurant or on the menu). By plugging the pen into a computer we obtain a sort of "Jiminy Cricket" i.e. a sort of "conscience" for the patient: "don't eat this, don't drink that".

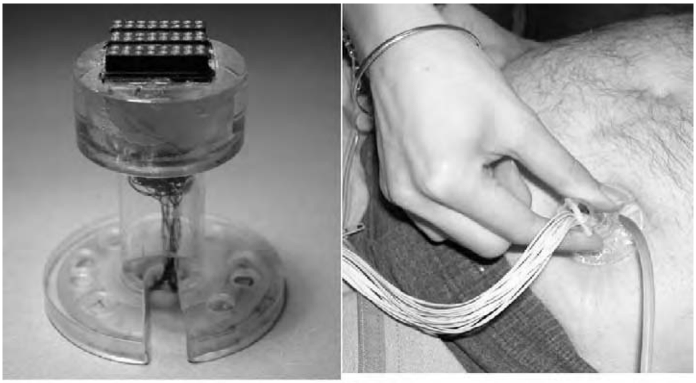
The prevention principle applied to food is not new: in "Don Quixote" Cervantes told us that Sancho Pança was promoted to governor of the island of "Baratiara". The official physician of this island (Pedro Rezio de Aguero) controlled the quality of each meal. He found that each of these meals was particularly dangerous and forbidden. Finally Sancho Pança had nothing to eat and he dismissed the physician.

The psychological impact, in daily life, of using such tools and approaches should be evaluated as well. Biomedical sensors should be considered as "friends" for citizens' health, not spies.

6.2. DEPIC Early Detection of Cutaneous Infection in Peritoneal Dialysis

DEPIC is a project funded in 2001 by the French Ministry of Research. It developed a non-invasive sensor analyzing the cutaneous thermal parameters around the permanent catheter used for peritoneal dialysis and can be handled by the patient at home (Figure 24). The device uses a flexible technology (Mylar®) for the membrane and 20 sensors for the mapping of the skin thermal parameters. As it is used by the patient himself or herself, two automatic controls are performed: the quality of the interface sensor/skin contact and the analysis of the data relevance.

This sensor is associated with instrumentation and an automatic device that alerts to the risk of infection, which can be or not be directly understood and used by the patient (light and sound signals). A portable device, autonomous, usable in hospital, but also at home, the DEPIC is designed to be connected to "DIATELIC" system of telemonitoring of dialysis at home which analyzes the data to detect alarm signals and to prevent



(a) (b)

Figure 24. DEPIC Sensor.

aggravations. If an alarm occurs, the system informs the nephrologists, the patient and the treating general practitioner [11]. This device allows the diagnosis of an infection before the appearance of clinical signs and complications and can alert the patient and the physician in time.

7. Bio-inspired approaches for designing biomedical wearable devices

The bio-inspired approach rapidly growing today consists of studying the concepts, mechanisms, materials, information and signal processing of living beings. The aim is to develop a more creative and imaginative design for biomedical engineering. This new design approach is not all about copying nature but takes advantage of recent progress in materials, signal processing and of the potential offered by micro and nanotechnologies to build devices on the same scale as nature. This gives access to the possibilities and concepts associated with small-scale phenomena [8].

Biological sensors are available in very large quantities; they are self-repairing, auto-adaptive, intelligent and multipurpose, economical with energy, possess small-volume energy storage and are recyclable. All these concepts and devices are working and have been tested for million of years.

Bio-inspired design (Figure 25) is particularly well-suited to biomedical engineering using a natural and basically biocompatible approach. It is not a religion but a new way of thinking that departs from the overly-classical “old highways of thinking”. The bio-inspired approach is a second-degree methodology. Usable across almost the whole spectrum of knowledge and particularly with micro/nanotechnologies, the bio-inspired approach is compatible with chemistry, genetics, and micro/nanotechnologies.

At this beginning of the 21st century, new trends are emerging for the definition and the design of man-made objects. For the harmonization of the relationship of man and his products with nature, the objects have to be more and more miniaturized, smart and recyclable, and also they have to use little energy, be low cost and highly reliable.

The major part of these characteristics corresponds to those of living beings and is most convenient for designing wearable devices, and particularly with soft matter such as textiles.

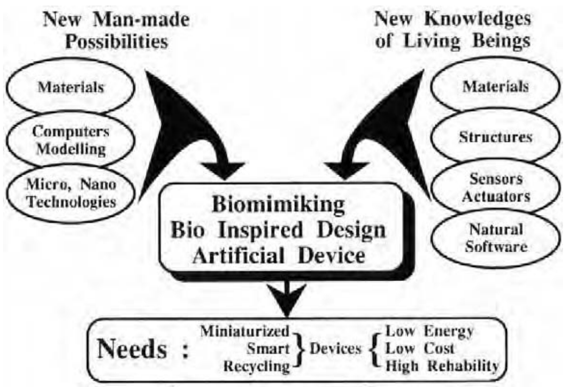


Figure 25. Main components of the bio-inspired approach. It is particularly useful for the design of smart miniaturized and low-energy devices.

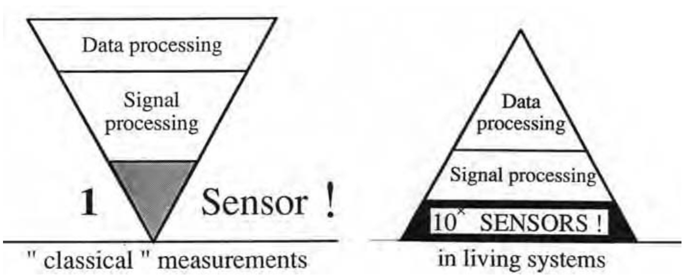


Figure 26. Strategies of man-made sensing and natural sensing.

In artificial systems (designed and built by humans) few sensors are used. Signal and data processing are sophisticated.

In "natural sensing" living systems (Figure 26), a lot of sensors are used (for example, a hand is equipped with about 100,000 sensors and the human retina with 130 million light detectors). Signal processing is basically simple but sensors are mutually connected and informed (Figure 26). This method is more "robust".

Smart clothes having a large surface in contact with the human body provide a good opportunity for using this strategy.

The huge progress in informatics, signal processing, telecommunications and materials contributes significantly to the design of new wearable biomedical devices; however the number of sensors currently used is limited. The time to market of sensors is long, usually up to 5 years. The lack of a non-invasive ambulatory glucose sensor after 25 years reflects this problem. The limited number of available sensors and the long life cycle of development and validation is a bottleneck for the progress of wearable biomedical devices.

8. Conclusion

Microtechnologies are changing the landscape of biomedical engineering. Their ability to produce sophisticated, miniaturized, low-energy, largely autonomous devices is partic-

Figure 27. Information, communication and sensors**.** So few sensors and so many routes for communication and signals.

ularly convenient for mini-invasive implantable devices and non-invasive and ambulatory devices. Furthermore, the access to microscale phenomena offers new possibilities for the development of sensors and actuators. In the beginning, microtechnology was almost all microelectronics, but now it includes micro-optics, micromechanics, micropackaging, microfluidics, microthermics, microtransmission etc.

Telemedicine, ambulatory monitoring, wrist devices, smart clothes, drug delivery, surgery and rehabilitation engineering have to take advantage of these new offerings.

Home care and ambulatory monitoring constitute a new approach in medicine. This is possible due to the fact that new possibilities and competences are available at the same time.

Chronobiology, chronodiagnostics and chronotherapy, using continuous monitoring, wrist devices, smart clothes and home care, now offer the possibility of a near future of synergies for almost all medical fields.

The actors in this new medicine are numerous and each one can be assured that his role is essential in this new context (Figure 28).

A hard task is faced in the coordination of all these components and also in changing the behavior of the administration and also of physicians ... and, finally, a new evaluation of health costs and ethics is also necessary.

A "societal health education" has to be provided to physicians and to patients for them to realize all the benefits of this new context.

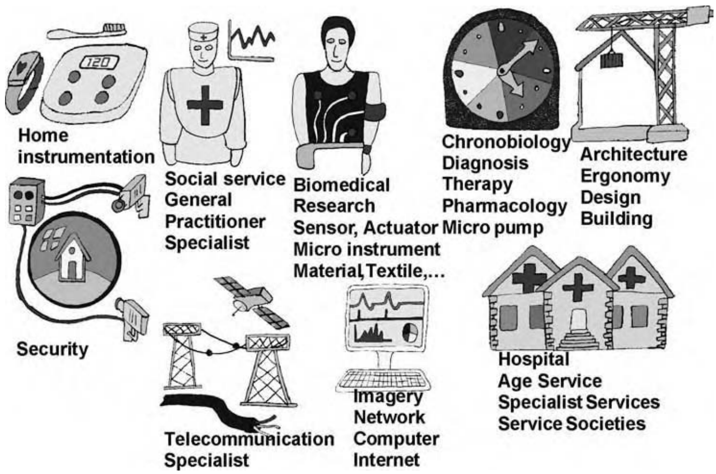


Figure 28. Actors involved in the healthcare and well-being landscape.

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MyHeart: Fighting Cardiovascular Disease by Preventive Lifestyle and Early Diagnosis

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Abstract. MyHeart is an integrated project of the 6th framework programme for research and development of the European Commission under Philips Research Aachen leadership for fighting Cardiovascular Diseases (CVD) by prevention and early diagnosis. The major goal of the project is to create business options using smart electronic systems and appropriate services that empower the users to take control of their own health status. MyHeart addresses a wide variety of applications in the cardiovascular disease space and intends to develop lifelong solutions for healthy people, at risk population as well for chronically ill patients.

Introduction

Cardiovascular disease (CVD) is the leading cause of death in developed countries. Roughly 45% of all deaths in the EU are due to cardiovascular diseases. More than 20% of all European citizens suffer from a chronic cardiovascular disease. This disease class includes myocardial infarction, congestive heart failure, arrhythmias, and stroke. It is medically widely recognised that hypertension, high cholesterol, diabetes, stress and obesity are the main risk factors for developing CVD. Any of these major risk factors, if left untreated for many years, has the potential to produce a cardiovascular disease.

Citizens with high scores on these risk factors often already suffer from limitations in their daily life. Obese patients encounter severe limitation in their ability to follow an active lifestyle. Especially after a major cardiovascular event, patients encounter severe impact of their life quality. In particular stroke patients suffer from mental and physical disabilities. Studies have identified that 20 % of all myocardial infarction patients will develop depressions. The majority of those patients live in such anxiety, that their ability to take actively part in social and economic life is limited. Therefore it could be said that CVD risk factors are influencing the citizens' quality of life.

CVD is not only a major threat in terms of mortality, morbidity and quality of life; it is also a major economic burden to all European countries. Annually Europe spends several hundred billion Euros on the management of CVD. The direct medical costs represent only a third of the overall cost for society. The major costs are the indirect costs to the community such as loss of productivity due to illness and premature death. For the USA, cardiovascular diseases account for a total of 329 billion dollars costs[1]. In Germany alone 13% of all direct healthcare costs are due to cardiovascular disease exceeding 20 B€[2].

With the overall aging population in Europe, it is expected that the number of chronic CVD patients - especially for congestive heart failure and atrial fibrillation - will increase the coming years and thus the cost of the disease management. Therefore, it is a challenge for Europe to deliver its citizens the best healthcare at affordable costs.

1. Scope of MyHeart

It is commonly accepted, that a healthy and preventive lifestyle as well as early diagnosis could systematically fight the origin of CVD and save millions of live-years. The MyHeart[3] mission is to empower citizens to fight cardiovascular diseases by preventive lifestyle and early diagnosis.

1.1. Clusters of Applications

The MyHeart project starts from the application point of view. Within MyHeart the cardiovascular application field has been grouped into five clusters. Each cluster addresses a prominent risk factor for developing cardiovascular diseases. The objective of MyHeart is to empower patients to actively improve preventive lifestyle and reduce morbidity and mortality addressed in the application clusters:

Table 1.1. Application Cluster and project objectives

Cluster	**Objective**	**% of Population affected**
CardioActive	Reduce sedentary lifestyle!	54 %
CardioSleep	Improve sleep quality!	25 %
CardioRelax	Reduce stress!	40 %
CardioBalance	Reduce Weight!	20 %
CardioSafe	Reduce acute events by early diagnosis!	15 %

1.2. Customer segmentation

The MyHeart project intends to provide solutions for a lifelong healthy living. The customer segmentation includes people who want to stay healthy, people with a recognized risk for developing cardiovascular disease, chronically ill and people after a cardiac event. Combining customer segmentation and applications defines the matrix shown in Figure 1.1.

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[2] Gesundheitsbericht Deutschland, Statistisches Bundesamt, Wiebaden, ISBN 3-8246-0569-4
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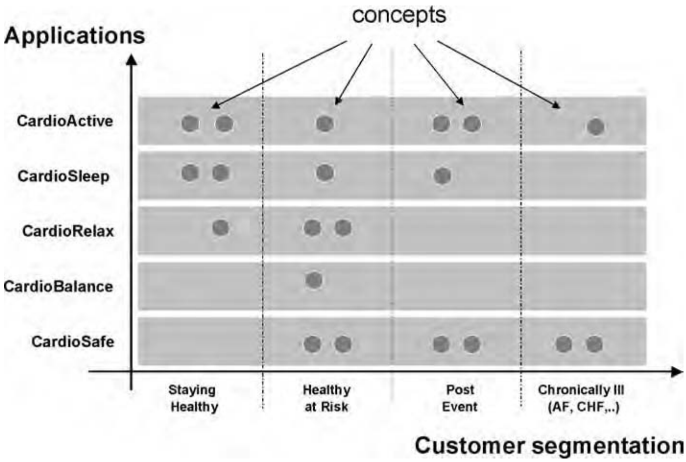

Figure 1.1. MyHeart Application Matrix: The application matrix represents the scope of MyHeart. Red dots depict individual concepts that are defined in this matrix by the addressed application and a specific customer group.

1.3. Concepts

MyHeart is composed of 16 autonomous concepts. Concepts are ideas for concrete business options within the cardiovascular application space, tailored to a specific user group or customer segment. Each concept has to answer five questions:

- What is the application/value proposition?
- Who is the customer and how can we address him?
- How to do it technically?
- How to prove evidence (medically, technically, economically)?
- What is the business model?

Examples of concepts are Stroke prevention, MI prevention, obesity management or outdoor rehabilitation. To guarantee medical excellence, each concept has a clinical partner included.

2. Technology

The key challenges for lowering the mortality rate in CVD and their related costs are by successful guiding, informing and motivating the citizen to adapt to a permanently healthier life style and the early diagnosis of acute events. It is the aim of the MyHeart project to develop innovative, personalised, easy-to-use solutions and tools, which help the citizen to adopt permanently a healthier lifestyle.

2.1. Technological Challenges

In order to realise these innovative systems the MyHeart project faces 5 major abstract technological challenges:

1. **Continuous monitoring:**
   Integrating novel sensors and monitoring systems into functional clothes and developing on-body electronics to create a complete continuous monitoring system.
2. **Continuous diagnosis and personal profiles:**
   Continuously assessing the health status and allowing diagnosis in a wearable on-body system. This includes extracting higher-level information and creating personalized profiles and algorithms.
3. **Continuous therapy:**
   Translating detailed and precise information on the actual health condition into direct therapy recommendations.
4. **Feedback to user:**
   Allowing the visualization of therapy recommendations and biofeedback in a home and in a mobile setting, anytime and anywhere.
5. **Remote access and professional interaction:**
   Connecting the user to medical professional services and to other users in a home and mobile setting.

2.2. *Intelligent Biomedical Clothes*

The development of Intelligent Biomedical Clothes (IBC) is the key technical innovation of the project. A prerequisite for lifestyle change is to get information about the current health status and lifestyle of the user. Therefore MyHeart will develop solutions that will continuously monitor vital signs and context information, diagnose and analyse the health status and acute events, provide user feedback and seamlessly provide access to clinical and professional expertise if required. For continuous measurements, the project will develop electronic systems that are embedded into functional clothes. Functional clothes are clothes with integrated textile and non-textile sensors. The combination of functional clothes and integrated electronics will be Intelligent Biomedical Clothes. In-

Figure 2.1. Major functional building blocks of the MyHeart system. MyHeart solutions consists of monitoring capabilities that enable a continuous diagnosis to adapt and enable therapy by direct feedback to the user but also to provide timely access to premium institutional points-of-care.

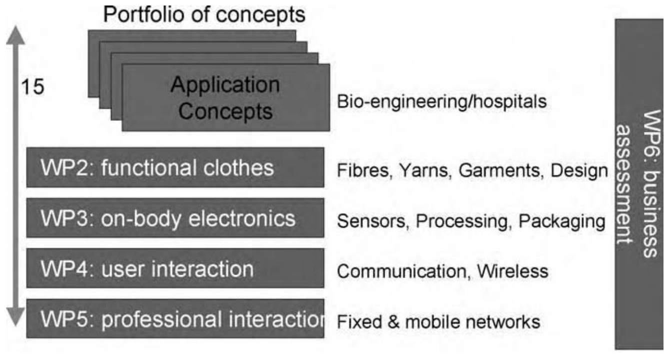

Figure 3.1. The workpackage structure of MyHeart. The MyHeart project consists of a vertical application workpackage 1, which defines the concepts and the functional requirements. The workpackages 2-5 are horizontal workpackages that provide platform technologies to realise the concepts. Workpackage 6 gives a framework for all concepts to assess the comparable economic value of the individual concepts.

telligent clothes are able to continuously monitor vital signs of the citizen, make diagnosis and trend detection and react on it (therapy recommendations). Intelligent clothes have integrated wireless technology to link to user feedback devices and if necessary to professional medical centres. Intelligent clothes together with user feedback devices form a complete system, which is called a MyHeart system. Figure 2.1 depicts the major functional building blocks of the MyHeart approach. Currently, there are no appropriate solutions available that comprise this functionality.

3. Project Organisation

The project's activities are organised in workpackages with the following RTD activities (Figure 3.1).

Workpackage 1 is responsible for the definition of concepts along the five questions. The different concepts are the main driver of the work in the horizontal technology workpackages WP2-6, as the concepts define the requirements for the different parts of the system and the motivation for these requirements. This workpackage also delivers the application specific personalized algorithms, belonging to a certain application.

Workpackage 2 (functional clothes) is responsible for the development of the novel textile sensors, the integration of the on-body electronics into clothes and for the design of the functional garments. This includes the development of special sensors suitable for long-term monitoring of a wide range of vital signals. It will also include developing new concepts for integrating electronics and sensors into clothing.

Workpackage 3 (on-body electronics) delivers the MyHeart hardware platform, the non-textile sensors and the generic processing algorithms for the sensors. A textile processor system able to manage all measured signals will be part of this workpackage. Packaging problems in terms of soft and wearable electronics with user-friendly power supply solutions will have to be tackled. Another important part of this workpackage is the development of generic processing modules that can extract higher-level context information out of measured data, as described in the high level system architecture description.

Workpackage 4 (User Interaction) aims for the research and development of new user interfacing concepts to interact with the user for information and feedback in the mobile setting and the home setting. This includes feedback to the user, data input from external measurement devices and sensors and the interaction with external professional services to complete and supervise therapy recommendations.

Workpackage 5 (Professional Interaction) provides integrated service architecture to deploy the professional supporting services for the applications as defined by WP1. This architecture will facilitate users (professionals and customers) interaction, enabling the provision of the projected services. This workpackage will address all the subjects concerning expert interaction that will consider both professional and user sides in MyHeart applications.

Workpackage 6 is called Business assessment. The objective of this workpackage is to provide organization and support for the user testing throughout the project and to assess the viability of possible business models for the different product concepts derived from the application tasks.

Workpackage 7 carries out the innovation related activities. This workpackage will deal with different plans for managing knowledge and IPR, training activities, dissemination of knowledge through publications. This will result in patents, scientific articles, workshops, courses and presentations in all covered scientific fields. The project management activities are organised in Workpackage 8. Main task is clear and proper project management for the whole project and the communication within and outside the consortium.

4. Project Phases

The project duration of 45 months is divided into three phases:

In *Project Phase 1* (Month 01-18) the project will implement basic functional prototypes and test these concepts in user focus groups. The definition of concepts will also enable the MyHeart team to assess the validity of each concept with relevant stakeholders from the medical domain and from payers like health insurance, employers, pension funds and specific user groups and boards. This intense *co-design with users* is a key innovation element addressing the main risk of user/stakeholder acceptance. The outcome of this assessment will used to validate business plans for each individual concept and will be used to select the most promising concepts for further technical and business development in the next phase. The selection criteria will be based on the technical feasibility, the business plan and the user acceptance.

In *Project Phase II* (Month 18-30) MyHeart project will take the most successful *concepts* and combine (if needed) these concepts to three to five *product concepts*.

These product-concepts are tailored to specific customer groups and can be composed of several concepts e.g. for post myocardial infarction patients MyHeart might combine some concepts out of different application area's like activity, sleep management with early detection of acute events. These product-concepts are prototype descriptions of future MyHeart products. They will be implemented and tested in clinical environments to show the effectiveness and feasibility in long-term test beds. On top of that, the product concepts will undergo a second iterative process of focus group assessment with end-users, professional service providers and medical professionals.

In *Project Phase III* (Month 31-45) the consortium will validate the product-concept in extensive test-beds and trials for long-term follow-up to show the effectiveness of the product concepts. With long-term test beds the project will show that users will use the system over months and years and will document the success in terms of adaptation of healthier life-style and in the reduction of acute events. The consortium intends to do the testing and trials with control arms to objectively document the advances in quality of care, quality of life and cost benefits.

The project will benchmark against clear outcome parameter like weight reduction, reduction in average heart rate, reduction in blood pressure, increase in physical activity and in the reduction of hospitalisation days for acute events. The outcome will be documented in improvement of the quality of care delivered to the participants.

In addition it will assess the cost benefits for the stakeholders in the health care delivery system. The final outcome includes documented test beds showing the effectiveness and efficiency and the design of business models for exploitation of the results. Special emphasis will be put on novel methods for reimbursement and derive financials benefits for users. The consortium intends to establish this health care delivery process into the medical guidelines for treatment ensuring Europe wide access to the outcome of the project. Additionally B2C (Business to Customer) approaches will be evaluated to ensure that anyone can access the solution before general reimbursement can be achieved with the national health care systems.

5. Conclusions

MyHeart is a 6th framework Integrated project in the e-health domain. The key objective of generating impact and addressing major societal needs is translated into research for novel application in the cardiovascular disease continuum. In order to safeguard a high probability of success an application and user centred innovation approach has been chosen. The portfolio approach of concepts (business options) and the selection process guarantees the highest success chances for the project.

Acknowledgment

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Health0: A New Health and Lifestyle Management Paradigm

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Abstract. The paper describes Health0: an innovative healthcare and lifestyle management wearable system that aims to bring an individual focused approach to healthcare. A modular architecture is proposed that combines a Linux-based PDA with a distributed wireless sensor-network and innovative bandage-sized (2.5 cm^2) sensor hardware. Real-world scenarios that can use the Health0 system are discussed.

Keywords. bio-sensors, medical telemetry, healthcare, wireless sensors, wearable architecture, standardization

Introduction

The current healthcare system is based on an approach where the hospitals and the physicians serve as the primary and the only source of medical diagnostics, feedback and information about diseases. Even for ascertaining the well being of one-self, one has to go through a series of exhaustive tests in a hospital on a regular basis. Although this approach has worked well so far, there are certain key trends that will prompt us to rethink our current hospital-centric healthcare:

- A rapidly aging population that will place increased demands on our healthcare system while at the same time an inability to have the sufficient number of physicians and nurses.
- The demand to provide twenty-four hour constant medical support at the press of a button to such a population while at the same time preventing overcrowding and bed blocking in hospitals.
- Widespread use of the internet that has led to a vast amount of knowledge, including medical knowledge, being made available to an individual. Thus unlike in the past, when only a physician had access to medical information, now an individual too can have the latest medical journals at his disposal. This has led to individuals being made more aware of the treatment being given to them and at the same wanting to have more control of information about oneself.
- A substantial increase in population being treated for diseases like depression and heart ailments that increase demand for medical compliance, remote monitoring and change of lifestyle, something that is not possible if an individual is not aware of the effect of his activities on his health.

- A trend towards a healthy lifestyle based on controlling one's diet, increased physical activity and being aware of oneself rather than just taking the prescribed medicines after a symptom develops.

The above trends inspire us to develop an individual-centric approach to healthcare. Health0 focuses on such a need and aims to make the individual the center of healthcare. In the next few sections we describe the Health0 architecture and real-world scenarios where Health0 attempts to provide a scalable solution to the problem.

1. General Overview of the System

Figure 1 gives an overview of the Health0 system: a composition of multiple feedback loops. The first and the most important feedback loop occurs within the individual that makes him more aware of his own bio-physiological signals. This loop has two important functions:

- To provide immediate feedback about the effect of drugs, diet, activities on an individual's health, and make him aware of his instantaneous physiological signal if he wishes like providing stress information.
- To act as a mechanism for long-term feedback about the effect of an individual's lifestyle on his health and promote well-being rather than just symptom based diagnosis.

Another feedback loop integrates an individual with his friends and family, who provide valuable social support. Additionally the user may desire to communicate his medical information to his home and office environment to effectively adapt it to his needs to promote his well-being.

Another level of feedback to hospitals and communities serves three important functions:

- Supplement the existing healthcare system with devices that can lead to better diagnosis.
- Aid in remotely monitoring patients and supporting new ways of drug delivery and diagnosis
- Provide a mechanism for the community to be an effective partner in the lifestyle management of the individual and for the hospitals to observe community health as a whole to prevent the spread of epidemics.

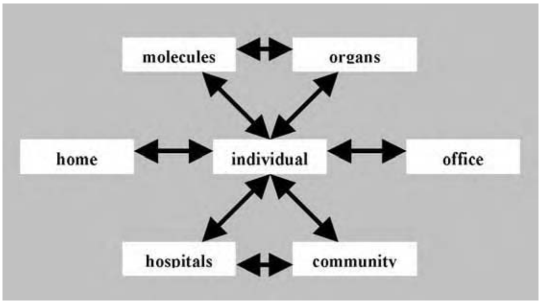

Figure 1. *Health0* Individual Centric Architecture.

Another unique aspect of Health0 is its layered architecture with three different layers: the physical layer, the network layer and the application layer. Each of the layers has a specific function that is discussed in the next few sections.

2. *Health0* Physical Architecture

The physical layer of the Health0 architecture consists of a central device wirelessly connected to a sensor network. The central device serves the need for local computation and storage while at the same time providing real-time signal processing and data-analysis capabilities. The current Health0 configuration uses a Linux-based PDA Sharp Zaurus SL-5500 as shown in Figure 2. A PDA was used because of its multimodal functionality and its pervasiveness in everyday use. Due to its widespread use, it provides an inexpensive, easy to use platform that can serve multiple functions. Increased integration, as has been the trend, will see the PDA becoming a combination of an MP3 player, a cell phone, a web browser, an applications manager and your lifestyle manager.

The Zaurus Sl-5500 is a complete embedded Linux system with a 206-MHz StrongARM process, 16 MB Flash, 64 MB SDRAM, CF and SD expansion slots, full duplex audio, qVGA color touch screen, an integrated QWERTY keyboard and a RS-232 serial port. Currently other wearable systems being used at the MIT Media Lab such as MIThril 2003 [3] also use this PDA. This provides us with excellent opportunities for integration with other wearable platforms to provide a highly integrated multifunctional device.

The sensors are connected wirelessly to the PDA through a sensor hub that interfaces with the serial port of the PDA and provides data acquisition, buffering and sequencing capabilities to the PDA [3].

Another unique attribute of the Health0 platform is its sensors. Currently most of the wearable systems have wired sensors that limit their usability for an average individual as it restricts body movement [3]. We are currently developing bandage-sized (2.5 cm2) sensors that use 2.4GHz transceivers from Nordic VLSI to communicate with the sensor-

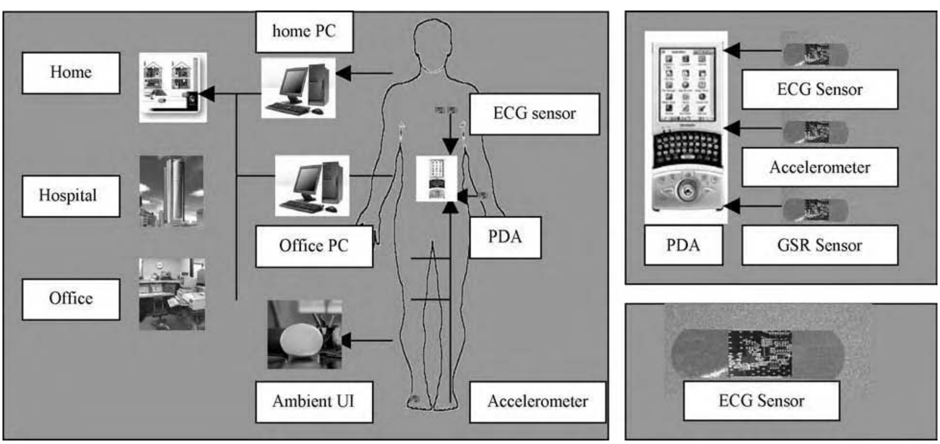

Figure 2. (Clockwise from left) The complete *Health0* architecture, the sensor architecture with the Zaurus PDA and the bandage-sized (2.5 cm^2) ECG sensor.

hub. Each of the bandage-sized sensors has a specific function like measuring acceleration, ECG, GSR, temperature etc. Currently we are in the process of developing EKG sensors. Figure 2 provides a picture of such a sensor. We also plan to develop analog and serial-interfaces that can be used to integrate a range of commercially available sensors. Some of the aspects that are being considered in the development of such sensors are low cost, small size and long battery life through the use of power saving modes and innovative algorithms. The possibility of using flexible substrates instead of the usual fabrication materials is also being explored.

3. *Health0* Network Architecture

The network architecture of the device deals with the issues of how Health0 connects with other devices present in the environment. There are many important factors that form part of the Health0 network architecture.

One important aspect of the network architecture arises from the importance of our social network in our health. Resource and information exchange that happens between individuals is based on their social networks and depends on the nature and the strength of ties between individuals [2]. This holds true even for healthcare information and resources exchanged in it. For example we feel free to exchange health information with our physician and those with whom we have the strongest ties. Often these are our family and close friends. Our work colleagues and neighbors, unless they are close friends, will tend to have less information about us. But for medical emergencies or for an activity partner, it is our neighbors and work colleagues who can be most effective rather than a close family member living in the next town.

Similarly looking at different environments, our home and personal car can be places where it is easier for us to share personal information as compared to an office environment. These factors were very important in deciding the current form of the Health0 architecture. Currently we are working on interfaces that effectively translate this knowledge of social networks into the way health information will be transmitted and visualized like the use of ambient interfaces [1] to alarm sounds. For example the color of the wallpaper of your spouse's cell phone may continuously change indicative of your health. It can change to an auditory alarm in case immediate assistance is required.

Another important feature in the design of Health0 is its planned ability to integrate with devices present in the environment like sensors and actuators in the house, office environment and the car. Such integration from different sensors can have an enormous impact in increasing the usability of the device and its ability to get contextual information without the need for user intervention.

Currently Channel IDs are used when communicating between the sensor and the sensor-hub to allow the functioning of multiple sensors and also the existence of multiple Health0 Devices in the same location. The communication between the sensors and the PDA has been made bi-directional, thus opening a possibility to remotely control the sensor by authorized users like the physician. However a lot needs to be done in this area to ensure safety of the patient and prevent abuse.

The PDA also provides an effective medium for connecting the user with the vast knowledge network that exists on the web regarding medical information and with users who may have similar experiences.

4. *Health0* Application Architecture

The application architecture for Health0 includes the information processing backbone, the classifier engine, the user interface and the particular application that is being used. We plan to use the MIThril Real-Time Context Engine that provides open-source architecture for the development of real-time context classifiers for wearable applications [4]. User interfaces need to be designed that require minimum user intervention and can self-adapt based on the present contextual information.

However a lot needs to be done in the area of application development such as developing applications that can do long-term analysis and prediction based on the collected bio-physiological data. Such an interface also needs to be personalized for the user and its context of use. For example, in a situation when one is watching a scary movie, it is predictable that ECG will vary more than in a normal situation. However that should not be the cause for an alarm.

The next section describes a real world application that will use the Health0 system.

5. Application Scenario: Diabetic Patient Health Monitoring

The Health0 platform is ideally suited for patient monitoring and long-term medical analysis where an individual can learn how his lifestyle affects his health. One such medical application is in the case of monitoring elderly diabetic patients. Diabetes is considered one of the "heavy-hitter" chronic diseases for the aging population. The aim is to connect a glucose monitoring sensor and an ECG sensor with the Zaurus PDA. The information obtained can be displayed to individuals who are intimately connected with the person through the use of ambient user interfaces like the ambient orb. An ambient interface is particular effective in ensuring that the visual information being presented has significance only for the concerned individual [1].

Another important function will be to integrate information available from sensors present in the home like on one's couch with the glucose-monitoring sensor. This simple two sensor combination can be very effective in encouraging individuals to increase their physical activity in case they are not doing the required minimum physical activity.

The PDA can be web-enabled to provide access to the vast knowledge-base that exists on the web related to the effective control of diabetes and the different user experiences. It can also serve as a medium to connect activity partners together in a local area and also educate people of the importance of physical activity.

6. Conclusions

The Health0 platform is an innovative healthcare and lifestyle management wearable system that aims to bring an individual-focused approach to healthcare. It has the potential to reduce many of the problems that currently face our healthcare industry. Its three-layered architecture is the first step towards standardization of a wearable platform in the medical domain. This would enable inter-operability and integration between the various commercially available sensors and wearable systems, and provide a pathway to the development of applications that can run independent of the underlying physical hardware.

Health0 is being developed with a hope that it will encourage collaboration with other industries and individuals working in the area. We are open to providing the necessary source code and hardware for different field studies that intend to use Health0.

7. Acknowledgment

We would like to recognize the help given by the Media Lab wearable community in understanding the MIThril2003 architecture and to Emmanuel Munguia Tapia and Natalia Marmasse for collaborating on Nordic VLSI applications.

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How Wearable Technologies Will Impact the Future of Health Care

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Abstract. After four hundred years of delivering health care in hospitals, industrialized countries are now shifting towards treating patients at the "point of need". This trend will likely accelerate demand for, and adoption of, wearable computing and smart fabric and interactive textile (SFIT) solutions. These healthcare solutions will be designed to provide real-time vital and diagnostic information to health care providers, patients, and related stakeholders in such a manner as to improve quality of care, reduce the cost of care, and allow patients greater control over their own health. The current market size for wearable computing and SFIT solutions is modest; however, the future outlook is extremely strong. Venture Development Corporation, a technology market research and strategy firm, was founded in 1971. Over the years, VDC has developed and implemented a unique and highly successful methodology for forecasting and analyzing highly dynamic technology markets. VDC has extensive experience in providing multi-client and proprietary analysis in the electronic components, advanced materials, and mobile computing markets.

Keywords. Wearable computing, smart fabrics and interactive textiles (SFIT), intelligent healthcare systems, wireless, sensing

Introduction

Venture Development has completed comprehensive market analyses of the current and emerging markets for wearable computing and smart fabrics and interactive textiles (SFIT). The ramifications of that analysis are just beginning to be realized in the marketplace with companies, such as: Philips Electronics, Invista, Siemens Medical Solutions Health Services, Infineon, Sante Fe Science and Technology, VivoMetrics, BodyMedia, and Sensatex. Additional companies are currently developing new products and technologies that will certainly play a role in the future of providing healthcare at the "point of need", including hospitals and medical centers.

In completing its wearable computing and smart fabric market studies [1,2], VDC surveyed over 500 end user respondents using both extensive phone interviews and web surveys to ascertain their current and future awareness of, demand for, and perceptions of wearable computing and SFIT solutions. In addition, VDC surveyed over 100 companies, government and academic organizations that are currently, or expected to be, involved in wearable computing and/or related SFIT product developments or R&D initiatives.

The feedback obtained from these primary interviews and select secondary research were the two primary drivers for the data, insights, and conclusions made in this paper. Due to NDA agreements with certain clients, VDC was unable to fully share its extensive data and insights as it relates to SFIT biophysical monitoring applications and the market opportunities for such products in this paper. It should be noted that it is VDC's belief that the largest near-term market opportunities for SFIT lie in biophysical monitoring and location/position applications. Therefore, the major source for this paper's focus is from VDC's own wearable computing and smart fabric market studies, as well as related secondary research conducted both during and after the studies' completions.

1. Definitions of Wearable Computing and Smart Fabric and Interactive Textiles (SFIT)

VDC defines a wearable computer as hardware devices that meet, but are not limited to, the following criteria:

- The hardware device must contain a CPU (microprocessor);
- The device is able to run user defined software applications. However, a device may also be configured for specific applications in which running a multitude of software applications is not required, and thus was not designed to do so, but the device could have been designed to run user selected software applications;
- The system is supported (worn) by the user's body enabling more of a "hands free" computing experience and/or non-invasive bio-monitoring functionality; and,
- The computer should be, although it is not a requirement, always accessible and ready to interact with the wearer, either through the use of a wired line and/or wireless communication network.

VDC defines smart fabrics and interactive textile solutions as textile- or garment-based marketable products or solution sets that meet, but are not limited to the following criteria: The solution incorporates a textile, fabric or fiber that in its pre- or post-converted state *enables or enhances any of the following interactions* with its environment or user:

- Conducts, transfers, or distributes electrical current, light energy, thermal energy, or molecular or particulate matter either through the material or across the membrane for the purposes of transmitting signal commands, moving sensory or other data, or transferring heat or matter between two or more points on the product (a garment, for example).
- Either through an external signal command from the user, or an internal or environmental stimulus (e.g. increased temperature, humidity, change in pH), certain physical properties of the material change (e.g. porosity, conductivity, permeability), enabling or enhancing any of the above functions. This is referred to as material phase change.
- Provides shielding & protection from electromagnetic (EM) and/or radio frequency (RF) interference.
- Provides environmental & hazard protection against any number of biological, chemical, or other threats to the integrity of the protected being or item utilizing the material.

- Through the incorporation of sensor and/or actuator elements, the SFIT solution can perform biophysical monitoring applications such as heart rate, respiration, movement, temperature, sleep, and other physiological measurements.

The second alternative criteria is that the solution is enabled to carry out any of the above functions, either through the use of fibers or other elements embedded into the textile, application of a substrate (e.g. coating or film) or other type of treatment to the fibers, fabric or textile material, or the application of 3rd-party components and enabling materials (e.g. sensors, electronics devices and wiring).

2. Market Size and Expected Growth Outlook

Based on the findings from VDC's market research studies, the outlook for demand of wearable computing and SFIT in healthcare/bio-monitoring related activities is one of very robust growth, albeit from a small current market base. VDC conducted several scenarios as to the shipments for consumption of wearable computers and SFIT products in bio-monitoring applications worldwide, the vast majority of which will be for use in healthcare related applications. Figures and 1 and 2 illustrate the worldwide shipment and forecasts for Smart Fabric and Interactive Textiles and Wearable Computers, respectively.

The major applications in which wearable computing and SFIT products are likely to gain traction within the healthcare segments include, but are not limited to, the following:

- Wearable electronic devices, such as BodyMedia's SenseWear^{TM}armband that provide non-invasive bio-physical monitoring of heart rate, temperature, caloric consumption, sleep habits, etc. Such devices would not be limited to usage in healthcare applications alone, although that would likely represent a majority share.
- SFIT products such as those being offered by VivoMetrics, Sensatex, Invista, etc., that are garments equipped with sensing elements that enable the wearer to monitor various physiological measurements such as heart rate, respiration, blood pressure, temperature, etc., that are commonly found in many healthcare applications.

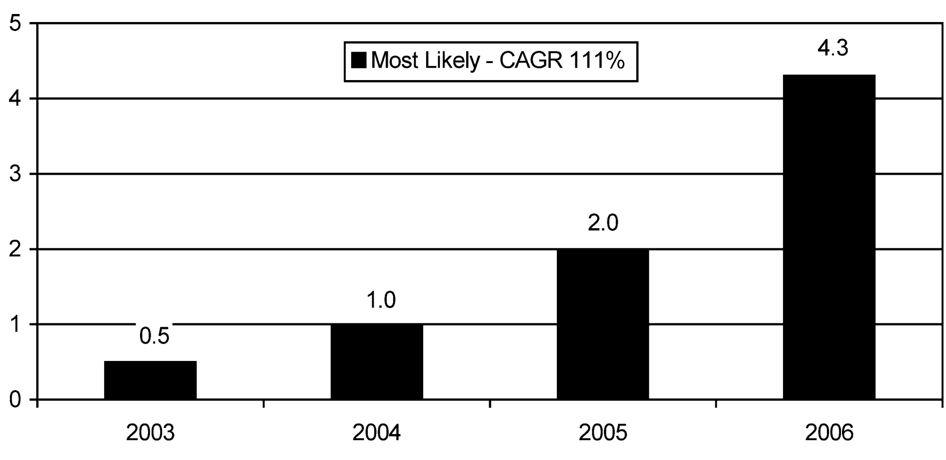

Figure 1. Worldwide Shipment and Forecasts of Smart Fabric and Interactive Textiles For Consumption in Health Care/Bio-Monitoring Applications (Dollars in Millions).

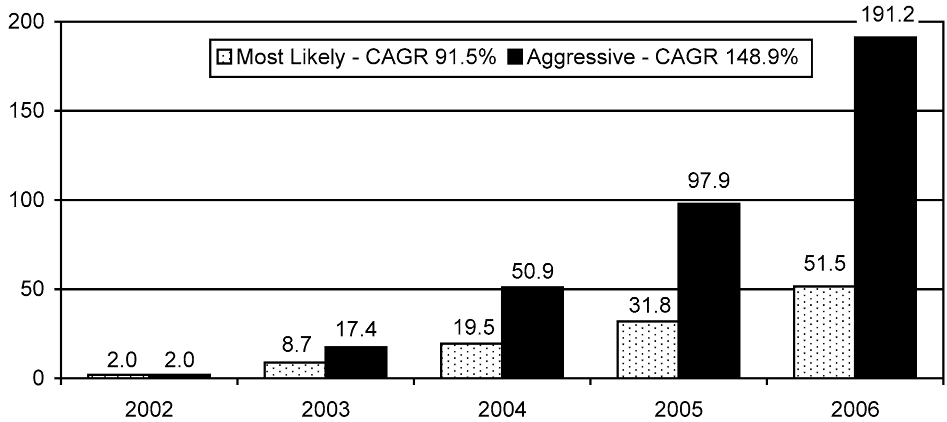

Figure 2. Worldwide Shipment and Forecasts of Wearable Computers For Consumption in Health Care/Bio-Monitoring Applications (Dollars in Millions)
*Excludes bio-monitoring wearable devices such as Polar's and FitSense's wrist watches (estimated at over $45 million in 2003).

The major user communities in the health care segment would include, but are not limited to, the following:

- Hospitals – those located in urban and suburban areas are expected to be earliest adopters, followed by those located in rural areas and 3rd world developed countries. Within hospitals, expected usage would be in from the following major departments: ER and ICU, obstetrics/gynecology, neonatology, cardiology, and pediatrics.
- Various geriatric organizations such as nursing homes, assisted living centers, and related facilities as the share of the U.S. population continues to grow older.
- Sleep labs and sleep clinics.
- A large future market would lie in home usage where the healthcare provider focus on "point of need" treatments that allow for more real-time diagnosis, quicker response times, and a more preventative care focus. The belief is that such care would ultimately lower the overall costs to provide such services.
- The military of western governments are also expected to be users of SFIT and wearable solutions for use in the treatment of their soldiers on the battlefield and for general population health care usage. The Objective Force Warrior program is one example of expected future military usage.

3. Technology Development Roadmap

VDC's roadmap for the implementation of wearable and SFIT technologies, includes the development of multiple interdependent components. Future healthcare applications within biophysical monitoring, biophysical assistance, and mobile computing will require the development of the following components that will be integrated within each healthcare solution:

- Traditional Textiles
- Electrically Conductive Materials (fibers, threads, fabrics)

Table 1. VDC's technology development roadmap: Applications, Components, and Market Opportunities

Wearable Computing/SFIT Applications	Components	Future Biophysical/Health Care Market Opportunities
Biophysical Monitoring & Cognitive Readiness	• Software/Database • Electronics • Textiles • Sensors	• Patient Health Care • Emergency Situations/First Responders • Sports Performance • Cognitive monitoring for health care providers
Biophysical Assistance and Protection	• Textiles	• Police Protection • Emergency Response • Hospitals/Airplanes/Hotels
Mobile Computing/ Processing	• Energy Generation • Electronics	• Heat Generation/Temperature Control • Location detection for Emergency Response, Patient Care.

- Microelectronics (CPU, displays)
- User Interfaces (Keyboards, speakers, microphones, sensors)
- Power sources (thermo-generation, photovoltaic)
- Communication Links (PAN, LAN, WAN)

If these technologies (e.g. wireless communications, sensing technologies) are integrated in a synergistic manner, it will minimize the cost of implementation, maximize the quality of health care provided, and lower the overall cost of healthcare. In addition, the technology solutions will be positioned to target additional market opportunities beyond the original application. Each technology solution can serve as a platform, to be leveraged across multiple vertical markets and applications. Table 1 illustrates VDC's technology development roadmap in respect to the components and future market opportunities, based on current wearable and SFIT applications.

4. Obstacles and Challenges

Despite the many promising benefits of wearable technology's usage in health care applications, there are several potential hurdles that must be addressed and overcome before widespread adoption is insured. Among some of these obstacles include, but are not limited to the following:

- Medical Liability and Insurance: The issue of medical liability (i.e. malpractice) will be a major concern. Physicians may not want to be held liable for their culpability in having access to real-time "always on, always with you" data as it may open them up to lawsuits if they failed to act on the information that was provided, or if there was an error in transmission that allowed them to take faulty courses of action based on inaccurate information. In addition, a sizeable barrier to adoption will be in determining which parties are responsible for paying the costs associated with wearable healthcare technologies: individuals, private businesses, or insurance carriers.
- Federal Regulations: Each country has its independent regulatory agency that evaluates and approves the safety of drugs and medical device technologies. The process of soliciting and receiving approval can be a slow, difficult, and unpredictable process, especially for products and applications that have initially small market sizes.

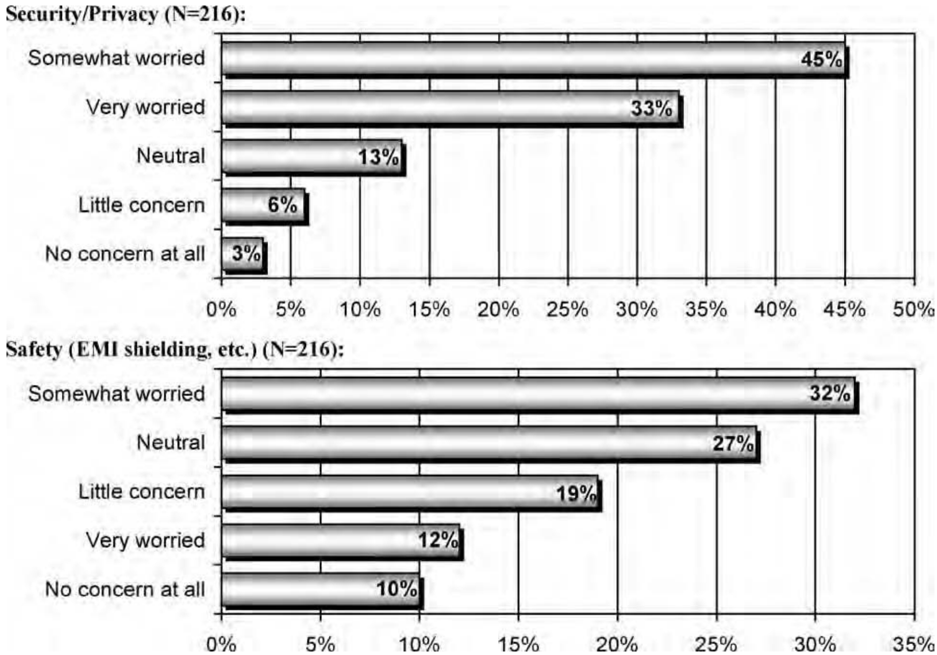

Figure 3. Level of Concern For Security/Privacy and Safety Among Future Users of Wearable Computers (Percent of User Respondents).

- Privacy: Patients themselves may have major concerns with the issues of privacy (medical information) and/or the safety of the wearable devices themselves. Based on data obtained during its wearable computing market study, as illustrated in Figure 3, VDC found that a sizable share of respondents were concerned about such issues.
- Technical: The development of SFIT technologies and Wearable Computers will require a number of suppliers or partners across the supply chain to integrate their technology into the healthcare solution. In addition, the infrastructure to support "always on, always with you" healthcare information systems requires an extensive network that needs to be supported, maintained, and funded. The process of partnering as well as integrating technologies and networks will likely extend the commercialization period for many of the future bio-monitoring applications.
- Commercial Development: The biggest challenge for commercialization is generating sufficient market demand that will enable businesses to generate profits.

5. How the Impact of Wearable Technology Will Benefit Health Care

The world's population is 6 billion and growing every day. Various experts estimate that worldwide IT spending for health care will reach $68 billion, or 4% of total worldwide IT spending of $1.7 trillion, in 2002. The adoption of wearable technology for use in health care applications will be driven in large part to the many benefits that can be derived from the usage of such products and technologies. The benefits include the opportunity to ultimately lower the overall cost of healthcare, while at the same time enhancing the quality of care provided. The specific health care benefits, include:

- Mobility: Wearable technology, via the use of wireless communications networks such as 802.11b, Bluetooth, and/or wireless wide area networks (WANs) such as GSM/GPRS or CMDA2000, will allow for "around the clock" coverage and monitoring of a patient's medical condition. No longer will patients be confined to hospital rooms or be hooked up to some piece of medical equipment that is typically immobile and likely to be more expensive than future wearable devices.
- Preventative Medicine: Wearable technology will enable health care providers to be able to access patient information in real-time, thus allowing for earlier and, most likely, more accurate diagnosis; thereby enabling the health care community to focus on a more proactive/preventive approach.
- Real-time Access: Health care providers such as doctors and nurses will be able to more closely monitor the status of their patient's well being by having access to information that will be transmitted by the wearable device worn by the patient to a mobile or wearable computer that they too will be utilizing in their daily work tasks.

The bottom line benefit of leveraging wearable and wireless technology is being able to more effectively manage health care at the "point of need" while improving quality of care provided using a more proactive approach, lowering costs as a result of fewer hospital visits or trips to the physician's offices, and enabling the healthcare community to leverage the increasing computational and communications tools that are, and will be, available.

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II. World-Wide Technical Overview

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Executive Summary

The contribution of Information and Communication Technology (ICT) towards higher quality of care, the technological innovation on wearable sensors and smart textiles and their integration into enhanced personal health systems, the contribution of the EC on eHealth and the view of users and textile market on wearable computing, smart fabrics and interactive textile (SFIT) are the main issues developed in this section.

At present, more and more stakeholders in health sector, including large technology and solutions industries, recognize that eHealth is a key tool for optimizing processes within the entire health system and for providing higher quality of care. Although the quality achieved in acute medicine is high, adverse events arising out of the institutional healthcare system causes many deaths, disabilities and a huge financial burden. The information gained from monitoring and wearable health systems combined with IT assisted workflow and knowledge supporting tools throughout the entire healthcare process will reduce unnecessary hospitalizations and examinations and consequently will improve quality and support cost-containment in healthcare.

During the last five years a significant amount of research and development activities were funded through the European Commission IST (Information Society Technologies) under Framework Programme V, focusing, among others, on integrated smart wearable solutions for health monitoring and warning, early detection and health promotion, anytime, anywhere. Advanced personal platforms that can be characterized as "Intelligent Serviceware" have been initiated i.e. IT-platforms with capabilities of gathering, analyzing and dealing with personal related information. Currently, the technology vision moves from wearable electronics towards smart fabrics and this vision could be split in three steps: miniaturization (ongoing), integration such as embedding electronic components on or into textile with full usability (immediate future) and fiber technology (next).

The current state of the art in research of wearable textile-integrated solutions for health and wellness services includes smart textiles with antimicrobials or microcapsules for drug-release. In the future, smart fabrics with embedded functions will enable quality of life support, for instance by control of motions, monitoring and therapy of stress, monitoring of overweight and body fat, immunization, control of various biofeedback mechanisms and applications against geriatric diseases. The overall interaction between humans and machines will evolve towards an efficient symbiosis including adaptive medical user interfaces, electronic controlled assistance and convenience, augmented reality and human-robotics cooperation.

Some of the most important technological advances in interactive textile systems come from the military sector. In particular the US Army has invested a large amount of human and financial resources to investigate various ways in which warrior systems may benefit from innovative textile solutions. With respect to healthcare, the Army's interest in interactive textile-based wearable systems lies in the area of physiological status but also status of attentiveness and cognitive functioning, wound detection and treatment. The civil sector could benefit from these developments and know-how as the fields of applications are similar and can be transposable from the concept "network-centric warfare" to the concept "network- centric welfare".

Consumer research shows key indicators regarding long term market needs that could drive R&D activities. Results from several consumer research studies, examining consumer preferences and their receptivity to health benefits delivered through clothing showed that consumers want all basic requirements such as comfort, a good fit, easy to care for, breathability and a good feeling. Additionally they would like a youthful, stylish fashion. In addition, the consumer research found out that there is high interest in "health" benefits of clothing among broad base of consumers. Physiological monitoring utilizing smart fabrics or interactive textiles shows a critical level of commercial activity. Medical applications focused on the aged, infant and critical patient care are taking the lead. However, there is still uncertainty about the systems and the questions are: "I'm not sure it will work", "Seems too good to be true" and "What is the cost"?

One key actor in the value chain of such development is the textile and clothing industry, one of the oldest industrial sectors in the world. It represents, in Europe, 190 billion euros turnover, more than 2 million workforce, more than 100.000 companies in 2002. After the liberalization of industrial markets in 2003, which increased the pressure on the industry to compete through quality, functionality and better services, the textile industry is looking for more innovation and a stream of new products for the global market based on new or improved materials, electronic textiles and intelligent fabrics. The eagerness of the sector to have a leading role in the new eTextile era contributes further towards the development and market exploitation of textile-based personalized wearable health systems.

Optimizing Workflow and Knowledge in Healthcare through Innovation

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Abstract. People's desire is to stay healthy during the entire course of their live. Innovations in medicine in care and technology have always contributed significantly to meet this desire as close as possible. Today, healthcare systems are faced with huge additional challenges. The focus of nearly every healthcare debate is on costs. But is this debate target-oriented and does it support the struggle for further enhancing the quality of care? The implementation of IT assisted workflow and knowledge supporting tools throughout the entire healthcare process - prevention to cure – leads to care which would be much more focused on people's needs and efficiency. The information gained from monitoring and wearable devices has to be included to these tools for delivering comprehensive patient information to the point of care. Then the puzzle of the different components in healthcare linked by IT will be complete, and the care process could be continuously optimized in an efficient way.

1. Medical Technology is Source for Efficiency

During the last century people's life expectancy in industrialized countries has doubled from roughly 40 years to 80 years in average. This is due to the progress in medical care, the increased awareness of people for their health and the development of innovative technologies. These good news are accompanied by an increase of expenditures for healthcare. For European countries, this is about 35% from 1992 to 2001 [1]. In the same time, the investments in high-tech equipment, e.g. Computed Tomography, Magnetic Resonance, or Angiography remained rather constant. During this time they accounted for only 0.2% of total annual healthcare expenditures. Even taking all electro-medical equipment into account, the investment was only 1%. And including all reimbursement fees, running costs only draw additional 4% (Figure 1). These statistics show, electro-medical equipment is not the source for driving the healthcare expenditures. But it is rather a source of safer diagnosis, more focused treatment and therefore curing the patient with less personal burden and with economic efficiency.

2. Focus on Quality

In the healthcare debate, the focus on pure cost reduction does not help to meet the demands of people. We have not only the obligation to keep healthcare systems affordable, but also to continuously increase quality of care. The key is to detect diseases much earlier, so the chances of complete cure is higher and the costs of treatment is respectively lower. If we consider the actual situation, we have good tools in place to treat acute cases well and with high quality. The cost situation, however, is sub-optimal.

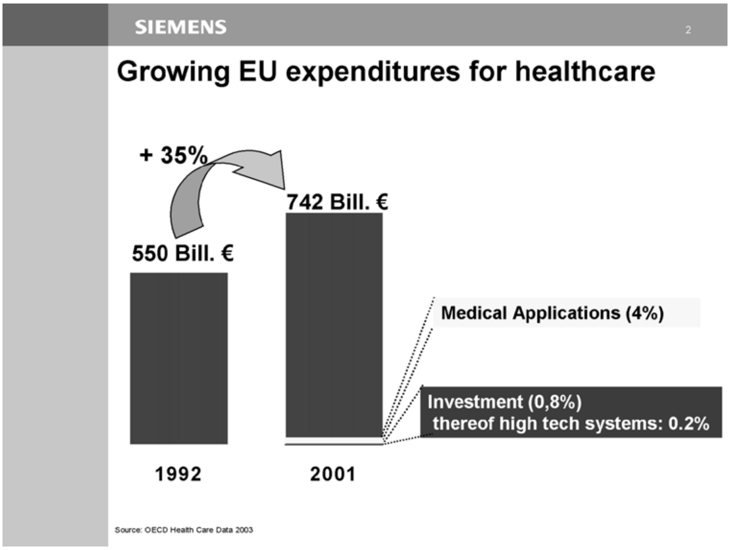

Figure 1. The increase of healthcare expenditures from 1992-2001 in European countries was 35%. However, the share of investment in medical equipment was just 1%.

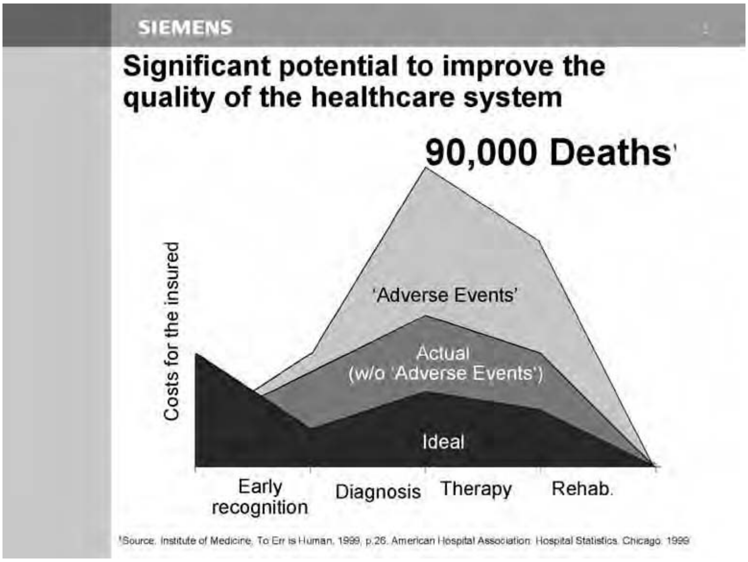

Figure 2. The costs for healthcare depend mainly on quality assurance. The total costs can be significantly reduced, if early recognition is included into the care process. The current healthcare process differs from the ideal course. In the case of "adverse events", costs explode.

And if, in addition, adverse events occur, the treatment will become really expensive combined with huge disadvantages for the patient (Figure 2). According to the study of the Institute of Medicine "To Err is Human", 90,000 deaths occur in the USA per year due to medical errors [2]. If we can avoid these cases, it would be a great advantage for the patient and the healthcare system by avoiding unnecessary treatment and costs.

Plus, if we include prevention measures into the care process, and therefore detect diseases earlier, targeted treatment is less expensive and the probability for complete cure is much higher.

3. Healthcare IT Supports Optimized Workflow

Medicine is a science which is very much based on knowledge and information. It is estimated that medical knowledge doubles every 5 years [3]. Therefore, information and communication technologies play a more and more important role in the daily practice of care. And the systems themselves become more and more sophisticated.

Today, diagnostic and therapeutic modalities have a common software platform with a unified user interface making the application much easier [4]. When the user chances e.g. form a CT to a MR examination, he finds the same display, which he is already accustomed to. Results are digitally stored and distributed within the hospital. Information is now available at the point of care. Time consuming manual transportation of reports and film-based images and the permanent risk to loose these documents is gone. This is an enormous facilitation in the hospital workflow.

Meanwhile, nobody doubts the benefit and potential of such IT-innovations in the healthcare continuum. If all components and aspects of care are integrated, all stakeholders, physicians, payers and patients also at their home, have one source of information for the multiple tasks to deal with. The workflow can be continuously optimized throughout the healthcare continuum.

4. Four Levels to Increase Efficiency in Healthcare

Such fundamental changes within healthcare will not happen from one day to the other. It is an evolutionary process which can be categorized in four levels. Every level bears huge potential for efficiency improvement (Figure 3).

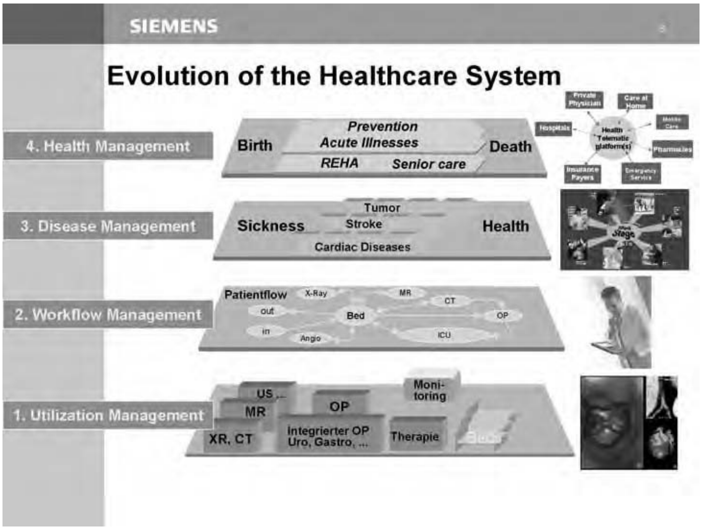

Figure 3. The four levels of evolution of healthcare systems demand increasingly the support of IT.

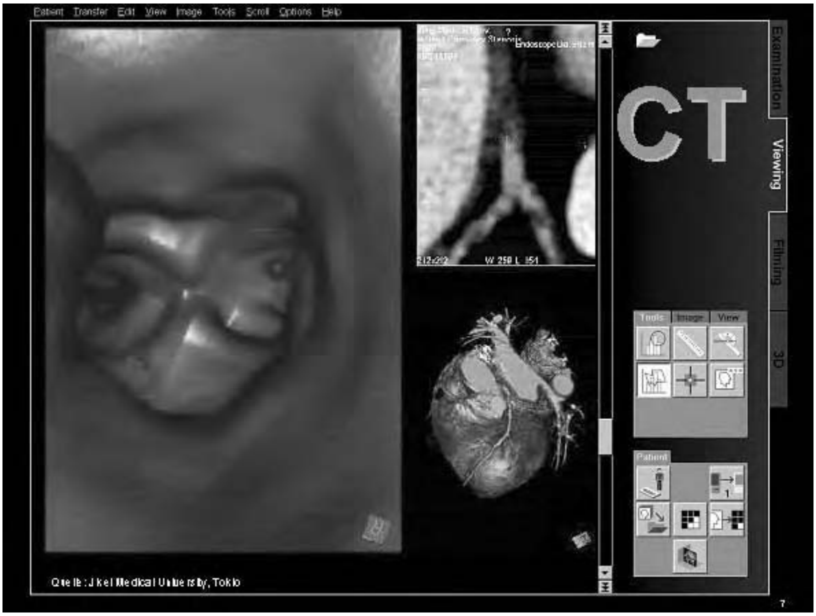

Figure 4. Multi-slice computed tomography of the heart. Left, a virtual flight through the coronary artery. The surface is displayed in the 3D-image on the right side and provides orientation.

Utilization management is the first level. Here, diagnostic and therapeutic systems are optimized towards specific diseases. No modality can be utilized for all questions in diagnosis and treatment, but all have their specific strength. E.g. computed tomography becomes so fast that its outstanding resolution can be utilized to image even moving organs like the heart [5]. Now, coronary arteries can be displayed in the 3D relation to the surrounding tissue. Calcification and stenosis can be detected and software allows a virtual fly through the coronary arteries to measure the degree of obstruction (Figure 4). This gives a more reliable basis to determine the right treatment strategy and is much less invasive as the conventional angiography with a heart catheter. Angiography, however, still keeps his power for therapeutic interventions, such as angioplasty.

On the second level, called workflow management, the comprehensive workflow within the hospital is optimized. Pre-requisite is an electronic patient record hosting the relevant patient information, such as personal data, diagnosis and treatment. Portable devices connected by Wireless LAN to the hospital information system, for displaying and sending patient specific information, guarantee the access anytime, anywhere (Figure 5).

Especially for the medication process the use of IT shows significant benefit for medical personnel and patients. The above mentioned Institute of Medicine report concluded that about 7,000 patients in US hospitals die annually due to medication errors. This has resulted in enormous efforts to optimize the medication process and reduce failure rates. The application of automated Physician Order Entry (POE) systems, supported by IT and barcode reading, has already led to significant efficiency improvements at the Ohio State University Health System (OSUHS), USA [6] and Soedersjukhuset, Sweden [6].

Disease management as the third level is a population based approach to manage the care process of chronic diseases in order to improve overall health and financial outcomes.

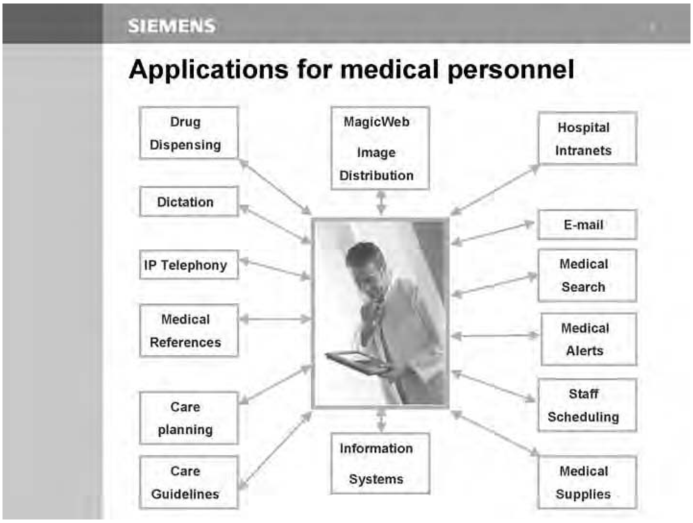

Figure 5. Wireless LAN enables medical personal to assess information from and to give information to the electronic patient record of the hospital.

Recently, the World Health Organization (WHO) mentioned that 60% of expenditures in healthcare are allocated to the treatment of chronic diseases. Tendency increasing. One aim of disease management is to increase the compliance of patients. The purpose is to avoid critical situations. This is accomplished by monitoring tools and communication technologies [7]. Internet platforms, ensuring data safety and security, support disease management programs as well as quality assured screening procedures.

One example: Diabetes patients have to monitor their glucose level in narrow time intervals. Better than filing the course of their level on paper, is an electronic record. The measurement of the glucose level can be performed by the patient at home and send via conventional touch tone telephone to the electronic patient record (Figure 6). A physician or a specialized competence center has insight and can act when it is necessary. Also, automatic alarms can be defined when critical situations occur. This has already proven to increase the compliance and patient satisfaction. The results are: less acute situations and therefore less hospital stays.

One big risk for these diabetes patients is blindness due to reduced blood circulation in the eye-background. Regular screening of the background of the patients' eyes is necessary to avoid it. This screening can be done at any place by a trained person, using a laser camera. The images are electronically sent to a competence center and there, the diagnosis is performed by a specialist. The quality of diabetes diagnosis can be measured and controlled because of the availability of meaningful statistics by using such standardized procedures.

Second example: Vascular diseases are the number one cause of death in industrialized countries, since leading to stroke, heart attack and other serious diseases. Avoiding these critical cases is not only a great benefit for the citizen but also a huge potential to save costs for the healthcare system and the economy. The vascular risk to suffer from stroke or heart attack can be quantified using the same technique for evaluating the eye-background [8]. In a pilot project, t@lkingeyes, performed in Erlangen, Germany,

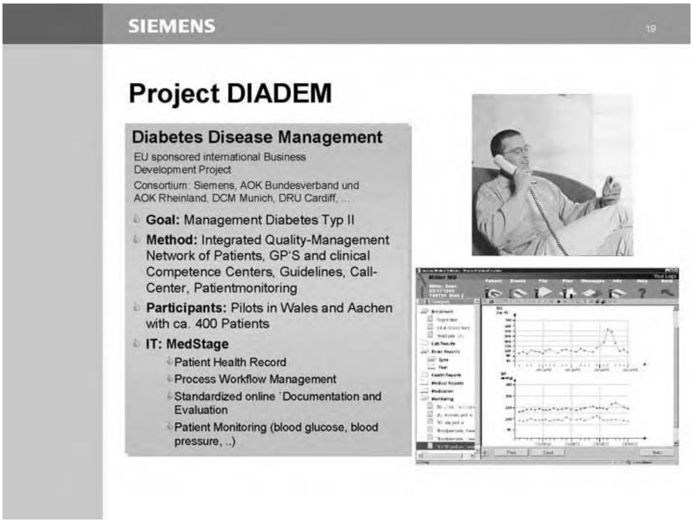

Figure 6. The project DIADEM already proved that compliance of diabetes patients can be improved using healthcare IT for monitoring and screening procedures.

8000 participants were screened during one year. The images of the eye-background were send to a server and recorded at the Ophthalmology Clinic of the University of Erlangen. The results showed: 20% of the participants had higher vascular risk compared to normal. They were invited to subscribe in a disease management program to define the individual causes and to receive consultation for dedicated medication and life style chances.

The forth level of healthcare development is called health management. It stands for performing any efficient measures to keep people healthy as long as possible. This means, to include early detection such as evidence-based screening procedures and evidence-based guidelines into a comprehensive healthcare process. Physicians examine and treat patients in a cooperative way and are reimbursed accordingly. Every expert should be able to include his special knowledge for the benefit of the patient. Incentives focus on measured high quality of care. In the US, hospitals are already reimbursed higher, if they proof their quality.

In the whole healthcare continuum this can be only realized if complete information is available (Figure 7). And quality measures must be defined, agreed upon and published at leased among the providers community. This results in an enormous learning effect and continuous quality increase because knowledge exchange is implemented. The keyword here is telematic. Telematic platforms fed with structured information and delivering this information with the consent of the patient to the point of care, have the potential to increase transparency with regard to quality and costs in healthcare. Necessary examinations and treatments are only done once and every physician can start his treatment at the point where his colleague finished. This avoids unnecessarily spending resources and enhances quality and patient satisfaction. If such telematic platforms can communicate with those of other European countries, trans-boarder care will be possible and highly specialized services will be available also for people from other countries.

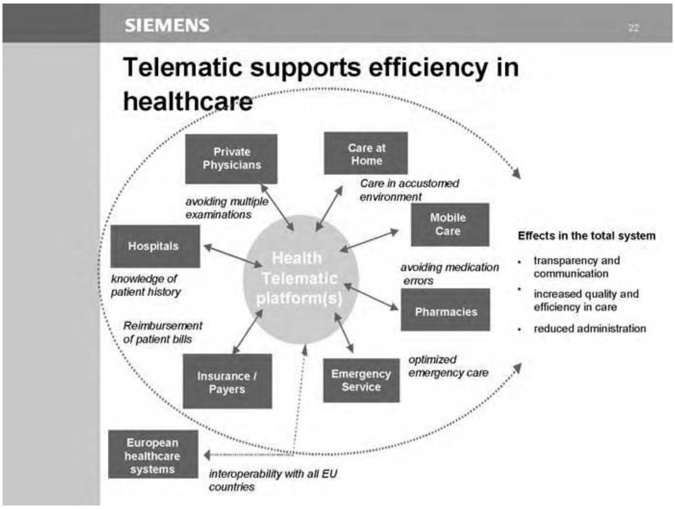

Figure 7. Telematic in the healthcare continuum leads to transparency regarding quality of care and costs. At any step, the patient is asked which information can be given to whom.

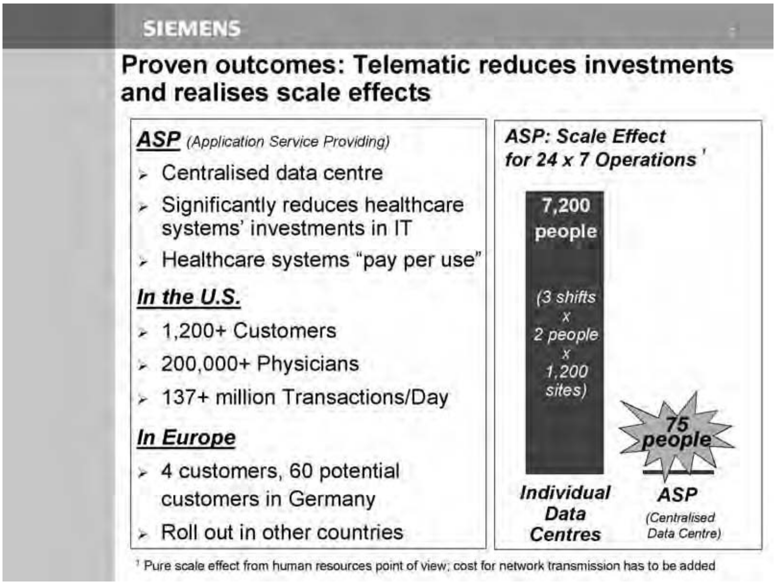

Figure 8. Telematic can centralize and scale healthcare transactions.

5. Reduced Investments

Through the use of Application Service Providers (ASP), healthcare providers no longer have to invest in their own hardware, no longer have to maintain their own IT department, and no longer have to operate their own data center [9]. All of this can be effectively outsourced and centrally hosted. The healthcare provider pays per use and receives all the applications via the net (Figure 8). This results in significant economies of scale.

ASP is real business today. In our data center in the United States [8], we already serve more than 1,200 customers with 200,000 physicians conducting 137 million transactions every day. If each of these 1,200 customers would maintain their own IT department, each of them would need at least two people during three shifts for seven days a week. In total, they would have at least 7,200 people. Our data center does the same work for them with 75 people. This shall only illustrate how telematic can be harnessed to improve efficiency and to significantly reduce investment in healthcare.

6. Reward Process-Oriented Healthcare Delivery

However, especially in general practitioner offices and pharmacies the benefits of these innovative technologies do not accrue to the purchasers who use them. While measurable financial savings as well as improved compliance with guidelines benefit especially the patients and payers, the healthcare providers must actually make the investment and use these innovative technologies. If no reimbursement, no reward or no little direct benefit for this investment is allocated, they are reluctant to invest and to change the way of performing their work. This is also valid for the use of information provided by monitoring and wearable devices. This is the most prominent reason why telematic and the wearable device market develops rather slowly. Reimbursement and incentives have to be reallocated to reward high quality in healthcare. This is the major task when optimizing healthcare systems.

7. Wearable Devices Complete the Puzzle

Information and communication systems have been introduced into our daily life proving the benefit of exchanging information in the business and private world. In health-

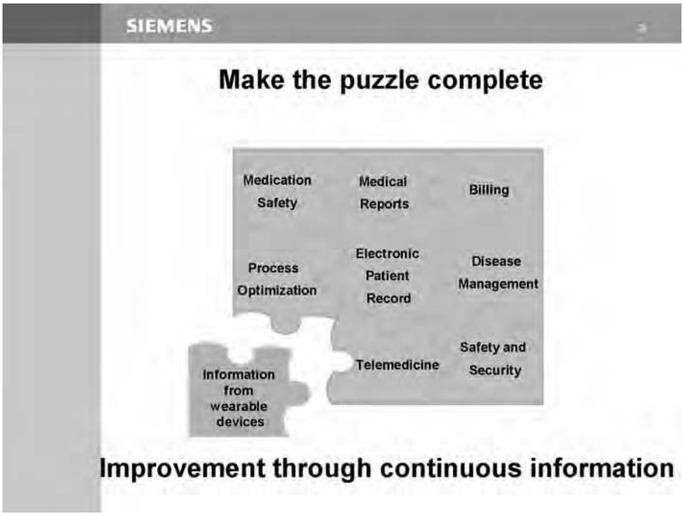

Figure 9. Comprehensive IT-support, process-oriented healthcare and reimbursement structures for co-operative care together with the integration of the information gained from monitoring and wearable devices is the lever for the increase of efficiency in healthcare.

care, however, IT is not used to its full potential. OECD has stated recently, that healthcare IT is the first innovation in healthcare which has the true potential to save money and increase efficiency in this highly sensitive and for all people very appreciated area. Also the information gained from monitoring and wearable devices has to be included to telematic platforms to make this valuable information available at the point of care (Figure 9).

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Wearable eHealth Systems for Personalised Health Management
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I-Wear for Health Care and Wellness – State of the Art and Future Possibilities

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Abstract. The background of the development of i-wear for health care and wellness are two actual trends: The wellness trend with its expectation to stay fit and healthy and the increasing life expectancy of the Europeans and the challenges, which are resulting thereof for the medicine and the technology that goes with it. Already in 2040 the amount of people over 60 years in Europe will amount to 40% of the entire population [1,2]. In recent years the co-operation of physicians, biologists, physiologists, engineers for electronics and information technologies and textile scientists has produced a multitude of innovative applications for textiles, especially in the medical and wellness field. This presentation will cover the state of the art and some future aspects of textile-integrated solutions for health and wellness services, with intelligent application forms or integrated electronics (i-wear), which are an increasing market for textiles.

1. State of the art of wellness and health textiles

Textiles and fillings with antimicrobial finishes have been used for many years to prolong the performance properties of (technical) textiles. Meanwhile, textiles equipped with antimicrobials like silver-zeolithes or triclosan have been technically enhanced and are also applied in the medical field to treat skin disorders like atopic dermatitis or as clothes in hospitals to combat nosocomial (i.e. hospital acquired) infections [8]. Another modern textile finish uses complexing agents, so-called cyclodextrins which may be chemically anchored to a variety of textile fibres and are suitable to release aromatic substances e.g. in aroma therapy. Cyclodextrins consist of small 6-8 glucose rings with an internal hydrophobic core hence they mainly complex non polar substances. The release of complexed substances out of the cyclodextrin cages as for example α-tocopherol/vitamin E, a natural free radical scavenger of the human skin, depends on the water vapour pressure of the human skin [6]. First textile-based medications or cosmetic applications also come from drug-releasing depots like microcapsules, (Figure 1) small capsules of a 1000 part of a millimeter, which are made from resin-formaldehyde or other polymers [5]. Textiles equipped with microcapsules are already available on the market as T-shirts or stockings. The encapsulated drug depots release substances like vitamin E, vitamin C, ginkgo or aloe vera with the aim to support the skin metabolism. To expand the market for textiles finished with antimicrobials, cyclodextrins or microcapsules, more scientific effort will be necessary to optimise the performance of these kinds of wellness textiles in terms of reasonable release rates and durability after care treatment.

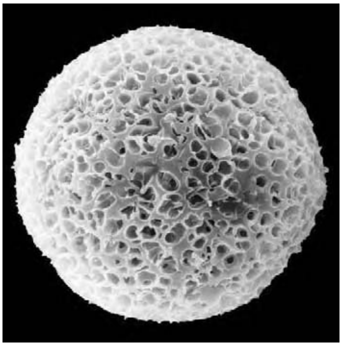

Figure 1. In the future nanocapsules will medically functionalize textile fibres as sensors or drug depots.

2. Textiles for seniors: a future business market

As already mentioned above, i-wear textiles with added wellness and health functions will be a future challenge and business area, especially for seniors [3,4]. Modern geriatric medicine aims at the addition of more quality rather than quantity to a seniors life, a task that may also be supported by future "intelligent" textiles. Hence the market will be facing textiles which are equipped with more sophisticated drug releasing depots (actuators) as e.g. microcapsules or even sensors to detect a certain biometric feature. Therefore it is reasonable to think of future i-wear fabrics supporting life´s quality for instance by control of motions, vitalisation, preservation of life, monitoring of overweight and body fat (nourishment control), immunisation, control of various biofeedback mechanisms, physico-therapeutical properties, or the application of anti-stress therapies (colour therapy, aroma therapy). Another challenge for i-wear will be reasonable applications against geriatric diseases. Despite recent progress in geriatric medicine, many seniors will still have to face typical geriatric diseases, e.g. recalcitrant chronic wounds. To combat problems with chronic wounds, recently a non-adhering wound bandage has been developed by use of nanotechnology. The novel wound bandage is covered by a Nano/Sol ceramic coating that does not "stick" to the granulation tissue of chronic wounds, but able it is still to keep the wound moist and thus to accelerate the wound healing process.

3. Detection of biosignals using i-wear

Nanotechnology and microsystem technology (MST) will be the most promising new innovative key technologies of the next years. It is generally believed that these technologies in conjunction with textile technology will help to reduce health-parameter-surveying sensors and drug-applying units for health care to the size of a fibre diameter or even smaller [3]. This produces varied possibilities of a textile-based medical biometry, which is, so far and with the existing technology impossible or hardly to accomplish. A present precursor in that direction is the so called "life shirt" made by VivoMetrics (Figure 2). It records fundamental functions for health surveillance: Heart sounds respiratory rates as well as the body posture. But so far the "life shirt" is an extremely unwieldy and expensive product. The "i-wear" of the future should be equipped with more sophisticated integrated microsensors, which help to survey the most important general health

Figure 2. Presently prototypes as the "life shirt" are unwieldy and expensive; however, the application of nano sensors will revolutionize technology within the next few years. Photo: Vivometrics.

parameters as body temperature, blood pressure, respiratory sounds and heart sound or will control biosignals like enzyme concentrations in case of cardiac diseases, increased blood sugar level of diabetes patients, cholesterol values or even drugs. Although the most important health parameters are still hidden within the blood, progress is being made to make these biosignals detectable from outside of the body (a major breakthrough has been the non invasive measurement of blood glucose level in diabetic patients).

4. Advantages of i-wear in respect to conventional textiles

i-wear systems using sensors integrated into the clothing have clear advantages in comparison with conventional sensor systems: Implanted sensors and drug depots require costly operations and well-tolerated materials, as they hold the risk of an undesirable immune response of the body due to a lack of biocompatibility. Moreover, external measuring and analysis systems assume a high degree of discipline of the patient, as reliable data can only be obtained under strict obeying of the guidelines, as for example the point in time of the measurement. Textiles on the other hand are being worn up to 24 hours a day and thus work regardless of the wearer's state of health.

5. Future tasks for i-wear

A look at the state of the art indicates that we have to make further progress in the optimisation and adaptation of i-wear. For example, to support the individual health status of a certain senior in his daily life at home, one should be able to invent flexible and convertible systems that can easily be adapted to the present health status of the wearer/senior by clipping on the essential medical sensors or actuators. Thus the next major task will be consumer friendly convertible i-wear systems, with exchangeable sensors, which not only can be adapted to the actual state of health, but that also can easily be reprocessed and care treated. On the way to a save i-wear application, the implementation of ecological aspects will also be of utmost importance, including a functional waste management of sensor or drug containing textiles, the exclusion of bioaccumulative pollutants or problems with electrostatic shielding.

6. How to prove i-wear for medical and wellness applications

However, the additional health and wellness functions of medical textiles listed above, must be provable. That's why textile research institutes like the Hohenstein Institutes are not only working intensively on the development of innovative clothing, but also on the development of test systems, to verify the function of the medical textiles and to optimise them. Interesting test systems, on the market, that may help to clear this topic are human in-vitro skin-organ cultures, so-called skin equivalents [7,9]. This bio-engineered skin, grown in the lab using small samples of human cells, has been on the market since 1997 and since then has shown major pros: The main advantage of a skin equivalent is that it corresponds to a large extent in function and reaction with the human skin. While such artificial skin was originally developed to help treat burn victims [11] and other patients, it and other engineered tissues are gaining new cachet as alternatives to animal testing for some basic research and drug-development tests [10–14]. Engineered tissues like skin equivalents are uniform from sample to sample whereas animal or human excised skin have biological differences that can affect test results. Thus, skin equivalents have the advantage of yielding test results that are easier to reproduce from lab to lab. Taken together, because of its similar cellular structure and behavior as normal living skin, skin equivalents are an ideal in vitro model for the cellular analysis of the interactions between skin and textiles. Today, for instance, skin equivalents are the only test system which allows an adequate mechanical in vitro imitation of the physiological textile/skin interactions. Hence, an experimental set up using skin equivalents can be used to study the major question of drug-delivering textiles: the transfer of substances from the textile into the skin, as well as their consecutive skin care or skin penetrating effects. (Figure 3.)

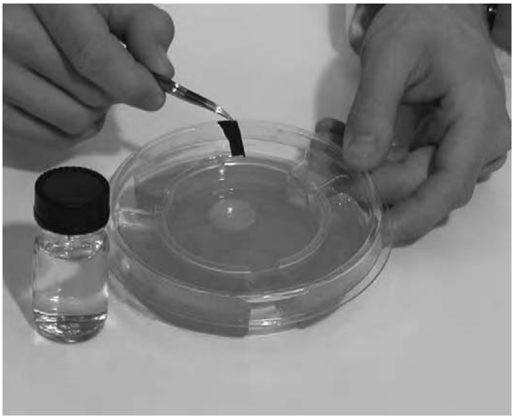

Figure 3. At the Hohenstein Institutes skin equivalents are used to evaluate the functions of medical textiles.

7. Conclusions

There is no doubt, that i-wear textiles for health care and wellness will play an important role in the future. Moreover, additional fields of application will result regarding personal wellness: Ranging from the surveying of the body functions during sport to the application of cosmetic and treatment agents via the textile. Test systems based on skin equivalents will help to develop future medical textiles as an interesting test system to proof the various functions of upcoming medical textiles, or as a standardized and reproducible method to study textile-derived added values.

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Research in Intelligent Biomedical Clothing vs. Realities in the European Textile Business

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Abstract. In order to make intelligent biomedical clothing a market reality, a critical mass of scientific, technical and industrial capacities from various disciplines and industries must be successfully brought together. The textiles and clothing sector, i.e. the industry that transform natural or man-made fibres into yarns then with a myriad of processing options into complex tissues and finally into clothing, is undoubtedly a crucial element in such development. With Europe disposing of the world's most diverse, productive and innovative textiles and clothing industry, in addition to relevant expertise and resources in other scientific disciplines and industrial sectors, it could play a leading role in the advancement of the concept of intelligent biomedical clothing. In this process, a great number of challenges – firstly scientific and technical in nature - still need to be overcome and support from public funding programmes could constitute the necessary trigger for research and industrial efforts to be seriously undertaken. In view of the great benefits of such new products for the individual consumer, national health care systems and the society as a whole, a concerted effort in private-public partnership seems merited.

1. The European textile and clothing industry today

The European Textiles and Clothing industry has a longstanding tradition of playing a leadership role in terms of innovation, and despite increasingly fierce global competition and continued relocation of manufacturing to low-wage countries, it still represents one of Europe's major industrial sectors with an annual turnover of 196 billion Euro and a total workforce of in excess of 2.0 million in more than 110,000 companies in the EU in 2002. It remains one of the main players in world trade, the first in textile exports and the third in clothing.

Creativity in fashion design; quality focus, innovation and flexible re-organisation in manufacturing as well as vertical integration and consumer brand building have been the main instruments of the European Textile/Clothing industry in preserving its leading edge in the global market place. However, one important element that has hampered the speed of innovation and the resources dedicated to it, is the particular structure of the industry, which is composed of a vast majority small if not very small enterprises that often lack the human, knowledge and financial resources to significantly invest in R&D. Planning and budgeting horizons of such companies are generally very short, often spanning a mere fashion season.

2. Future challenges

2.1. Changes in the global trading environment

The liberalisation of industrial nations' markets through the complete removal of import quotas for all textile products by 2005 will further increase the pressure on the industry to differentiate itself and compete through quality, functionality, environmental friendliness and consumer appeal of its products and the flexibility and quick response of its services, rather than on price alone.

This can only be achieved by a large-scale industrial deployment of leading-edge research results, a highly efficient process organisation and supply chain management, and a highly qualified workforce. Prerequisite for the achievement of this goal is an industrial awareness of the latest developments in a research field that is very broad and multidisciplinary, spanning materials science, chemistry, precision engineering, electronics and informatics, which further complicates the matter, especially for the many smaller companies.

However, awareness of available knowledge and expertise and information on critical issues will foster a range of applications with considerable impact on industry and society. The impact will be measured in improved industrial competitiveness as well as higher added-value for consumers, ranging from entirely new functionalities to better quality and safety, health care at all levels, to greater environmental friendliness.

2.2. Changes in consumer patterns

The share of total available consumer income spent on clothing and on textiles for home decoration has been in constant decline in all industrialised countries over the last two decades. Massive productivity gains especially in textiles processing, intensified clothing production in the lowest labour cost locations around the globe and significant changes in the retail structure (the rise of global supermarket and discount chains) have led to significant real price declines for clothing products over time.

At the same time, other areas of consumer spending like health care and well-being, travel, sports and other leisure activities as well as corporate spending on performance and protective equipment have registered healthy gains from which certain specialised clothing categories, like sports and outdoor active wear, work wear, uniforms and protective clothing have greatly benefited.

In this process many traditional commodity textile and mass market clothing manufacturers have disappeared from Europe or transformed themselves into (multi-)niche players and many newcomers have entered the market and created a whole new generation of more innovative, flexible and specialised textile and clothing manufacturers, retailers or service companies.

3. Opportunities through new materials, innovative products and non-conventional textile applications

Through relentless product innovation based on new or improved (fibrous) materials, new combinations or processing of existing materials, continuous creation of new styles and designs or the application of textile materials to more and more consumer and industrial uses these companies have entered into entirely new markets or broadened and diversified their existing ones. This trend is believed to continue with all the above areas still providing enormous scope for innovation and a stream of new products for the global market.

Property improvements at the fibre level significantly influence both processing options at subsequent stages of the chain as well as properties and functions of the final product. Fibres that respond in a “smart” way to external influences like temperature changes, humidity, chemicals and bacteria, light and radiation, fire, electric charge or mechanical use enable the production of functional or smart clothing for sports and leisure wear as well as work wear and protective clothing, which all represent growing markets.

Fibres, filaments and textiles that conduct electric current or light, accumulate energy, store information or receive and transfer radio waves will open up a whole new market for intelligent garments containing sensors and actuators and advance the vision of wearable technology that can monitor, control, alert, inform, relax or entertain the wearer.

Last but not least, textiles with medical and hygienic properties will find a multitude of applications in the healthcare sector, be it in the form of biocompatible implants and tissues, antibacterial wound treatment material or anti-allergic clothing or home textiles for infants, children or skin-sensitive persons.

Such high added value products that draw from traditional European strengths like engineering and industrial design skills can give the industry tremendous opportunities to be competitive on markets worldwide.

4. Intelligent biomedical clothing – a fascinating market

Textile products with certain medical properties and functions have always been indispensable elements in all fields from personal hygiene to the intensive care hospital environment. Contrary to such *functional* products like wound dressings, diapers, face masks etc. truly *intelligent* biomedical clothing that can combine the function of sophisticated medical devices with the comfort and user-friendliness of apparel products could only be conceived through a combination of recent advances in fields as diverse as polymer and fibre research, advanced material processing, microelectronics, sensors, telecommunications or informatics.

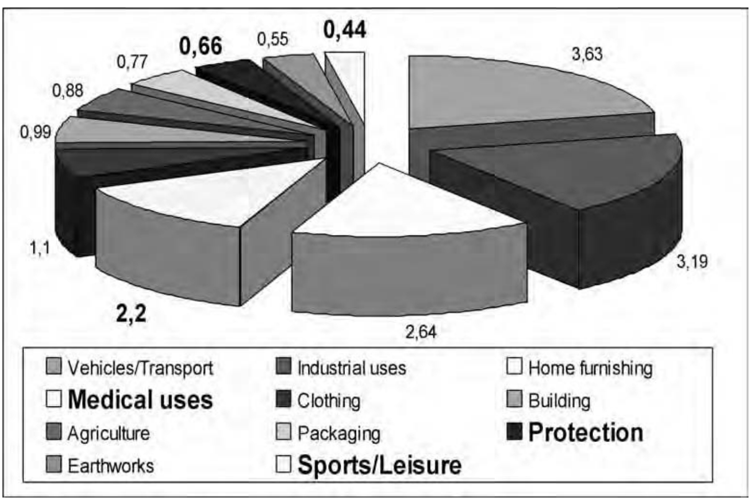
The special attraction of such products is the fact that they can not only replace existing cumbersome or stationary medical devices but also have the potential to open whole new markets in fields like constant monitoring of body functions of persons at risk or performance measurement of workers, drivers, sportsmen, emergency staff or soldiers while performing their tasks. The functions of such biomedical clothing can then be extended from passive monitoring to active corrective measures, with or without intervention of the wearer, in case anomalies are registered

Such new products have the potential to combine desired functionality with the traditional aesthetic and personal expression element of fashion items like garments and other wearable.

5. Assessing the European Market Potential for Intelligent Biomedical Clothes

It is certainly extremely difficult to assess a future market potential for a product category that merely exists in the form of conceptual prototypes in research labs and for which a clear unambiguous definition is not in sight.

However assuming that these products should be principally textile-based and they should be worn by users in the form of clothing, an assessment can be tried based on some breakdown and extrapolation of current market figures for textiles and clothing. Out of a current total EU production of textiles worth almost 100 billion €, about one quarter in value terms represents products destined for various functional purposes other than general clothing and interior furnishing. Out of these commonly called technical textiles, 3.3 billion € worth of production is dedicated to purposes to which also intelligent biomedical clothes could be targeted in the future, i.e. medical use, protection and sports/leisure (see below chart, based on figures of [1] and [2]).



Clothing on the other hand represented a total worth of approximately 75 billion € in production value in the EU in 2003. Out of this total an estimated 6 % or 4.5 billion € represented work wear and uniforms, which are promising markets for intelligent sensor and actuator equipped garments in the coming years. Combining technical textiles of relevant uses with the work wear/uniform segment of clothing and figuring in a low single digit growth rate of these markets, intelligent biomedical textiles and clothing could find an addressable market of in excess of 9 billion €) in production value at the horizon of 2010 in the current EU-15 alone.

This figure would certainly need to be substantiated by estimates for relevant applications of medical systems that could be substituted by intelligent biomedical clothing and their respective addressable markets and market growth rates.

A completely different and massively enlarged market scenario could be drawn under the assumption that intelligent biomedical garments also find their way into the fashion domain. Tapping a market worth about 250 billion € in consumption value in the EU in 2002 would indeed represent an highly attractive long-term objective and strong driver of development efforts for products that could at the same time satisfy human needs for fashionable dressing, biomedical surveillance and support in all types of work and leisure activities. Under such a scenario, not only current users of medical devices, i.e. predominantly patients with known chronic health problems, would be potential consumers, but also healthy people interested in performance or health monitoring for informative and preventive purposes.

6. Challenges to overcome

While the potential of such new products seems highly promising, a great number of challenges need to be overcome to make it possible to efficiently develop, manufacture, and market them.

For design and product development, multidisciplinary teams from companies in different markets and research centres in different discipline need to effectively collaborate in overcoming entrenched frontiers of the own scientific or technical field of specialisation. Before bringing such products to market, extensive safety and reliability testing needs to be carried out, and complex lengthy regulatory approval processes need to be cleared.

For efficient manufacturing new processes, machinery, equipment, measurement and control devices will have to be developed. Inter-sectorial supply chains will have to be built and effectively managed.

Alternative marketing concepts will have to be developed in which traditional sales channels of medical systems and fashion products may overlap. Multi-skill sales personnel must be trained and finally the end consumer must be convinced of the added value of the new products.

However, the single biggest challenge may be to combine entirely different industry cultures and ways of doing business in sectors as diverse as clothing, consumer electronics, telecommunications and medical systems. The following table provides a (non-exhaustive) overview of current differences between the medical systems and the clothing business.

	Medical Devices	**Clothing**
Product focus	Hard factors (function, safety, reliability)	Soft factors (appeal, comfort, brand)
Product Life Cycles	Long	Ultra-short
Time to market	Years	Months
PD key expertise	Scientific	Creative
Manufacturing	Assembly of Pieces	Chain of Processes
Salesman	Health expert	Retail shop (assistant)
Buy decision	Need	Desire
Product warranty/liability	Very strict	(almost) unknown

7. Conclusions

Intelligent biomedical clothing is a fascinating new multidisciplinary research and product development challenge which may turn into a huge market of high added value products for an almost unlimited field of applications.

However, in order to succeed it will require the willingness and ability to combine scientific excellence from a variety of disciplines, the manufacturing experience of multiple sectors, the marketing feel and intelligence for different currently unrelated markets and a favourable regulatory environment. A few highly visible successful pilot products and pioneering companies will be necessary to open this market. The substantial risk involved in such ventures certainly merits public support, because the potential societal return in the form better quality of life in addition to economic growth can be immense.

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Current and Future R&D Activities of the EC-IST Programme in *e*Health

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Abstract. The EU support to R&D in *e*Health over the last few years has addressed citizens, patients and health professionals needs in their activities. The societal challenges based on the principle of citizen-centred care have found solutions in the many projects financed through the IST programme.

Major paradigm shifts have emerged e.g. from "hospital centred healthcare" to "patient/citizen centred health" and from "treatment" to "prevention". Information technologies became one of the major driving forces for healthcare evolution, receiving acceptance by an increasing number of health professionals. In addition, a new industrial sector was clearly identified; the "Health Telematics Industry".

This paper present the main research and development activities carried out in *e*Health during the 5th R&D Framework Programme and the future research and development activities in the 6th R&D Framework Programme.

Introduction

The research and development activities in Information Technologies applied to Medicine ("Medical Informatics"), and later in conjunction with Telecommunication Technologies in Healthcare ("Health Telematics"), have gradually reconfigured healthcare provision during the last 10 years. Telemedicine, commonly accepted and implemented in daily practice today, still evolves, offering new solutions to chronic diseases management in addition to disease prevention and healthy lifestyle promotion.

The European Union has strongly supported this area through successive research and development Framework Programmes. The first programmes were the "Exploratory Advanced Informatics in Medicine (AIM)" (1988-1990) and "AIM" (1991-1994) [1]. These initiatives resulted in the creation of a collaborative environment among healthcare and IT actors, standardisation, information and communication tools multimedia applications for exchange of medical information and tools for diagnosis and treatment.

From the mid 90s, the concept of health telematics has been reinforced in Europe and achieved further development and practice in Electronic Patients Records [2], applications for collaborative work of health professionals, medical imaging applications and

[1] The views developed in this paper are that of the authors and do not reflect necessarily the position of the European Commission

health information for citizens (4FP[i], 1994-1998) [3]. The concept of “continuity of care” has been largely adopted, broadening the scope of telemedicine, to get promptly access to medical knowledge for health professionals regardless location, to improve quality and access for patients and citizens to health and healthcare.

In the 5FP[i], major shift paradigms have emerged e.g. from “hospital centred healthcare” to “patient/citizen centred health” and from “treatment” to “prevention” [4]. Information technologies became one of the major driving forces towards accessible and cost effective high quality healthcare receiving acceptance by an increasing number of health professionals [5]. In addition, a new industrial sector was clearly identified; the “Health Telematics Industry” [6].

This paper present the main research and development activities carried out during the 5FP and the future activities in the 6FP[i].

1. Fifth Research and Development Framework Programme Activities

The 5FP (1998-2002) [7] is a key milestone in the last fifteen years of research and development activities in the domain of integration and use of Information and Communication Technologies for healthcare. The figure below outlines the past evolution of the R&D activities in *e*Health in terms of objectives and approach as well as in terms of budget and results. It also indicates the future main themes which will be covered in the 6FP.

During 5FP, the strategic objective was to increase the benefits of the Information Society for healthcare and health sector, both by accelerating its emergence and by ensuring that the needs of individuals (health professionals, citizens and patients) as well as businesses and society were met. The benefits could be measured against benchmarks like “Quality”, “Access” and “Cost” of healthcare and health.

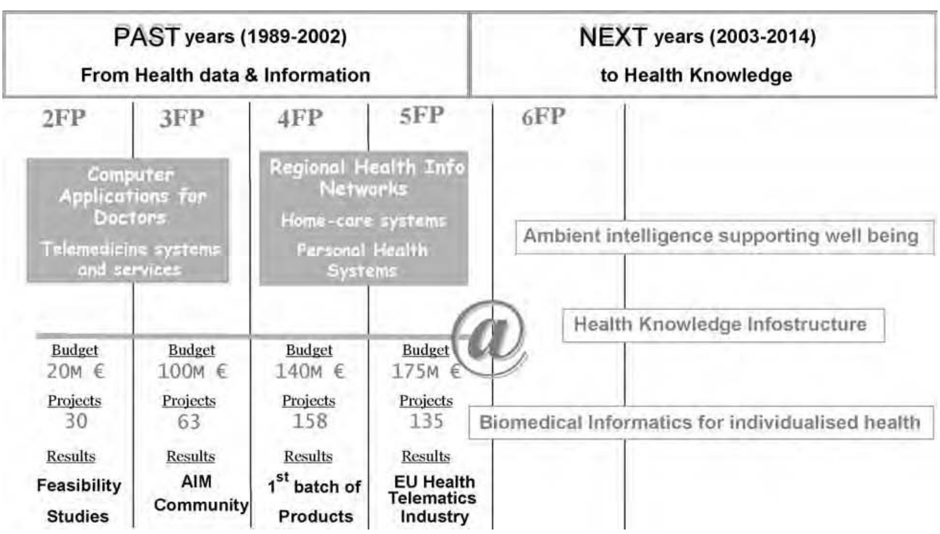

Figure 1. Evolution of EU-funded R&D in *e*Health.

Three main societal needs were identified:

- for *health professionals*, the key needs are the optimisation of the human, technical and financial resources allocated to the healthcare systems;
- for *patients*, the key needs are to receive the best possible quality of care;
- for *citizens*, the key needs are the requirement to stay healthy and to protect general well being.

In addition to the R&D activities, common issues to all three groups such as info-ethics and legal regulation have been supported. Common strategic tasks also include interoperability and certification, as well as implementation and exploitation of research results.

In order to maximise the impact of the individual projects and the set of projects as a whole, projects have been grouped into clusters according to the three main user groups and societal needs. The main objectives of a cluster are to (i) maximise technological, industrial and societal relevance; (ii) foster standardisation, inter-operability, benchmarking and best practice; (iii) facilitate assessment and technical validation of results; (iv) create synergies and identify common dissemination activities and routes for commercialisation and (v) stimulate user awareness and exploitation, and identify future RTD requirements.

1.1. Healthcare Professionals

The cluster of "*Healthcare Professionals"* gathers projects addressing specific needs of health professionals. Topics includes (i) decision support for (early) diagnosis, treatment planning and therapy through enhanced ICT tools and systems; (ii) timely access to specific health information from anywhere through user-friendly portable environments and (iii) continuous learning, training and collaborative work in the health domain.

Major application research areas have emerged from these projects such as non-invasive and *minimally invasive* diagnosis and treatment planning, *human computer interaction* and *mobility* of health professionals.

1.1.1. Non-Invasive and Minimally-Invasive Systems

The trend towards greater use of non-invasive and minimally invasive devices has recently gained further momentum. The market includes medical imaging equipment, patient monitoring devices, audiological devices as well as therapeutic and mixed-use devices (e.g. lasers, lithotripters, devices for pain suppression and endoscopes). Patients benefit from the use of these devices by feeling less pain or discomfort while experiencing more rapid diagnosis, which allows the elimination or shortening of hospital stays and often avoids the need for extensive surgery.

The projects funded by the IST programme in this area cover various specific topics e.g. software visualisation techniques for treatment; Virtual Reality environment for the planning and rehearsal of surgical procedures; medical image processing for diagnosis; decision support systems for antibiotics treatment; remote diagnosis with robotics; image guided tumours therapy and biopsy; intracorporeal videoprobe for gastrointestinal examination; "electronic nose" for wound assessment and monitoring.

1.1.2. Human Computer Interaction

The means by which users interact with computers continues to evolve rapidly. The increasingly widespread use of computers by health professionals and by citizens and patients who experience a wide range of health conditions is also likely to lead to questions relating to access, accessibility, usability, and design. Human computer interaction is a contributing element to several *e*Health projects; it underpins much of the work that is undertaken. The IS4ALL[ii] project developed and validated a comprehensive code of design practice for the whole life cycle of *e*Health products and services.

1.1.3. Intelligent Systems for Mobility of Health Professionals

A significant research and development effort has been placed on systems that make use of Personal Digital Assistants (PDA) at point-of-care in a wireless distributed computing environment. This enables access to a myriad of remotely based information systems. From checking medical references to working with electronic medical records systems, a growing number of physicians are making handheld computers part of their daily life.

A large part of the research in this group of projects has been centred on the development of medical digital assistants in addition to the implementation and validation of state-of-the-art speech recognition technologies in specific clinical environments; the use of natural language understanding systems in health care and evidence based medicine and decision support tools. Finally, some projects, involving mobile and wireless technologies, aim at supporting intelligent collaborative environments and patient. Special consideration was given to the market of Medical Digital Assistants and business models for making a success of these applications. The MEMO[iii] project is co-ordinating these activities.

1.2. Patients

After four centuries of delivering healthcare in hospitals, industrialised countries are now shifting towards treating patients at the point of need. The cluster of "*Intelligent Systems for Patients*" is a response to this evolution/change of paradigm in health. It is divided into two groups, one dealing with the delivery of home care and the second one on fostering co-operation between health professionals delivering such home care.

1.2.1. Home Telecare and Care at the Point of Need

Today many physiological parameters, such as ECG data, blood pressure and oxygen levels, and temperature can be reliably measured outside a hospital environment and sent securely to healthcare professionals, enabling them to remotely monitor a patient's health and alerting the clinician that action may be required. The expected benefits include improved quality of life for the patient and their family while needing fewer healthcare resources, such as hospital beds.

Current research is seeking solutions to the main obstacles preventing more widespread implementation of home telecare. These are of different nature; legal/administrative, lack of impact assessment and technical. The legal/administrative problems concern the attribution of clinical responsibility for patients recovering at home, and mechanisms for the reimbursement of treatment costs. The technical challenges include the development of more unobtrusive, mobile, comfortable monitoring devices, the development of sensors and treatment devices to cover a wider range of illnesses, and further integration of home telecare systems into mainstream clinical care.

Several projects have been funded in the area of portable and wearable health monitoring, e.g. continuous health status monitoring for early detection of health problems for cardiovascular diseases. In addition, a large scale trial of Body Area Networks through GPRS and UMTS telecommunications and a pioneering activity in the field of biomedical smart fabrics have been carried out.

1.2.2. Collaboration between Health Professionals

These projects strive to improve collaboration between health professionals for better home care delivery. It has touched on several aspects, from drug delivery to co-operative work in clinical labs and to care at the point of need. Technologies included IT for quality assessment, remote maintenance of medical equipment and workflow issues in the health chain. MOEBIUS is an example of such a project which develops innovative approach to therapy and disease management, in which IT is leverage in order to provide advantages for both patients, maintaining as much as possible their normal lifestyle during therapy, and doctors by accessing online a centralised server with all patients' medical records.

1.3. Citizens

This cluster of "*citizen*" regroups projects aiming at supporting European citizens to stay healthy by researching IT technologies and systems for health promotion and disease prevention. In particular the cluster targets citizens, including those predisposed to diseases, to respond to risk factors (such as high cholesterol level, high blood pressure, or if appropriate genetic profile) by actively facilitating lifestyle changes. Major application research areas have emerged from these projects such as health promotion, disease prevention and provision of health information.

1.3.1. Health Promotion and Disease Prevention

A core group of projects were directly dealing with health promotion and disease prevention. The major results include a collaborative environment dedicated to oncology; a monitoring system of body composition; a virtual marketplace for healthy nutritional plans; a personal health assistant; an interactive platform for deriving personal genetic information; an environment for diagnoses, treatment and prevention of eating disorders; a personal information support for weight control and a platform for reliable advice to individuals.

These projects were grouped under the umbrella of a cluster project, ACTIVE-HEALTH[iv], aiming at enabling citizens to implement appropriate lifestyle changes for better health and illness prevention and support information flows between the citizens, the medical/paramedical professions and the health-lifestyle industry. The three main axes of action of the cluster are: (i) promoting interoperability of integrated intelligent portable health devices; (ii) developing generic and coherent approaches in the use of IT tools which help reduce risk factors related to lifestyle; and (iii) staging common and coherent dissemination activities.

1.3.2. Provision of Health Information

The provision of health information to citizens was particularly important during FP5. Health related information is among the top three most searched for topics on the Internet. The citizens search for trustful information. The code of ethics produced by Health on Net[v] has been influential in this context. Among the projects facilitating the access to health information the main results are a community building platform for chronic diseases; a health interactive satellite channel; a life style management system using interactive TV and a network of services for women's health management. The work performed demonstrated that the provision of personalised health information to the citizen should be mediated through a health professional (assuming the liability) and that viable business models for health-related web sites were still to be found.

2. Future Research and Development Activities

In the 6th Framework Programme, the formal model structuring the research activities is "Knowledge for Health". This knowledge is presently shared between the molecular level ("e-molecule"), represented by the *bio-informatics* sciences, the cellular level ("e-cell"), and the classical medical information level ("e-individual").

An important effort, in the next ten years of RTD activities, will be in this combined domain of "Biomedical Informatics" in order to promote the citizen centred-approach of "Integrated Intelligent Environment for Health".

More precisely, research activities in Information Society Technologies for health will focus on intelligent systems aimed at supporting health professionals, at providing patients with personalised health care and information, and at stimulating health promotion and disease prevention in the general population.

Health professionals need the creation of a "Health Knowledge Infrastructure", a network of interactive and secure medical and health systems allowing timely interaction with heterogeneous, distributed, medical and other health-related databanks, for decision support, research, and continuous on-the-job training of health professionals.

Care for Patients requires research to target intelligent and communicating micro- and nano-technologies based on systems which are wearable, implantable or embedded in everyday objects, for health status monitoring and personalised support. These systems together with terrestrial and space-based telemedicine and *e*health systems will improve the quality of care and access to care at the point of need.

Such advanced technologies should bring quantum leaps in medical therapies and support the efficiency and effectiveness of future health delivery systems. Common to all the target groups will be the need for seamless, mobile networks and systems, capable of delivering personalised health information and health status both on the move and in remote and variable locations. The personalisation of healthcare could be based on factors such as genetics, habits, environmental issues, background, and education. Research and technological development in *e*Health could include mobile applications, open source software, security and trust of information, HealthGRID applications, *e*pharmacology and smart bio-clothing.

A key issue which needs to be addressed is the evidence of the impact and effectiveness of *e*Health solution. In this context, a new assessment methodology could be proposed based on three complementary quantitative and qualitative criteria – Access to care, Quality of care and Economic aspects. It could provide an answer to the present need to support the wide acceptance of *e*Health applications by all users, decision-makers, health professionals and citizens. This methodology is under development.

Finally, in addition to further research initiatives, the competitiveness of the European Union in *e*Health will not be maintained without creating clear and strong national plans for implementation.

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Endnotes

[i] 4FP, 5FP, 6FP – Fourth, Fifth and Sixth EU Research and Development Framework Programme

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[iii] MEMO – http://med-mobile.org/MEMO/index.php

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[v] Health on the Net – http://www.hon.ch

Interactive Textiles for Warrior Systems Applications

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Abstract. The purpose of this paper is to briefly summarize the basis of the U.S. Army's interest in Interactive Textiles and to describe some of the salient needs in the area of healthcare and E-Textiles and finally to indicate the current and near term market for interactive textile solutions. The basis of current Army, indeed DoD interest in Interactive Textiles including E-Textiles is found in the concept of Network-Centric Warfare. The individual soldier in this concept is often at the hub of a vast information network than shares information across platforms such as vehicles and aircraft as well as across echelongs of command from the font line to the rearmost command and control centers. In order to realize the advantages of such a war fighting concept, E-Textiles are required in a number of areas including soldier's uniforms, tentage and airdrop systems. With respect to healthcare, the Army's interest in E-Textile solutions lie in the areas of human performance monitoring (broadly defined to include physiological states such as blood pressure and hydration as well as the more difficult to measure states of attentiveness and cognitive functioning), wound detection and treatment, energy harvesting and flexible displays.

Introduction

The purpose in this paper is to present some of the various ways in which warrior systems items may benefit from innovative textile solutions. It is fair to say that the current vision for the Army's Objective Force Warrior cannot be achieved without developments in innovative textile solutions.

The paper intends to go a bit beyond what may normally be considered as "E-Textiles". First, this is such a new field that isn't sure there is an accepted definition of "E-Textiles". Is a phase-change material activated by an electronic signal an "E-Textile"? Second, the author would like to adopt a broad viewpoint and a term such as "interactive" textiles is better suited to that objective. And though the conference focus is on applications in medicine and health, applications in other areas as well will be mentioned.

The advantage of taking a broad viewpoint is that we may see applications that might escape our attention if we think of, for example, only conductive fibers and physiological status monitoring.

1. Interactive textiles

The definition of Interactive Textiles we find useful is as follows:

a textile that exhibits at least one unique and valuable property that "intelligently" responds to a stimulus. These materials could have the ability to sense and react (e.g., color change, oscillate, swell), conduct electricity, perform computational operations, and/or collect/store energy.

From this perspective, E-Textiles are the quite large subset of materials that perform their function with some sort of electrical energy involved.

Just another note for clarification: wearables are sometimes equated with E-Textiles. In the context of Interactive Textiles, wearable are restricted to those items that are attached to the system as opposed to being an integral part of the system.

2. Network-Centric Warfare: A Driver for E-Textile Military R&D

In order to understand the military interest in Interactive Textiles – more specifically in this case, e-textiles – one should appreciate the concept of Network-Centric Warfare. A recent DoD (Department of Defense) Report to Congress (http://www.defenselink.mil/nii/NCW/) (1) summarizes this concept. Quoting from the Executive Summary:

> "Battlespace entities (platforms, units, sensors, shooters) must be designed "net-ready." Increased emphasis must be placed upon research in developing awareness, shared situational awareness, and new organizational approaches to achieving synchronization." (pg ii)
>
> "The evidence provided in this report demonstrates clearly that warfighters employing NCW concepts can leverage shared situational awareness and knowledge to achieve situational dominance and dramatically increase survivability, lethality, speed, timeliness, and responsiveness." (pg iv)

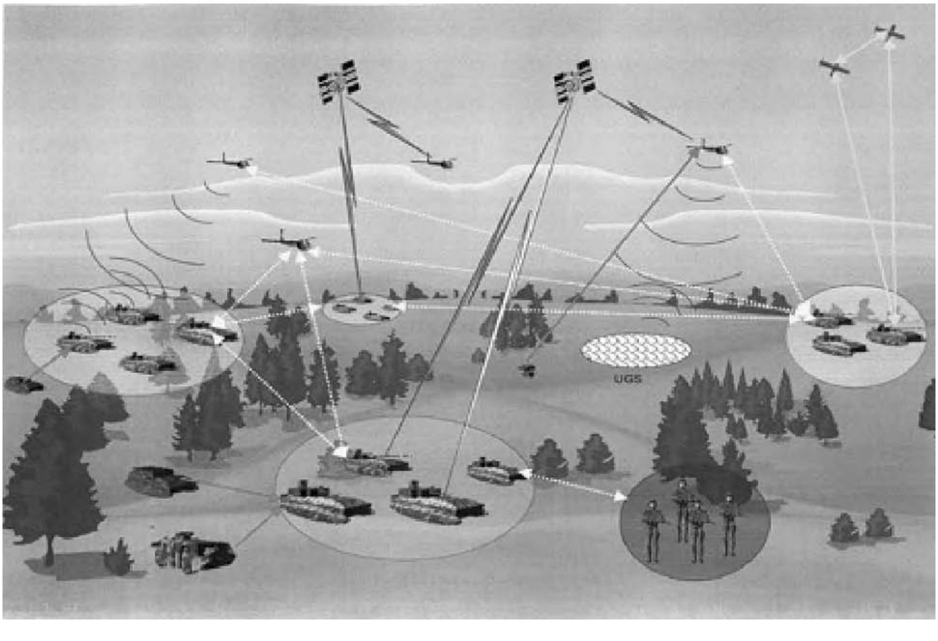

Figure 1. Artist's Concept of Network-Centric Warfare.

Figure 1 portrays an artist concept of a Battlespace operating in the mode of Network-Centric Warfare operations.

E-Textiles, such as embedded antennas, conductive fibers linked to sensors, flexible keypads and displays, must be developed in order to make the individual combatant "platform" "net-ready" and to achieve the expected increase in combat power. It is a belief that this overall DoD viewpoint will sustain R&D in Interactive or E-textiles for some time to come.

3. Some specific applications

Given the mandate to develop Network-Centric Warfare capability, here are some of the specific areas in which research is progressing.

3.1. Human Performance Sensor Suite(s)

Figure 2 depicts a future warrior and some of the sensor suites that are being envisioned to increase force capability. It is hard to read an article about Objective Force Warrior or future warrior concepts without seeing mention of the need for Physiological Status Monitoring. The vision here is that embedded conductive fibers connecting sensors on the body with a radio also worn by the individual could provide field commanders and medical staff with vital information on individual soldier's physical and mental states during combat operations. The Army is looking to monitor not only vital signs such as heart rate, body temperature and blood oxygen level, but what the PM Soldier calls "Readiness Assessment Factors. These include sleep status, hydration state, alertness, cognitive readiness and nutrient status.

With respect to monitoring vital signs, the technology seems to be currently available in restricted settings: e.g. hospitals. Researchers at the University of Bruge have

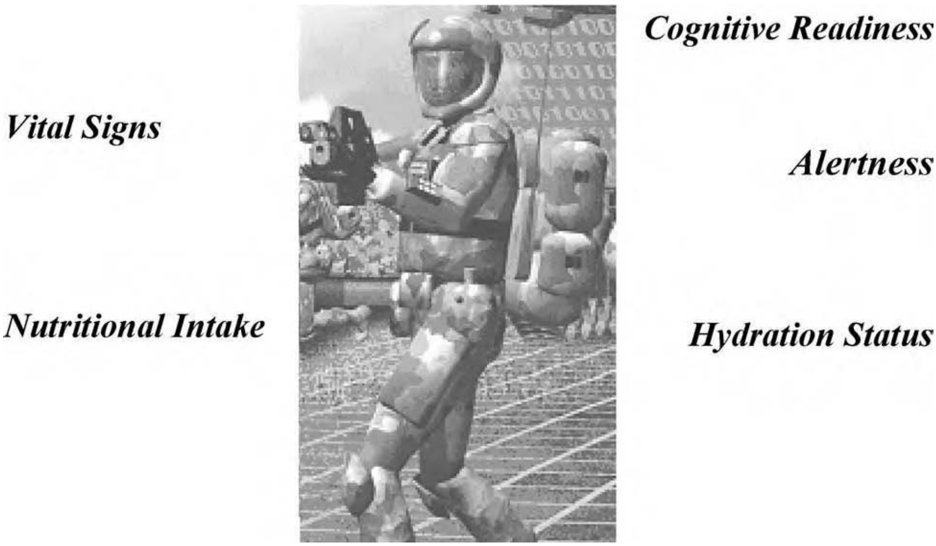

Figure 2. Key Aspects of Human Performance Sensor Suites.

Figure 3. The Warrior's Environment.

produced a band worn around an infant's chest to monitor vital signs in newborns. The Wearable Motherboard has been developed and will be described in a following paper in this seminar.

Work in the area of Cognitive Readiness and Alertness is being conducted by researchers at the Army Institute for Environmental Medicine. Cognitive Readiness, as used in the Department of Defense, is a broad term to encompass the effect of mental activity/states on warrior performance. Belt and wrist worn monitors have been developed to measure such Cognitive Readiness factors as mood, sleep loss and vigilance.

The challenge in this area seems to be less an issue of developing an E-textile sensor/monitor/transmitter suite than in establishing the physiological determinants of alertness and other cognitive processes and then relating them to performance levels.

And there is another challenge as shown in Figure 3. A garment or uniform containing the physiological status sensor/monitor/transmitter system must be comfortable and, at least in the military, must function in very hostile environments.

3.2. In-Uniform Tourniquet

Another feature, often find described in descriptions of the Objective Force Warrior involves an in-uniform tourniquet. Probably the interest in this subject relates to the effectiveness of the latest issues of body armor. Torso wounds have been - and probably will continue to be – reduced as newer body armor systems are developed [2]. It isn't so sure extremities can be as well protected unless we look into the far future – 2025 and beyond.

In the meantime, as stated in a recent article [3]:

> [Current] "Technologies for self and buddy aid are focused on simple measures to stop hemorrhage. The long-term objective is to integrate technologies into the Objective Force Warrior uniform that will feature automated activation of hemorrhage control technology upon wounding." (pg 9)

No doubt this objective will be facilitated by work in the area of physiological status measurement. The sensor/monitor suite would contain an actuator that causes a small sleeve to contract.

Again, the challenges are significant – durability, power demands, how much pressure to maintain for what time period to name just a few. But as long as American tolerance for military casualties remains as low as it is, the Army will continue to seek new technologies in this area.

3.3. Artificial Muscle

Artificial muscle is one of the technologies that could provide some part of an in-uniform tourniquet, but has other applications as well. In addition to combat uniforms and load carriage applications, artificial muscles might be useful in airdrop and shelter applications.

While one of the goals of the OFW Program is reduce the soldier load to roughly 30% of the individual's body weight, there may be circumstances wherein even that amount reduces mobility to less than desirable levels. There may be a need, for example, to quickly remove a fallen team member from a killing zone – and a robot may not be available. In this case, an exoskeleton artificial muscle system might provide a quick increase in strength needed to quickly move a wounded, inert buddy.

3.4. Energy Harvesting

E-Textiles in this category include all those designed to convert, collect and/or store electrical energy from a variety of sources. Power is often cited as a critical need in the Land Warrior and Objective Force Warrior Programs. It appears that many efforts are being devoted to exploiting sunlight for conversion and generation of electrical power – and some of the papers in this symposium describe these efforts. The NSC also has a project in this area. But perhaps other sources could be explored as well; e.g. – converting body heat generated during soldier's marches or generating current from movements as individuals are walking.

The utility of this research – particularly in photovoltaics - should benefit not only individual combatants, but shelter programs as well. "Tent cities" provide a large expanse of soft and hard shelter surfaces from which to capture sunlight and convert it to the many needs in these facilities. Power for medical field hospitals, for environmental control, and for recharging renewable power sources would reduce current systems reliance on generators that could be characterized as a necessary evil in today's systems.

3.5. Flexible Displays

Another item on the PM-Soldiers list of needs is flexible displays. To this category should be added at least flexible keyboards and networks. Given the amount of information that will be shared in Network-Centric Warfare, it is not likely that all of it can or should be presented in a helmet-mounted visor. Flexible displays on the soldier's arms could be used to display types of non-target information such as unit positions. From the medical viewpoint, such displays coupled with the Physiological Monitoring Suite could provide the soldier with information such as hydration status, because the feeling of thirst is not a timely indicator of the need to take water. Critical nutrient needs might also be displayed. In general, any biofeedback that might prevent performance decrements would be a "force multiplier" for the individual.

In the future, perhaps 2025 or beyond, the Network-Centric war fighter's uniform might be a computer as well. As displays, keypads, transistors, networks, data storage and processing items are built on flexible substrates, the possibility of a "cloth computer" may become reality. Of course, the challenges of comfort and durability in hostile environments must be overcome.

4. The military market for interactive textiles

Venture Development Corporation recently completed a market survey for Interactive Textiles – Smart Fabrics in their terminology [4]. Paraphrasing some of the study report:

- "Market demand for Smart Fabrics/Interactive Textiles (SFIT) is generally very light. Little is known in most consumer markets and many commercial markets. Most of the material demands for SFIT technology is coming from the military and medical communities. . . based on mission critical requirements." (pg 71)
- "Medical application of smart fabric technology providing bacteriostatic or biocidal functionality is a quick growing segment, and is beginning to see market penetration into the consumer and military apparel markets." (pg 83)
- [on "Technology Transfer Paths] "Military/Research lab direct to commercial application – this will prove to be a good path, one that will be pressed because potential quantity will be higher in commercial and industrial applications and most suppliers in the materials and fiber areas will want this." (pg 93)

The VDC report indicates that military spending on SFIT was a little over $30 million as shown in Table 1. This number includes all expenditures: military conducted or sponsored research, development and procurement of product. This constituted roughly 10% of the total market. The future projections, conservative and optimistic or aggressive, range from just over $58 and $118 million respectively by 2008. These results demonstrate once again that the current DoD emphasis on dual (military and civilian) use technologies is the only feasible alternative for equipping our force.

Table 1. Estimates of the Market for Interactive Textiles in 2003 and 2008

Category/Year	2003 $	2008 $ (1)	2008 $ (2)
Conduct/distribute electrical current	140	8,871	28,062
Conduct/distribute light enerqy		96	1,820
Conduct/distribute thermal energy	20,149	31,200	55,500
Transfer/distribute matter		3,500	
Material phase change		2,000	
Electricallsignal shielding & protection	10,000	17,814	18,500
Environmental & hazard protection	300	500	800
Total Military	30,589	58,471	118,282
Total All	303,840	520,000	1,073,000

Notes: *(1) Conservative Estimate*
(2) Aggressive Etimate
Amounts are in Thousands of Dollars

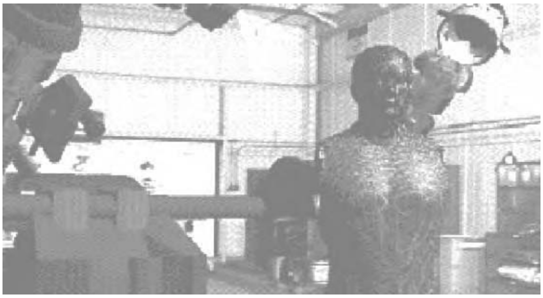

Figure 4. A Futuristic Clothing Production Method.

5. A future manufacturing concept

Finally, the author would like to suggest one way that INTEXT clothing might be manufactured in the future. One otherwise astute prognosticator said that clothing has been made by sewing or weaving for the last 5000 years and – here's the surprising part – that they will be made the same way for the next 5000 years. The author doesn't agree. If we marry Electrospinning with 3-D body scanning technology, future clothing could be made as shown here. It has to be pointed out that both technologies are in use by laboratory scientists today.

6. Conclusion

The conclusion is fairly straightforward. Given the DoD emphasis on Network-Centric Warfare and the Civilian Sector interest in such technologies as Telemedicine, E-textiles will become an increasingly important element in the textile industry and our everyday lives.

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Challenges of Ambulatory Physiological Sensing

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Abstract. Applications for ambulatory monitoring span the spectrum from fitness optimization to cardiac defibrillation. This range of applications is associated with a corresponding range of required detection accuracies and a range of inconvenience and discomfort that wearers are willing to tolerate. This paper describes a selection of physiological sensors and how they might best be worn in the unconstrained ambulatory environment to provide the most robust measurements and the greatest comfort to the wearer. Using wireless mobile computing devices, it will be possible to record, analyze and respond to changes in the wearers' physiological signals in real time using these sensors.

Introduction

Physiological sensors were initially designed to be used in a hospital or laboratory. The subjects studied were generally seriously ill, stationary patients in hospital beds. Sensors were carefully applied on clean skin by trained technicians and gels and adhesives were used to guarantee a good connection between the skin and the electrode. These patients generally had no choice but to wear the prescribed sensors and usually had more serious problems that would overshadow an "itchy" electrode patch or the inconvenience of a dangling wire. Healthier patients also wear physiological sensors either for treadmill based stress tests or for single 24 hour Holter monitoring if they fear that they may be suffering from a serious condition. These sensors are more compact, but they are also applied by trained professionals. Exercise enthusiasts, interested in measuring cardiac performance, will wear sensors such as the Polar heart rate monitor which are easy to put on and give a robust estimate of heart rate. The less life threatening the condition, the more comfortable the sensors must be and the easier they must be to put on, however the accuracy requirements of the measurements are also less strict.

To be worn everyday, sensors in biomedical clothing must be designed for comfort and ease of use. The clothing must also be affordably priced and require minimal upkeep, for example the clothing must not be overly burdensome to wash, the batteries should be easily rechargeable (or require infrequent replacement) and data should be effortlessly offloaded. The sensors in the clothing must also tolerate the actions associated with daily life: walking, talking; eating; sitting; standing; sweating; and frequent changes in body geometry. In some extreme circumstances, people will tolerate sensors being implanted, including post-myocardial infarction patients and diabetic patients whose lives are at risk.

People without life threatening demand minimally invasive sensors on the surface of the skin. Additionally, they desire a high degree of comfort and will want to simply slip sensor clothing on and off as easily as regular clothing. Most will not want to bother with adjusting sensors to be in a precise location, preparing their skin using rubbing alcohol and applying an assortment of special gels and adhesives to make good contact with electrodes. These issues are especially important for elderly patients who often have difficulty dressing with conventional clothing and who should not carry any additional weight such as batteries or a laptop computer.

These additional constraints for sensors in biomedical clothing often result in obtaining a far weaker and noisier signal than would be obtained by hospital equipment. This chapter presents several suggestions for using sensor placement to avoid noise artifacts, using multiple sensors to account for noise and demonstrating medical applications that use biomedical clothing. Ideally we will find sensors that are accurate, robust and that give as clean a signal as can be obtained from subcutaneous measurements, but these are not currently available. In biomedical clothing we are constrained to sensing physiological signals on or above the surface of the skin either through electrodes, optics, strain gauges or electro-magnetic field sensors.

1. Considerations for Wearability

There are many issues that should be considered when developing sensors for biomedical clothing. Some of these include: appropriate placement of the sensor on the body for measuring the physiologic signal; assuring constant contact with the sensor; minimizing signal artifact from changes in pressure; and minimizing or understanding the effects of movement and body position on the signal reading. The effects of these considerations will vary depending on the sensor and signal of interest. Some examples for electrocardiogram (ECG), photoplethysmograph for blood volume pulse (BVP), skin conductivity or Galvanic skin response (GSR), respiration and temperature are discussed in the following subsections.

1.1. Placement

Placement is a key aspect of measuring physiologic signals because where a sensor is placed can have an effect on exactly what you are measuring. The heart can be considered to be an electric and the ECG measures changes in surface voltage on the skin as this dipole moves through its cycle, creating a trace of characteristic features including the P-wave, QRS complex and T-wave. ECG leads can be placed on several different locations on the body (leads) and each of these positions will give a slightly different ECG tracing, for example, in order to detect the strongest R-wave peak (used for determining heart rate), the optimal lead placement is to have one electrode on the right shoulder and one electrode on the right hip [1].

Another example is the signal from a photoplethysmograph, used for measuring blood volume pulse (BVP). This sensor detects emits either red or infrared light and uses an opto-electronic sensor to detect reflected light. A small proportion of reflected light varies due to the pulsation of arterial blood and this variation is used to measure pulse. The amplitude of the signal is also used to measure blood vessel contraction. For the best reading, this sensor must be placed directly over a peripheral blood vessel; if the blood vessel is too large, the pulsation will not cause a proportionally large change in reflectance. The sensor must also be secure with respect to placement on the skin; if the sensor moves with respect to the surface of the skin the baseline reflectance can change drastically.

The GSR sensor measures the change in the conductivity of the skin in response to the sweat glands filling with ionic sweat. The magnitude of the reading is proportional both to the number of sweat glands and the amount of sweat within the glands. The body contains different numbers and types of sweat glands in different locations, for example sweat glands under the armpits are more thermoregulatory while sweat glands on the palms on the hands and the soles of the feet are more responsive to sympathetic activity [2]. To best measure sympathetic activity through GSR, the best placement for the sensors is on the palms of the hands or the soles of the feet where these glands are most plentiful. Even choosing particular placements of sensors across the palm has been shown to result in major changes in this measurement [43].

1.2. Contact

Sensor contact is another important consideration in designing sensors for biomedical clothing. The human body is constantly moving within clothing and constant contact is difficult to achieve without adhesives. Most casual wearers of physiologic sensors consider adhesives intolerable, due to the increased difficulty of affixing the sensors, the painful experience of removing the sensors and the skin irritation that sometimes occurs even after the sensor is removed. Unfortunately, many physiological readings require skin contact and if a constant contact is not maintained, the sensor baseline must be reassessed and the measurement can be invalidated. To solve the problem of contact, most biomedical clothing has focused on tight fitting shirts such as the Vivometrics Lifeshirt [4] and the Sensatex Smartshirt [5] or close fitting gloves such as the Galvactivator [6]. However, in the ambulatory environment, even these closer fitting garments can experience problems with contact as people twist, bend, reach, sit or open and close their hands.

1.3. Pressure

Biomedical sensors embedded in shoes, gloves or even clothing can experience pressure artifacts due to normal actions daily such as typing, grasping or walking. For sensors that use electrodes, including GSR, ECG and electromyograph (EMG), pressure at the point of contact of the sensor increases the contact and therefore the measured voltage, resulting in artifact. Pressure artifacts are especially important to consider when designing embedded GSR readings since these are best taken from the palm of the hand and the hands are constantly used to grab in move objects. The GSR reading can also be taken from the sole of the foot, but this reading is also subject to pressure artifact from walking. EMG readings on the shoulder or back can also be susceptible to pressure artifacts if the person being monitored wears a heavy jacket or carries a shoulder bag or backpack. The increased contact caused by pressure on the electrode may result in a reading showing that muscle is under far more stress than it actually is.

Pressure on a photoplethysmograph is likely to strongly decrease any measurement due to two factors. The first is that the increased pressure is likely to compress the small blood vessel which the sensor is measuring, the second is that the increased pressure can cause increased scatter of the emitted light, proportionally decreasing the reflected light. Non-contact sensors would be the ideal solution to the problems of pressure and contact and currently these are being explored with optics based sensors [5,7].

1.4. Movement

One of the most challenging problems for biomedical clothing is movement, including both body movement and sensor movement both with respect to the body and with respect to other sensors. When the body moves, multiple physiological processes change which can affect several sensors. When a muscle contracts, an electrical voltage is created on the surface of the skin. This voltage is measured to obtain an EMG reading, however all other surface electrode sensors, such as ECG and electro-encephalogram (EEG) may also register this voltage (as a noise source). Regular clothing is in general loose fitting and moves with respect to the wearer's body during normal daily activities. This is a serious problem for biomedical clothing and seems to require that sensor clothing should fit snugly against the skin, however even close fitting clothing experiences stretching and slippage with respect to the skin in normal wear. Even if the fabric itself acts as a sensor, its electrical properties may change with stretch [8].

Movement artifacts most exaggerated when readings are taken from the extremities instead of the torso or body core. When GSR readings are taken using the standard configuration of placing two electrodes on the inner side of the hand problems arise with sensor interference when the two electrodes move rapidly with respect to each other such as when a person is typing. Alternative configurations such as the one shown in the biking glove in Figure 1 and that of the Galvactivator [6] where the electrodes are placed more centrally on the palm decrease movement artifact. Sensor placed on extremities is also subject to greater force when the body moves, for example, Figure 2 shows two sensors placed on the ear. The figure on the left shows a sensor placed on the ear lobe and the sensor on the right shows a sensor placed inside the ear. The sensor on the earlobe was much more susceptible to noise artifact from the wearer turning their head. The weight of the sensor in this design also contributed to slippage of the sensor with respect to the skin.

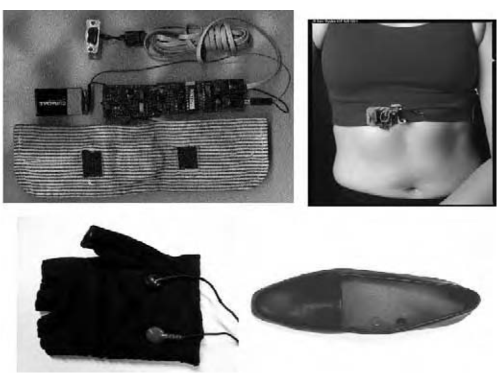

Figure 1. Examples of various sensors embedded in clothing including rubber electrodes embedded in a shirt cuff (upper left) a respiration sensor in a sports bra (upper right), electrodes for GSR in the palm of a biking glove (lower left) and electrodes in the insole of a shoe (lower right).

Figure 2. The photoplethysmograph sensor (left) is very sensitive to placement and motion artifacts. The thermistor sensor on the right is much less sensitive. Both can be used to measure heart rate.

1.5. Body Position

Sensor readings are also affected when a person changes body position. Blood pressure changes drastically when a person changes from a sitting to a standing position and any blood volume or blood pressure reading taken from the hand or finger is greatly diminished is when the person raises their hand above their heart. Capacitance based measures are also effected when a person changes position such that the sensors are brought close together [7].

2. Using Secondary Signals

The difference between signal and artifact can be one of interpretation. In the previous section, movement and body geometry were described as sources of artifact, however occasionally such artifacts can be interpreted as signals. This interpretation can allow two different physiological signals to be obtained from a single sensor. One example of this type of secondary artifact signal is the pulse signal that modulates skin temperature in the ear. A thermistor placed inside the ear to measure temperature, as shown in Figure 3, will fluctuate as blood pulses in peripheral vessels, generating a signal that mimics the BVP signal, allowing heart rate to be measured. Another example of a secondary signal is the respiration modulation of the ECG signal. As a person breathes, the chest cavity expands and contracts causing the distance between ECG chest electrodes to increase and decrease. This movement causes a modulation in the amplitude of the ECG signal which tracks the respiration signal as shown in Figure 2. This respiration signal can be extracted with freely available software (www.physionet.org) [10]. Using secondary signals can potentially decrease the number of sensors that need to be embedded in biomedical clothing, however to use secondary signals high precision sensors must be used.

3. Integrating Sensors into Clothing

The greatest difficulty in embedding sensors into clothing is that clothing is made of loose-fitting washable cloth and sensors are made of non-washable electronics that must adhere snugly to the body. Wearable monitoring systems [11,12] can simply be sensor systems worn underneath the clothes using standard electrodes, gels and adhesives. To

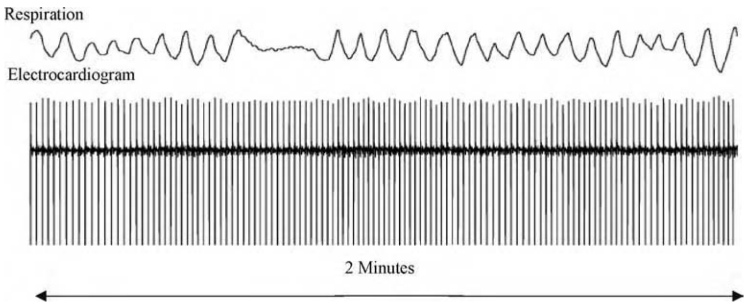

Figure 3. Two minutes of respiration and electrocardiogram (ECG) data during a period of sleep apnea. Note the slight modulation of the amplitude of the ECG that corresponds to the respiration signal. This modulation is caused by a change in distance between the ECG electrodes on the chest due to the expansion and contraction of the chest during respiration. Image courtesy of George Moody, using data freely available at www.physionet.org.

ensure proper sensor placement, loops can be sewn into the clothing to hold wires and sensors [13]. In these systems the electronics are entirely separable from the clothing.

A first step towards integration, electrodes can be embedded into clothing and attached to wires and electronics using snaps. Figure 3 shows various examples of sensor integration. The upper left image shows a striped shirt cuff with embedded washable rubber electrodes. These electrodes snap onto the PIC based wireless radio frequency (RF) transmitter shown directly above the cuff. The image in the upper right shows a respiration sensor attached to an elastic band already present in an existing sports bra. The lower left image shows traditional metal electrodes embedded in a biking glove and the lower right images shows two electrodes embedded in an insole that can be worn inside a regular shoe. Both of these placements for the electrodes can be used to measure GSR. These electrodes are attached by snaps to a wired sensing system [14].

4. Recording Context Information

A critical aspect of analysis and evaluation of physiological data is the collection and assessment of context information. Sudden changes in physiological signals can occur for a variety of reasons, including movement or sensor malfunction, but they might also indicate catastrophic physiological events. Recording context information along with physiological data is one way to try to determine what is actually happening. This context information can take many forms including accelerometers data to determine if a person has fallen down and tracking information to see if the person has suddenly stopped moving [15].

Another possibility for annotating sensor data is recording video snapshots at regular intervals. Figure 4 shows images that were captures using a prototype wearable computer with an attached digital camera [16]. Using this system, the computer automatically captures an image every 30 seconds and indexes the image with the same time stamp used for the physiological data collection. This allows the wearer or a health professional to see at a glance a person's activity over an hour by looking at a page of thumbnail images, showing at what time they were outside, eating lunch, climbing stairs, etc. If there an abnormality in the signal data, the images allows for a better understanding for the

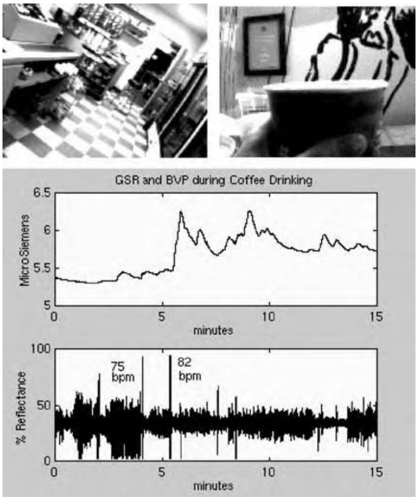

Figure 4. Small digital snapshots record daily events that can explain physiological changes. Here increases in heart rate and GSR occur after drinking coffee.

causes of the physiological changes. The data in Figure 4 shows in increase in heart rate and skin conductivity and also a decrease in the amplitude of the BVP signal. The images show that this was caused by the person drinking coffee. The intake of caffeine can explain an increase in heart rate and GSR and the decrease in the amplitude of the BVP signal can be explained both by a contraction of the blood vessel due to a sympathetic response to adrenaline and by pressure exerted on the BVP sensor (which was placed on the distal finger of the right hand) as the coffee cup was grasped. This type of image could be obtained by the very small cameras found in cell phones or by new cameras that are available in prototype sunglasses [17].

5. Discussion

Despite the difficulties, there are still many applications for which biomedical clothing devices are a viable solution. One of the most commonly investigated applications is an emergency alert system which could call a help center when an adverse event is detected. Another possibility is physiological monitoring for overall health maintenance including exercise, stress reduction and behavior modification. Every year monitoring systems become more robust and integrated into clothing, and soon solutions will be available to suit every purpose.

Acknowledgements

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Driver Monitoring – New Challenges for Smart Sensor-Based Systems

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Abstract. Decreased vigilance and fatigue are major factors accounting for driver error. Moreover, it is one of the most common causes of traffic accidents. The development and integration of non invasive systems to detect driver fatigue in real time is a challenging task for the near future. Smart systems promise new approaches to sensor development, signal processing and interpretation to asses the evolution of the physiological state of the driver. At the same time, however, driver monitoring should be realistic in terms of automotive constraints, price and robustness.

Can smart materials meet those requirements? Issues involved in driver monitoring will be discussed and an overview of the demands placed on smart materials by the automotive environment will be given.

Introduction

In most of the developed world traffic had been increasing considerably in the last ten years. Across the 15 EU member states there are 43 000 road deaths per year and an estimated 3.5 million casualties [1]. Drivers spend longer hours on the road but at the same time spend more time with non driving tasks and less time with the core driving task. This is mainly due to the panoply of multimedia technology inside today's vehicles but also to the considerable improvements in assistive technologies. From a purely manual, physical task, driving is developing into a task where monitoring is one of the main activities.

In parallel, vast improvements in healthcare mean that citizens are more active and healthier at an older age. Today, more and more premium class car drivers are over 50 years old. One of the likely effects of an elderly driver population is the risk of increased driver error related accidents. Often regarded as one of the most extensive studies of crash causes, the 'tri-level study' [2] determined that driver error was a definite or probable cause, or a severity-increasing factor, in 93% of crashes.

Various national and international initiatives are currently trying to find ways to increase road safety and reduce accident rates. The Automated Highway System program (1992-1997) in the US and Intelligent Road Systems elsewhere were taken as countermeasures [3]. Furthermore, extensive implementation of countermeasures such as "ITS Systems", informing motorists of traffic conditions and demand management amongst others were thought to improve road infrastructure together with vehicle structural reinforcement. However, driver impairment in broad terms remains one of the most common

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causes for traffic accidents. Horne et al. [4] states that 20% of all accidents are related to driver fatigue while Garder [5] maintains that 40% of fatal accidents on US highways are sleep-related with figures rising even higher for truck drivers. Thus, in the context of impairment, decreased vigilance and fatigue are major factors accounting for driver errors, considered to be the most common causes of traffic accidents.

From a prevention standpoint, attribution of crashes to driver error may obscure the fact that safety enhancements to the vehicle (e.g. collision warning system), infrastructure (e.g. intelligent signing), or both may make crashes due to driver error less likely to occur. Driver assistance systems, in particular, offer a considerable potential for improving driving safety and comfort.

On-road safety measures can be divided into three groups. The first group addresses pre-crash scenarios or active safety, the second includes all the passive safety measures involved during the crash and the third deals with post-crash measurements. Driver assistance systems form part of the active safety group. They can be classified into longitudinal support systems, which support driving tasks in the forward direction of driving, such as speed and headway keeping; lateral support systems, which support driving tasks in the sideward direction like lane keeping, and integrated support systems, which support tasks in both forward and sideward directions. Adaptive Cruise Control (ACC) - an extension of a conventional cruise control system that does not only keep a fixed speed but adapts also, by means of a radar sensor, the distance to a preceding car - was the first of a series of Advanced Driver Assistance Systems (ADAS), to be recently introduced on the market [6]. Possibly the next system to be marketed will be a Stop & Go assistant, capable of handling the speed range between zero and about 40 km/h - currently not covered by the ACC system . Pending, is the Heading Control (HC) system, which assists the driver in the lane-keeping task [7,8]. In the more distant future, several combinations of assistance for longitudinal and lateral control with varying degrees of automation are to be expected.

1. Driver Monitoring

In line with the implementation of these automated systems and the new role the driver will adapt, the human factor is likely to become the weakest point in the interaction. The advantage that driver monitoring offers in increasing traffic safety lies in its potential to address traffic scenarios at a higher level, keeping the driver as the main actor in road safety. Basic work for driver monitoring was carried out in the EU funded PROMETHEUS-project. Continuation for driver impairment monitoring was realized in the SAVE-project, where a solution for all kinds of driver impairment monitoring was proposed by means of sensor fusion. An overview about current systems is given in Table1.

Most of the systems are at research level and still far from being commercially available, as yet too many problems remain unsolved. It is estimated, however, that by introducing those systems and improving them over the next 6 years, fatality rates could be reduced by 10% and contribute to decreasing the overall rate of fatigue-related accidents. The greatest impact is estimated to be on accidents caused by human error, or more precisely, due to 'loss of control' i.e. driver impairment, exceeded speed, fatigue or underload, typically occurring in rear-end collisions, overtaking or lane-change situations and

Table 1. Current types of driver monitoring systems

	eyelid	facial image	lateral position	eye-gaze	steering wheel movement	steering grip sensor
Nissan	x					
Toyota	x	x				
BMW			x			
Daimler Chrysler			x	x		
Safetrack Carnegie Mellon U			x			
Steering Action Mon. System, SAM					x	
Attention Technologies Perclos	x					
Travel Alert system					x	
Alert Driver	x			x		
AWAKE	x		x	x	x	x

also accidents involving pedestrians. In particular, night time accidents and accidents in adverse weather conditions could be reduced.

A number of previous and running projects such as SAVE and AWAKE could serve as an excellent starting point for future initiatives in the driver monitoring area. The main objective for future developments is to assess driver fatigue and hypovigilance in order to create innovative warning strategies. There is the need for developing a non-invasive system capable of detecting driver fatigue in real time using existing and new advancements in sensor technologies. Fatigue monitoring systems will contribute to the preventive safety applications in the area of ADAS work covering the driver, in one of the three sensing areas: environment, car and driver. Not until all three of these areas are addressed, will there be a possibility to develop the accident free vehicle of the future.

2. Drivers Fatigue

2.1. Definitions of Fatigue States and Measurement Parameters

To address the drivers state, it is necessary to understand the factors involved in driver drowsiness/fatigue as well as how this state degradation can be measured and monitored. Only then, can reliable detection and effective countermeasures be integrated in the system. Defining drivers fatigue depends mainly on how the concept of fatigue itself is understood. Fatigue is often used as a collective term to describe the physiological and psychological experience of being sleepy, tired or exhausted. Common causes of fatigue while driving are long driving hours without adequate rest periods, adverse weather or road conditions, driving alone, current mental and physical state, operator stress, climatic conditions, the quality of the environment in the drivers cabin, the monotony of the scenery or a combination of any of these factors. Drivers' workload constitutes of the actual cognitive and attentional load, visual gaze, general attention, driver intention(s) as well as the his or her physiological and emotional state. If the workload falls below or exceeds a threshold level, decreased human vigilance and attention during driving will follow.

The definition of *vigilance* is described by the state of the driver in which all mental functions can be realized and when all receptor signals are accepted and well processed. [9] *Attention* denotes the form of vigilance, where the dominant part of mental functions is concentrated on external objects (focused attention).[9]. It is considered to be a special case of vigilance. Whereas vigilance describes a state where the driver can react to all received signals, attention focuses on particular signals, for optimal task performance. Selective attention enables the driver to fully concentrate on the task at hand and not to attend to secondary signals unnecessary for task fulfilment.

2.2. Current Initiatives

In order to detect a decrease in attention, we need to select a set of significant parameters which can be used for identifying attention decrease and the onset of micro-sleep. Such parameters include electro-magnetic activity of the brain, frequency of breath, frequency of heart beats, eye movements, eyelid blink rates, skin resistance, facial expressions, etc. All these parameters are fairly difficult to measure and require sophisticated software. One of the main areas where most of these parameters are frequently considered is in the ambulatory health monitoring systems.

There is an electronic health initiative (e-health) within the 6th European framework, which aims to develop devices to monitor heart-rate, respiratory rate or activity levels to provide information to the health care provider. Systems under investigation use mobile services to transfer data from the patient to their practitioner. This offers tremendous opportunities in the future to improve health care and be able to intervene at the first sign of a health problem. As the patients profiting from these facilities are from all age groups and mostly very mobile the service needs to also be available whilst driving. The devices have to fulfil users mobility needs and could be an additional source of information about drivers fatigue, since measurement parameters are similar. The following section gives an account of the implications mobile systems face in an automotive environment.

3. E-health and Driver Monitoring

3.1. Recent Developments in Driver Monitoring

Various national and international initiatives have proven to contribute to the global standardisation and implementation of active safety systems on a broader base. At the same time those initiatives serve as a network for information and communication tools for decreasing accident rates. The European union has strongly supported successive research and development programs. Projects such as the EU funded PROMETHEUS project, and more recently, SAVE and AWAKE are developing sensor technologies for exactly this purpose.

Within the 6th European framework program further innovative developments in the field of driver monitoring are expected. Particular emphasis lies in the monitoring of driver movements (head and eye movement) posture, face recognition, driving environment, vehicle movements and driver status. The necessary advances in sensor technologies together with methodologies for sensor fusion, signal processing and effective countermeasures are to be integrated into a driver monitoring system to give advice on preventative measures in the event of driver inattention and/ or driver fatigue. However, such systems cannot be easily integrated without increasing the costs for the consumer. To be able to reduce accidents rated by 2010, there will be the need for a fast introduction of an inexpensive driver monitoring and warning system by 2010.

In order to do so, research has to be done into using existing, readily available sensor technologies in a different way. As drivers state diagnostic is based on the fusion of information provided by physiological sensors, driver behavioural sensor and vehicle behavioural sensor, a variety of technologies on the market for quite different applications could be looked at. As the realisation of effective active safety systems relies on the driver, one might look at the medical market and what sensors are currently or in the near future going to become available. Existing opportunities include wearable health-monitoring devices. The problem thus, is how to improve safety without using systems which are too invasive for the driver.

3.2. Automotive Requirements

Automotive constraints are not easily met as the requirements of existing technologies need to be met at the sensor level, operator level and data/ software level to be conceivable for future implementation. The integration of new technologies including various solutions of e-health systems, however, could also be realised at several levels of the driver monitoring system itself as the range of applications spans from the sensing array and their associated processing units (e.g. image processing) over the data pre-processing unit or the core of the system, the diagnostic unit(s) that estimates the evolution of the driver state and takes the final decision to the HMI by which is decision is communicated (for details see picture1).

Requirements are therefore not limited to sensor development or hardware but also on software development, data processing and feature extraction. Additional requirements of equal importance, that driver monitoring sensors and sensors used for ambulatory health monitoring should fulfil, are in terms of acceptable price and robustness. In general terms a system architecture consisting of a common platform that is robust, stable and yet easily adaptable and expandable (plug-and-play) would be desirable to guarantee a high level of adaptivity.

Emphasising on driver activity and movements by means of new sensors and existing sensors applied in a new way puts a strong need to validate the developed sensors. One way to do this, is with an enhanced EEG reference system, to identify sensor performance and improve their reliability rate. EEG measurements can be reliably obtained in laboratory settings. The university of Warsaw [9] also obtained promising EEG results in a moving vehicle. There is a real hope that in the not too distant future, such EEG measurements will be able to be successfully performed for practical applications in moving vehicles. As yet, however, validating results still poses a considerable problem as EEG is one of the most accurate means of validating driver fatigue sensor and measurement systems. Apart from reliable systems performance a major and very important issue is the user acceptance of the system. Driver status is to be communicated by an HMI (via visual, acoustic or haptic feedback) which will give an informed decision based on the fusion of information of driver status (via the diagnostic unit) and output of the ADAS. Providing interconnectivity of the driver monitoring system with other monitoring devices used outside the car such as mobile phones, PDA´s, Personal health-monitors could

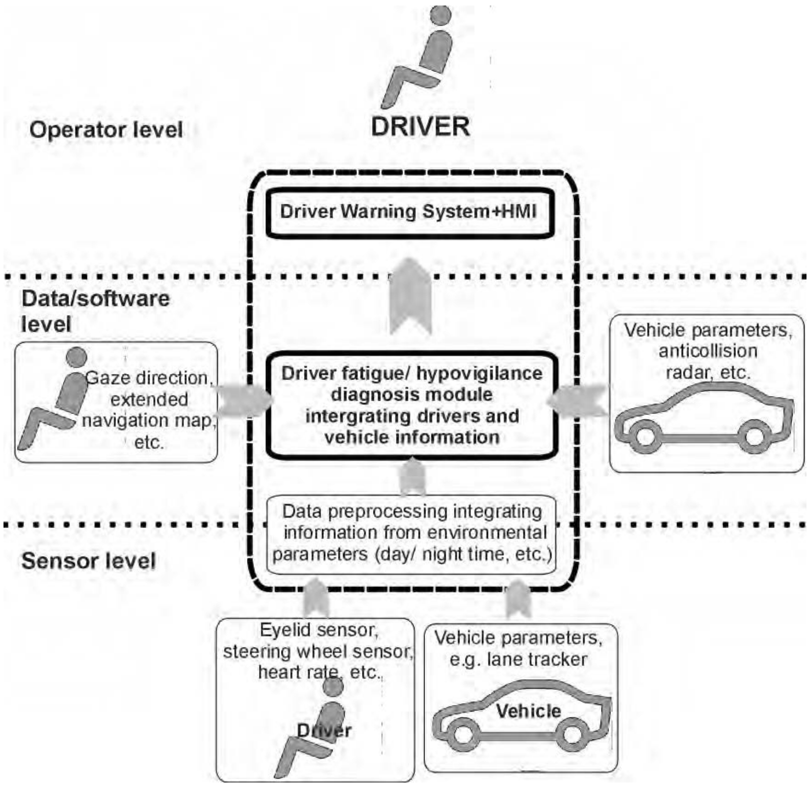

Figure 1. Possible components of future fatigue detection systems.

greatly enhance the assessment as well as the communication of driver state. User acceptance will be enhanced by inter and intra driver variability through diagnostic personalization and adaptation.

The requirements for such a driver fatigue monitoring system would then be twofold, namely at system and at user level. Both the sensors and the core diagnostic elements responsible for the emittance of warnings must be able to cope with the high demands corresponding to an unambiguous error free system. The user interface should be easy to read, simple to understand and to operate. It should be unobstrusive and always leave the driver in charge of the situation. Sensors, especially those required for driver monitoring should be unobstrusive and should not give the driver the feeling of being watched or monitored. One of the reasons for user unfriendly interfaces is the increasing complexity of the systems, increasing demands on the operator's ability, and increasing demands on his/her level of continuous, long-term attention. The cognitive load imposed by the driver monitoring system should be kept as small as possible. Unpredictable reactions by the system should be avoided, therefore system behaviour should be consistent. To be able to predict human behaviours in a fatigued state in response to a monitoring and warning system, studies are of great importance, but difficult and time-consuming and require access to large special databases storing the results of many measurements of human subject interaction reliability markers. The Micro Sleep Base is an example of such a database.

4. Conclusions

The development and integration of non invasive systems to detect driver fatigue in real time is a challenging task for the near future. Future systems have to be adaptive, take into account personal warning preferences, comply to individual constraints and effectively warn drivers without being too intrusive. At the same time, the driver should still feel in charge of the situation and be able to overwrite the system at any time.

E-health systems such as personal heart rate monitoring devices or devices making the health status of the driver available to their practitioner, especially in the case of chronic diseases, for example, would be helpful additions to enhance the driver status monitoring systems. Furthermore, E-health systems are interesting as an unobstrusive way to validate devices for passive and active safety. In which case they would have to comply with automotive constraints such as being insensitive to electromagnetic fields, motion artifacts and be non-invasive. They would also be welcome in research application for generating more in-depth knowledge about drivers physiological state as well as driving reactions and to establishing how these parameters relate to safety and driver fatigue. By their nature, E-health devices offer excellent opportunities for testing in non-laboratory settings to validate driver fatigue monitoring systems.

An extensive account has been given about the constraints and demands placed on driver monitoring systems at system and drivers level. Current research into electronic health applications could provide an enhancement to future systems and could even be integrated, at a later stage, as a plug and play solution for driver fatigue warning systems. One of the problems still facing the introduction of electronic health systems in the vehicle is that they are mainly required to be carried on the body. Future developments in both driver assistive technology and E-health systems will show if a plug and play solution is sustainable and whether these systems can also operate when they are not acting directly on the body of the person. Not withstanding these advancements, the harsh automotive environment and the constraints which it poses will still need to be considered and automotive regulations to be complied with. The scope of those developments will probably go well beyond the year 2010. Nonetheless, current research show that there will be exiting opportunities in future for interconnecting mobile devices with car based systems to further enhance safety.

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Market Research on Garment-Based "Wearables" and Biophysical Monitoring and a New Monitoring Method

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Abstract. Technology advancements are foremost on the minds of scientists and developers who are working to overcome the many hurdles associated with bringing consumers the enhanced benefits associated with next generation wearable health systems. Often the technology work takes a front seat to the basic requirements of traditional consumer apparel. The choices of what consumers elect to place and carry on their body can be practical, logical, emotional and sometimes seemingly random. By providing insights and data to support the claims, developers of wearable health systems of the future will be able improve their chance of consumer adoption and continued use by gaining a clearer picture of the people that will be wearing the systems. Results from 5 different consumer research studies are presented, examining consumer buying patterns, gender differences, regional differences, their receptivity to health benefits delivered via clothing and what they want from technology enhanced clothing. Market research related to biophysical monitoring utilizing smart fabrics or interactive textiles show a critical level of commercial activity. Medical applications focused on the aged, infant and critical patient care are taking the lead. This paper presents a look at the biophysical monitoring market and discusses new materials useful in garment systems and the challenges remaining for their development and integration with textiles. A new method of non-invasive monitoring of periodic activity is discussed.

Introduction

At $7Billion in annual sales, INVISTA Inc, formerly DuPont Textiles & Interiors, is the world's largest producer and seller of synthetic fibers into the textile apparel and home interiors market. Because of it's stable of well know brands like Lycra®, Stainmaster®, Coolmax®, Cordura®, Thermolite®, and Teflon®, INVISTA invests over $40MM US$ each year to support it's consumer brand equity via advertisement and marketing support.

One of the major investments that INVISTA makes is in consumer market research to understand short-term trends like fashion, style, silhouette and fabric preferences of the consuming public. In addition, and more importantly, consumer research is a key indicator of longer term market-back needs and is often the best input to drive successful R&D programs. Consumer Research to understand future wants, needs, and requirements should be the starting point to define technology research efforts.

One such area of research is Textronics^{TM}, which represents the integration of electronic components into textiles used in apparel, home interior and automotive applications. As opposed to postproduction assembly, integrating electronic components directly into textiles during their manufacture generally means minimized added cost of manufacture. The efforts of many firms to incorporate electronic devices into garments and to provide new functionality to wearables are well represented in the literature and patent publications. However, there remain hurdles to providing robust systems friendly to textile integration. The preferred embodiment is a level of integration not noticeable to the wearer and totally compatible with the design of the garment and suitable for customary care (washing and ironing). The design of the garment plays a major role in consumer acceptance [1–3]. Research in Textronics^{TM} is focused on new electronic materials for textile integration, connectors and textile sensors. Recent efforts are focused on biophysical monitoring.

1. Market Research

1.1. Today's Consumer Buying Habits

National Panel Data [1] gives insight to the current market size of the apparel top-weight market. Gender data, Regional perspective and retail channel outlet ranking provides a baseline to understand of current consumer purchase habits. Understanding the "big picture" will provide a view of just how large the apparel-based wearable market could become. Nearly 2.3 billion t-shirts are sold each year in North America. Cotton based shirts make up 80% of the total and are favorites of consumers. With 75% of the shirts sold at less that $15 US dollars, insight is provided to the price sensitivity that consumers have toward their apparel purchases. Providers of wearable health solutions need to be mindful of the value orientation of their future customers.

1.2. Consumer Apparel Requirements

In order for consumers to enthusiastically embrace wearable health system, it will be important to provide them all of the classic familiar benefits they currently demand from their clothing. Wirthlin Qualitative Research, Research Institute for Social-Cultural Change and Applied Research Consulting data [2–4] offers a view of basic expectations that men and women in North America and Europe have of their clothing. Those basic requirements include a comfortable feel, fit, easy care, breathability and that the product simply feels good. Additionally, consumers prefer youthful, stylish fashion. It will be important for the wearable technology developer to understand what is "sacred" to consumers and can not be compromised while working to bring e- medical system closer to their individual environment via clothing.

1.3. Consumer Views about "Medical Clothing"

Consumers have very rooted beliefs about their clothing. They range from being a practical vehicle for protection from the elements and a modesty shield to being a very personal statement of self-expression. AcuPoll Research [5] offers an early perspective on how European and North American women feel about health benefits being provided via clothing. While very receptive to the added benefits, there is skepticism about the veracity of the performance claims due to lack of understanding. These include but are not limited too concerns about reliability of the product, concerns about cost of the product and to some it simply seems to good to be true to have health benefits incorporated into clothing. Research suggested that a "money back guarantee" is the most convincing re-assurance.

1.3.1. Market research on Biophysical Monitoring devices

The market for biophysical monitoring devices is estimated at $2.7 billion and will expand in the future, based on latest market research [6]. The market is segmented into medical, government and health/fitness. Currently, there are several products and technologies available providing biophysical monitoring functions, some are included in these captions: professional services, "smart fabrics and interactive textiles" (SFIT), electronic systems solutions like stationary devices and wristwatch or chest belt based systems. Applications of these systems include heart rate monitoring, body temperature, respiration, micro-environment and biofeedback.

SFIT focused solutions are likely to be led by the medical industry. Medical applications will be engaged largely with infant and critical patient care. Figure 1 estimate units of biophysical monitoring solutions used utilizing SFIT. However, those SFIT solutions must be affordable, accurate, easy to use and non-invasive, as well as, value adding. Current awareness to SFIT-BMP systems is low. The price points, ease of use, liability, accuracy and consumer friendliness (fashion) are unknowns. For example, the designers of electronic circuitry often overlook fashion yet it is crucial to consumer acceptance. The role of fashion is expected to be less important to the early adopters of SFIT solutions. It is expected that those first to adopt these solutions be involved in hospital and home care, emergency and intensive care units, health and fitness clubs, as well as, sleep monitoring, and weight management.

Based on market research presented here, there is no clear favorite form factor, users have a choice of wearables for biophysical monitoring which include garments, wristwatch (possibly including a chest strap or shoe pod) or an arm band. SFIT solutions will

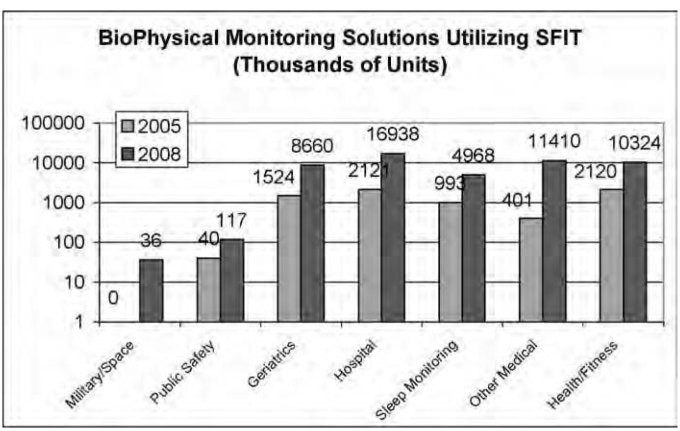

Figure 1. Biophysical monitoring solutions utilizing SFIT in thousands of units.

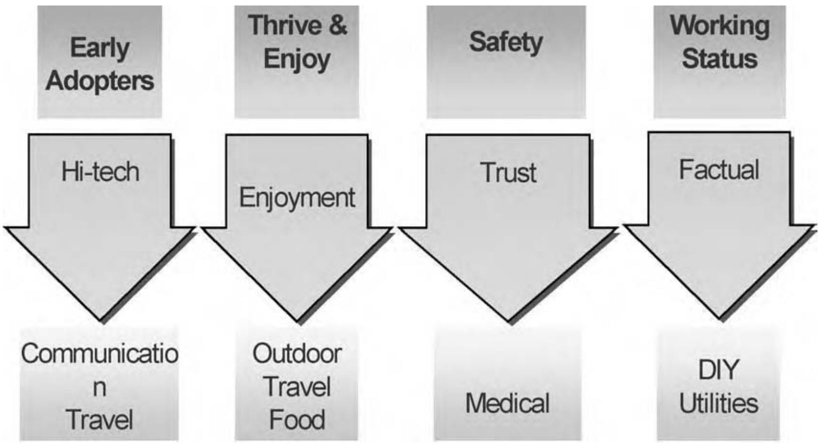

Figure 2. Key consumer segments. Identified are key consumer segments and their preferred tone of communications (large arrows). The lower boxes identify areas of interest of each respective group.

capture a portion of the wearable biophysical monitoring market where there is a need for comfort, lightweight, a large area sensor array, real-time response and actuation or the need to sense across the body or chest.

1.4. Target Consumers for Technology Integrated Clothing

An in-depth look at European and North American consumers will disclose who is most receptive to technology in their clothing [7]. Distinct consumer segmentations are identified, all receptive to clothing integrated technology but for very different reasons. Figure 2 shows targeted key consumer segments and their tone of communication and coupled interest for embedded technology. Insight to the performance benefits they are seeking and their motivations for using what is being created in todays most advanced institutions will be explored. It is obvious from the profile of the "early adopters" that those are the most likely to test and try new gadget and developments.

2. A new approach to biophysical monitoring

2.1. System description

Numerous systems of smart garments have been discussed in the literature and prototypes are being developed. A recent overview of such intelligent textile prototypes is given in Gould [8]. Not all of these systems comprise true textile integration. Often the electronic components are worn on a belt or elsewhere on the garment versus being integrated into the garment [9]. However, other references [10] provide examples of textile based sensors. The sensors are based on fabric stretch and are based on conduction path increased when the knit pattern is deformed during use.

Here a fabric system useful for monitoring motion, such as motion generated by a geometric chance in the body surface in response to physiological activity is discussed.

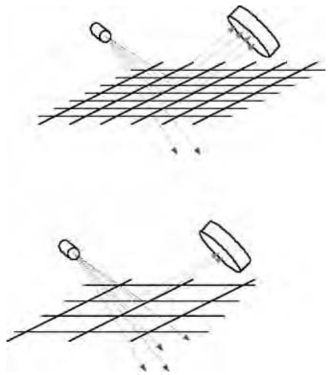

Figure 3. A sensor (805nm source) "looking" at a fabric in neutral position. The arrows penetrating are the transmitted light, while the other hitting the reflector are reflected light. As the subject breathes and the fabric grid expands the amount of reflected light is less as shown in the lower case.

The measurements are non-invasive. The new system as presented consists of a fabric, which exhibits light transmission and reflection properties. It can be placed strategically in a garment or this fabric can be used to make the entire garment depending on monitoring needs. The amount of light transmitted thought the fabric is relative to the amount of light reflected by the fabric changes when the fabric stretches in response to a motion. The schematic in Figure 3 illustrates the above.

Currently, the prototype system is operated with a 805nm transmission sensor. The source and the detector are attached to the fabric in relative positions such that the reception of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric when the fabric stretches in response motion due to geometric changes in the body of the subject wearing the garment or the component having the mantle thereon. A signal processor converts a signal from the detector representative of radiation at 805nm incident thereon into a signal representative of at least predetermined physiological parameter of a wearer of the garment. A commercially available emitter – detector package from Fourier System Ltd. was used to process the signals.

2.2. Monitoring a periodic physical activity

Human respiration and heart rate were monitored as an example of a use for this new system. Figure 4 shows the raw signal from a person, a composite of the heart rate and breathing rate. The details of the signal processing are explained below.

This signal is a composite of frequencies containing at least the respiration cycle and heart rate of the subject. Certain noise sources contribute to the overall waveform. Such noise sources are believed to arise from extraneous motion of the subject not associated with respiration and heart rate. These sources of noise could be filtered using appropriate electronic filtering techniques. Specifically, high frequency and low frequency pass filters appropriately chosen can create a cleaner raw overall waveform. Such filters could be selected accordingly by methods known in order to obtain a signal associated only with respiration or one associated only with heartbeat. Equivalently, filters to reduce known sources of signal noise are also easily employed in the data acquisition system.

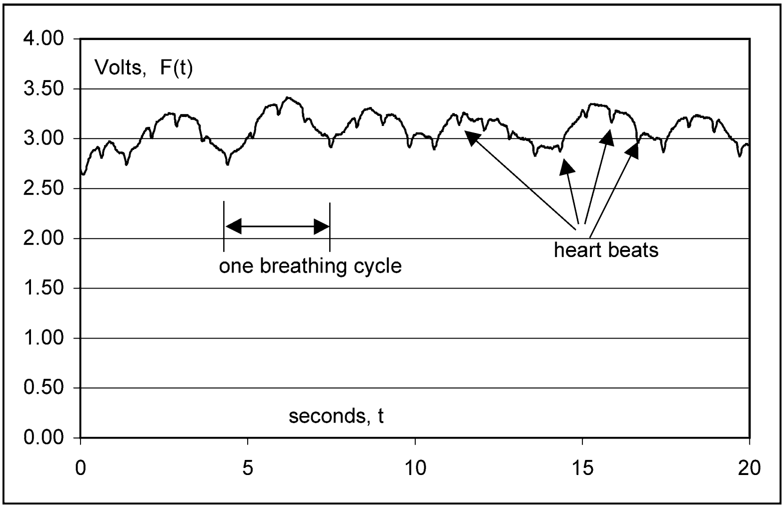

Figure 4. Raw signal obtained from subject breathing.

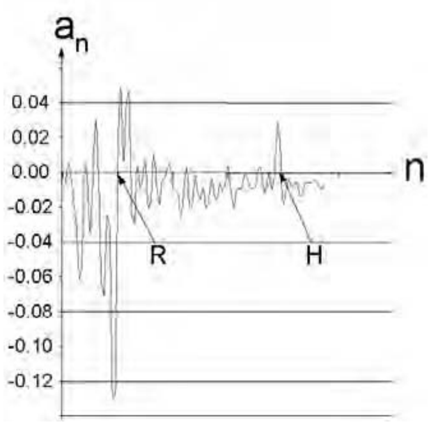

Figure 5. Fourier coefficients obtained from algorithm. R shows the respiratory rate of the subject while H is related to the heart rate (a_{23} and a_{78}).

The composite frequency waveform of Figure 4 is resolvable into the frequency domain spectrum. In this example the raw signal of Figure 4 was downloaded to a computer and processed using a Fourier frequency deconvolution algorithm. The equations used to determine the coefficients are below, where a_n denote the Fourier coefficients (Eqns. 1 and 2).

The predominating frequencies were found and represent the respiration and heart rate of the wearer. This is shown in Figure 5. This result illustrates that a garment having a portion of monitoring fabric strategically located thereon can successfully report the breathing (respiration) rate and heart rate of the garment wearer. The garment or monitoring patch does not require being wetted or the application of special gels prior to use.

$$F(t) = a_0 + a_n \sum_{n=1}^{\infty} \sin(2\pi n f t) \tag{1}$$

$$a_n = \left(\frac{2}{L}\right) \int_0^L F(t) \sin(2\pi n f t) dt \tag{2}$$

3. Summary and Conclusion

Data and research presented in this paper could be useful to help the wearable health community step back from the issues surrounding integration, electronics, power, signal process and data transmission and take the time to put a human face on the consumers. Through better visualization of the ultimate user and understanding their relatively "simple" clothing needs, it will be possible to bring health systems to the public which will be not only revolutionary but also embraced.

Consumer preferences are known and have been quantified. The minimum basics are understood but differ by gender, country and garment type. In addition to performance, consumers want the systems to function reliably, look good and feel good. Four distinct target consumer groups interested in technology in clothing have been identified. They have different needs and tone of communications as well as distinctly different interests. It was found that enhanced, preventive and reactive health applications have a distinct audience. Women will be key decision-makers in that category as they are making decision regarding their family as well as their aging parents. Technology in this category will only be adapted if it is reliable and easy to use. For an audience below the age of 35, the systems need to look and feel good and fulfill their current fashion needs.

A new non-invasive method to monitor motion generated by geometric change in the body has been demonstrated. The prototype developed successfully monitors respiration and heart rate of the wearer. The monitoring patch necessary can be easily and unobtrusively incorporated into existing systems.

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III. Smart Wearable Monitoring and Diagnostic Systems

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Executive Summary

This section gives an overview of the latest major research and development achievements in smart wearable sensors and healthcare systems and services, in the context of eHealth, demonstrating in practice major ongoing shift paradigms such as "patient-centred healthcare" and "self- assessment of health status".

Despite recent advances made in ambulatory health monitoring, physicians and researchers have limited possibilities to receive and assess multiple physiological data and patient reports on their health or well being problems in daily life. However, this information could be crucial, in case of a health event, for the clinical assessment and decision on therapy. Monitoring of multiple physiological, behavioural and other personal parameters has been too complicated to achieve and has required special equipment that has been unavailable, too expensive, or too cumbersome to be used effectively. After several years of research and development on a new generation of biomedical sensors, on telecommunications, in computer engineering and user interfaces, the first results start to appear in the public domain. European research has significantly contributed to this international landscape through eHealth funded projects, under the EC Information Society Technologies R&D program, leading to integrated multiparametric monitoring applications for e.g. monitoring and rehabilitation of athletes, home telecare and monitoring during pregnancy. Still, the development of reliable and cost-effective systems is a real challenge since it involves several technical, medical, legal, ethical, market and usability issues, most of them not being solved at present.

Cardiology is one of the most promising application examples where personalised, wearable and ubiquitous systems could significantly improve quality and cost-effectiveness of healthcare. Heart disease is the main cause of early disability and premature death in western countries and steadily increases because of the aging of the population. Considering that most of the cardiac deaths occur outside of the hospital, the main problem to solve is how to reduce the time before treatment. This can be done through detection, as early as possible, of the onset of cardiac events and involvement of the health care structures without delay but only if necessary. Cutting-edge solutions are under ongoing research and development, integrating pervasive computing and ambient intelligence into, for example, personalised wearable ECG monitor for the early detection of cardiac ischemia and arrhythmia. Pervasive computing has been used also in association with contact centres and telemedicine, to develop applications for monitoring, treating and managing chronically ill patients at home. The CHS project application consists of vital signs submission (blood pressure, weight, heart pulse, ECG) and browsing of educational content for stress control, diet information and lifestyle management. The results of the trials confirmed that such a home care model has a positive impact on the amelioration of the health status of the patients, on their quality and on the economic benefits, reducing significantly unnecessary hospital visits and hospitalization days.

The integration of sensors in a "true wearable garment" can offer additional advantages in terms of comfort, usability and body measurements. The Lifeshirt^{TM} is composed from a garment, containing respiratory inductive plethysmography ECG, a data recorder and the PC based analysis software. It delivers a dynamic cardiopulmonary profile, respiration, ECG, accelerometer and electronic diary. Applications are related to respiratory function, sleep diagnostics, early hospital discharge, pre and post operative monitoring and cardiopulmonary function.

A smart wearable personal system has to be interactive and capable of exchanging information with other health-related information and service points. The motivation of Body Area Network concept, BAN, is based on the need for wireless networking among more than one body-worn sensor or actor unit, at the human body that is linked to the existing health infrastructure to enable seamless ambulatory communication chains and personalised integration of health-related services. It requires sufficiently high data rates, multi-link capability, and quality of service by using reliable radiofrequency band as well as minimal electromagnetic radiation and power consumption. This is a key infrastructure element in the future personal health service scenario. MobiHealth project investigates how ambulant healthcare can benefit from GPRS and/or UMTS technology. The major challenges are the long distance, the large delays and the power consumption. Such platforms are currently trialled in Europe with a view to create and commercialize the service.

One of the major challenges for provision of telemonitoring and alarming services is the improvement of communication and the interoperability of devices and care providers and the information integration into an electronic health record (EHR). A major obstacle in achieving such goals is a lack of standards for devices as well as procedures and lack of databases with information on “normal” variability of many medical parameters to be monitored. Valuable standardisation work is currently performed by key players in the field but basic problems are still to be solved such as the introduction of a uniform patient identification, which is a prerequisite for the establishment of a universal standard electronic health record.

New Paradigms in Telemedicine: Ambient Intelligence, Wearable, Pervasive and Personalized

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Abstract. After decades of development of information systems dedicated to health professionals, there is an increasing demand for personalized and non-hospital based care. An especially critical domain is cardiology: almost two third of cardiac deaths occur out of hospital, and victims do not survive long enough to benefit from in-hospital treatments. We need to reduce the time before treatment. But symptoms are often interpreted wrongly. The only immediate diagnostic tool to assess the possibility of a cardiac event is the electrocardiogram (ECG). Event and transtelephonic ECG recorders are used to improve decision making but require setting up new infrastructures. The European EPI-MEDICS project has developed an intelligent Personal ECG Monitor (PEM) for the early detection of cardiac events. The PEM embeds advanced decision making techniques, generates different alarm levels and forwards alarm messages to the relevant care providers by means of new generation wireless communication. It is cost saving, involving care provider only if necessary and requiring no specific infrastructure. This solution is a typical example of pervasive computing and ambient intelligence that demonstrates how personalized, wearable, ubiquitous devices could improve healthcare.

Introduction

Several new classes of computing and communication devices like smart cards, handheld computers (PDA), smart phones, and more recently, intelligent and wearable medical devices have been designed during the past decade. Combined to the recent proliferation of wireless communication solutions, this presents exciting opportunities for health care. For example, in Italy and in the US, several patients are currently using PDAs to send critical medical data to physicians who also have a similar handheld device [1]. In the Cardiology application domain, the European EPI-MEDICS project [2] has developed a Portable ECG Monitor (PEM) having the capabilities of recording and analysing a simplified – but of professional quality – electrocardiogram (ECG), of performing in real time advanced decision-making based on the interpretation of serial ECG analysis results by means of a committee of Artificial Neuronal Networks that mimic a multi-expert approach, and to automatically transmit an emergency request message to an alarm server connected to an emergency call centre in case of detection of a severe arrhythmia or of an acute myocardial infarction [3]. In ambulatory situations, the PEM alone with an appropriate mobile phone can be considered as a minimum first-aid cardiology kit.

These smart devices together with the advances of wireless technologies such as Bluetooth, GPRS or WIFI will allow the citizens to access and/or transmit their data anywhere and anytime and to act as a consumer responsible of his own health. This concept is called Pervasive Computing in eHealth.

1. Ambient intelligence and pervasive computing

Pervasive Computing is a new concept that not only includes portable or wearable medical monitoring devices, but also entertainment systems such as MP3 players, household appliances and point-of-sales terminals [4].

Another recent concept is Ambient Intelligence. Defined by the EC Information Society Technologies Advisory Group in 1999, this idiom describes a potential future in which we will be surrounded by intelligent objects and in which the environment will recognize the presence of persons and will respond to it in an undetectable manner [5]. Ambient Intelligence is based on three recent key technologies:

- Ubiquitous computing that describes the fact that microprocessors are embedded into everyday objects and so, that many computers are made available throughout the physical environment while being invisible to the user [6].
- Ubiquitous Communication that enables these objects to communicate by means of wireless technologies with other devices, hosts and users.
- Intelligent User Interfaces that enable the citizens to interact with such an intelligent environment not only in a natural way but also in a personalized way [7].

2. Towards a new paradigm in healthcare: self-care

Citizen's/patient's needs are changing: "Fitness and health are trendy and are becoming a life style" [8]. Patients want to be more involved in the management of their own health, preferring painless methods of diagnosis and treatments. Healthcare is moving from traditional institution-centred care towards a patient, citizen-centred one. "Instead of being viewed as the apex of a system of care that hardly recognises the large amount of self care that occurs now, professional care will be viewed as the support to a system that emphasises self care" [9]. This general trend is especially perceptible in the field of cardiology.

2.1. Towards self-care in Cardiology

In western countries, heart disease is the main cause of early disability and premature death. Furthermore, because the population is rapidly aging, the number of cardiac patients is steadily increasing and almost 2/3 of the cardiac patients die in the pre-hospital phase. Persons with acute myocardial infarction (AMI) who survive long enough to enter hospital undoubtedly benefit from the improvement of the quality of care introduced into routine practice within the last decade. But epidemiological data suggest that greater deployment of resources for pre-hospital care has more potential to reduce the fatality rate of AMI than has the intensification of treatment in hospital. The clear message of the different studies is the earlier treatment is given the better: when matters more than where. New strategies are thus needed to reduce the time between the onset of the first symptoms and the decision to treat.

A key symptom for diagnosing acute ischemia is chest pain. However, correct and timely diagnosis of acute ischemia is a very difficult task. Chest pain may be caused by other diseases, such as pericarditis, or due to other problems, such as muscle-skeletal or gastro-oesophageal problems. There are also other ischemia episodes, which are silent, like patients suffering from diabetes. The only immediately available and useful diagnostic tool for assessing the probability of a cardiac event, for stratifying its degree (stable, unstable angina, AMI, risk of out-hospital or in-hospital death) and for guiding therapy is the electrocardiogram. The diagnostic power of the ECG may be further increased if a previous reference tracing is available. The ECG is like a fingerprint and analysing serial changes will allow to overcome inter-subject variability and thus to considerably improve the sensitivity and the specificity of the diagnostic tool. But performing serial ECG analysis implies that reference ECGs and relevant clinical information concerning the patient have previously been stored, with the perspective of their future use, either on central databases or at the physician office or in a personal portable device such as an EPI-MEDICS PEM device or on a Smart Card.

During previous European Framework Programmes, several solutions have been designed to improve cardiac patient health by providing seamless patient information availability and sharing throughout Europe. Attempts have been made to improve the management of cardiac care: campaigns to teach symptoms of heart attacks, use of the agreed common European emergency number (112), strategic positioning of ambulances, pre-hospital triage and arrangements for cardiac care based on advanced information from the ambulance or the patient [10]. Nevertheless, only small trends to shorter time intervals before treatment have been reported. Although call-to-needle time can be very short when patients receive pre-hospital thrombolysis from GPs or from the ambulance staff, the interval from the onset of symptoms until the call for medical assistance varies widely from one patient to the other. Symptoms are often interpreted incorrectly.

Event recorders and transtelephonic ECG recorders are increasingly used to improve decision making in the pre-hospital phase, but these systems are usually unable to capture transient ECG events such as infrequent arrhythmias or ischemic episodes. Moreover, all these systems require setting up new information technology infrastructures and medical services and need skilled personnel to interpret the ECG and take decisions for the patient care. This approach would be very impractical for patients with infrequent symptoms such as arrhythmias and ischemia that represent 85% of the cardiac diseased patients, and would be very expensive if adapted for every citizen at risk.

The challenge is twofold:

- detect as early as possible the onset of ischemic events, even for citizens that have not yet any known cardiac disease,
- involve the health care structures without delay, but only if necessary.

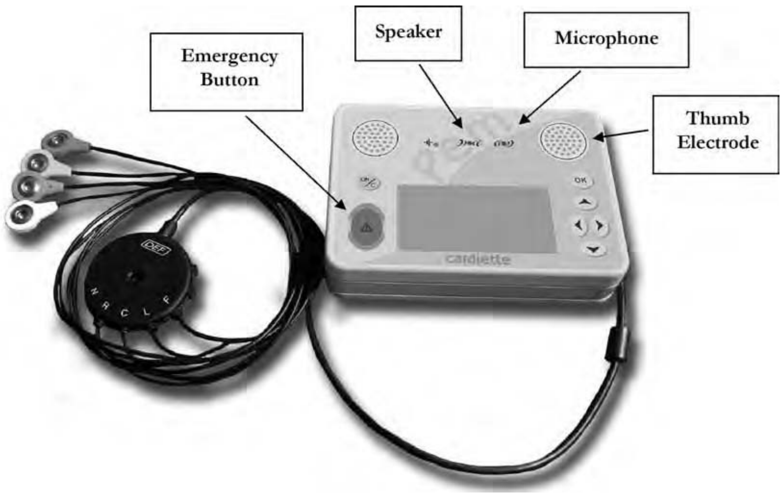

Figure 1. Picture of the PEM device with a 4 electrode cable. In case the patient is capable to hold himself the PEM device in his/her hands, he/she may use the thumb electrodes for recording the DI ECG lead. In this situation, the PEM would require only a simplified, two electrodes cable for recording the additional V2 and the DII leads. The emergency button is used to bypass the standard processing steps and to transmit the recorded ECG and the patient health record to an emergency centre, whatever the embedded ECG analysis and decision making results.

2.2. The EPI-MEDICS solution

The solution proposed by the European EPI-MEDICS project [1,2] is a novel, enhanced, portable and intelligent Personal ECG Monitor (PEM) for the early detection of cardiac ischemia and arrhythmia (Figure 1). The PEM is able to record a pseudo-orthogonal, 3-lead subset of the standard 12-lead ECG (DI, DII and V2), store and derive the corresponding standard 12-lead ECG, incorporate intelligent self-adaptive serial ECG data processing and decision-making techniques (Figure 2), generate different levels of alarms taking into account both the ECG signals and the patient's clinical history that have been previously stored on a Smart Media Card inserted in the PEM device, and forward the alarm messages with the recorded signals and the patient's Electronic Health Record (EHR) to the relevant health care providers by means of new generation wireless communication protocols (Bluetooth and GSM/GPRS) (Figure 3).

The ECG signals are compliant with the SCP-ECG standard [11]. The messages and the EHR are encoded in XML. Major alarm messages are automatically transmitted to the nearest emergency call centre (Figure 3). Data leading to medium or minor alarms are temporarily stored on a central Web Server and the health professionals are informed by a SMS (Figure 4).

The PEM embeds itself a web server [12] to facilitate the reviewing and/or updating of the embedded EHR during a routine visit at the GP's or the cardiologist's office (Figures 5 and 6). Thus only a standard web browser and Internet connectivity are requested for accessing the data embedded in the PEM. No specific drivers are needed on the PEM user's computers. The user manipulates the PEM device as he browses the web: he is in a familiar environment.

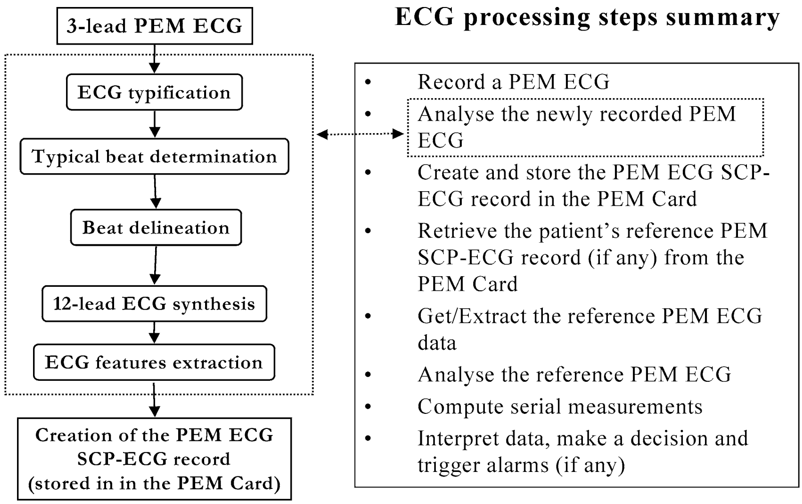

Figure 2. ECG processing steps performed by the PEM device. The PEM embeds professional quality unary and serial ECG signal analysis software and performs advanced decision making for the detection of ischemia.

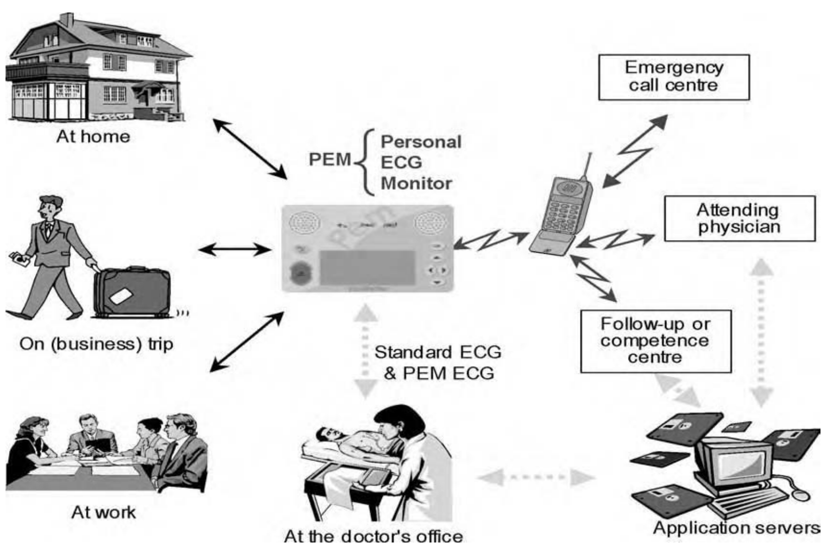

Figure 3. Simplified model of the EPI-MEDICS concept. The PEM may be used on demand at different occasions at home, at work, during a trip. Depending on the alarm level and/or on the scenario of use, the alarm message and the ECGs may be automatically sent together with the embedded Electronic Health Record via a standard Bluetooth enabled GSM/GPRS compatible mobile phone to an emergency call centre.

Decision making is performed at different levels: detection of arrhythmias and ischemia, alarm generation taking into account additional clinical information such as the patient's risk factors, management of the alarms in case there are problems in contacting the relevant health care providers (Figures 7 and 8). Furthermore, the care providers are involved only if necessary and no specific infrastructures are required: communications are based on standard external tools, and different Web services are being offered to pro-

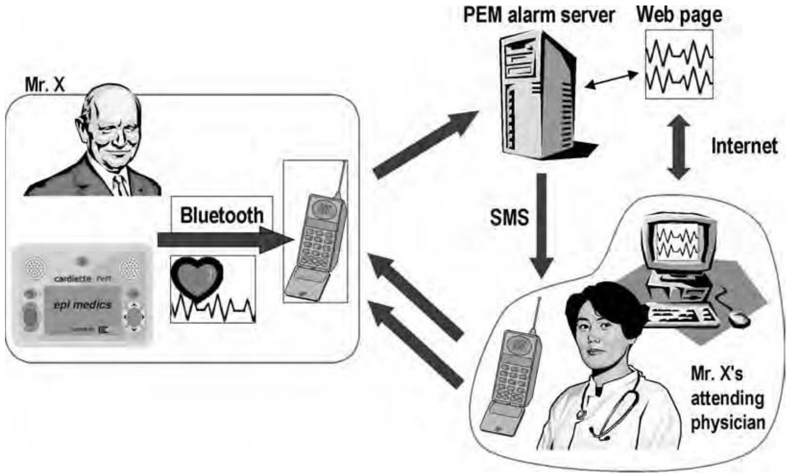

Figure 4. Medium alarm scenario. The PEM sends the alarm message together with the last recorded ECG, the reference ECG and the patient's Electronic Health Record to the PEM alarm server which in term sends an SMS message to the attending physician. The latter accesses the alarm server that automatically formats the data according to the type of equipment (PC , Notepad, ..) used to connect to the alarm server and takes the appropriate actions.

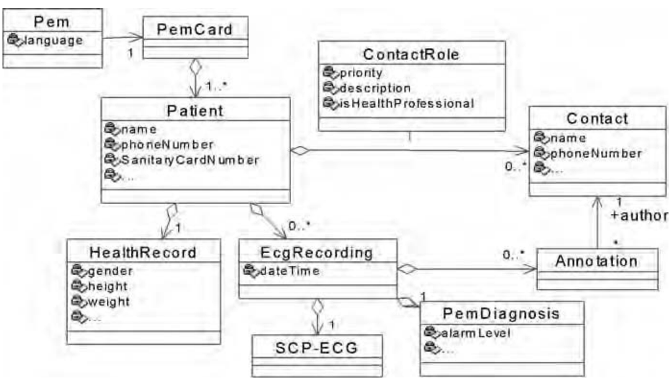

Figure 5. Simplified model of the embedded Electronic Health Record (EHR).

vide up-to-date business components used for the setup or update of the PEM devices, for the computation of a patient specific 3-lead to 12-lead ECG transformation matrix, the update of the ANN structure, weights and biases, and the customisation of some of the parameters of the decision-making process [13].

Customisation is also performed for several other processing steps: signal processing, data browsing and display.

All the software complexity has been embedded in the PEM device (Figure 9) and in the application servers. Thus no specific software is required for the end user and/or for the health professionals' workstations. The PEM software and the decision making rules are easy to upgrade via the Web servers. This approach facilitates the deployment of the EPI-MEDICS solution and guarantees that all PEMs will include the latest ECG signal analysis and decision making components.

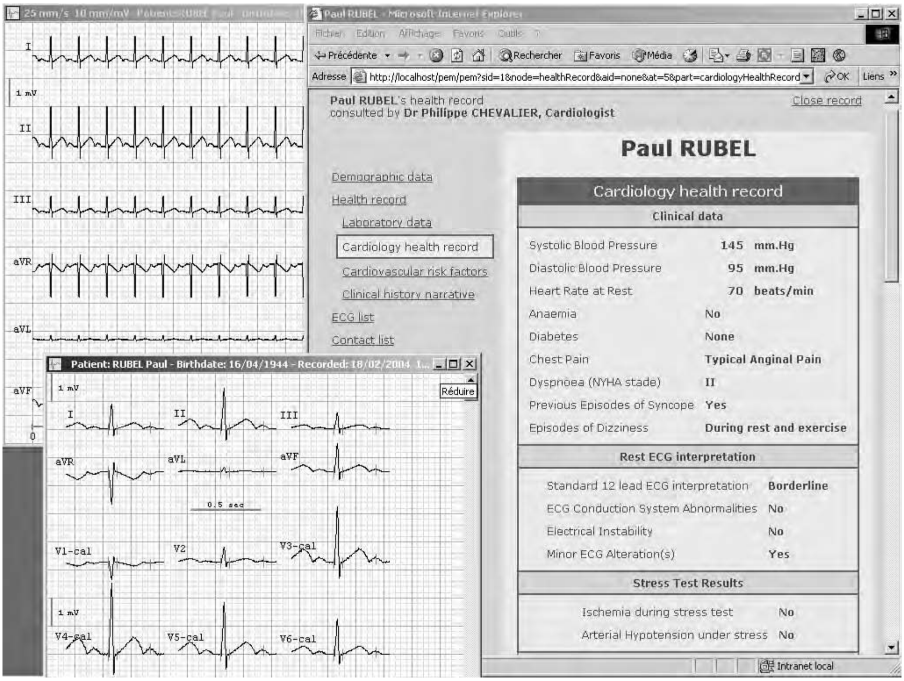

Figure 6. Snapshot of the display of part of a patient's Cardiology Health Record and of his/her latest ECG during a routine visit at the physician's office. Only a standard Web browser and RS232 or Bluetooth connectivity are required to access the EHR stored in the PEM' Smart Media data card.

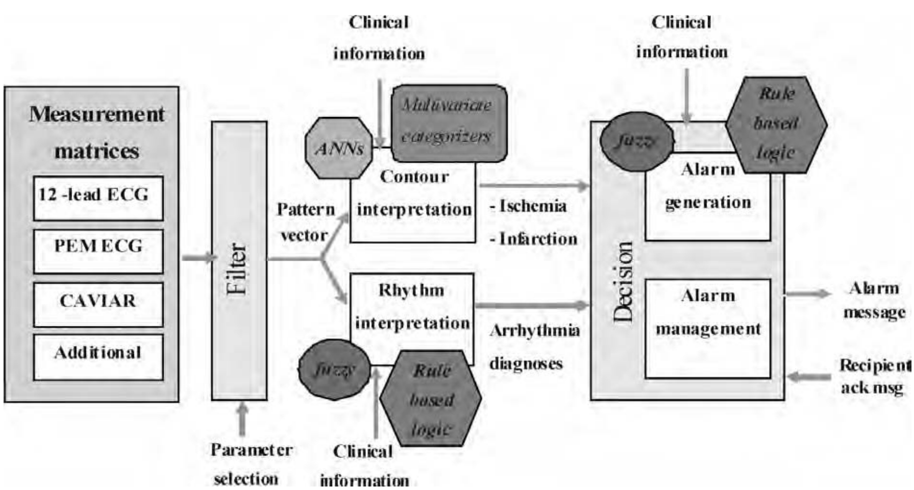

Figure 7. Synthetic diagram of the decision making strategy embedded in the PEM. Rhythm interpretation is achieved by rule based logic that may be customised according to the patient's specificities. Cardiac ischemia and acute myocardial infarction are detected by a committee of 100 Artificial Neural Networks (ANNs) working as a multi-expert system.

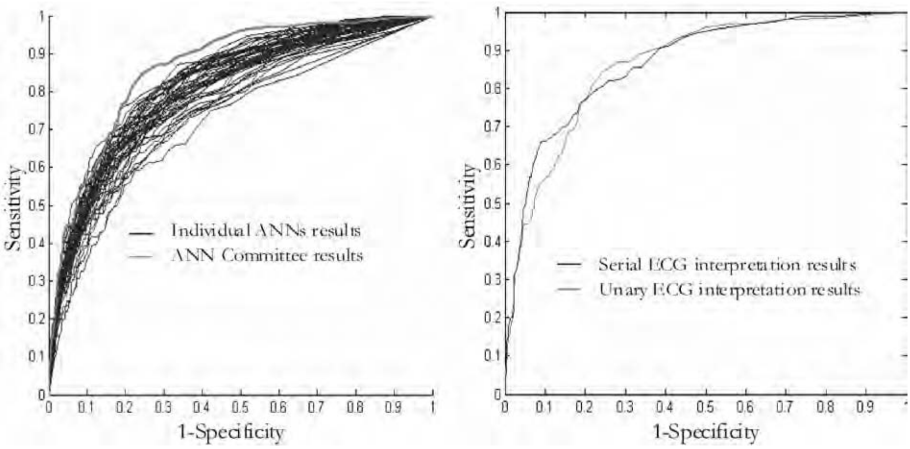

Figure 8. ROC curves for the diagnosis of cardiac ischemia assessed on the Lund myocardial infarction database [14]. Left panel: unary analysis test results for the set of 100 individual ANNs and for the corresponding ANN committee results consisting in the calculation of the mean value of the 100 individual ANNs. As expected from the application of the Central Limit Theorem, the performance of the ANN committee is better than each individual ANN. Right panel: serial ECG analysis results for a committee of 100 ANNs trained to take into account the measurement changes between the latest ECG and a reference ECG. Performing serial ECG analysis results in a 9 % sensitivity improvement for the 90 % specificity operating point. Decision making customisation is achieved by changing the operating point position and the corresponding alarm thresholds to take account of the patient specificities (risk factor, heart position, etc...) and of the number of false alarms and/or missed ischemia detections.

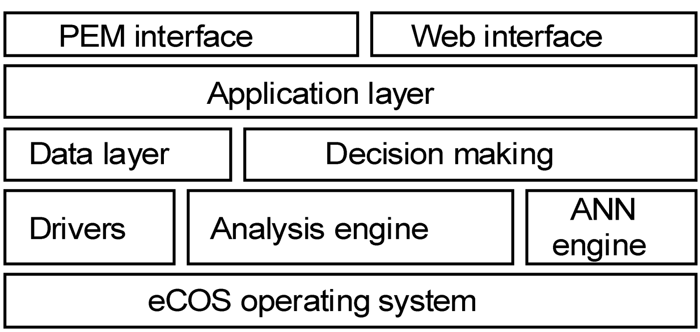

Figure 9. PEM core software modules and layers. The low level firmware is empowered by eCOS, a real time Linux based Operating System. The analysis engine implements the different ECG processing steps described in figure 2. The PEM complexity is mastered thanks to a carefully designed components approach that guarantees evolutivity, robustness and reusability.

3. Conclusion

After decades of development of information systems dedicated to health professionals, there is an increasing demand for personalized and non-hospital based care [15]. We can imagine a near future in which citizens and patients will use as in the EPI-MEDICS project smart, wearable technologies to transmit and/or access information anywhere, anytime, and above all, to act as health consumers by controlling their own health status. They will be able to perform relevant tests at the early stage of the onset of the symptoms without involving skilled personnel, and call for assistance only when needed. Additional services like the flow management process of the PEM alarm messages and of tele-expertise requests to and between health professionals are also being implemented in emergency call centres and/or in the informatics departments of several hospitals [13]. All these software components will be driven by intelligent mobile agents to facilitate their communication via XML format, to update the databases storing the patients EHRs with new data collected at home or in ambulatory recording conditions, and for efficient data retrieval [13]. A new era has started: “Healthcare will become personalized, wearable, and ubiquitous”.

Acknowledgements

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The LifeShirt: A Multi-Function Ambulatory System Monitoring Health, Disease, and Medical Intervention in the Real World

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Abstract. Despite advances made in health-related ambulatory monitoring, medical practitioners and researchers have remained seriously constrained in their ability to acquire concurrent assessments of multiple physiological systems, as well as patient reports of symptoms and well being in daily life: Almost all past and current applications have been limited to the registration of a single variable (e.g. the electrocardiogram or blood pressure), and this has resulted in incomplete information about other relevant physiological and environmental factors likely to contribute to disease or its amelioration. Monitoring of multiple physiological functions has been too complicated to achieve and has required special measurement devices that have been unavailable, too expensive, or too cumbersome to effectively employ. Concurrent assessment of pertinent information about patient activities during monitoring has remained difficult to accomplish, although such information is likely to be crucial for the interpretation of physiological findings and patients' perceptions of improvement.

The LifeShirt™ (Vivometrics, Inc., Ventura, CA, U.S.A.) is a multi-function ambulatory device capable of simultaneously monitoring several physiological signals and patient reports of symptoms and well being. The LifeShirt system is an extensible data acquisition and processing platform consisting of a garment, a data recorder, and PC-based analysis software. Sensors in the LifeShirt garment continuously monitor respiration, the electrocardiogram, activity and posture. Other functions are easily plugged into the system, including pulse oximetry, EEG/ EOG measurement, blood pressure, temperature, capnometry and acoustic monitoring. Subjective patient data may also be entered into the LifeShirt recorder, and all data are encrypted and written to a flash memory card. Vivologic™ analysis software provides full-disclosure analysis and display of high-resolution waveforms and over 30 derived parameters; the software also produces summary reports for clinical diagnostic purposes. The LifeShirt has been rigorously tested for more than 38,000 hours in 90 studies with 1,750 subjects. The device has received all necessary regulatory approvals and is currently used in leading research institutions throughout the United States, Canada and Europe. Clinical applications include sleep diagnostics, heart disease, pulmonary disorders, cardiopulmonary rehabilitation, early hospital discharge and pre- and post-operative monitoring, human-factors in ergonomics and behavioral medicine.

Keywords. Ambulatory monitoring, Clinical and research applications, Physiology, Multi-signal, Respiration, Electrocardiogram, Accelerometry, Oximetry, Heart-rate variability, Electronic diary of patient symptoms

Introduction

Medical monitoring of health, disease, therapy and management has almost solely relied upon measurements made in the physician practice, clinic or hospital setting. Inferences about symptom improvement and quality of life have also been based exclusively upon occasional self-reports of patients during medical visits. Because the ecological validity of this approach seriously limits our potential to adequately diagnose and treat patients, there has been increasing interest in ambulatory monitoring for a variety of conditions. Despite advances made in health-related ambulatory monitoring, medical practitioners and researchers have remained seriously constrained in their ability to acquire concurrent assessments of multiple physiological systems, as well as patient reports of symptoms and well being in daily life: Almost all past and current applications have been limited to the registration of a single variable (e.g. the electrocardiogram or blood pressure), and this has resulted in incomplete information about other relevant physiological and environmental factors likely to contribute to disease or its amelioration. Monitoring of multiple physiological functions has been too complicated to achieve and has required special measurement devices that have been unavailable, too expensive, or too cumbersome to effectively employ. Concurrent assessment of pertinent information about patient activities during monitoring has remained difficult to accomplish, although such information is likely to be crucial for the interpretation of physiological findings and patients' perceptions of improvement.

1. The LifeShirt^{TM}: A multi-function ambulatory monitoring device

The LifeShirt^{TM} (Vivometrics, Inc., Ventura, CA, U.S.A.) is a multi-function ambulatory device capable of simultaneously monitoring several physiological signals and patient reports of symptoms and well being. The system is characterized by an extensible data acquisition and processing platform consisting of three parts: a garment, a data recorder, and PC-based analysis software (see Figure 1).

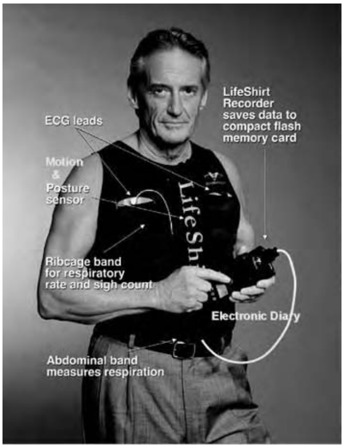

Figure 1. The LifeShirt system: the monitoring vest and data acquisition and electronic diary unit.

Sensors in or attached to the LifeShirt garment continuously monitor respiration, the electrocardiogram, activity and posture. Respiratory measures are derived from thoracic and abdominal inductive plethysmography bands sewn into the Lycra vest. Inductive plethysmography provides the gold standard for non-invasive assessment of respiratory pattern. The U.S. National Institutes of Health recognize respiratory inductance plethysmography (RIP) as the best non-invasive method to assess sleep disordered breathing in infants [1]. The International Task Force of the European Respiratory Society, the Australasian Sleep Association and the American Thoracic Society also concluded that RIP was the best noninvasive method of monitoring sleep disordered breathing in adults [2].

Respiratory parameters derived from the LifeShirt include volumetric (e.g. minute ventilation volume), timing (e.g. respiration rate) and flow (peak-expiratory flow) measures. These measures are relevant for a number of diverse disorders, such as pulmonary disease, heart failure, and anxiety disorders. Minute ventilation volume can also ordinarily be used as an index of metabolic activity. This variable, together with the accelerometer activity and posture signal, yield valuable information regarding activity pattern that aid in interpretation of other signals. The ECG signal is employed to detect arrhythmic activity and to quantify heart rate variability. Other additional functions may be simply plugged into the LifeShirt system via an available port to expand the number of simultaneous signals. These include pulse oximetry, the EEG and EOG, blood pressure, temperature, CO2 capnometry and acoustic monitoring. Subjective patient data (e.g. momentary reports of symptom and well being) are also easily entered into the LifeShirt recorder PDA by means of a programmable diary/questionnaire inventory adaptable to any disorder or health-related issue.

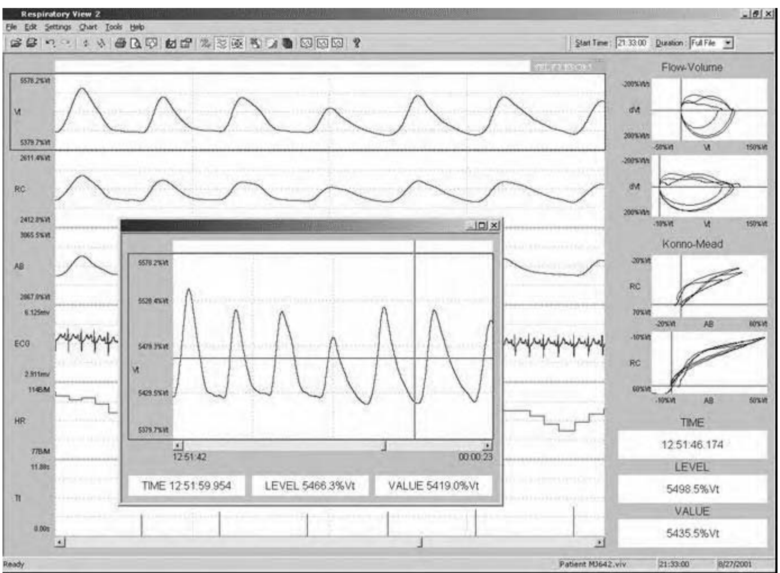

Figure 2. Sample output of selected variables from Vivologic analysis software program. The five panels to the left (top to bottom) are the tidal volume respiratory signal, the ribcage respiratory signal, the ECG, derived heart rate, and total respiratory cycle time. Note the full-disclosure of the respiratory and ECG waveforms (i.e. both original waveforms and derived parameters may be displayed). The center pop-up is a close-up of the ventilatory waveform, and the panels to the right are different respiratory flow-volume graphic relationships. Upper pink tab indicates diary entry.

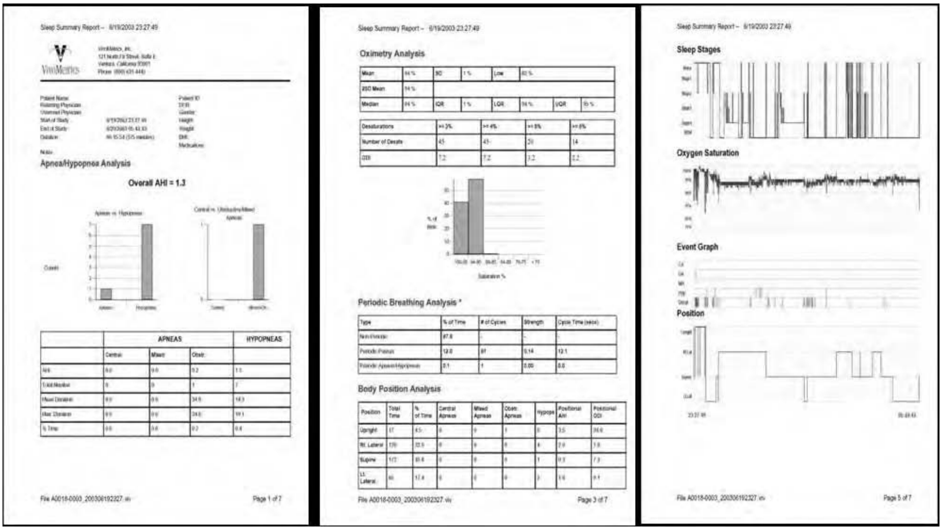

Figure 3. Example of a sleep report. Left panel, hypopnea/apnea analysis; middle panel, oximetry, periodic breathing and body position analyses; right panel, examples of specific parameters.

All data are encrypted and written to a flash memory card. Vivologic^{TM} analysis software provides full-disclosure analysis and display of high-resolution waveforms and over 35 derived parameters (see Figure 2). Physiological data may be flexibly exported to spreadsheet programs for statistical analysis based on minute-to-minute averages, breath-by-breath analysis, or the digitized raw waveform. Moreover, newly developed software is capable of automatically analyzing segments of data synchronized to patient diary entries (see pink tab in Figure 2); for example, physiological signal patterns immediately preceding a symptom entry can be simply analyzed to examine whether discrete physiological changes trigger symptoms. Vivologic software also produces summary reports for clinical diagnostic purposes. Figure 3 provides an example of a sleep diagnostic report automatically generated after visual editing.

The LifeShirt system has received all necessary regulatory approvals:

ISO 9001 certification – October 2001
European CE mark – November 2001
FDA market clearance – April 2002
Canadian market clearance – July 2002
Compliance with 21 CFR Pt 11 – August 2002
FDA audit – December 2002

2. Real World Applications

Until very recently, ambulatory monitoring for medical purposes has been largely limited to ECG and blood pressure registrations. Clinical and research cardiologists employ such recordings to evaluate cardiovascular abnormalities that may occur frequently during daily life but typically go undetected during clinical examinations. The information provided by such 24- or 48- hour recordings has greatly furthered the diagnosis, treatment and understanding of cardiovascular disorders, including coronary artery disease (CAD), congestive heart failure and hypertension. Analysis of ambulatory ECG data, along with derived heart-rate variability measures, have yielded insights into mechanisms of disease and treatment and have contributed to prediction of risk among both healthy and ill populations [3].

A joint statement by the American College of Cardiology and the American Heart Association acknowledges the necessity for ambulatory ECG monitoring: "Ambulatory electrocardiography is used in clinical practice to detect, document and characterize occurrences of abnormal cardiac electrical behavior of the heart during ordinary daily life. Because certain abnormalities may occur only during sleep or with mental, emotional or exercise-induced changes in cardiac oxygenation or function, an ECG may need to be recorded over long periods of time [4]." Both hypertension research and clinical practice have made clear that blood pressure measures taken by a physician are not closely correlated with average blood pressure levels outside the doctor's office. In fact, results from ambulatory blood pressure monitoring have served to challenge the very definition of hypertension by pointing to the importance for prognosis and treatment of blood pressure levels that occur outside the clinical practice [5–7].

3. Potential Applications of More Comprehensive Ambulatory Monitoring

3.1. Physical Activity and Energy Expenditure in Disease

Many disorders are typically described in terms of aberrant levels of daily activity. Examples include depression, chronic fatigue syndrome, fibromyalgia, chronic pain syndromes, attention deficit disorder, obesity, peripheral arterial occlusive disease and coronary artery disease. For instance, second only to depressed mood itself, tiredness, low energy, and listlessness are the most common symptoms associated with depression [8]. In fact, almost all illness, from the common cold to cancer, causes diverse symptoms of fatigue, loss of energy and immobility. Yet the measurement of activity in medicine has generally been based upon patients' subjective evaluations of their own state of physical mobility. On the other hand, it is well known that subjective ratings of activity are poorly related to actual direct measurements, e.g. [9]. Therefore, precise and quantitative evaluation of daily physical activity and energy expenditure are necessary to verify subjective reports and might help experts better to characterize conditions: Can distinctive patterns of activity and energy expenditure during waking hours be seen for particular disorders? Is the frequency, range or duration of physical mobility altered among patients in contrast to healthy individuals? Do self-reports of activity level correspond to actual level of activity? These and many other questions remain, in general, unaddressed, although evidence indicates that such information may be very useful [10–15].

Various studies have indicated particular patterns of inactivity to be positively associated with risk factors for coronary artery disease [16]. Other investigations have suggested that a variety of behavioral activities can act as triggers for episodes of myocardial ischemia in coronary patients [16–20]; still others, that level of physical activity predicts and is likely to causally contribute to the natural course of disease, e.g. [21]. Yet this research has almost completely relied upon incomplete and often inaccurate diary or other self-report information as proxies for direct assessment of activity, behaviors and emotion. Thus, despite the acknowledged significance of ambulatory electrocardiography, little progress has been made in developing tools to help directly identify specific situations and activities that trigger dangerous cardiac events.

3.2. Intervention Efficacy

In addition to a better understanding of disease states, monitoring of mobility and metabolic activity could improve evaluations of interventions aimed at those many syndromes in which impaired activity is a major complaint. Here, too, assessment of treatment effects has relied heavily upon self-reports and psychometric scales of quality of life and emotional functioning. Although such variables are important, quantifiable assessment of actual changes in physical mobility and energy expenditure during daily life yields concrete evidence to supplement subjective evaluations of behavioral change [14]. Not only can global changes in activity be depicted and classified, ambulatory monitoring of activity and energy expenditure permits a characterization of specific types of activities that may be affected by treatment. Knowledge of this kind is likely to lead to better evaluations of treatment effects and to improved understanding of disorders themselves. Where interventions include homework assignments of daily physical exercise-as in cardiac rehabilitation programs- ambulatory monitoring of ventilation and activity could be used to assess compliance and improvements in physical conditioning.

3.3. Pharmacological Trials

Another prime area of application for ambulatory activity monitoring pertains to clinical trials of pharmacological interventions. To date, the effects of drug interactions with physical and behavioral activities in everyday life have been greatly neglected, as have the effects of all but very gross side effects upon such activities. However, many investigations point to the situational dependency of certain drugs both for their efficacy and for their adverse side effects [6]. Drugs may be effective under certain conditions of daily life but may not work or may even exacerbate symptoms during others. For example, a particular medication may prevent episodes of ischemia during sedentary activities but not during moderate levels of increased physical workload. Another drug may manifest disturbing side effects during a limited but commonly occurring range of situations [22]. Continuous real-life registration of ventilation and activity would offer the possibility of examining the efficacy and side effects of drug interventions during specific kinds of naturally occurring activities and behavioral demands. This could provide much more refined analyses of drug effects and enable investigators and physicians precisely to determine when medications are effective and when they are not.

4. LifeShirt Applications to Date

The LifeShirt has been rigorously tested for more than 38,000 hours in 90 studies with 1,750 subjects. The units have also functioned reliably under a variety of extreme conditions, including U.S. Air Force pilot-testing at 7.5G, mountaineering at 4,500 m, Indianapolis 500 automobile racing, and long-haul trailer trucking driving. Not only is the system robust, but it is extremely comfortable, and user-friendly in terms of patient experience, instrumentation, data analysis and clinical interpretation.

The clinical applications of the Lifeshirt technology are equally wide-ranging. The LifeShirt makes possible ambulatory, inductive plethymographic measurement of numer-

Table 1. Therapeutic Areas of Medical Applications

	Number of Installations
CNS	*25*
Respiratory	*10*
Cardiac	*7*
Exercise Physiology	*7*
Neurology	*5*
Other	*7*

ous respiratory parameters. Respiration has long been recognized as a critical indicator of many disease states but has not been previously reliably measurable in settings outside the hospital. Additionally, diagnosis and management of the whole range of pulmonary diseases from asthma to chronic obstructive pulmonary disorders is certain to benefit from ambulatory assessment of ventilatory activity during everyday life, since all current assessment procedures rely on clinical respiratory maneuvers and not the spontaneous breathing behavior abnormalities that are the source of patient complaints.

Clinical applications of the LifeShirt are, however, not limited to respiratory disorders. Concurrent measurement of respiration, activity and other physiological signals are important for a host of medical syndromes and applications. Active research or clinical investigations using the LifeShirt are now taking place in the areas of sleep disorders, heart disease, anxiety disorders, diabetes, cancer, neurological conditions and functional somatic disorders, such as fibromyalgia, chronic fatigue syndrome and irritable bowel syndrome. Moreover, substantial evidence is available that measurement of heart-rate variability (HRV)–an important predictor of cardiovascular mortality and morbidity–would be greatly improved by taking into account respiratory and activity measures that confound HRV assessment [23,24], something not previously possible. Simultaneous physiological monitoring and patient diary assessment of complaints and reported activity can lead to new insights into the relation between objective physiology and experienced symptoms. For example, for the first time, we can examine whether chronic fatigue patients manifest objective indices of fatigue reflected by activity, respiratory and cardiac measures.

There are also a number of obvious clinical applications that relate to therapy and management of patients outside the hospital and clinic and may create more cost-effective means for treating patients. These include the use of the Lifeshirt for home screening of sleep related disorder, and monitoring of drug effects across the day, cardiopulmonary rehabilitation, early hospital discharge and pre- and post-operative monitoring. Additionally there are also other non-medical applications related to human-factors in ergonomics, as illustrated by some of the extreme conditions mentioned earlier under which the LifeShirt has been tested.

The LifeShirt is, in fact, being used in leading research and medical in the United States, Canada, and Europe. About 30 of the top-ranked U.S. Medical school and hospitals are currently employing the LifeShirt in clinical or research applications (see Table 1). Additionally various departments of numerous universities in Switzerland, Germany Canada, UK, Italy, France, Belgium, the U.K. and the U.S. have acquired the LifeShirt as a research tool.

5. Conclusions

The LifeShirt constitutes a novel, perhaps revolutionary, multi-function approach to the areas of diagnosis and management of medical disorders, and provides new avenues for examining other non-medical areas of human function, such as human factors research in the real world. This has been made possible by the development of a monitoring system capable of continuously and simultaneously monitoring multiple physiological systems and patient dairy entries relating to momentary symptoms, activities and environmental context. Of particular importance is the ease of all aspects of monitoring and data analysis: The unit is robust, comfortable to wear and simple to apply. Furthermore, the multi-function data analysis, data management and interpretation of results is straightforward and uncomplicated. A significant challenge remains for healthcare adoption of this technology: Reimbursement rules remain a significant constraint, and implementation of LifeShirt technology will require changes of attitude for patients, health care providers and payers, alike. Nevertheless, it seems apparent that such innovation is inevitable and will serve to greatly improve the medical management of health and disease, as well as to enhance our scientific understanding of human functioning beyond the clinic.

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Body Area Network – A Key Infrastructure Element for Patient-Centered Telemedicine

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Abstract. The Body Area Network (BAN) extends the range of existing wireless network technologies by an ultra-low range, ultra-low power network solution optimised for long-term or continuous healthcare applications. It enables wireless radio communication between several miniaturised, intelligent Body Sensor (or actor) Units (BSU) and a single Body Central Unit (BCU) worn at the human body. A separate wireless transmission link from the BCU to a network access point - using different technology - provides for online access to BAN components via usual network infrastructure. The BAN network protocol maintains dynamic ad-hoc network configuration scenarios and co-existence of multiple networks.

BAN is expected to become a basic infrastructure element for electronic health services: By integrating patient-attached sensors and mobile actor units, distributed information and data processing systems, the range of medical workflow can be extended to include applications like wireless multi-parameter patient monitoring and therapy support. Beyond clinical use and professional disease management environments, private personal health assistance scenarios (without financial reimbursement by health agencies / insurance companies) enable a wide range of applications and services in future pervasive computing and networking environments.

Keywords. wireless network, mobile multi-sensor, multi-parameter monitoring, personal health assistance, low power, low range, low radiation, Body Sensor Unit, Body Central Unit, ad-hoc network configuration

1. Introduction and Motivation

Permanent logging of vital signs is a proven method for supervising the status of patients suffering from chronic diseases, such as Diabetes and Asthma. Most prominent area of application for long-term logging of patient data is cardiology, where long-term-ECGs are required for therapy control and as early indicators for impending heart attacks. In general there is an increasing demand for continuous patient monitoring.

Medical monitoring procedures usually require more than one sensor to be attached to the human body: Stroke risk patients not only should observe their mere blood pressure values, but supervise additional parameters related to blood oxygen saturation, temperature and weight on a long-term basis. Patients with high blood pressure are facing an increased risk of serious cardiac diseases without any symptoms of pain - continuous mon-

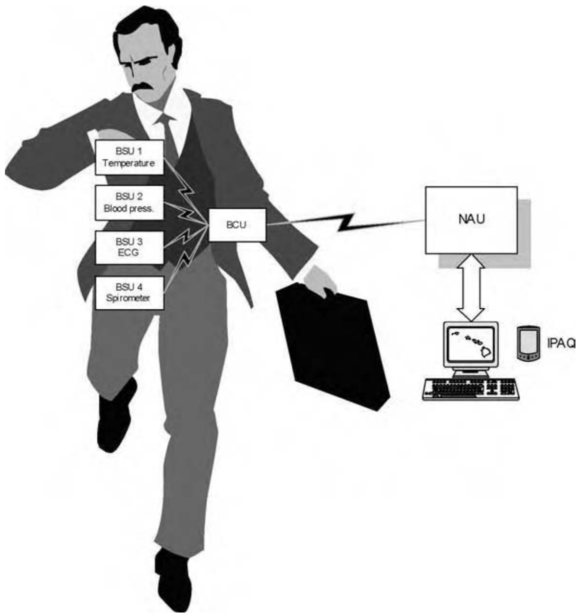

Figure 1. BAN components.

itoring of related parameters enables efficient early warning mechanisms and prevention measures.

Current monitoring technology requires "cabling" of patients wearing a set of wired sensor elements, linked to one or several devices for processing and visualisation of the sensor signals. For external connectivity, typical remotely used stand-alone systems provide just a serial port. Using wireless multi-parameter monitoring technology, a wide range of diseases could be prevented, treated and managed more effectively today – for the benefit of both patients and the health system. Existing wireless transmission schemes do not meet the requirements in terms of minimising radiation and transmission power consumption to just match the range of human body dimensions.

2. Technical Concept

2.1. Components

The Body Area Network (BAN) concept enables wireless communication between several miniaturised, intelligent Body Sensor (or actor) Units (BSU) and a single Body Central Unit (BCU) worn at the human body. A separate wireless transmission link from the BCU to a network access point - using different technology - provides for online access to BAN data via usual network infrastructure.

2.2. System Overview

The core functionality of BAN – in Figure 2 located within the frame entitled "BAN Com" – provides wireless interconnection between several BSU units and a single BCU

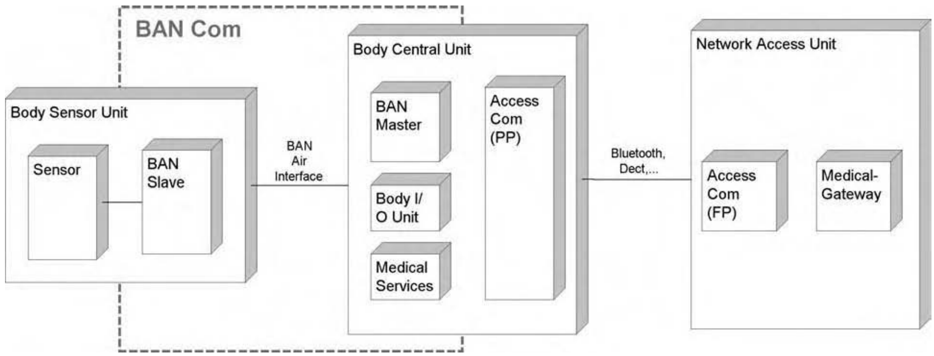

Figure 2. BAN system overview.

via an air interface reserved for medical use [1]. The BAN Slave represents a miniaturised embedded system with limited processing capabilities to adapt sensor components.

The air interface between BSU and BCU is characterised by the 2m maximum distance typical for human body dimensions. As a result of practical evaluation, the adequate transmission frequency – at least for Europe – was determined at 403 MHz, with a RF bandwidth of 3 MHz.

A BCU concentrates the data streams from multiple attached BSUs and performs the communication to the outside world by the Access Com module which is application-specific and generally represents standard wireless communication technology like DECT, WLAN or Bluetooth.

Not defined as a core functionality component, the Network Access Unit (NAU) may incorporate a medical gateway with an embedded web-server transmitting the medical data in a standard-based format via WAN communication network.

For optimal flexibility and inter-operability in distributed healthcare environments, BAN is prepared for the implementation of future ISO/IEEE CEN 11073 standards for point-of-care medical device communication (similar to European ENV 13734/13735 VITAL) providing trans-institutional, potentially worldwide interoperability between BAN networks and remote professional or clinical service providers.

2.3. "Physical Layer" Transmission Characteristics

A lot of different wireless data transmission systems for specific medical applications and components such as implants or hearing aid systems have been developed until today. All of them use point-to-point communication links, mostly unidirectional. Available solutions can be separated into electric field, magnetic field and radio frequency transmission systems [2,3].

For intra-body communication, particularly with implants, magnetic coupled systemS are frequently used. Their advantage is the capability of also transmitting power to the implant, which makes a battery unessential.

Radio frequency transmission is getting more and more popular, as semiconductor technology allows for sophisticated transceiver architectures and increased shrinking of the radio frequency components. A lot of various systems exist for different frequency ranges from 40 MHz up to 2.4 GHz; e.g. hearing aid systems operating at 174 MHz, latest pacemaker developments using 402 MHz for wireless data transmission.

Research results at the Fraunhofer-Institute for Integrated Circuits (Fraunhofer IIS) have shown that RF transmission is most adequate regarding medical Body Area Network applications, whereas magnetic field transmission is not capable to cover the whole body area using small coil antennas. RF systems fulfil requirements like small antenna size, appropriate data rates and good propagation near the human body without a need for contacting the body surface.

Actually the frequency range between 402 and 405 MHz was chosen for the Body Area Network, which is already used for implant communication, but it can also be adopted to other regulatory requirements worldwide [4,5]. The system uses a DQPSK modulation scheme which allows for a data rate of up to 180 kbit/s and requires a maximum bandwidth of 300 kHz. A time division multiple access (TDMA) structure is used to multiplex several BCUs and to ensure bi-directional transmission.

2.4. Medium Access Control Characteristics

As a new challenge for medical telemetry systems, the main focus in BAN communication system development was on multi-user capabilities enabling links to more than one medical subscriber (e.g. sensor or actor) while minimising power consumption per subscriber unit. A range of up to 2 meters is allowed to provide secure data transmission along and near the body. For medical applications the system has to deal with different kind of sensors, which require different data or sampling rates. On the one hand there are sensors like temperature or blood pressure sensors with only few data bits, which are sampled once every few minutes. On the other hand sensor with continuous data stream are used like ECG or pulse oxymeter, which need a data rate up to 115.2 kbit/s. In total the system is capable to handle up to 15 devices with a total data rate of 180 kbit/s.

BAN uses a timing scheme providing 16 time slots – 2ms each – which can be allocated individually depending on the required data size and sample rate of each sensor. The time slot assignment is adjusted after each frame period. Each sensor is allowed to receive or transmit during a specific time slot and is in sleep mode during the remaining time period. The master BCU controls the time scheme and forces the unused sensor units in a power saving sleep mode. Sleep times of up to 30 minutes can be realised. A sophisticated combination of guaranteed and best effort time slot assignment covers the needs of sensors both with constant and dynamic bandwidth requirements. A random frame is reserved for alarm functions.

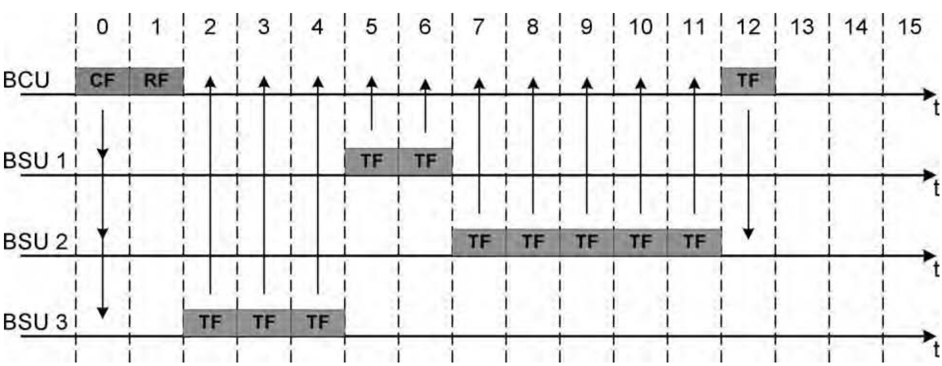

Figure 3. BAN TDMA multiframe timing scheme.

Figure 3 shows an example data transmission during a multiframe, while three BSUs are participating to a network. At the beginning of a multiframe the assignment of the following frames will be broadcasted to all BSUs.

2.5. Technology and Implementation Characteristics

Extensive miniaturisation is essential to meet the BAN system application requirements. Hence the basic functional blocks have to be integrated in CMOS silicon technology. As a first step a dual-chip module was developed comprising the RF front-end and the base-band processing units. As a further step a single chip solution is in preparation. The chips will be mounted on flexible substrates. Combination with a flexible battery or accumulator technology will ease adaptation to the shape of the human body and application by plaster-like packaging and fixing of the BAN modules. All circuitry has to meet low power requirements, for the BSU resource-optimised design is essential.

3. Potential Areas of Medical BAN Applications

Medical applications potentially relevant for BAN can be subdivided into professional and consumer-oriented ones. While professional use of BAN is considered for the whole range of clinical, doctor's practice, home and mobile environments, consumer applications are limited to home and public areas. For both domains a wide range of future applications is expected. In particular, BAN can be applied in the following range of scenarios:

3.1. Clinical Intensive Care

In intensive care units (ICU), typical monitoring of vital parameters like blood pressure, body temperature, or ECG currently requires extensive wired instrumentation. Patients – regardless of medical indications – are not only bound to bed, but fixed by numerous cables and wires, unable to turn or just even move in bed. Secondary diseases, such as thrombosis, may result. The risk of unintentional disruption caused by moving patients, the uncomfortable handling of cables and wires, but also their expensive replacement are aspects which can be eliminated by BAN application.

3.2. General Clinical Patient Care

Due to both economical and medical considerations, reducing the duration of stay at intensive care units is desirable. Practicability of monitoring in non-ICU ("intermediate") clinical wards could be enhanced using BAN as a platform for the acquisition of most vital signs data (temperature, pulse rate, ECG, SpO_2 oxygen saturation, weight, ...). For additional benefit, the BAN Body Central Unit (BCU) – to be implemented as a wrist watch or a small belt-worn box – can provide or support identification, authorisation and authentication procedures. In future pervasive clinical communication environments, nearly all services used and interactions performed by patients during hospital stays – admission and discharge, interactions with medical workflow, patient feedback and supervision, confirmation and acceptance of diagnostic or therapeutic measures, billing and quality control etc. – could be guided by a permanently worn personal BAN system.

3.3. Home Care

Patient monitoring in home environments is one of the most attractive areas of BAN application. Costs saving aspects are increasingly urging hospitals to minimise the duration of in-patient stays. BAN as an open, wearable mobile platform enables seamless connectivity in both environments; hospital and home: The BAN BCU is able to interconnect with home network access points via wireless indoor communication systems like WLAN, DECT or Bluetooth. Patient monitoring services can also benefit from the technical service infrastructure provided by future set-top boxes, which are under development as a platform for network-based home services. The Open Service Gateway Initiative (OSGI) has developed relevant concepts and specifications in this area, in particular defining the functionality, interfaces and resources required for such a multipurpose residential gateway which could be well utilised for accessing medical services.

Wireless BAN-based monitoring (e.g. blood pressure, ECG, respiration and SpO2 oxygen saturation) is most desirable for patients with chronic diseases such as cardiovascular diseases, asthma and diabetes. In addition, rehabilitation measures and post-operational care are within the scope of BAN.

3.4. Mobile Care

A BAN BCU with modules for accessing global wireless networks like GSM or UMTS can provide potentially world-wide mobility for BAN users. Thus the quality of life can be significantly improved in particular for patients suffering from chronic diseases which require permanent monitoring of vital signs. To limit communication costs, the real-time transmission of measurement data streams will be restricted to particular patient conditions whereas during normal operation the BCU performs processing, cumulating and compressing of information before delivery.

3.5. Personal Health Support

Terms like “wellness” and “fitness” mark the area of private personal health support, which currently tends to dramatically increase its social and economical significance. Personal health support utilises technical infrastructure, devices and systems which assist a person in preventing diseases, supporting diagnostic procedures and optimising therapeutic actions. Possible BAN applications include specific monitoring during sport activities, supervision of patients with less manifest symptoms (e.g. increased, but sub-critical blood pressure), monitoring of pharmaceutical product application, observation of biological cycles, support of training and rehabilitation programs, and the control of body weight. For all of these applications BAN technology opens new dimensions of comfort and quality.

3.6. Medical Process Evaluation

Additional factors are driving the development and application of pervasive communication and information technology: Health insurance companies and public health authorities increasingly tend to apply “Evidence Based Medicine” principles when evaluating existing or introducing novel medical methods and procedures. Processes and actions of healthcare professionals have to be based on the best available medical knowledge.

BAN instrumentation-based acquisition and processing of measured patient data in medical processes can potentially be evaluated by externally applied objective methods. Vice versa the delivery and processing of BAN-acquired data may substantially contribute to epidemiological research by delivering comprehensive and consistent information.

4. Conclusions

The BAN system provides a flexible, wearable infrastructure for acquisition, processing and wireless transmission of medical data and information at the human body. For the communication between several Body Sensor Units and a single Body Central Unit a specific RF-transmission scheme has been developed showing best results regarding the targeted parameters as minimal RF emission and power consumption, adequate data rate and coverage limitations to body dimensions.

Application-specific requirements are forcing circuit integration and driving module miniaturisation beyond existing technological barriers. Currently a dual-chip solution for BAN modules has been developed using standard CMOS technology. A single chip implementation is in preparation. For optimal adaptation to the human body flexible substrates integrating chip(s), antenna, battery and sensor are foreseen.

Using BAN, multiple vital signs can be wirelessly monitored even in mobile environments. With an additional wireless network access unit and standard-based communication protocols and data formats BAN provides seamless inter-operability with multiple medical service providers enabling a wide range of professional as well as personal health support applications.

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Contact Centers, Pervasive Computing and Telemedicine: A Quality Health Care Triangle

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Abstract. The Citizen Health System (CHS) is a European Commission (CEC) funded project in the field of IST for Health. Its main goal is to develop a generic contact center which in its pilot stage can be used in the monitoring, treatment and management of chronically ill patients at home in Greece, Spain, and Germany. Such contact centers, using any type of communication technology, and providing timely and preventive prompting to the patients are envisaged in the future to evolve into well-being contact centers providing services to all citizens. In this paper, we present the structure of such a generic contact center and present its major achievements, and their impact to the quality of health delivery.

Introduction

Health care is in a very dynamic stage. The model used over the past decades which led to the explosion of the hospitals and the costs is revised, and at the same time new opportunities coming from the development and application of Information and Communication Technologies in the health care field are coming in the picture offering attractive alternatives to the health delivery process.

Perhaps the most commonly used word today in health care is the word quality. Quality as viewed in different levels, namely health services, life, financial matters, health organization. Quality is also linked with prevention of medical errors, which as shown in the AHRQ report has reached alarming levels in the USA where quantitative data are available [1].

In order to increase quality in health care, and to reduce errors it was suggested by AHRQ that increasing quality in health delivery would require changes in four crucial forces, a) payments, b) clinical knowledge, c) professional workforce, d) information technology (IT) [2]. In the IT field we can identify a number of main streams but perhaps the most important ones are the field of communication, information processing and management and interfacing with the medical personnel which provides the health services. A very important development in the IT field is the evolution of contact centers which are very much used in home care delivery.

Home care delivery is a very important issue, starting from the management of chronic diseases such as diabetes, congestive heart failure, coronary heart disease, etc [3]. These chronic diseases demand a continuous monitoring of basic parameters of the patient's condition in a continuous fashion so as to avoid complications. IT based applications for home care delivery are important media to increase health care quality, increase quality of life, and create a better educational platform, which in turn is expected to be instrumental in creating a collaborative environment between the patient and the physician, which is beneficial to both [4].

Pivotal to these purposes are contact centers, which act as mediators between the medical staff and the citizens seeking advice and/or therapy. Main platforms used for the development of such applications are the INTERNET and PCs. Telecommunication networks, including mobile solutions and microdevices, are used for the recording of vital parameters [5].

In our work we have concentrated on two issues. The quality in communication between the patient and the medical personnel via the use of a contact center acting as a mediator, the quality in biosignals and bio-data when recorded via microdevices anywhere, and the interfacing capabilities between the citizen and the medical domain whether it is medical advice, health service provision or access to medical educational material.

The contact center presented here was developed in the context of an IST project (project IST-1999-13352) with title 'Distance Information Technologies for Home Care: The Citizen Health System (CHS)'. One of the most interesting aims was to design and run clinical trials in order to produce evidence-based medicine for supporting the use of the contact centers in the health delivery system. Pervasive computing solutions were employed, developed and tested through CHS, and telemedicine services were delivered to the participating patients and assessed. It is shown through the clinical trials for chronic disease patients that the contact center solution is a very attractive solution for health delivery at home, and at a regional level.

1. The CHS Project Objectives

The overall objective of this project is the use of Information Technology for the increased quality of health care at the European and Transatlantic level. From the business point of view, the creation of a new large market that would involve every single home and every single health care level is the ultimate objective. In particular, the objectives of the project can be divided into three major categories:

1.1. Information technology related objectives

- Development of new generation telemedicine services for home care.
- Development of user acceptable Man Machine Interfaces (MMIs) and graphical user interfaces (GUIs) for easy and error free data fusion, browsing and education.
- Development of new generation decision support systems based on Neural Networks, Digital Filtering and/or Fuzzy Logic for artefact rejection due to sensor and microdevice related errors, and due to the wrong use by the citizens.
- Integration techniques for developing a complete health system for home care addressing issues such as integration of telematics technologies, data acquisition devices, educational material through the WWW, data security and data fusion.

1.2. Quality of health care objectives

- Cost effectiveness of health care delivery via the use of the home health care system, which would permit the avoidance of unnecessary patient visits to the hospital.
- Citizen involvement in health care delivery by use of recording microdevices, and by the continuing education process delivered through the health system to be developed in this project.
- Better diagnosis opportunities for the clinical staff through the increased sampling frequency of vital parameters and signals from the patients through the home care system platform.
- Development of a transatlantic network for home care delivery and exchange of data and experiences for health care delivery harmonisation in diverse cultural environments.

1.3. Economic and business objectives

The creation of a major market for health care delivery, analogous to that of the INTERNET market, through penetration to European and US homes through applications of the home health care system.

- Deployment of the new technology of microdevices for routine daily use by patients and citizens at home, increasing sales and the IT sector economic basis.
- Integration of the Neural Network and Fuzzy Logic modules for artefact rejection in the home health care system, increasing job opportunities and industry income in this area.
- The industrial partners of CHS, consider a good metric of success the ability to obtain reimbursement for the products/services derived by the CHS project.

2. The CHS System Functionality

In the CHS System, the Contact Centre offers the means for gathering medical data submitted by the patients and makes available for them educational procedures. Mechanisms for patient administration and reviewing of patients' data are also among the functionalities offered by the Contact Centre (Figure 1).

The CHS system consists of several modules designed to serve the Contact Centre functionality. These modules, presented in the following sections, are used to transmit and authenticate information, filter received data, process and manage queries from both patients and doctors and provide decision support and intervention tools at the clinician's site for quality and timely health delivery.

One of the basic concepts of the CHS system design was the need for a parametric and customisable patient data model (and consequently a database architecture), which would facilitate personalised procedures and treatments. Different communication means, suitable to different patient lifestyles and adaptation to technology were available and different kinds of information were accordingly included. Thus, a middle-tier architecture, able to communicate with different interfaces, was implemented.

Besides the modules of the CHS system serving the basic functions of the contact centre, intelligence should be incorporated in the system, towards the aim of pervasive

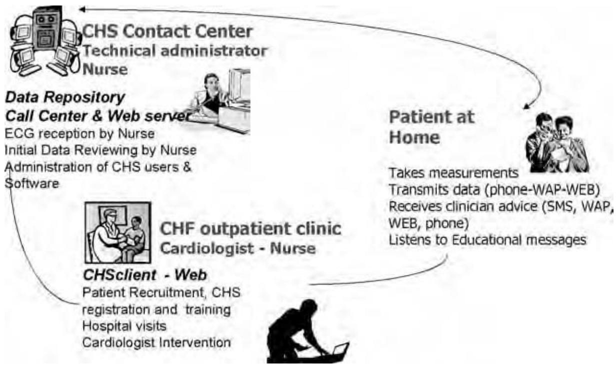

Figure 1. The functionality of the CHS Contact Centre.

healthcare. For this purpose, tools for knowledge extraction and management, as well as information filtering, were incorporated at the system's back-end for the efficient interpretation and handling of data. Other issues such as multilinguality and security were also addressed in the database and interface design.

3. Project results and achievements

The CHS project produced a number of deliverables encapsulating the scientific and business results and achievements. Based on the deliverables the project's results and achievements can be summarized as follows:

1. CHS developed a fully functional, modular and expandable contact center for use in the remote monitoring of patients at home, enhancing communication between the patient and the health provider, and applying pervasive telemedicine solutions.
2. CHS has been able to use three widely used communication means such as computer telephony, WAP application and INTERNET thus providing flexibility in choosing one's way to communicate with the health provider.
3. CHS is based on a multilingual medical knowledge base developed for diabetic, congestive heart failure and post trauma patients. This knowledge base was developed using a generic model for building such knowledge bases, and it contains categorized information in the form of short and long messages (capable of being used by telephones and any voice system), as well as multimedia information available at the INTERNET as well as at mobile telephony applications.
4. CHS encompasses modules on medical decision support (e.g. rule editor, and data mining algorithms), biomedical information archiving and processing modules, as well as modules enabling communication with external applications and other Hospital Information Systems via the use of CCOW/HL7 compatible interfaces and messaging concepts.
5. CHS has been able to develop services for supporting the implementation of clinical trials related with pervasive telemedicine solutions, for the production of evidence-based medicine.
6. CHS was able to completely characterize in terms of certification processes its modules and services, both at the EU and USA level.

7. CHS has produced a specific ISO based evaluation process for evaluating the health services, quality of life and quality of health of the players using the CHS contact center.
8. CHS implemented clinical trials to produce scientific evidence regarding the increased health provision quality, the quality of life and the economic benefits one has when using a system like CHS. The results in the three clinical trials with diabetic, congestive heart failure and post trauma patients confirmed that the home care model proposed by CHS both in the case of chronic disease patients and in the case of short term home care provision has a positive impact on the amelioration of the health status of the patients, on their quality of life and on the economic benefits one has when using a home care system like CHS.
9. CHS was implemented and tested in diverse EU countries (Greece, Germany, Spain) as well as in the USA, proving that it can be adjusted to the local environment both technically and medically.
10. CHS produced a whole new concept for business models in telemedicine and home care provision by studying a number of components (e.g. technical, clinical, legal, cultural, economic, and political) individually or together. That resulted in an IOS Press book that followed a very successful conference at Columbia, MO, USA that has some new directives in the issue of Information Technology Business Models for Quality Health Care.

4. Discussion

In this paper we have described the main objectives and results of a European project in the area of home care with acronym CHS (Citizen Health System). One of the main goals of this project was to develop a generic contact center that can deliver telehealth services to patients at home and in general wherever they are via pervasive monitoring solutions. The main idea behind this project is to propose a quality protocol for remote health services provision through a contact center that can be used as the major mediator between the patients and the medical doctors. The contact center has as main tasks to regulate the communication flow between the patients and the medical doctors, to assure the quality of the data transmitted, to ensure easy and secure access from the health services providers to the data, and to provide multimedia information material as well as medical knowledge when such a request exists. It is foreseen in the future that such contact centers shall be integral components of large scale health delivery platforms such as for example the digital platform which can use advanced communication ways such as the interactive TV for example. The latter is already applied in the PANACEIA-ITV project where the digital platform specifically is used for data communication, and the contact center is used in conjunction with a portal for the regulation and quality assurance of the information exchange between the home environment on the one side and the patients and health service providers on the other side [6]. Finally, such contact centers can be integral in filling the knowledge matrix, where a number of physiological states of a certain individual can be linked with specific measurements and characteristics of vital signs and signals which can be monitored at home via the use of sensors based on nanotechnologies. For example, a specific shape in the ECG waves recorded at home by a patient who fainted can be of great help in identifying the state of the patient in the future by looking at such associated patterns and measurements. In this way, we could be able to link physiologic measurements and other advanced data analysis techniques with specific and individualized states of a patient. This is a very interesting example of an integrated health provision environment based on the quality of measurements, the communication of the measurements via the contact center to the physician, the medical assessment and decision and the feedback from the physician to the patient via the contact center. In this way it is envisaged the quality in health delivery would be enhanced in the future.

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Research and Development of Smart Wearable Health Applications: The Challenge Ahead

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Abstract. Continuous monitoring of physiological and physical parameters is necessary for the assessment and management of personal health status. It can significantly contribute to the reduction of healthcare cost by avoiding unnecessary hospitalisations and ensuring that those who need urgent care get it sooner. In conjunction with cost-effective telemedicine platforms, ubiquitous health monitoring can significantly contribute to the enhancement of disease prevention and early diagnosis, disease management, treatment and home rehabilitation. Latest developments in the area of micro and nanotechnologies, information processing and wireless communication offer, today, the possibility for minimally (or non) invasive biomedical measurement but also wearable sensing, processing and data communication. Although the systems are being developed to satisfy specific user needs, a number of common critical issues have to be tackled to achieve reliable and acceptable smart health wearable applications e.g. biomedical sensors, user interface, clinical validation, data security and confidentiality, scenarios of use, decision support, user acceptance and business models. Major technological achievements have been realised the last few years. Cutting edge development combining functional clothing and integrated electronics open a new research area and possibilities for body sensing and communicating health parameters. This paper reviews the current status of research and development on smart wearable health systems and applications and discusses the outstanding issues and future challenges.

Introduction

Demographic changes in Europe reveal an ageing population that is increasingly demanding better quality and access to care, especially from, and at home [1]. At the same time, health managers are strangling to contain healthcare costs.

People become ”health conscious” and are more eager to take an active role in managing their own health [2]. The classical “hospital-centred healthcare” structure cannot respond to the increasing demand of patients and citizens for personalised, high quality and cost-effective services e.g. continuous risk management, home rehabilitation, prevention and lifestyle management.

[1] The views developed in this paper are that of the author and do not reflect necessarily the position of the European Commission.

Recent developments in ambulatory monitoring and personal telemedicine reveal the potential to enable personalised health management and significant reduction of the total cost of care by avoiding unnecessary hospitalisations and ensuring that those who need the urgent care get it sooner. These developments are driven by a continuous technological innovation on miniaturised and communicative healthcare systems and an increasing market demand for personalised health services. For example, the market of heart pacemakers, blood pressure sensors, hearing aids, cochlear implants and biochips was representing in 2001 a total revenue of $ 5,2 billion [3]. Other technological driving forces are advances in mobile telecommunications, human-computer interface and software technologies. Thanks to this progress it is possible, today, to integrate sensing, processing and communication functions into a user-friendly wearable system. Thanks also to the huge increase of medical knowledge it is possible to make the best use of these systems in order to support disease management and homecare, as well as early diagnosis and disease prevention through healthy lifestyle management tools.

During the last few years the research and development on smart wearable healthcare systems has been accelerated through consequent public and private financial support. The actors have being looking for design, integration and testing of the right H/W and S/W technologies e.g. biomedical sensors, medical decision algorithms, data transmission and security. The target of these projects is to provide user-friendly environments and scenarios of use that could lead to market exploitation in a short to mid term future (3-5 years). The clinical and socio-economic assessment of these systems is a great challenge (as it is the case for Telemedicine as a whole). The technologies involved have impact at several levels of the society and can be characterised as “diffuse technologies”, therefore the classical assessment methodology used for drugs and medical device products is not appropriated in this case.

Despite the fact that current research on “smart health wearables” focuses on systems and applications addressing specific user needs, a number of common issues need to be tackled, such as:

- Technical, e.g. development of biomedical sensors and their integration with materials (e.g. textile), signal processing and power consumption.
- Business, e.g. clinical validation, scenarios of use, interoperability, business models, reimbursement scheme (third payers).
- Legal and ethical, e.g. data confidentiality and new responsibilities for the health providers and citizens/patients
- Societal issues, e.g. user awareness and adoption, lifestyle and culture.

This paper proposes a summary review of common issues as well as lessons to be learned from R&D projects on smart wearable health systems and applications, especially those funded under the European Commission, IST programme [4]. It also discusses state-of-the-art and future R&D challenges in this area.

1. Smart Wearable Health Systems: User Requirements and Current State-of-the-Art

Commercial personal healthcare equipment offers today mainly instantaneous single-parameter measurement and transmission. During the last few years a great effort has been put on research and development of ”more autonomous” and user-friendly wearable systems allowing not only continuous physiological monitoring and treatment but also medical decision support. These systems can be adapted to homecare environment but also to care at the point-of-need. Several such systems and applications have been supported world-wide and in particular in Europe through the 5^{th} Research and Development Framework Programme of the European Commission (1998-2002). Such applications have being targeting, disease management, e.g.: glucose monitoring and drug delivery for diabetic patients, monitoring and alert for cardiovascular & pulmonary diseases and detection and monitoring of activity performances for neuromotory diseases; monitoring of health condition and sport performance of athletes; monitoring during pregnancy; and prevention and lifestyle management. However, although R&D is well advanced, the clinical validation of such wearable systems lags behind.

Currently there is no smart wearable system and service in the market integrating, multiple sensors, embedded decision support and continuous interaction with health providers. Only few prototypes or exploratory products fulfil some of these requirements e.g. "lifeshirt", a wearable shirt providing continuous ambulatory monitoring through collection and local storage of respiratory and cardiac parameters [5] and "Mamagoose", a pyjama for the detection of Sudden Infant Death Syndrome [6]. Two other wearable prototype systems that provide continuous monitoring of personal data through combination of advance textile engineering, integrated sensors and data processing are the SmartShirt™ [7] and the "medical assistance suit" (VTAMN Project) [8].

One of the most important development phases of a smart health wearable is "user requirements". The analysis of user requirements should address the needs of all the actors involved in the whole value-chain process e.g. medical specialists, general practitioners, nurses, hospital management staff, patients, citizens, members of scientific and professional societies, engineers/technicians, but also industrials, business managers and third payers.

Generally, a smart wearable personal system should be light weight and low power consumption, of reasonable price with a capacity of operation by totally unskilled persons, with embedded processing and alarming capability and able to keep an uninterrupted connection with a remote medical center 24 hours a day (even if not always necessary).

The issues that have to be addressed in order to satisfy the user needs and that should be implemented within the development and validation phase of a smart health wearable application are numerous. Some of the most important are presented below.

Usability: It deals with daily use issues e.g. operation of the system, wearability, cleaning, washing (in case of textile wearables) and power autonomy. *User interface* deals with issues such as graphical user interface (sensors connection control, menu, sounds and voice messages, status of the system, display of data, etc), speaker, keys, led and other device functions like vibration. Usability is a key issue for adoption of the application.

Embedded medical decision: special medical algorithms should be developed to integrate the medical data collected from different sensors, to analyse multiple changes in several parameters and suggest the best possible medical diagnosis leading to the timely and most appropriate medical intervention. No such algorithms are in clinical use today in homecare or ambulatory devices, although experiments are being conducted to discover interrelations between parameters, which can indicate a dangerous situation in the patients' health. Medical decision algorithms are a great challenge for the acceptance and full implementation of smart wearable systems and services.

Telemedicine/eHealth service: the data transmitted to the health or service provider have to be of good quality, interpretable and compatible with the electronic patient record. They can be also used for research purposes. The on-line center has to develop secure telemonitoring facilities that enable health providers to communicate over telecommunication networks with the wearer. Also, the time-to intervention in emergency situations as well as the overall quality of services is critical to the viability of the application.

Storage: a backup data solution is usually necessary. The length of recording and the type of data to record depend on the medical protocol and should be decided by the medical team. Energy storage could also be considered for better use and autonomy.

Telecommunication and networking: a wearable health system is part of one or several networks. Short and long range wireless and mobile communications are involved, e.g. Bluetooth, GPRS and UMTS. These links have to be interoperable, secure, reliable, immune to interference and safe for the wearer.

Validation plan: The full clinical validation of smart wearable applications in healthcare is complex, time and resource consuming. Therefore it is usually performed (or completed) separately from an R&D project. One of the most important validation aspects deals with the possible clinical scenarios that have to be tested in respect with normal and abnormal medical values, e.g. diagnostic tests (where a disease is suspected) and screening tests (where there is little of no evidence that the person has the disease). The outcome of the clinical validation has a great impact on the user acceptance, on the health professionals' community and other stakeholders.

Standardisation and interoperability: wearable devices are being developed in a way that precludes communication between them and with hospitals and other health related information systems. The need for technical standardisation and the development or use of protocols enabling communication in a structured and open way, with subsequent clinical, administrative and research benefits, is absolutely required.

Legal and ethical issues: deals with personal medical data protection and user confidentiality measures.

Risk analysis: It tackles security problems for each specific application and assists the selection of countermeasures that ensure a level of security, analogous to the level of risks, in a cost-effective manner. Risk analysis deals also with the interaction between the wearable and the wearer i.e. the safety.

Biomedical sensors: The new generation of biomedical sensors presents a large spectrum bandwidth allowing new measurements on human and new approaches for diagnosis, ambulatory healthcare, care at home and at the point of need, anytime. Non-invasive sensors are the most challenging and advantaged to monitor physiological functions but also daily activities and individual behaviour [9], offering painless measurement, comfort and prevention from infections and contamination. The wearable non-invasive sensors can be applied in contact with or near to the body and measure a large number of body parameters such as vital signs (ECG, pulse, blood oxygen saturation, respiration, skin temperature, blood pressure, CO2), body kinematics but also sensorial, emotional and cognitive reactivity (e.g. EMG, posture, fall, movement, speed, acceleration and pressure) [10,11]. The wearable devices benefit today from the significant progress in system integration and miniaturisation and can be applied in different body locations, e.g. wrist and abdomen. However, such wearables cover only a specific (and generally small) body measurement area, not being able to fulfil in one wearable unit all needs for sensing, actuating, displaying, interacting with the user and health provider. A possible solution to overcome this limitation could be the integration of the different sensors into a unified, user-friendly wearable platform that has large contact surface with the body, i.e. the clothe.

2. Future R&D Challenges

The future development of Intelligent Biomedical Clothing (IBC) [12], based on full integration of sensors/actuators, energy sources, processing and communication within the clothes, could overcome existing barriers in the use of wearable health systems and be a key enabler platform for cost-effective personalised healthcare and lifestyle management. IBC research and development is based on multidisciplinary fields of knowledge and technologies and requires a strong co-operation between engineers, scientists and designers ranging from wireless communication, to microsystems and nanotechnologies, textile materials, biomedical engineering, public health, medicine and economics.

The approach of ongoing R&D is to integrate monitoring, diagnosis, treatment and communication functions into fabrics. The combination of the biomedical functionality, the added healthcare value and fashion aspect, is regarded as the key success factor to make long term monitoring a lifestyle product. There are a number of possible IBC applications spanning from a citizens' health watch, to patients' disease and overall lifestyle management. For example, IBC has the potential to increase the quality of life of chronically ill patients by providing, continuously, the highest quality of care possible, shortening or avoiding hospital stays and optimisation of the medication therapy, as well as reinforcing the psychological status (peace of mind). It can also significantly contribute to the reduction of health risk factors by supporting healthy lifestyle and predicting acute events as well as reducing time to intervention. It can also ensure intelligent monitoring of the users during, for instance, everyday tasks and physical exercise.

The integration part of the technologies into a real IBC product is at present stage at the point of developing pilot projects. Several issues, technical as well as medical, remain to be solved before clinical trials are performed. Among the most important challenges are the production of higher conductivity textile material according to current industrial processes, as well as the interfacing and protection of electronic components. Along with these challenges, the cleaning and washing issues have to be solved. Further research is required also in signal processing, data interpretation, user acceptance, cost effectiveness, product adaptation, market segmentation and business models.

The European Union supports strongly this area through current R&D activities, e.g. WEALTHY project, developing a wearable interface, by integrating smart sensors, in fibre and yarn form, advanced signal processing techniques and modern telecommunication systems on a textile platform, (http://www.wealthy-ist.com/). Another major R&D work is expected to be performed through the project MyHeart which is focussing on prevention of cardiovascular disease and life style management through biomedical clothing applications.

The new means for personal health management have the potential to significantly reshape the provision of healthcare services and health support, assigning new responsibilities for the medical device manufacturer, the health practitioner as well as the patient and citizen. Given the decentralised instrumentation (medical centres, home, anywhere) and the increasing mobility of patients and doctors, the responsibilities of each involved actor but also the information and services provision paths have to be redefined. In addition, total quality management associated with traceability have to be applied at all levels.

Finally, the clinical validation of personal telemedicine and wearable health management systems as well as cost-effectiveness have to be further assessed in order to provide critical mass of data that would convince decision makers, third payers, health providers and citizens.

3. Conclusion

Smart wearables have the potential to offer a minimally-obtrusive telemedicine platform for individualised health services that are easily and timely accessible, of better quality for the patient and citizen than the today solutions, and hopefully cost-effective. The current technological development is of high level but the available prototypes still have some limitations. The R&D approach where sensing, processing and communication are integrated in a woven structure to monitor physiological signals and biomechanical variables is very promising and could provide more user-friendly and functional solutions. However, the integration of biomedical sensors into a textile towards a reliable and meaningful health management system is a great technical and medical challenge.

In addition, other than technological issues still remain open. Especially, the assessment and proof of added value in respect with cost, access and quality of health services remains a challenge due to the difficulty to assess telemedicine applications.

Finally, smart health wearables designed for daily use, obviously involve a number of ethical issues e.g. misuse of data collected.

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Wearable eHealth Systems for Personalised Health Management
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On-Body Diagnosis for Wearable Systems Serving Biomedical Needs

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Abstract. Early diagnosis as well as a healthy and preventive lifestyle can help slowing the onset of many health problems and save millions of lives per year. To achieve this objective, long-term monitoring of human vital signs are required to obtain knowledge on a person's health status. Continuous monitoring of vital signs is mandatory, but continuous transmission is expensive, in terms of financial costs as well as power consumption for battery operated portable systems. Clothing is like a second skin to us: intelligent biomedical clothes may make everyday life easier for people in poor health, helping them to lead productive lives, senior citizens and also for athletes. Clothing means fashion and fun: smart clothes will combine health problem prevention, entertainment, comfort, convenience and communication with fashion. This paper presents essential issues in wearable electronics, including interface with the garment, signal sensing and enhancement, signal processing of signal combination, on-body diagnosis and on-body and distant communication. The paper reports on experience acquired through related projects running at the Swiss Center for Electronics and Microtechnology.

Keywords. Intelligent wearable clothing, intelligent biomedical clothes, wearable computing, wearable electronics, on-body diagnosis, smart clothes, e-textile

Introduction

Portable sensing of human physiological signals is becoming an essential part of modern or emerging monitoring systems. Initiated with portable devices and expanded by the trend to wearable intelligent biomedical clothes, long term monitoring, from days to months, is becoming practical. These new wearable systems raise several societal, clinical, psychological and technical questions, which should be carefully addressed to ensure their usefulness, reliability and security. Social implications and psychological impact will not be discussed, but should be kept in mind. This paper focuses on the technological aspects of such wearable sensing systems, from the low-level physiological signal sensors to the high- level interpretation of the extracted information and possible biofeedback.

1. Overview of Portable Monitoring Systems

Early portable biomedical monitoring systems can be considered as tele-alarm systems with additional telemonitoring features. In addition to alarms manually triggered by the users when they fell unwell, these systems are able to automatically send an alarm when something occurred (e.g. pulse rate becoming too high, detection of a fall, etc.). Tele-alarm systems have been first extended for telemonitoring for indoor use. The availability of mobile communication has then made possible to design systems for outdoor use.

1.1. Monitoring Systems for Indoor Use

The following figure shows a system for indoor use. This type of systems may benefit from a local wireless point-to-point communication to transmit the signals and data from the subject to a home base unit. The fixed home unit relays the information to a monitoring center over standard PSTN (Public Switched Telephone Network also called POTS standing for Plain Old Telephone Service) or ISDN (Integrated Services Digital Network) telephone lines.

Radiofrequency systems are currently the widely used wireless technology for medical monitoring (other wireless technologies include diffused infrared, ultrasound and induction; they have significant limitations for this type of applications). Local wireless communications for non-implanted devices make preferably use of ISM bands (Industry Scientific and Medical), but the recommendations and regulations still differ from country to country [1], in Europe [2,3] and North America [4]. In Europe, preferred ISM bands include the frequencies 433MHz, 868MHz and 2.4GHz with their respective operating modalities and country recommendations (refer to ERC Recommendation 70-03 relating to the use of Short Range Devices). In North America, preferred ISM band frequencies for telemonitoring include 608-614MHz (Wireless Medical Telemetry System – WMTS for the latter) and 2.4 GHz, beside other frequency bands used as secondary user. The 2.4 GHz band is therefore available both in Europe and North America, although FCC recommends use of WMTS in United States. Two common communication standards operate in this band: Bluetooth used for short communication distances and lower data-rate networks (10m for Class 2 and 100m for Class 2, up to 720kbit/s of user data shared by up to seven nodes) and 802.11b for higher ranges and data rates (30m and up to 11Mbit/s).

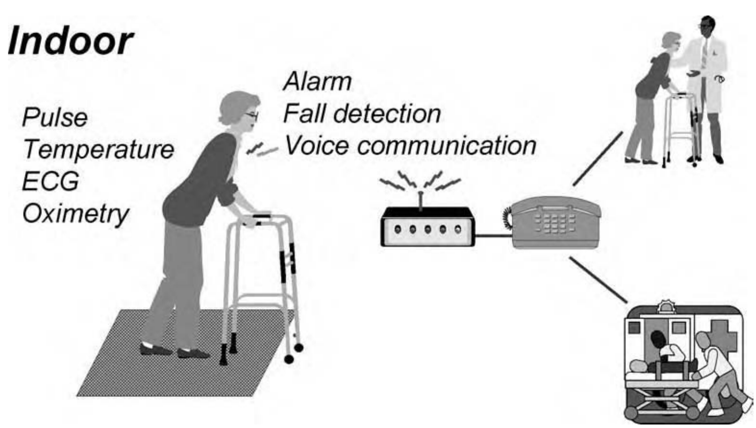

Figure 1. Telemonitoring system for indoor usage.

1.2. Monitoring Systems with Outdoor Communication

A modem for fixed telephone lines allows forwarding the alarms and signals to a monitoring center responsible for the appropriate action: generally to callback the user and to send help.

The above scheme has been further extended to provide full mobility to the patient allowing him to be monitored outside the home. Alarm generation and intervention capabilities were maintained compared to indoor use by adding location feature relying on Global Positioning System (GPS) combined with mobile communication. Research was also performed to raise user comfort and to provide natural human interface using for instance speech recognition. Data communication with a monitoring center is performed over mobile network (GSM and GPRS). Mobile GPRS (General Packer Radio Service) communication is also used as gateway to the Internet.

1.3. Local Area Network

Beside the distant communication over GSM and GPRS mentioned above, Figure 2 shows that the requirements on the body communication increases with the number and diversity of the sensing nodes, i.e. the physiological signals (ECG, SpO_2, skin temperature, etc.) and physical ones (acceleration, position, etc.) are measured at different locations and the signals have to be combined to extract the best possible health information. In order to avoid cables and wires between the sensing units along the body, wireless communication is preferred when no wired textile is used. The communication is then performed digitally either over point-to-point links or using a local area network, with a preference for the latter due to intrinsic advantages. Among others:

- Scalability to the number of communication nodes and to different data rates. The number of sensor sites can be more easily adapted and the acquisition of physiological signals with different data rates can be more easily accommodated.
- Combined transport of physiological signals and communication management data. Transmission of signals and communication data is made more transparent, remote access to system diagnosis and calibration features is unified.

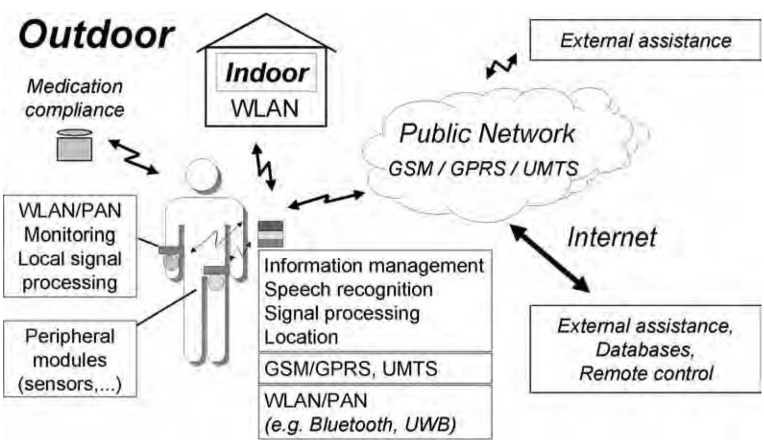

Figure 2. Mobile medical telemonitoring platform for homecare.

- Transmission of sensor values to other nodes, which allows combining the signals for data processing and avoids the duplication of sensors. The duplication of sensors is most of the time not practical.

There are nevertheless some drawbacks. The major ones are a reduction of the maximum data rate due to the sharing of the communication medium and the risk incurred by the network as a single point failure. Network communication allows a layer-oriented design. However, several layers are usually combined in portable applications to reduce the code size and increase efficiency with the limited available resources.

Furthermore, a Wireless Personal Area Network (WPAN) as shown in Figure 2 allows the communication between the sensor nodes as well as between the subject and a fixed indoor unit.

The price to pay is additional batteries and communication modules in each sensing and processing units, which increase the size and the cost of the system components. These drawbacks are probably the first reasons that prevented these systems from spreading on the market.

1.4. Signal Processing

The portable system includes local pre-processing close to the physiological signal acquisition locations and global processing which combines the available types of signals to ultimately provide information to the user and professional caregiver at system level. Signal processing is further described below (section 3 and following).

2. Wearable Monitoring Systems and Intelligent Biomedical Clothes

2.1. Technical Motivations

Discrete units interfacing groups of sensors (e.g. ECG and respiration belts) are not practical for continuous use due to size, weight, batteries, difficulty in placing the sensors by the user, as well as user discomfort. It is therefore elegant to embed the sensors and processing directly in the clothes, making use of the presence of tissue over large areas of the body to avoid the discomfort of precursor portable systems. The clothes, sensors, electronics and processing must satisfy specific requirements generally applying to clothes (size, shape, flexibility, washability, etc.) as well as being tailored for the specific health monitoring needs and applications of the users (disease, professional, sports), and last but not least, satisfy fashion requirements. This is becoming possible thanks to the combination of advances in sensor technology, in microelectronics and data processing as well as the availability of telecommunication for wearable applications and progress in the use of “intelligent materials” and in material science. Indeed, smart materials in fiber form showing enhanced material properties are being developed to make wearable non-obtrusive systems leading to “smart clothes” or “intelligent biomedical clothes” addressing biomedical needs.

2.2. Biomedical Motivations and Benefits

Target users of the intelligent biomedical clothes include patients during rehabilitation and early release from hospitals, professional personnel at risk and people during sport activities (professional or leisure). Intelligent biomedical clothes can for instance:

- Provide an integrated view of normal and abnormal patterns of activity, which would be otherwise difficult to detect and in situations that are usually uncontrollable by physicians.
- Improve the quality of care for patients by monitoring health status during rehabilitation activities, allowing them to perform their everyday activities.
- Monitor professional workers operating in extreme environmental conditions.
- Support citizen and athletes by providing monitoring and processing of physiological parameters while they are performing sport activities.

2.3. Smart Garments

Smart garments or e-textiles have built-in sensors and interconnections. Non-tissue sensors, such as accelerometers, are added to provide additional parameters not available from tissue sensors. Processing allows reducing the noise and e.g. artifact due to movements, to combine the parameters on the clothes and to extract the relevant data and signal for further analysis and transmission to a monitoring center. Combination of conducting small wires with the yarn allows both data communication and power supply of the sensors. Signal classification is eased by the combination of several types of signals. For comfort reasons, the garments should make as much as possible use of sensors directly woven, knitted or braided into the fabric. Electronic interconnections and packaging require very special care, since the garment has to be soft and washable: interconnections have to be very small and robust and packaging should provide temperature, shock and water resistance while remaining small and not incommodious for the user. Figure 3 shows a prototype built in the framework of the European project WEALTHY [5].

Figure 3. Prototype of smart clothes with electrodes for movement measurement at shoulders and respiration bands (courtesy of European IST WEALTHY project) [5].

2.4. Interface between Textile and Electronics

The interface between textile and electronic circuits is very difficult: textiles are flexible, they present elastic properties, are lightweight, support wearing stresses and aren't subject to breaks; the dimensions of integrated circuits and textiles differ by several decades. Two approaches for the interconnections are described in [6]:

- Conductive yarns of the fabric are prepared for contact with the integrated circuit by soldering tiny metal contacts where the circuit will be wire-bonded.
- Thin flexible circuit board with electrodes is glued to the textile.

The module and the wires are then molded for mechanical protection. The interconnections remain therefore a challenge. The Georgia Tech Wearable Motherboard (GTWM) has represented a significant step in the connection of sensors and the communication modules [7,8]. The routing of data communication and power supply was for instance further addressed in [9]. The electrical impedance of the yarns is much higher than standard wires making more difficult the acquisition of sensor signals and the transfer of data with limited susceptibility to the electromagnetic environment. To our point of view, the problem of interconnection has not been satisfactorily solved yet.

On the side of power generation: thermoelectrically generated power from the body heat has been shown feasible for low-power applications [10,11], when contact with the skin is possible over large areas like on the trunk.

In the last years, several major sport and leisure electronics-companies have developed alliances with clothes industries to combine electronic functions and fashion into the clothes [11–14].

2.5. Fault Tolerance

Without preventive measures, the sensor nodes, their interfaces with the textile and the communication and power lines are single point failures. Furthermore, even if globally resistant to mechanical stresses, textiles are very prone to cracks and tears. Smart garment should therefore be tolerant to faults and be able to use the remaining resources in the best way possible in case of textile micro-tears. Many schemes have been described in the literature to manage and take advantage of the redundancy; the e-textiles require and to cope with faults [6,15]. At the firmware level, fault-tolerance and adaptability lead to system reconfiguration (e.g. remapping, code migration), which coupled with redundancy is opposed to the limited hardware and software availability.

2.6. Features of Intelligent Biomedical Clothes

Electronic textiles present the following main features:

- Capable to provide increased user comfort compared to standard collection of discrete portable monitoring devices.
- Ability to collect and combine physiological and physical signals from several nodes spread on the garment.
- Limited resources in terms of processing power and data storage are available on each node. Energy storage is centralized and is distributed to the nodes.

Application layer	**User application**	**Professional application**
Processing layer	**Observable outcomes**	
	Global feature extraction	
Sensor layer	**Local signal processing**	
	Sensor conditioning and signal filtering	
	Garment and sensors	
Body layer	**User body**	

Figure 4. Layer representation of the wearable system (possible direct feedback to the body has not been represented).

- Subject to important node failures due to mechanical stresses and textile tears. The risk increases for larger garment areas and may affect the sensor interface and electronics (local processing), the global processing, the communication lines between nodes as well as the power lines.

There is therefore a need to provide fault-tolerance, to be flexible with respect to resource usage and to be scalable to user needs. Furthermore, like standard clothes, they have to remain low-cost systems and fashionable for large-scale adoption by the citizens.

3. Layer Representation

A layer representation of the wearable system illustrates and facilitates the description of the system (see Figure 4).

The lowest layer corresponds to the body, where the skin interface makes the separation with the (usually non-invasive) sensor layer. The sensor layer is comprised of three sub-layers: garment and sensors, conditioning and filtering of the signals and local processing. The processing layer combines the different sensor signals, extracts global features and classifies the signals to provide high-level outcomes for the application layer. The application layer provides the feedback to the user and to the professional, according to the specific applications according to the user needs. This layer can be extended to close the loop with the human body, e.g. for drug supply according to monitoring.

3.1. Sensor Layer

The garment and sensors sub-layer is occupied by new fiber materials and soft electronics technologies, which allow convenient long-term monitoring. As discussed above, interconnections with the textile and electronic packaging are key issues to make the electronics soft and wearable. Textile sensors, integrated into garments, are very well suited for long-term monitoring solutions, but often provide lower quality signals implying an increase in the complexity of the analog and digital processing of the signals. Typical textile sensors include: ECG, breathing and galvanic skin response. Small non-textile sensors (like temperature sensors, optical sensors for oximetry, accelerometers) are used to complement the signals obtained by textile sensors to perform upper layer processing and reliable classification. Actuators may be used when closed-loop is implemented (e.g. closing the loop on a liquid pump for medication dispensing). The integration of non-textile sensors and electronics into garment requires a high degree of miniaturization, advanced packaging technologies, and last but not least, reliable connections and wiring between sensors and electronics. This is a very sensitive and difficult part of the design, since the clothes should have minimum loss (ideally none) of flexibility and comfort compared to standard tissues.

Since it is neither possible nor desirable to ask the user to remain quiet during the measurements, signal processing has to be used to remove not only signal noise but also signal artifacts due to movements, sensor slipping or not well in contact with the skin (not stable interface in the time) during the acquisition. Information about the activity and movements of the persons can of course be very efficiently used to really enhance the signals.

Low-level signal processing in this layer includes: noise cancellation and artifact reduction algorithms at the price of additional electronics close to the sensors and power lines to supply the local processors. This first level of processing can be essential to enhance the signal-to-noise ratio using simple algorithms in term of processing power due to the limited computation resources (number of possible operations per second and memory size) that can be embedded in the garment [15,16].

3.2. *Communication between Nodes*

Electrified clothes avoid the problems of wireless personal area network previously discussed. Wires embedded in the garment allow communicating between the nodes and to gather the information to be processed at application level before the resulting top-level information is being fed-back to the user or eventually transmitted to a professional caregiver.

Communication among processing nodes is further minimized by partitioning the signal processing into small blocks computed locally: only meaningful signals (considered so at the node level) are transmitted between nodes and to a portable base unit or smart clothes controller, where the application processing and distant communication are performed. Special attention has to be brought to signal and power supply wiring. Using a data bus can be a solution to reduce the number of wires between sensors with local digital processor [9,17]. Typically, a three-wire bus can be used: one wire for the data transmitted serially, one wire for the power supply and one common wire. A further reduction of the number of wires is to transmit data over power lines (2 wires). The drawback of the later solution is to require additional transceivers to modulate and demodulate data on power supply voltage, where electronics has to be very small and thin. A further advantage of bus communication shared by several nodes compared to dedicated wires for each sensors is to make each sensor signal available to other sensor nodes, which improves the local signal processing outcome.

3.3. *Processing and Application Layers*

The sensor layer is connected to the processing layer, where feature extraction and global outcome algorithms are performed. Examples of data classification are [18–21]: classification of movement patterns such as sitting, walking or resting by using accelerometer data or ECG parameters such as ST distance extracted from raw ECG data [22,23]; another example is the estimation of the energy consumption of the body.

Current portable telemonitoring systems only provide this information to a distant monitoring center or to the user, as described above. The approach sought with wearable computing is to make direct use of the information by the worn system, which derives the therapy recommendations and determines the action to be taken. Therefore, in new systems, the global outcomes may be passed to the application layer, where the personal profile algorithm determines the current health condition and compares it to the personal reference profile, which also contains personal standard values for the collected parameters. The "on-body diagnosis" results from the combination of the acquired physiological signals, environmental information such as accelerations, air temperature and atmospheric pressure, previous health measurements and outcomes, knowledge about health record of the subject and, instructions provided by the physician doctors and caregivers about the actions to be taken. Based on these outcomes, the system may eventually be able to close the loop for instance to automatically supply medication to specific part of the body.

The application layer comprises the professional and user applications, respectively responsible to address the caregiver and the user needs. Their actions include physiological and derived health data transmission to professional caregivers, information and biofeedback to the patient, when needed. The distant communication is naturally performed over mobile communication, i.e. GPRS is currently the most appropriate technology, although not available as widely than GSM. The memory of the mobile module can furthermore be used as mass storage for the acquired signal and processed data, since memorization is power consuming and can be advantageously combined with the battery recharging of the mobile phone.

Of course, additional remote processing, comparisons and data storage can be achieved by the monitoring centers. Therapy recommendations can be presented to the user using a personal feedback device in a mobile or home setting.

4. Conclusion

Wearable sensing and electronics is a new, very promising ambulatory mean of monitoring physiological signals. On-body diagnosis is a tool to help the user take action and the professional to evaluate and make decision about the treatment. To address the general needs of telemonitoring, mobile communication allows physicians and caregivers to remotely monitor vital signs, other physiological parameters, extracted parameters and observable outcomes, not only when something wrong is detected by the wearable system, but also on-demand. On-body diagnosis, based on signals acquired by biomedical clothes, shows great potential. Many improvements are still to come, in particular for ergonomy, local and global processing, decision (expert) system, power management, interconnection, fault-tolerance, etc. User functionality performances and clinical relevance of the extracted information will impinge on the final market potentials, rather than the individual sensor technical performances. Without doubt, within 5 to 10 years, some of these systems will become available on the market, and CSEM is aiming at playing an important role in the development.

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Communication and Interoperability for Serial Comparison in Continuous Health Care – The New Challenges

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Abstract. The evolution of information technology and of telematics and increasing efforts to establish an electronic health record stimulate the development and introduction of new concepts in health care. However, compared to other application areas, e.g., tourism, banking, commerce etc. the use of information technology in health care is still of limited success. In Hospitals as well in ambulatory medicine (General Practitioner systems) computers are often only used for administrative purposes. Fully operational Hospital Information Systems (HIS) are rare and often island solutions. The situation is somewhat better for department systems (DIS), e.g., where image analysis, processing of biochemical data or of biosignals is in the clinical focus.

Even before we have solved the various problems in health care data processing and management within the "conventional" care institutions new challenges are coming up with concepts of telemedicine for assisted and non-assisted home care for patients with chronic diseases or people at high risk.

The major challenges for provision of tele-monitoring and alarming services are improvement of communication and interoperability of devices and care providers. A major obstacle in achieving such goals are lack of standards for devices as well for procedures and a lack of databases with information on "normal" variability of many medical parameters to be monitored by serial comparison in continuous medical care. Some of these aspects will be discussed in more detail.

Keywords. Interoperability, Medical devices Communication, Serial comparison of Biosignals

Introduction

During the past 2-3 decades development work on computerised Medical Devices was focused on improving their functionality (device functionality and handling, signal analysis, pattern recognition and classification). Communication of, for instance, biosignals between the acquisition unit and an associated Data Base Management System (DBMS) has been a long time subject to proprietary solutions. At present the dominant user requirement is information communication and integration. Interconnectivity and interoperability of devices are now key features to be provided.

Additionally, the community of care providers (physicians, medical technicians) as well as of researchers and certification institutions (like FDA and others) want to have freely available tools for easy visualisation and quality control of processed information.

We shall discuss in the following the aspects of communication, interoperability and of the variability in serial recordings (with the ECG as example) for continuous care.

1. Communication of biosignals

1.1. A conceptual reference model for biosignals acquisition and communication

Development of micro-sensors and micro-processors particularly for home care systems progresses continuously. Acquisition of multiple biosignals, e.g., blood pressure (BP), ECGs, respiration, urine flow and other biosignals, may be performed by means of patient worn devices. Collection and communication of data takes place via Body Area Networks (BAN). One example is the German project IMEX ("Implantierbare und extrakorporale modulare Mikrosystemplattform") [1].

Establishing a BAN and it's communication with external device systems and healthcare institutions resulted in a very detailed analysis of all possible interfaces and their communication requirements (see Figure1).

Discussion of this model will help to identify where today standards for Biosignals acquisition and communication are available, or to be extended or added. The figure depicts a scenario with three sensors and one actor. The sensors could be pulse oximetry, for temperature, for ECGs, fluid detection, diabetes management etc. An actor could be, for instance, a stimulator for supporting patients with incontinence. As can be seen from the figure the whole communication path from the sensor to a monitor device, to a hospital information system or another care provider via the "Telematic" system has been included into the system configuration. We shall now briefly discuss the interfaces **Sx** at the different locations within the system

S0 refers to the standard between origin of the signal, electrode and sensor input. This interface is typically defined by medical conventions which might be considered as "Standard".

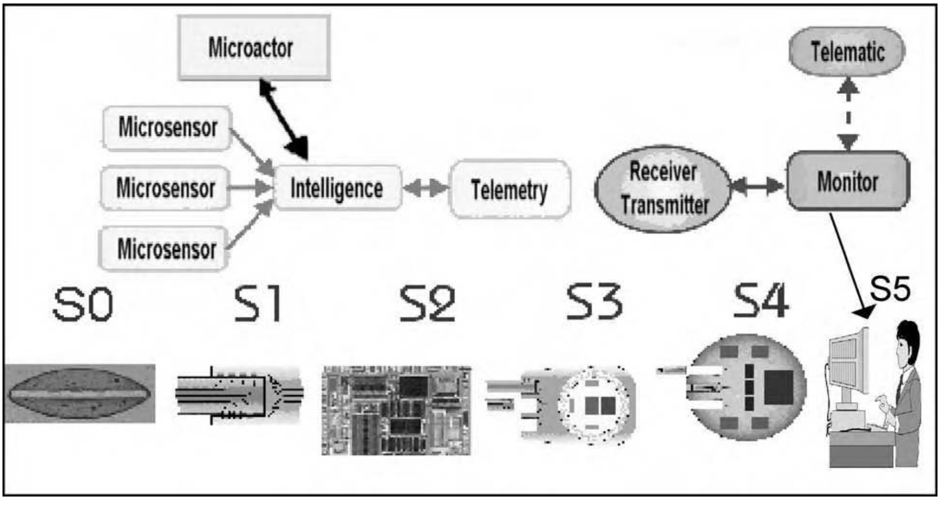

Figure 1. Conceptual Reference for Biosignals acquisition and communication.

For electrocardiography this would refer to the lead system and could include the electrode types. The electrode positions for routine electrocardiography are specified in medical text books as well as in the technical standard for electrocardiographic devices [2] and it is widely accepted that silver-chloride electrodes are the "sensors" of choice.

The interfaces **S1** and **S2** respectively at the input and output of the "intelligence" assembly unit comprise at the input typically an analogue piece of electronics and subsequently analogue to digital conversion and often integrated digital processing of the sensed signal. Fortunately to day these processors are powerful enough to make possible a sufficient sampling rate and amplitude quantisation for distortion free digital signal representation. However, so far only for electrocardiography methods and procedures have been developed for evaluation (and certification) of appropriate accuracy of the analysis algorithms which might be embedded in the digital part of the "intelligent" section of this unit. In other system configurations where only the signal digitisation is integrated with the sensor and the digitised signal is fed into a separate PC at the interface S1 proprietary protocols are used. Then already the sensor is not interoperable.

For electrocardiography **S1** (analogue input) is specified, e.g., within the IEC Standard 60601-2-CDV51 [2]. For PC or palmtop coupled sensors a standardisation of the S1 interfaces is highly desirable.

For electrocardiography **S2/S3** either at the output of an ECG cart or of a PC-ECG system an applicable standard is available since 1993: the **SCP-ECG** European prestandard ENV 1064 [3] and since 2001 the revised version (1.3) of this standard is as AAMI standard (EC71-D 2001) in place.

It is clear that interfacing the "Intelligence" (i.e., the processing module with the "Telemetry" module) **S2** and **S3** must use the same data interchange format specification. **S2** and **S3** must be fully compatible from the physical layer up to the presentation layer.

In 2002, the European OpenECG project [4] was launched to support ECG interoperability and the broad application of the SCP standard. While the FDA requirements brought into focus mainly the necessity of platform and program language independent ECG viewing capabilities, the OpenECG project puts emphasis on getting manufacturers using interoperability standards like SCP.

A significant problem for integrating Biosignals into an electronic health record is still a uniform patient and record identification. This information is transported in ECG data through section 1 of an SCP record. Section one is structured in up to 35 tags containing demographic patient and other medical data, data about the device, it's settings, the recording location, time stamping and many further details on the biosignal record which may be necessary for later comparison with other recordings of this patient.

Within the IMEX project a deep analysis is being performed to optimise format and structure of these data for handling them with micro technology within a BAN as well as for communication with external applications. Up to now it is open whether these data are to be inserted by the "intelligent" section of the acquisition module (S2) or by the telemetry assembly group.

1.2. Interoperability between a device system and a human application

So far, we have discussed from the reference model Figure 1 the interfaces **S1-S3**. Dependent on the system configuration at he application site **S4** could still be an interface like **S3** as long as the data are to be transported electronically, e.g. for telematics appli-

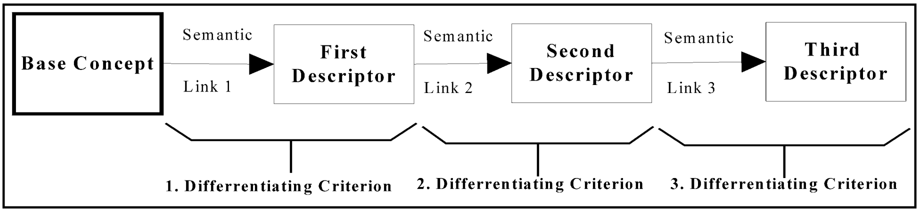

Figure 2. Structure of systematic names used to establish a domain nomenclature.

cations. If, however, at the transmitter output human interaction with the system takes place, the electronic data need to be visualised and converted for human perception. An additional interface **S5** with an associated standard is necessary for the machine – human communication.

A methodology for communicating medical data (starting from health care scenarios in and around an Intensive Care Unit (ICU)) has been developed and is described in the European Vital Signs Information Representation Standard ENV 13734 [5], published in 2001. A major task after definition of an adequate Domain Information Model (DIM) with all of it's object and attribute definitions was to structure the information gathered by the large variety of instruments at many points in time from numberless organs or locations on the patient. Only if for each single measurement (object instantiation) an unequivocal term could be found a unique code could be assigned to each measurement and only then an unambiguous information transfer would be possible. We call such a system of terms a *nomenclature.* Its entities form the Medical Information Data Base (MDIB) and are also called the "Data Dictionary".

A prerequisite to develop a nomenclature is the establishment of "systematic" names. For this we have used the methodology described in the European pre-standard prENV 12264 (1995): Categorial Structures of Systems of Concepts – Model for Representation of Semantics (MOSE) [6]. Figure 2 depicts the basic structure of the systematic names used to characterise uniquely each measurement, annotation or any diagnostic interpretation [6,7].

For the **base concepts** in Electrocardiography terms like *Electric Potential, Magnitude, Duration, Angle Slope or Pattern* turned out to be useful. For **semantic links** terms like *has origin, has method, is, computed as, concerns* or *has context* were found. **Descriptors** following the semantic links could be ECG<lead>, Vector, Maximum P(-wave), Arrhythmia, CVS (Cardio-Vascular-System).

The following examples illustrate the systematic names for description of an ECG measurement and a specific pattern and the assigned codes:

(a) QRS Duration in lead V6:
Duration|ECG<v6>,QRS|Heart|CVS >code 7936
(b) ECG with Arrhythmia
Pattern|Arrhythmia|ECG,Heart|CVS >code 17424

Meanwhile, two code blocks of 16 bit size have been specified for ECG measurements; the first one by the CEN project team that has essentially worked out the Vital standard [6] and the second one by members of the IEEE 1073/HL7 [8] working group focussing on beat-, wave component, rhythm and noise annotations to support the FDA-HL7 project.

For details the reader is referred to [5,6]. The essential message of this part is that only a world wide uniform concept of terms allows the allocation of an uniform encoding scheme and only then a complete interoperability across devices and across national borders between different health care systems is warranted.

2. Problems of comparing serial recordings in continuous tele-medical (home) care

Quantitative analysis of serial biosignals recordings is the most challenging requirement. Influential factors in serial comparison are the slightly different sensor placements, unknown positional changes at the various recordings, circadian effects and often differences in other environmental conditions. Also, different equipment performance with different parameter settings may be involved. And in non-assisted home care (i.e., placement of sensors or taking the measurement by the patient himself without assistance by a trained technician) high noise might be picked up and super-imposed on the sensor signal.

Again electrocardiography may help to illustrate the problem. Figure 3 depicts a set of vector-cardiographic recordings taken at Medical School Hannover for investigation of record to record variability in healthy persons. To reduce the influence of random electrode placement errors their locations were precisely marked and at each subsequent recording electrodes were attached at the marked places. Furthermore, to reduce as much as possible circadian effects the ECGs were taken at the same time of the day. The Figure depicts the 10s average beats for the Frank X,Y,Z leads with the marked wave onset and offset locations. On the right hand side of this figure the diagnostic interpretation (*Normal versus Pathologic), the number of Ventricular Extra systoles -within these recordings none-* and *heart rate)* are marked.

On the ECG waveforms qualitatively almost no differences can be recognised. However, the quantitative data shown in table1 indicate partly remarkable differences!

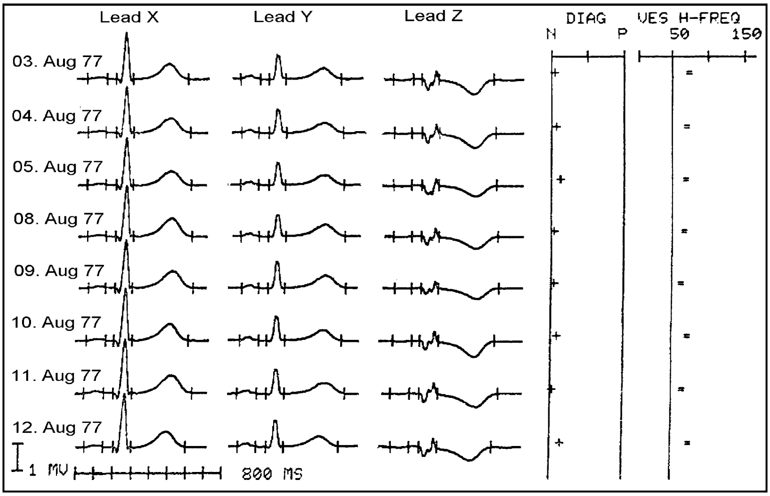

Figure 3. Example of serial VCG recordings taken in a Clinic with marked electrode localisation.

Table 1. Quantitative data of ECG parameter variability from clinically controlled recordings

Date of Acquis.	QRS Dur. ms	R-Max µV	QRS Elev. µV	R-X Ampl. µV	R-Y Ampl. µV	Q-Z Ampl. µV	T-Max µV	HF BPM	QT ms
03. Aug 77	92	2047	26	1816	935	-442	945	75	394
04. Aug 77	96	2030	26	1819	963	-419	920	70	410
05. Aug 77	94	2148	25	1916	913	-374	834	70	412
08. Aug 77	96	2297	23	2108	910	-366	1041	65	418
09. Aug 77	94	2226	28	1958	1032	-240	984	60	428
10. Aug 77	98	2314	23	2118	991	-377	1007	70	408
11. Aug 77	100	2372	24	2171	1011	-374	1009	60	430
12. Aug 77	96	2335	26	2144	1067	-356	899	75	398
15. Aug 77	98	2171	26	1955	971	-397	704	74	396
16. Aug 77	98	2099	27	1869	1030	-401	786	77	388
25. Aug 77	90	1906	27	1662	873	-342	727	75	396
26. Aug 77	94	1842	29	1584	891	-393	750	73	400
Mean	95.5	2148.9	25.8	1926.7	965.6	-373.4	883.8	70.3	406.5
Std. Dev.	2.8	170.6	1.9	189.0	62.2	50.1	119.8	5.8	13.6
Var. coeff.%	3.0	7.9	7.2	9.8	6.4	13.4	13.5	8.3	3.3
Std. Error	0.9	54.0	0.6	59.8	19.7	15.9	37.9	1.8	4.3

Table 1 shows the key measurements of VCGs from figure 3 (one healthy male). The records were taken to get estimates for VCG variability within a period of approximately one month, every morning approximately at the same time.

There are a couple of remarkable observations:

(1) The vector magnitude (R-Max as well as all other amplitudes have coefficients of variation 6.4 - 13.4%.
(2) The QRS elevation is relatively stable (STD=1.9°)
(3) The largest relative variability has been found in the T-wave. The coefficient of variation reaches 13.5% and the largest T-amplitude difference between two records exceeds 300 µV.

The variability shown here is smaller than in recordings where, e.g. the electrode location and other experimental parameters are monitored less carefully. Also the Beat to Beat Variability (BBV) within one ECG record needs to be considered. Each ECG measurement should consist of the mean value accompanied by its standard error for estimation of confidence intervals. This is of outmost importance for correct statistical testing when serial recordings are to be compared in clinical studies, therapy monitoring or telemetric home care monitoring for alarm settings.

To support this we have added to the HES-ECG analysis programs features that allow to evaluate the BBV and to provide the standard errors for a set of selectable Parameters. This is illustrated in Figure 4 and figure 5 (next page).

During the large European study Common Standards for Quantitative Electrocardiography (CSE Project 1979-1990) computer processing of electrocardiograms has been investigated extensively. A data base with expert annotation of fundamentally important measurement points has been established. Sets of identical digital ECGs have been fed into 15 VCG and ECG analysis systems and measurements obtained for noise-free and noisy ECGs from the different processing systems have been analysed and compared in detail. One of the clear results was that programs performing signal averaging (of the quasi stationary periodic ECG cycles) exhibit better measurement stability versus noise. However, the beats show some variability (BBV) within a 10s record. This variability may be due to a stochastic behaviour of the depolarisation/repolarisation process within

Figure 4. Analysis of BBV may be done in the HES analysis system. Once a record is chosen averaging is possible interactively beat by beat or the automatically computed average beat and it's dispersion will be displayed.

the heart ventricles or due to respiration and other biological influence factors. On figure 5 eleven ECG cycles of one 10s record are superimposed for each lead. As can be seen variability are different in each lead and as well for the different wave form parts (P,QRS,T).

The correct statistical comparison testing becomes more complicated if series' of ECG recordings are to be compared. To asses differences the appropriate approach is to perform an analysis of variance which could provide the necessary test parameters. A model equation is given by:

$$\xi_{ijk} = \mu + a_i + b_j + c_k + ab_{ij} + ac_{ik} + bc_{ik} + abc_{ijk} + \varepsilon_{ijk}$$

where

ξ_{ijkl}	the single measurement value	
μ:	total mean	
a_i, b_j:	influence of beat ,person	$\sim N(0,\sigma_A^2)\ N(0,\sigma_B^2)$
c_k:	influence of day	$\sim N(0,\sigma_k^2)$
ab_{ij}:	interaction beat and person	$\sim N(0,\sigma_{AB}^2)$
ac_{ik}:	interaction beat and day	$\sim N(0,\sigma_{AC}^2)$
abc_{ijk}	interaction beat, person, day	$\sim N(0,\sigma_{ABC}^2)$
ε_{ijk}:	measurement and random error	$\sim N(0,\sigma^2)$

Indexes: i = 1... number of beats, j = 1... number of persons, k = 1 number of days.

These considerations show clearly that (besides the solution of technical interoperability) substantial studies on comparison of serial recordings must be performed and data bases on variability of serial recordings need to be established before tele-health care can be brought into successful operation.

Figure 5. The superimposed ECG cycles (+ cycle included in average) and their variability is shown. Mean and standard error of any parameter selected within the "Combo box" may be displayed and print out. Selection of parameters is possible independently for each lead. Statically rather "stable" confidence intervals are obtained if at least 6-8 beats are averaged.

3. Summary and Conclusion

The evolution of information technology and increasing efforts to establish an electronic health stimulate the development and introduction of new concepts in health care [7].

By means of telecommunication the point starts to move from the locations of care providers to the patient. A pre-requisite is easy storage, retrieval and access to health care information at any time from any place. This requires interoperability of (medical) devices and device systems and even all types of networks.

For the last decades development of computer-assisted medical devices was focused on improving ergonomic functionality and improving performance of measurement accuracy and medical decision making.

The challenge today is to built-in and to improve interoperability with regard to hardware and software. Information integration is the key requirement! No doubt that this must be based on standards and development of standards must be speeded up.

Introduction of tele-monitoring and tele-health-care brings into focus also a medical problem: quality assurance in all data acquisition processes at the patient site and the lack of "hard" knowledge (essentially data bases) on the variability of vital sign parameters in healthy individuals and in many disease groups. We need urgently to establish appropriate "backup" information bases to be able to perform, e.g., tele-monitoring with meaningful settings for alarming and intervention thresholds. Because of the large inter-individual variability from the authors point of view concepts for those “back up” data bases must include primarily capabilities for assessing intra-individual variability of vital parameters and in the second place means to investigate and to assess the variation within statistically stratified subgroups of healthy and diseased individuals. The example of the variance-analytic model for the simple scenario of repeated ECG recordings gives hints which amount of work is still to be done before an efficient use of tele-healthcare facilities can be expected.

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Wireless Body Area Networks for Healthcare: the MobiHealth Project

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Abstract. The forthcoming wide availability of high bandwidth public wireless networks will give rise to new mobile health care services. Towards this direction the MobiHealth[1,2] project has developed and trialed a highly customisable vital signals' monitoring system based on a Body Area Network (BAN) and an m-health service platform utilizing next generation public wireless networks.

The developed system allows the incorporation of diverse medical sensors via wireless connections, and the live transmission of the measured vital signals over public wireless networks to healthcare providers.

Nine trials with different health care cases and patient groups in four different European countries have been conducted to test and verify the system, the service and the network infrastructure for its suitability and the restrictions it imposes to mobile health care applications.

Introduction

One of the most important technology advances that will mark the first decade of the 3rd millennium will be the implementation and wide availability of public broadband wireless networks, and namely 3G (UMTS) and 4G networks. Today many public network operators in Europe and around the world are installing and operating or testing UMTS networks, providing coverage and high mobile bandwidth to important parts of the population. In the next few years it is expected that the coverage will increase and eventually will cover almost the totality of the population, as it is the case today with the GSM networks.

This expansion and availability of high (mobile) bandwidth, combined with the ever-advancing miniaturization of sensor devices and computers, will give rise to new services

[1]The MobiHealth project was supported by the Commission of the European Union in the frame of the 5th research Framework under the project number IST-2001-36006.

[2]The project site http://www.mobihealth.org provides more information regarding the partners and current status of the project.

and applications that will affect and change the daily life of citizens. An area where these new technological advances will have a major effect is health care. Citizens, being patients or non-patients, will to not only be able get medical advice from a distance but will also be able to send from any location full, detailed and accurate vital signal measurements, as if they had been taken in a medical center, implementing what we can call “ubiquitous medical care”.

The MobiHealth project started in May 2002 and to be completed in February 2004, has developed a system and a service for ambulant patient monitoring over public wireless networks. Based on a body area network interconnecting different vital signal sensors and actuators, the measurements are transmitted using UMTS [1] (or GPRS) to the health care center where they are presented live to the medical personnel. This way patients can be continuously monitored and receive advice when needed. In the last months of the project 9 different trials scenarios were implemented for different types of patients. These trials allowed us to identify problems and issues in the development of mobile e-health services and identify limitations and shortcomings of the existing and forthcoming public network infrastructure.

1. The MobiHealth system

The MobiHealth system provides a complete end-to-end e-health platform for ambulant patient monitoring, deployed over UMTS and GPRS networks. The MobiHealth patient/user is equipped with different vital constant sensors, like blood pressure, pulse rate and ECG interconnected via the *healthcare Body Area Network* (BAN. The *Mobile Base Unit* (MBU) is the central point of the healthcare BAN, acting as a gateway aggregating the vital sensor measurements (*intra-BAN communication* based on wireless networks like Bluetoot [2] and Zigbee [3]) and transmitting them to the back-end system (*extra-BAN communication* based on GPRS and UMTS*)*, which can be located within the health broker premises or be part of wireless services provider. From there the measurements are dispatched to the health care broker where the medical personnel monitor them. It must be noted that automated monitoring and patient feedback is currently not supported by the MobiHealth system, as this was outside the scope of the project. Figure 1 shows the architecture of a healthcare BAN. Sensors and actuators establish an ad-hoc network and use the MBU to communicate outside the BAN.

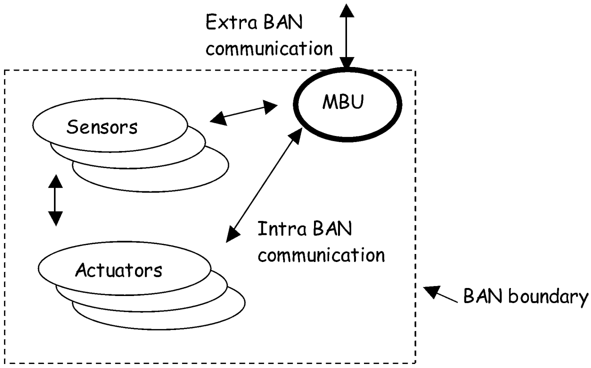

Figure 1. Healthcare BAN architecture.

The concept of the Body Area Network originally came from IBM [4] and was developed further by many other researchers, for example at Philips [5], at the University of Twente [6], and at Fraunhofer [7]. In the Wireless World Research Forum's *Book of Visions*, we define a BAN as "*a collection of (inter) communicating devices which are worn on the body, providing an integrated set of personalised services to the user*" [9].

In the context of the MobiHealth project the *Healthcare BAN* is a health monitoring tool that consists of sensors, actuators, communication and processing facilities connected via a wireless network which is worn on the body and which moves around with the person (i.e., the BAN is the unit of roaming). A sensor is responsible for the data acquisition process, ensuring that a physical phenomenon, such as patient movement, muscle activity or blood flow, is first converted to an electrical signal, which is then amplified, conditioned, digitised and communicated within the BAN.

The Healthcare BAN sensors can be self-supporting and/or front-end supported. Self-supporting sensors have a power supply and facilities for amplification, conditioning, digitisation and communication. Self-supporting sensors are independent building blocks of a BAN and ensure a highly configurable healthcare BAN. However, each sensor runs at its own internal clock and may have a different sample frequency. Consequently, mechanisms for the synchronization between sensors may be needed.

Front-end supported sensors share a common power supply and data acquisition facilities. Consequently, front-end supported sensors typically operate on the same front-end clock and jointly provide multiplexed sensor samples as a single data block. This avoids the need for synchronization between sensors.

1.1. Service platform architecture

Collecting and transmitting the vital signal measurements is only part of the healthcare service platform developed in the MobiHealth project and shown in Figure 2. The dotted square boxes indicate the physical location where parts of the service platform are executing. The rounded boxes represent the functional layers of the architecture. The M-health service platform consists of sensor and actuator services, intra-BAN and extra-BAN communication providers and an M-health service layer. The M-health service layer integrates and adds value to the intra-BAN and extra-BAN communication providers masking applications from specific characteristics of the underlying communication providers.

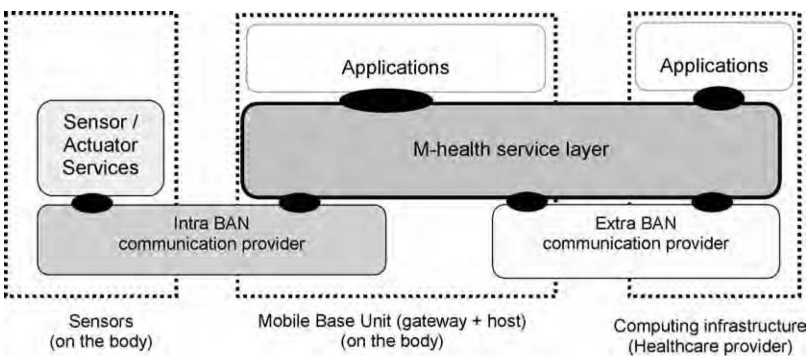

Figure 2. Service platform functional architecture.

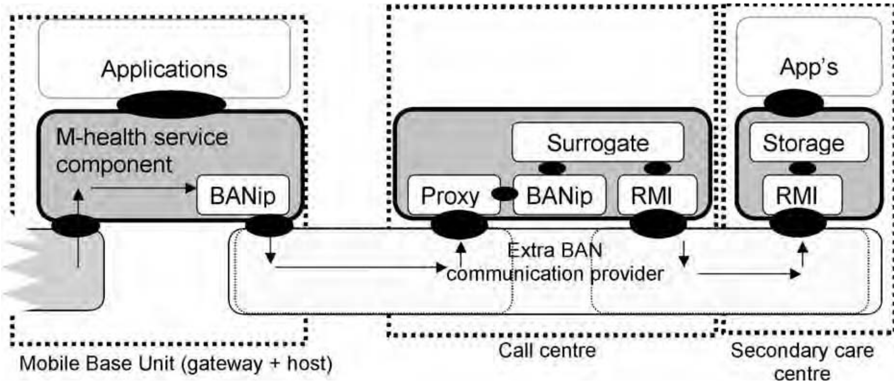

Figure 3. Refined view of the service platform.

Applications that run on top of the service platform can either be deployed on the MBU (for on-site use e.g. by a visiting nurse) or on the servers or workstations of the healthcare provider, i.e. the call centre or the co-located secondary care centre in Figure 2. For this the M-health service platform offers a number of services including:

- *BAN registration*: the service platform maintains a list of active BANs and allows applications to retrieve the specific configuration of a BAN.
- *BAN discovery*: applications can subscribe to the platform to receive a notification in case a BAN becomes active (i.e. a patient switches on a BAN).
- *BAN authorization and authentication*: the service platform authenticates BANs and only allows authorized BANs to convey data.
- *BAN data encryption*: the platform encrypts data that is conveyed over unsecured networks
- *BAN configuration*: the service platform allows online configuration and management of the BANs, such as (de)activation of specific sensors or modification of the sample frequency of a sensor.
- *Data acquisition control*: the service platform enables applications to start, stop or temporarily interrupt the data acquisition process of a BAN.
- *Query and modify actuator status*: applications can manipulate actuators from a distance.
- *BAN data storage*: the service platform can act as an intermediate storage provider to applications. Applications determine the minimal duration of the storage.
- *BAN data monitoring*: the service platform can apply filtering algorithms on the BAN data to determine if an interesting event has taken place (e.g. a patient has dropped on the floor) and report this event to the application layer.

A refined view of the M-Health service layer is shown in Figure 3 for the case where the M-health service platform user (e.g. at a hospital) is not co-located remotely with the call centre. The arrows in the figure show the flow of the BAN data. The BANip entity is a protocol entity for the BAN interconnect protocol [10]. Peer entities can be found on the MBU and on the computing infrastructure (in the 'fixed' network). The BANip entities communicate through a proxy, that authenticates and authorizes the BANs' connection.

The surrogate component uses the BANip protocol to obtain BAN data. This component contains a representation of the BAN (i.e. the surrogate) and shields other components in the 'fixed' network from the BANip and direct interaction with the BAN. The surrogate component can be accessed by any application protocol, including Remote Method Invocation (RMI) as depicted in Figure 3. The storage entity uses RMI to interact with the surrogate as if it interacts with the remote BAN at the location of the patient, without the burden of the discovery, registration and authentication of the BANs. The surrogate component is therefore the intermediary whereto BAN data from the location of the patient is pushed and wherefrom the data is pulled by the application component residing at the secondary care centre. The storage entity provides the BAN data storage service to the application layer. Configuration, discovery and monitoring services are offered as separate entities, with the same structure as the storage entity.

Applications that use the m-health service layer can range from simple viewer applications that provide a graphical display of the BAN data, to complicated applications that analyse the data.

1.2. Service platform technical requirements

To leverage the healthcare BAN for use as a *remote* monitoring tool several issues and considerations were taken into account in the design and development of the supporting healthcare service platform. These issues reflect both commercial and social needs or restrictions, as well as technical limitations of underlying infrastructures [8]. The most important ones being *scalability*, *security* and *extra-Ban network restrictions*.

Scalability: The healthcare service platform must be able to support services that cover niche healthcare cases that require the simultaneous monitoring of small numbers of patients (e.g., ranging from 10 to 100 BANs) to large-scale chronic disease management processes (e.g., 100.000+ BANs used to monitor COPD patients). In addition geographical scalability, that is global coverage, should be supported.

Security. The healthcare service platform connects the BAN with the Internet. Consequently, the BAN is subject to attacks from malicious Internet users who either try to break into the system or frustrate its use. Therefore the healthcare service platform should be protected from attacks like Denial of Service (DoS). Mechanisms that ensure data integrity must be included to prevent corruption of BAN data. Each BAN should authenticate itself with the service platform, which should only allow authorized BANs to send BAN data.

Mask 'inverted-producer-consumer' problem. Traditionally, providers of data (such as web servers) are deployed on a computing infrastructure with sufficient network and processing capacity. Consumers of data (such as web browsers) assume that providers are available most of the time (except for maintenance) and have sufficient bandwidth to serve a reasonable amount of consumers. This model was the one adopted by the public wireless network operators where the data consumer, i.e., the mobile device, initiates a network connection to the producer. Based on this assumption, most network operators of 2.5/3G networks hand out private space IP addresses to mobile devices. Connection establishment initiated from a fixed host on the public Internet to a mobile device is therefore inhibited.

However in the MobiHealth system each BAN *is a data producer*. For the service platform, the producer and consumer roles are thus inverted because the provider of data is deployed on a mobile device (i.e. the MBU) while the consumer of data is deployed on a fixed host with sufficient processing and communication capacity. The MBU may

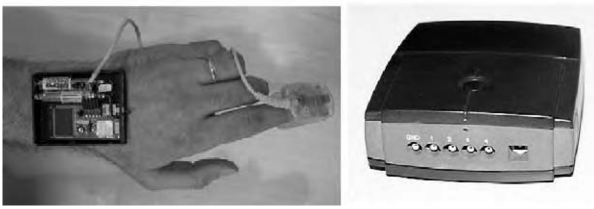

Figure 4. Self supporting sensor and a front-end.

Figure 5. iPAQ H3870 acts as MBU.

be temporary unavailable, due to the short life-time of batteries or because it has moved to an area without coverage of the public wireless infrastructure. The service platform therefore masks the inversion of the producer-consumer roles from the BAN and the end-users (e.g., a patient wearing the BAN or a medical specialist analyzing the BAN data).

1.3. Implementation details

The Healthcare BAN has been implemented using both front-end supported and self-supporting sensors. Figure 4 shows the self-supporting EISlab sensor [10] (left) and a TMSI front-end (right). Both approaches use Bluetooth for intra-BAN communication. The front-end also allows ZigBee as an alternative intra-BAN communication technology. Electrodes, a movement sensor, a pulse oximeter and an alarm button are examples of sensing devices that can be attached to the front-end.

The MBU was implemented on an iPAQ H3870. This device has built-in Bluetooth capabilities and can be extended with a GPRS extension jacket. Figure 5 shows a picture of the MBU that also runs a viewer application.

The BANip [10] has been implemented using Java 2 Micro Edition (J2ME)[12] The BANip is implemented on the MBU as an HTTP client that collects a number of samples into the payload of an HTTP POST request and invokes the post on the surrogate. We've used a standard HTTP proxy to act as a security gateway of the surrogate. In case the surrogate needs to control the MBU, these control commands are carried as payload of the HTTP reply.

The surrogate has been implemented using the Jini Surrogate architecture[13]. Jini provides the implementation for auto-discovery and registration of the BAN. In terms of the Jini architecture the surrogate is a service provider. Other components, such as the BAN data storage component, are service users from the perspective of the surrogate.

2. The MobiHealth Trials

The primary question addressed by the MobiHealth project was whether 2.5/3G communications technologies can support the MobiHealth vision, i.e., enable the move towards empowered managed care based on mobile health care systems. To obtain an (as much as possible) valid reply to this question, we organized and conducted nine different trials in four different countries around Europe, expecting that for some trials the existing infrastructure will be adequate while for others it may be insufficient. We must note however that the conducted trials were *not* clinical trials, the primary target of the project being the evaluation of the 2.5/3G infrastructures. The trials also provide us the basis for a market validation of the system and service, towards further commercialisation.

The trials were selected to represent a range of bandwidth requirements ranging from 12 kbps to greater than 24 Kbps and include both real-time and non-real time requirements.

Trial 1 - Germany: Telemonitoring of patients with cardiac arrhythmia

The target group in this trial are patients with ventricular arrhythmia who are undergoing drug therapy. Cardiac arrhythmia is very common and in many cases is related to coronary heart disease. Around one million patients suffer from coronary heart disease in Germany today. In patients suffering from arrhythmia, ECG measurements have to be taken regularly to monitor the efficacy of drug therapy. In order to save time and reduce costs, the patient is able to transmit ECG and blood pressure via GPRS from home or elsewhere to the health call centre, where the vital signs are monitored by a cardiologist. The intention is that irregular patterns will be detected quickly and appropriate intervention can be initiated. This trial will evaluate how the patients and the cardiologist can gain time and reduce the related costs.

Trial 2 - The Netherlands: Integrated homecare for women with high-risk pregnancies

The trial will use the MobiHealth BAN to support integrated homecare for women with high-risk pregnancies. Women with high-risk pregnancies are often admitted to the hospital for longer periods of time because of possible pregnancy-related complications. Admission is necessary for the intensive monitoring of the patient and the unborn child. Homecare with continuous monitoring is desirable and can postpone hospitalisation and reduce costs, as well as offering more security for the mother and unborn child. In this trial, patients are monitored from home using the MobiHealth BAN and the (maternal and foetal) biosignals are transmitted to the hospital. An additional objective of the trial is to evaluate if such a solution postpones hospitalisation and reduces costs. The trial will use both GPRS and UMTS networks.

Trial 3 - The Netherlands: Tele trauma team

MobiHealth BANs will be used in trauma care both for patients and for health professionals (ambulance paramedics). The trauma patient BAN will measure vital signs which will be transmitted from the scene to the members of the trauma team located at the hospital. The paramedics wear trauma team BANs which incorporate an audio system and a wireless communication link to the hospital. The purpose of this trial is to evaluate whether use of mobile communications can improve quality of care and decrease lag-time between the accident and the intervention. When using telemetry technology, time can be saved and thus treatment and chances for patient recovery improved. Parameters to be measured are breathing frequency, oxygen saturation, pulse rate, blood pressure, pupil size and reactions and amount of fluids infused. The trial will use both GPRS and UMTS networks.

Trial 4 – Spain: Support of home-based healthcare services

This trial involves use of GPRS for supporting remote assistance and home-based care for elderly and chronically ill patients suffering from co-morbidities including COPD. The MobiHealth nurse-BAN will be used to perform patient measurements during nurse home visits and the MobiHealth patient-BAN will be used for continuous monitoring during patient rehabilitation at home, or even outdoors. It is very important to facilitate patients' access to healthcare professionals without saturating the available resources, and this is one of main expected outcomes of the MobiHealth remote monitoring approach. Parameters to be measured are oxygen saturation, ECG, spirometry, temperature, glucose and blood pressure.

Trial 5 - Spain: Outdoor patient rehabilitation

The patients involved in this trial are chronic respiratory patients who are expected to benefit from rehabilitation programs to improve their functional status. The study aims to check the feasibility of remotely supervised outdoor training programs based on control of walking speed enabled by use of the MobiHealth BAN. The physiotherapist will receive online information on the patient's exercise performance and will provide feedback and advice. It is expected that by enabling patients to perform physical training in their own local settings, the benefits, in terms of cost and social acceptance, can be significant. Parameters to be measured are pulse oximetry, ECG and mobility with audio communication between patient and remote supervising physiotherapist.

Trial 6 - Sweden: Lighthouse alarm and locator trial

The target group involved in the trials are patients at the Lighthouse care resource centre and also clients living at home, but with the common characteristic that all have an alarm system located in their room at the Lighthouse Centre or in their home. The current system does not allow the patient any freedom related to mobility and forces the patient to be trapped at home or in their room at the Centre. By replacing the fixed alarm system with the mobile MobiHealth system the patient can move freely anywhere. In addition, positioning and vital signs are monitored and video communication is planned with UMTS. The effectiveness of the new GPRS/UMTS-based alarm and locating device (a variant of the MobiHealth BAN) will be tested according to several determining factors: safety, convenience, empowerment of user, mobility of user and improvement in efficiency of care given.

Trial 7 - Sweden : Physical activity and impediments to activity for women with RA

Trial subjects will be women with Rheumatoid Arthritis. The use of the BAN together with the mobile communications will enable collection of a completely new kind of research data which will enhance the understanding of the difficulties and limitations which these patients face. The objective is to offer solutions that will make their lives easier.

By this collection of data, the scarce knowledge about what factors impede normal life will be supplemented and quality of life of RA patients may thereby be improved. By use of the MobiHealth BANs, the activity of the patients will be continually monitored. Parameters measured include heart rate, activity level, walking distance and stride length.

Trial 8 – Sweden: Monitoring of vital parameters in patients with respiratory insufficiency

The group of patients involved in the trial suffer from respiratory insufficiency due to chronic pulmonary diseases. These people need to be under constant medical supervision in case they suffer an aggravation of their condition. Besides needing regular check-ups, they are also dependent on oxygen therapy at home, which means oxygen delivery and close supervision. The use of the MobiHealth BANs is designed to enable the early detection of this group of diseases but also to support homecare for diagnosed patients by detecting situations where the patient requires intervention. The expected benefits are a reduction of the number of check-ups and hospitalisations needed, thus saving both time and money. Parameters measured are pulse rate, oxygen saturation and signals from a motion sensor (accelerometer).

Trial 9 – Sweden: Home care and remote consultation for recently released patients in a rural area

Home care services and the possibility of monitoring health conditions at a distance are changing the way of providing care in different situations. If suitable, home-based services are provided and patients do not need to be in hospital, for example they are recovering from an intervention. By investing in home care, hospitals have been able to significantly reduce pressure on beds and on staff time dedicated to the kind of patients named above. This trial tests transmission of clinical patient data by means of portable GPRS/UMTS equipment to a physician or a registered district nurse (RDN) from patients living in a rural, low population density area. The expected benefit is that this solution will reduce the number of cases where the patient is supposed to visit a hospital for consultation unnecessarily.

3. Evaluation of the trials

During the trials different types of data is collected in view of an evaluation of the results. The target of the evaluation is dual: first we want to verify the state of the UMTS (and GPRS) infrastructure and its suitability for mobile health applications, and second we want to explore the added value that the MobiHealth system can bring to different healthcare domains.

At the moment of the writing of this paper (January 2004), the trials are still ongoing and the evaluation was not yet completed. Nevertheless some preliminary results are available and are presented in the next section.

The trials are evaluated using a methodology developed in the project. Specifically we evaluate the trials from the technical point of view (technical evaluation), the medical point of view (end-user and social evaluation) and from the business point of view (market evaluation).

The technical evaluation focuses on the evaluation of the performance of the communication infrastructure characterized in terms of: availability, bandwidth characteristics, percentage of data loss/corruption, transmission delay and its variation ("jitter"). In addition to the network performance the technical evaluation will also assess the overall system in terms of validity, accuracy and robustness of the Sensor / Actuator Service and application, the BAN and the intra-BAN communications, time delays etc.

The system performance related parameters are logged at the BAN side, while the generated traffic is logged by the 2.5/3G network measurement system. Logs at the BAN side declare if there were any problem regarding access to the network and the process of transmitting the data to the BEsys. The network log reports are used to verify if any of the logged problems at the BAN side could have been caused by the current status of the network during that time. Due to different restrictions it might not be always possible to log the network data during the trials. In this case general statistical data will be used instead.

The performance characteristics of the MobiHealth communication infrastructure are derived in two ways: objective and subjective evaluation.

The *objective evaluation* of the infrastructure includes active and passive measurements. For the active measurements an external data stream is generated (that is, we have no real MobiHealth data) and the performance characteristics of the communication paths are measured. The passive measurements will be performed in the up-and-running MobiHealth system so that real MobiHealth data are used. During the passive measurement phase, the participating operators will also perform some core-network data logging of the MobiHealth traffic characteristics.

The *subjective evaluation* of the infrastructure's performance will be done by the end-users (healthcare professionals) who will express their perceptions of functionality and performance characteristics as experienced during the usage of the MobiHealth system.

The end user evaluation describes the usability/acceptance of the MobiHealth Services over 2.5/3G infrastructure and it will seek the subjective opinion of users regarding the new services, their usability, user interaction, satisfaction, suitability, usefulness, acceptance, independence and experiences. Also the question about the perception on the performance characteristics of the system, like: system accuracy, validity, robustness, its speed or availability of the service will be addressed by the professional users. End users in this project are defined as the patients and the health care personnel who are involved in the trials and are using the MobiHealth system.

The results of the end-user evaluation are collected using diaries, questionnaires, interviews and some objective measurements, e.g. walking distance and step-length for mobility assessments. End-users evaluation results will be compared against the performance measurements of platform to analyse existence of expected correlations. For example, the receipt of a not useful poor quality ECG, which cannot be interpreted by a professional, that coincides with large delays and packet drops in the system indicates communication throughput problems.

The goal of ***the market evaluation*** is to provide a set of criteria which will allow making valid statements and decisions regarding the market value and potential of the MobiHealth system in the respective trial settings. The factors which are important and decisive in this context include: health political issues, existing market structures and processes, market players, business scenarios, value chains, potential users, users' characterization (behaviour, acceptance requirements), health economic relevance, realization of market potentials (how much and when), barriers of entry, opportunities and threats.

3.1. Some preliminary technical evaluation results

Although at the time of writing of this paper the trials are still on-going and the measurements are yet to be completed, some preliminary results regarding the performance of the UMTS and GPRS networks and technical issues related to MobiHealth BAN can be sketched. We present here some of the results from the UMTS tests and trials performed in the Netherlands using the Vodafone pre-commercial UMTS network. We must note however that the MobiHealth project is the *only* user of the Vodafone UMTS network in the Twente region. Thus we are running under the best-case environment, that is, on an empty network.

One of the first problems that we encountered in the use of the UTMS (and GPRS) networks the *reverse producer-consumer* model (see section 1.2). The consequence of this reversal is that the network and terminal devices cannot support (in their present configuration) high bandwidth transmission emanating from the end-user. This is a limiting factor for the measurements that the MobiHealth system can send to the health broker.

To enhance portability and compatibility with the operating systems available on portable telephones, the MobiHealth application on the MBU was programmed in Java under the CLDC Java Virtual Machine [14]. As a result we have been forced to use the HTTP protocol for transporting vital signals. However the current CLDC HTTP protocol implementation does not allow for persistent HTTP connections. That means that whenever the MBU needs to send data it must establish a new TCP/IP connection. This however is very expensive, in terms of performance.

A second issue related to the use of the HTTP protocol is the fact that every time a request is sent, the communication is blocked until an acknowledgment or reply is received. To solve this problem we used a technique called *chunking* [15] where multiple requests are sent without having to wait for a reply. However not all operators allow the use of chunking for their GPRS network. This eventually might cause standardization problems for services and applications that transmit continuous real time data over the GPRS and possibly UMTS

During the UMTS performance tests (active measurements) we emulated a high load of the network by running 10 simultaneous UMTS transmissions. The tests (still ongoing) indicate a performance degradation (network failure) when high bandwidth from 10 UMTS connections is simultaneously transmitted. The reason for this failure is not clear yet we hope to have more data and information at the end of the tests.

A problem was also observed with the functionality available to the different PCMCI network cards. The available data bandwidth over GPRS (and UMTS) depends on the strength of the signal at the user location. Although the GPRS and UMTS telephones do indicate the signal strength during operation, this is not the case for the PCMCIA cards integrated with the iPAQ. PCMCIA cards allow the control of the signal strength using proprietary software, *but only during set up*. During data transmission the signal strength information is not available. However this information is of major importance for the MobiHealth application, since it will allow us to estimate the available bandwidth and to control the data transmission rate accordingly. Currently, we have the situation that when transmitting at data rate at an area with strong signal and we pass to an area where the signal is low, we are not able to lower the data transmission rate and as a consequence the connection breaks down. The signal strength as well as the encoding schema used during the transmission should be thus available to the application under a standardized API for all types of GPRS/UMTS terminals, whether these terminals are PCMCIA cards or regular mobile phones.

On the positive side we were able to confirm the stability of the Vodafone UMTS network in the Netherlands. Tests done with a moving station (a car roaming within the Enschede coverage area) allowed us to maintain a connection of at least 64Kbps (up and down link) crossing over cell boundaries and under different speeds. The maximum bandwidth available for a fixed station of 64Kbps uplink and 384 downlink is readily available and stable thought out the coverage area (our terminal devices – Nokia UMTS telephones – do not allow us to obtain higher bandwidths).

4. Conclusions

At time of writing the MobiHealth project has been running for 20 months (since May 2002). In the rather short duration of the project a great many problems and challenges have been encountered and much progress has been made. The starting point was a vision of ubiquitous mobile health services based on Body Area Networks. During the project we have designed and prototyped a health BAN and a BAN service platform and developed services for different patient groups according to the requirements specified by the clinical partners. Nine trials in different European countries are on-going and evaluation data are under collection for further analysis. The main element of this evaluation will be an analysis of the suitability of 2.5/3G public wireless infrastructures for the support of remote healthcare monitoring.

First results indicate that several issues need to be resolved by both network operators and hardware manufacturers for a better support to mobile health services. Ambulatory monitoring is more successful for some biosignals than others, for example some measurements are severely disrupted by movement artefacts. Some monitoring equipment is still too cumbersome for ambulatory use, because of the nature of the equipment or because of power requirements, while even with 2.5 and 3G we still suffer from limited bandwidth for applications that serve many simultaneous users. Other challenges relate to security, integrity and privacy of data during transmission to both local transmission (eg. intra-BAN) and long range (eg. extra-BAN) communications. Powering *always on* devices and continuous transmission will continue to raise technical challenges. Business models for healthcare and accounting and billing models for network services need to evolve if technical innovations are to be exploited fully. Standardisation at all levels is essential for open solutions to prevail. At the same time specialization, customisation and personalisation are widely considered to be success criteria for innovative services.

Although our formal work in the MobiHealth project will be completed in the end of February of 2004, plans are underway for the creation of a venture for the further development and commercialisation of the results. The great interest shown by healthcare organizations and commercial companies, as well as the products that become available in the market every day and the interest shown by patients encourages us to proceed as fast as possible in the creation of a company that will promote and commercialise the MobiHealth services and platform. We expect that by the end of the 2004 to have a first version of a commercial system available to interested users in different European countries.

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Wearable eHealth Systems for Personalised Health Management
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Development of Electronic Textiles for U.S. Military Protective Clothing Systems

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Abstract. The focus of this paper is on the development of a wearable electronic network that provides data and power transport. A materials and manufacturing survey was conducted to determine the best performing and most durable materials to withstand the rigors of textile manufacturing and potential military use. Narrow woven technology was selected as the most appropriate manufacturing method. A working wearable narrow fabric version of the Universal Serial Bus (USB) was successfully developed and fabricated as well as related wearable connectors. Military products developed include a personal area network and body borne antenna.

Keywords. Textiles, Electronics, Conductivity, Network, Antenna, Communications, Military, Soldier

Introduction

The need for real time information technology on the battlefield is well documented. Electronic devices are being miniaturized for personal use; however, there is no technology to integrate electronics into clothing. Military combat clothing materials are passive and the ability to integrate electronics into textiles provides the potential to achieve revolutionary improvements in performance. The proposed solution is the development of a wearable electronic network providing data and power transport that is lightweight, flexible, durable, washable, low cost, and can be applied to any garment. The use of this point-to-point network could include transport of power from a battery pack to a wearable computer. The standard USB 2.0 protocol was selected to prove the technical feasibility of this concept because it is commonly used and well understood. A materials and textile manufacturing survey was conducted to determine the best performing and most durable materials to withstand the rigors of textile manufacturing and potential military use. Narrow woven technology was selected as the most appropriate textile manufacturing method because the narrow fabric could be used to create a continuous network on a garment without seam discontinuities and could be applied to any garment. A working wearable narrow fabric version of the USB cable was successfully developed and fabricated as well as related wearable connectors. Military products developed include a personal area network and body borne antenna.

1. Materials and Methods

A survey was conducted of both commercial materials and textile manufacturing methods [1]. A variety of materials were investigated, tested and evaluated including conductive polymers, metallic fibers, novelty embroidery materials, and materials not commonly used in textile manufacture such as tinsel wire. Copper wire of 32 AWG was used as a benchmark for conductivity and has a value of 1.6 x 10^{6} siemens per centimeter. None of the fiber forming polymers investigated demonstrated conductivities approaching copper wire. Other polymers such as polyaniline and polypyrrole are conductive but the level did not approach that of copper and the mechanical properties of the polymers were known to be poor. Metallic fibers such as DuPont's metal coated Kevlar, known as "Aracon," and Nobel Fiber's "X-static," a silver coated nylon, are both available in broad product ranges including products with the potential to provide conductivity and others that provide shielding. Embroidery materials, which are metalized Mylar wrapped around core fibers, demonstrated relatively high resistance and poor mechanical properties. Tinsel wire, commonly used in the telecommunications industry, is composed of a bundle of core fibers, usually polyester or Kevlar, that are double wrapped with metallic foil. The typical resistance of an individual tinsel wire was 0.015 ohms per centimeter. Typical resistance values of copper wire are listed in Table 1.

Traditional textile manufacturing methods were investigated to determine if fine gauge wires as well as tinsel wire and metallic fibers could be integrated into a manufactured fabric. Narrow woven technology was selected as the most appropriate textile manufacturing method because the narrow fabric could be used to create a continuous network on a garment without seam discontinuities and could be applied to any garment. The standard USB protocol was selected to prove the technical feasibility of the development of a point-to-point wearable personal area network. The first prototype was manufactured in accordance with the Institute of Electrical and Electronics Engineers (IEEE) USB 2.0 specifications and the following materials were used:

- Data Transmission Medium: 28 AWG twisted copper pair, PVC insulated, wrapped with aluminum Mylar foil for low-frequency shielding
- Power Wires: 20 AWG stranded, tinned copper with PVC insulation
- Drain: 28 AWG copper wire in contact with data medium
- Warp and Filling Yarn: Filament Nylon

Table 1. Benchmark Conductors

*Copper Wire, AWG**	*Resistance, ohm/cm*	*Diameter, mm*
28	*0.0021*	*0.32*
30	*0.0034*	*0.25*
36	*0.014*	*0.12*

* American Wire Gauge

Table 2. Group 6 Signal Integrity Test Results - Initial

Test	*Requirements*	*USB*
Examination	*No Damage*	*Pass*
Impedance	*76.5 to 103.5*	*Pass*
Attenuation	*3.2 dB and 5.8 dB max between 200 and 400 MHz*	*Pass*
Propagation Delay	*5.2 nS/m max*	*Pass*
Propagation Delay Skew	*100 pS max*	*Pass*
Capacitive Load	*200 to 450 pF*	*Pass*
Shielding Effectiveness	*20 dB between 30 MHz and 1GHz*	*Pass*

Table 3. Group 6 Signal Integrity Testing After Cyclic Loading

Test	Requirements	5k Cycles	10k Cycles	20k Cycles	40k Cycles
Examination	No Damage	Pass	Pass	Pass	Pass
Impedance	76.5 to 103.5	Pass	Pass	Pass	Pass
Attenuation	3.2 dB and 5.8 dB max between 200 & 400 MHz	Pass	Pass	Pass	Pass
Propagation Delay	5.2 nS/m max	Pass	Pass	Pass	Pass
Propagation Delay Skew	100 pS max	Pass	Pass	Pass	Pass
Capacitive Load	200 to 450 pF	Pass	Pass	Pass	Pass

2. Results and Discussion

Fiber forming conductive polymers would be the most desired type of conductive fiber for integration into protective clothing. However, due to the limitation of the current state-of-the-art, conductive copper wire was used. The prototype electro-textile cable was approximately one inch wide, woven in a double plain weave. It was tested and evaluated against the IEEE's Group 6 Signal Integrity tests for the USB 2.0 [2]. It passed all tests and the data are listed in Table 2.

To measure durability related performance the electro-textile cable was tested and evaluated after abrasion and cyclic loading. The cyclic loading was carried out using a load profile that varied from 0 to 250 pounds for 5,000, 10,000, 20,000 and 40,000 cycles. Signal integrity testing results in Table 3 show that the electro-textile cables were fully functional even after 40,000 cycles. In addition, the electro-textile cables had a breaking strength of nearly 2000 pounds.

Abrasion testing was performed in accordance with U.S. Federal Test Standard 191, Test Method 5309 – Abrasion Resistance of Textile Webbing. After 1,000 abrasion cycles the power wires began to poke through the electro-textile. By 4,000 cycles the shielded twisted pair also began to poke through as well. Table 4 shows the effect this had on signal integrity testing, specifically the impedance.

Since the copper wires were critical performance components in the electro-textile cables, stiffness is a concern for body worn applications. Stiffness testing was conducted in accordance with a modified version of American Society for Testing and Materials (ASTM) D 1388, "Stiffness of Fabrics" [3]. Several material alternatives were identified that reduced overall stiffness without affecting performance including:

Table 4. Group 6 Signal Integrity Testing After Abrasion

Test	Requirements	1k Cycles	2k Cycles	4k Cycles
Examination	No Damage	Pass	Pass	Pass
Impedance	76.5 to 103.5	High	High	High
Attenuation	3.2 dB and 5.8 dB max between 200 and 400 MHz	Pass	Pass	Pass
Propagation Delay	5.2 nS/m max	Pass	Pass	Pass
Propagation Delay Skew	100pS max	Pass	Pass	Pass
Capacitive Load	200 to 450 pF	Pass	Pass	Pass

Figure 5a. Proposed USB Connector Design.

Figure 5b. Final Implementation.

- Low durometer insulation on wires
- Highly stranded conductors
- Replace foil shielding with round hollow braid of metallic fibers

Once the feasibility of the electro-textile cable concept was demonstrated, a connector was designed that incorporated the IEEE USB 2.0 interface standard. As shown in Figures 5a and 5b, a low profile ergonomic form was created using a rigid premold for durability that was then covered with a soft overmold of Santoprene providing a level of conformability. The electro-textile cable to overmold bond strength was in excess of 400 pounds.

Objective Force Warrior (OFW) is the future soldier system for the U.S. military. A personal area network was developed and integrated into the OFW prototype system to serve as the soldiers' electronic backbone. As shown in Figure 6, use of the point-to-point network includes transport of power from the battery packs to the wearable central processing unit (CPU), and transport of data and power from the CPU to the wrist display, drink-o-meter, and headgear.

The narrow fabric technology and conductive materials were also used to develop a body worn antenna. Maintaining communications on the battlefield is critical to coordinate and control units and firepower. Radio operators are easily identified by their protruding antennas and are prime targets. In addition, antennas are easily broken by tree branches and bushes, limit soldier mobility, and are relatively inefficient radiators. A rigid Merenda double-loop antenna was transformed into a wearable, flexible, textile based antenna that was compatible with the Single Channel Ground and Airborne Radio System (SINCGARS) functioning in the 30 to 88 MHz range [4]. It has been inte-

Figure 6. OFW CPU with Attached Electro-Textile Cables.

Figure 7. Double Loop Antenna Integrated into MOLLE Vest.

grated into the Modular Lightweight Load Carrying Equipment (MOLLE) vest as shown in Figure 7. It has advantages over the standard 30-inch whip antenna in that it is body conformal and visually covert, not compromising the soldier's silhouette.

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IV. Smart Wearable and Implantable Disease Management Systems

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Executive Summary

The section focuses on implantable and wearable sensor-based systems and applications for personal disease management and rehabilitation.

Research and development in biomedical sensors during the last 15 years shows a clear design and performances evolution with different platforms such as in-vivo, biochip, on-body and breath monitors. Such sensors include cardiac mapping harnesses and ECG electrodes. However, in certain cases implant sensors are preferred; for example a multisensor silicon needle could enable early detection of myocardial ischemia during cardiac surgery. Another example is the CRT (cardiac resynchronization therapy) device for stimulation of the left and right ventricle; the integration of implantable sensors in the CRT for tracking several valuable clinical parameters like activity, heart rate and heart rate variability could provide quick and objective assessment of the progression of the heart failure and patient's physical status. These simple measurements could be used to guide cost-effective use of therapeutic interventions in order to prevent progression of heart failure and premature death.

Currently there are very few implanted, electronically driven medical devices available on the market mainly because of materials' limitation for encapsulation in the human body, limitation of data and power in the body and lengthy time to market. A number of core technologies, such as RF communications, power source and biocompatible material, for a specific range of implants, such as cochlear, retina, pressure and glaucoma sensors, have been identified and will be developed and validated within Healthy Aims, a European project.

The relevance of teletherapy, spanning from prevention to rehabilitation, in the new "integrated care" paradigm, is increasing. By mapping the clinical therapy to teletherapy, user-friendly computer-based applications could shorten hospitalization, accompany patients from the hospital to their home and enable more intensive training without increasing therapists' average work time per patient. The experiments that have been made with EvoCare, a teletherapy system based on personal training programs and patient status and performance monitoring in the area of neurological rehabilitation and orthopaedic prevention, show advantages for the involved patients and confirm previous results of telerehabilitation in regard with medical effectiveness and economical viability.

Rehabilitation and treatment could highly benefit from advances in materials, sensing and actuation techniques and haptic interfaces. Such example of cutting-edge research is the wearable upper limb artificial kinaesthesia system, intended to be used in post surgery and post stroke telerehabilitation. The wearable sensing system is obtained by printing a set of sensors and the connecting wires directly on the fabric. The actuating system, instead, is envisioned by using electroactive polymers as artificial muscle. Although at an early stage of implementation and testing, this development could revolutionise rehabilitation for large numbers of patient groups.

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Wearable and Implantable Monitoring Systems: 10 Years Experience at University of Ulster

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Abstract. Over the past 10 years or more, NIBEC and, more recently, Sensor Technology and Devices Ltd have been at the forefront of developments in sensor-related technologies which underpin a wide range of monitoring systems presently commercialised by leading multinationals. Systems developed/ commercialised include astronaut-monitoring arrays, cardiac mapping harnesses, ECG electrodes, Telemedicine systems and implant sensor arrays. This paper presents the main developments in this area and discusses outstanding issues for future research.

Introduction

The development of miniaturised, integrated sensor/electrode-based devices are revolutionising both the delivery of health care and the quality of environmental monitoring and remediation. In the medical arena, the widespread push towards faster, cheaper and more efficient diagnostic techniques is principally focused in the areas of ‘Point of Care’, Wearable and Implant Sensors. Over the past ten years, NIBEC at the University of Ulster (UU) and, more recently, a University spin out company, Sensor Technology and Devices have been pioneering key technologies associated with these exciting areas and have commercialised a range of innovative products.

1. Aerospace Harnesses

In 1990, NIBEC was approached by the Electrical Impedance Tomography (EIT) group at Sheffield to design an electrode harness for their EIT system. The electrodes were to be used in conjunction with the Sheffield system to monitor fluid shifts within an astronaut during the 1991 Anglo-Soviet space mission JUNO.

In order to obtain an Electrical Impedance Tomogram of a cross section through part of the body, impedance measurements must be made using an array of electrodes surrounding the part of the body under investigation, the number and relative position of the electrodes depending on the given E.I.T. system. The accurate individual application of

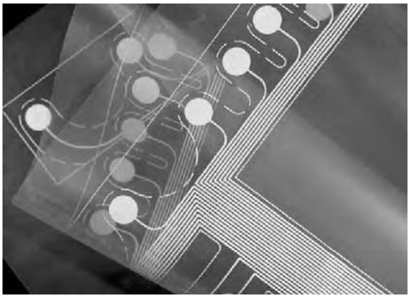

Figure 1. Printed Flexible substrate.

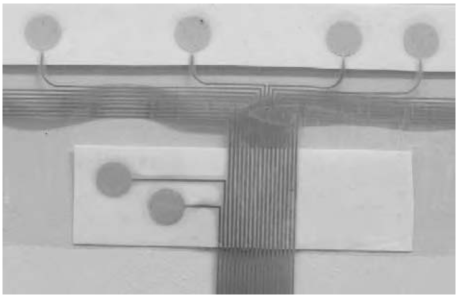

Figure 2. Assembled EIT Harness.

a large number of electrodes to a patient is tedious and time-consuming and would prove a major drawback to the routine clinical use of E.I.T.

Of interest to the E.I.T. work was an electrode system which

i) adhered the electrodes to the body;
ii) accurately located the electrodes in their correct positions
iii) was comfortable to wear under a space suit and
iii) accommodated variations in the body segment's contours or dimensions due to, for example, respiration or patient movement and
iv) gave rise to good electrical performances

In the NIBEC EIT harness, the sensors and leads were printed onto a thin (50 μm) flexible substrate using dielectric and silver-based serigraphic inks (Figure 1). In order to ensure optimal electrode performances, the 2cm diameter silver ink electrodes were chlorided electrolytically. [The use of serigraphic inks in medical sensors was still in its infancy and the Ag/AgCl inks available were less than optimal]. 'Solid', conductive, adhesive hydrogel pads were used, thus dispensing with the need for the traditional gel-impregnated sponges and retaining rings. The overall electrode harness was therefore very thin and flexible, with no hard components that could give rise to skin irritation problems.

The printed and gelled substrate was cut out in such a way as to form highly flexible "fingers" of printed substrate [1]. The electrodes were thus free to accommodate changes in inter-electrode spacing. A narrow band of stretchable adhesive foam was used to link the electrodes and thus served to maintain the correct initial inter-electrode spacings as well as to firmly adhere the complete system to the patient (Figure 2).

The NIBEC EIT electrode harness was successfully used to monitor heart and lung performances under microgravity conditions. The harness was later modified and used in the German-Soviet MIR '92 Space Mission to study muscle wastage.

Subsequently, the low profile, light weight, highly flexible NIBEC EIT harness also proved successful in the long term EIT imaging of ambulatory and bedridden patients [1].

2. Cardiac Mapping Harnesses

The serigraphic technologies pioneered for the aerospace missions were then further developed for more 'down to earth' clinical applications. A disposable ECG electrode was designed and patented in 1994 [2] and licensed to Tyco Medical and Meridian Medical. The electrode was/is marketed by several leading multinationals including Hewlett-Packard and NDM

NIBEC then developed a cardiac mapping harness which has been successfully commercialised by Meridian Medical [3]. Delays in accurate diagnosis are not only costly, but can be fatal. Current 12-lead technology, diagnoses less than 50% of heart attack patients, necessitating hospital admission and further testing. Meridian's PRIME 80-lead ECG system can detect significantly more heart attack victims within minutes (Figure 3). PRIME's rapid and accurate diagnosis is critical during the first several hours after a heart attack when treatment with thrombolytic agents, "clot-busters", can minimise damage to the heart.

UU pioneered the development of a portable Trans-telephonic monitoring electrode system that is marketed by SHL Telemedicine International Ltd and Philips Heart Care Telemedicine Services. The use of electrode gels poses considerable problems, either the gel dries out, the patient misplaces the tube of gel and/or physically gelling all the electrodes before application takes up too much time. The electrode harness therefore incorporates reusable dry electrodes [4], easily held on the chest in the correct location by the patient.

One commercialised system is a personal 12-lead ECG transmitter, designed for remote, real-time diagnosis of any electrocardiographic disturbance. The patient subscriber is provided with the Trans-telephonic ECG transmitter [Figure 4] and a lidocaine auto-injector. 24 hours a day, subscribers can call the monitor centre and, using any telephone or cellular phone, they can transmit a full 12 lead ECG to the dedicated monitoring centre, staffed by nurses under physician supervision, for the purpose of remote real time diagnosis of arrhythmia, ischemia, and MI. This real-time monitoring device has proven highly effective in encouraging patients to call for help and obtain diagnosis shortly after the onset of symptoms. This helps reduce irreversible damage to the heart muscle and mortality rates following a heart attack or other severe cardiac incidents

In order to further improve patient compliance, the dry electrodes and associated electronics were built into a standard leather wallet. The pocket system serves as a one-lead

Figure 3. Mapping Harness.

Figure 4. TransTelephonic System.

(rhythm strip) ECG transmitter for diagnosing heart rhythm disturbances. By simply placing the wallet and its electrodes against the chest and using any telephone or cellular phone, the user can transmit a real-time ECG strip to the remote monitoring centre within seconds for immediate diagnosis and advice

3. Sensor Technology & Devices Ltd

In 2001 a new University-based company was formed by the present authors. Sensor Technology & Devices Ltd. specialises in the application of sensor technologies to all aspects of physiological measurement. The corporate goal of STD Ltd is to identify and meet the needs of organisations for specialist sensors research, development and manufacturing. The company has been involved in developing innovative sensor-based devices in such areas as Vital Signs Monitoring, Labour onset prediction and an Electronic nose (MEMS based). The company has been accredited ISO 9001, ISO 13485 and EN 46001.

One of our projects in an advanced stage of development is the wireless-based V-Patch vital signs system. V-Patch is a small unobtrusive noninvasive device which measures, processes and transmits vital signs information to a monitor or processor up to 100 meters from the patient. The telemetry system, which will eventually be disposable, is an industry-standard, secure system which allows the patch to communicate with numerous devices including PDAs, PCs and mobile phones. Currently the vital signs measured are core temperature, respiration rate and ECG, but the electronics have been designed to integrate with our new generation sensors such as Ion Selective and blood sugar.

4. Point of Care sensors

Present trends in Biomedicine include exciting developments in what has come to be known as 'Point-of-Care Medicine'. Historically, most laboratory testing has been carried out in a remote, centralised laboratory and hence involves considerable time, manpower and expense. The demand for improved continuous analyte monitoring technology is growing in importance as government increases the pressure to reduce health care costs, maximise efficiency and reduce the length of hospital stays - without compromise to the quality of patient care.

Recently, there has been a rapid shift towards near-patient or 'point-of-care' testing of key analytes where a rapid 'turn-around' time is essential in the successful management of critically ill patients, especially during open-heart surgery [5]. Many advantages in this approach have been reported and it is progressively being introduced in to a wide range of 'non-life-threatening', patient monitoring applications. Sample volumes are generally very small as modern biosensors only require one or two drops of blood taken by finger pricking and the procedure is quick and convenient for patients. Continuous, 'point of care' monitoring is an important factor affecting 'quality of life' as it results in a huge reduction in the critical time taken between patient sample, analysis and therapeutic decision, thus facilitating on-going management of chronic disease. As there is no need to transport the specimen for remote testing, there is a reduced biohazard and practically no possibility of mix-ups between patients' results.

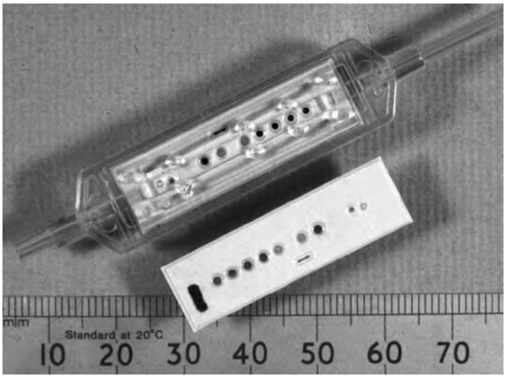

Figure 5. SenDx thick-film sensor system.

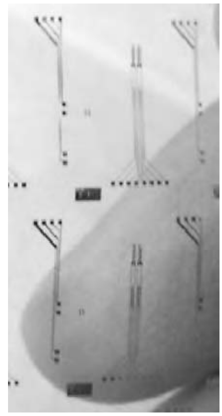

Figure 6. NIBEC flexible thin-film array.

Devices successfully introduced to the market include those of I-STAT and SenDx. These miniaturised laboratory systems are based on thick-film sensor technology and NIBEC staff were involved in the development of the SenDx sensor system [6] [Figure 5]. These thick film-based sensor systems incorporate an array of individually designed sensors capable of detecting specific analytes such as pH, pCO2, pO2, Na+,and haematocrit from whole blood. A small sample of blood, for example, flows past the sensors and all the parameters are measured in less than 60 seconds. Current research is addressing the roles of nanomaterials, nanotechnology and nonofabrication in aiding further developments in POC micro-moulded systems, integrated 'system-on-chip' sensors and revolutionary DNA diagnostic arrays

5. Implants

In certain instances, it may be desirable to further extend the 'point-of-care' monitoring concept and implant the sensor in the patient, temporarily at present and permanently in the future. NIBEC have been involved in several European research programs developing sensor arrays for temporary implantation into the heart during open heart surgery or during organ transport and transplant The MICROCARD device consists of a thin multisensor silicon needle for simultaneous measurement of transmural changes in the myocardial tissue impedance, extracellular K+ concentration and pH induced by acute myocardial ischemia. The device is to be used in the early detection of myocardial ischemia during cardiac surgery. In MICROTRANS a multifunctional silicon microprobe with integrated microsensors is implanted in the organ during transportation and key parameters are monitored continuously to ensure organ viability.

The use of thin film, flexible structures, in conjunction with the optimisation of the materials and processes used, will enable the fabrication of novel electrodes, which when implanted, will give rise to less mechanical irritation to the tissues, a reduction in the thickness of the fibrous encapsulation, optimised electrical performances and improved 'biocompatibility'. NIBEC has been developing flexible thin film impedance and ion selective electrodes on PTFE and polyimide substrates for a range of applications [7] [Figure 6].

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Artificial Kinesthetic Systems for Telerehabilitation

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Abstract. Artificial sensory motor systems are now under development in a truly wearable form using an innovative technology based on electroactive polymers. The integration of electroactive polymeric materials into wearable garments endorses them with strain sensing and mechanical actuation properties. The methodology underlying the design of haptic garments has necessarily to rely on knowledge of biological perceptual and motor processes which is, however, scattered and fragmented. Notwithstanding, the combined use of new polymeric electroactive materials in the form of fibers and fabrics with emerging concepts of biomimetic nature in sensor data analysis, pseudomuscular actuator control and biomechanical design may not only provide new avenues toward the realization of truly wearable kinesthetic and haptic interfaces, but also clues and instruments to better comprehend human manipulative and gestual functions. In this talk the conception, early stage implementation and preliminary testing of a fabric-based wearable interface endowed with spatially redundant strain sensing and distributed actuation are illustrated with reference to a wearable upper limb artificial kinesthesia system, intended to be used in telerehabilitation of post stroke patient.

1. Wearable Sensing System

In biological systems the intrinsic noisy, sloppy and poorly selective characteristics of individual mechanoreceptors are masterfully compensated by redundant allocation, powerful peripheral processing and efficient and continuous calibration though supervised and unsupervised learning and training. A truly biomimetic sensing system should have these features to some extent not just as a mimicking exercise, but as a result of solid engineering reasoning. Guided by these arguments we are investigating strain sensing elastic fabrics to realize adherent wearable systems with excellent mechanical matching with body tissues [1,2].

The innovative goal we have obtained consists in printing the set of sensors and the connecting wires directly on the fabric by using a carbon filled silicone rubber. This mixture shows piezoresistive properties and can be used both as sensors and as wires. By using this technology, no external cables are necessary to interconnect the sensors on the glove. The mixture we use is produced by WACKER Ltd (Elastil LR 3162 A/B) and is available on the market.

Since both sensors and interconnections are realized by galley proofs of the same mixture (Figure 1), and only the resistance values of the sensors are meaningful, the

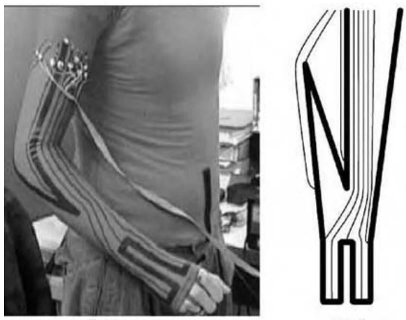

Figure 1. (a) A wearable upper limb kinesthetic interfaces. (b) The mask used to print sensors and wires on the fabric: The bold track represents the series of sensors; the thin tracks represent the connection wires.

sensing garments require an ad hoc reading technique to neglect the resistance variation of the wires [3].

The location and density of strain fabric sensors are factors in the hands of the system designer though appropriate textile techniques. Criteria for selecting appropriate spatial distribution of sensing elements, however, is a complex process since the root of the problem resides in solving an inverse problem which is (mathematically) ill-posed, not presenting a unique and stable solution. Heuristic and common sense reasoning can help in setting sensor allocation and assessing the level of redundancy required to cope with subject anatomical variability and relative displacement between the worn system and the body, inevitably occurring when the subject moves [4].

2. Wearable actuating system

Electroactive polymers as artificial muscle are under study in our laboratory. Electrostrictive polymers and dielectric elastomers possess excellent figures of merit as linear actuation strain up to 60 %, fast response time (down to tens of milliseconds) and sizable generated stresses (of the order of a MPa) [5]. The price for achieving these performances is the very high required electric fields (up to 100 MV/m). By assuming that the deformation in EP fibers, which work as capacitors, occurs under isovolumic conditions when an electric field is applied, it is possible to define the rest length (μ) of a fiber as the maximum length that it can assume without exerting forces. The rest length is controllable by setting the electric field and the fiber externs forces related to the differences between the rest length and the actual length, which is determined by the properties of the entire system in which the muscle is inserted. By supposing that what changes is the rest length and not the Young modulus, the relation between force and length in a fiber of this material can be expressed as ([6]):

$$f_b = EV_0 \left(\frac{1}{\mu} - \frac{1}{x} \right) u(x - \mu)$$

where x is the actual length of the fiber, u(t) represents the Heaviside's function, fb is the (elastic) force performed by a fibers, E the Young modulus, V0 the volume. Even if the curve represented by fb has a different behavior from the elastic characteristic of a biological muscle, according to the Feldman's model in the equilibrium point theory [7], the working principle is the same, and μ plays the same role of λ, the rest length of a muscle directly controlled by the central nervous system (CNS).

By realizing a parallel fiber bundle and by implementing a recruitment paradigm controlled by a local device it is possible to compensate the differences between the mechanical characteristics and allow the actuator phenomenologically behaving as a biological muscle. Two of these actuators, in an agonist-antagonist configuration, are so controlled by a couple of parameters (eventually time-varying) which in function of the muscular characteristic implemented by the local controller, impose position and stiffness of the mechanical system.

3. Upper limb artificial kinesthesia

The long-term goal of our research is to develop a family of wearable, bidirectional (sensing and display) haptic interfaces to be used in post surgery and post stroke rehabilitation (Figure 1). To achieve this distant goal several methodologies and techniques need to be developed in terms of sensing (tactile and kinesthetic), actuation and control. Skin like tactile sensors both for fine-form discrimination [8] and for incipient object slippage detection [9] have been investigated in our laboratory. In their original implementation, however, they are not usable as wearable, non-obtrusive devices. On the other hand, the technology described this paper may enable the realization of redundant systems of sensors and actuators in the form of wearable kinesthetic (not yet haptic) exoskeleton.

A few prototypes already realize by us [10] have shown reasonable capabilities to detect and monitor body segments position by reading the mutual angles between the bones. In particular, gleno-humeral joint, elbow joints, and the joints of the hand have been investigated. We have attributed three degrees of freedom to the shoulder (flexion-extension, adduction- abbuction, and rotation), two to the elbow (flexion-extension and pronation-supination), one degree of freedom for each interphalangeal joint of the hand, two to each metacarpo-phalangeal joint and two degree of freedom to the trapezium-metacarpal joint. Moreover, relative movements between matacarpal bones have been considered. In these early prototypes, sensors have been intuitively located in correspondence to each joint in a number equal to the degrees of freedom. In the new generation of prototypes, the strategy of redundant allocation is adopted and a large set of sensors is distributed over the garment. The adopted philosophy has been in a certain sense functional, i.e. the final aim of our work is to know which gesture a subject holds, and not which individual sensor has modified its status. From this point of view, redundant sets of sensing fabrics patches linked in different topological networks can be regarded as a spatially distributed sensing field. Existing interconnections allow one to drastically reduce the number of channels of the data acquisition system and, by simultaneously comparing the sensing field with the value of the joints variables in the identification phase, to reconstruct the posture in the data acquisition phase. By comparing data obtained in the identification phase with set of movements (known), it is possible to determine if adopted sensors allocation is appropriate. The emphasis of the method is anyway the observation of the global status of the system, comparing all the sensors simultaneously. The identification phase has been executed by having a subject wearing the sensing device and pointing by a handhold laser a lattice of markers fixed in a measurement environment. An entire set of sensor data has been recorded for each pointed position. This data have then been interpolated by a piecewise linear function. We have tested posture detection system over a second lattice (said of the target) in the space of the positions, where data obtained by the sensors have not been used to interpolate the piecewise linear function, but only to check the device accuracy. As an example, the reconstruction of a target related to the position of an arm will be reported. Abduction-adduction angle and flexion-extension angle of the gleno-humeral joint are reported respectively in the abscissa and the ordinate. Each piecewise line is the solution of the equations holding for significant sensors (responses from sensors which are not influential for the detection of this particular posture degenerate into the entire plane), projected from the entire space of joints variables into the plane of the coordinates of the shoulder. The estimated position is given by the intersection of these solutions. The distance between the calculated position of the target and the real one is of about 10 cm in a range of about 2.5 meters, that's an error less than 4 per cent. In other cases we have obtained larger errors, always less than 8 per cent [10].

At this stage of our work, biomimetic actuation has only been investigated in relation to an active glove. Two different muscle systems act on the hand: muscles that lie in the hand (intrinsic) or in the forearm (extrinsic). The extrinsic muscles realize flexion and extension of the fingers, while the intrinsics generate adduction/abduction of the fingers, stabilization and part of the opposition of the thumb. Muscles that lie in the forearm are connected to finger bones by long tendons. In order to emulate the functionality of the hand, we can choose to replicate the extrinsic system either by placing a certain number of actuators over the forearm or by covering the fingers of active fiber lying in the direction of tendons. In fact, the stress generated by the artificial muscles considered in the last section, may consent to generate the same force of human muscle with a considerable reduction in volume. Practically a set of three groups of fibers for each finger (replicating agonist and antagonist muscle to control position and stiffness) lies in correspondence of the flexor and extensor tendons to realize flexion and extension of the finger. The same results hold for the flexion-extension of the thumb. The technique we employ is an application of the matter described in [11].

4. Conclusions

In this paper we reported on an artificial kinaesthetic system developed in a truly wearable form using an innovative technology based on electroactive polymers. Although at an early stage implementation and preliminary testing, we envisioned a fabric-based wearable interface endowed with spatially redundant strain sensing and distributed actuation. This system is conceived for a wearable upper limb artificial kinesthesia system, intended to be used in telerehabilitation of post sroke patient. The wearable sensing system was obtained in printing a set of sensors and the connecting wires directly on the fabric by using a carbon filled silicone rubber. This mixture shows piezoresistive properties and can be used both as sensors and as wires. The actuating system, instead, was envisioned by using electroactive polymers as artificial muscle. Here we have tested the feasibility of a long-term research project aimed at developing a family of wearable, bidirectional (sensing and dispaly) haptic interfaces to be used in post surgery and post stroke rehabilitation.

Acknowledgement

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Implantable Medical Devices: Current Status and Future Developments within the Healthy-Aims Project

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Abstract. This paper describes the current situation concerning medical implants and suggests why the number of available devices is so limited. It then goes on to describe how a consortium was established from an EU network focussing specifically on Medical Devices. This consortium was successful in obtaining EU funding for the development of a range of medical implants that will help patients with specific disabilities relating to the nervous system, including deafness, blindness, lack of limb motion and urinary incontinence.

Keywords. Medical implants, Microsystems, biomaterials, NEXUS

1. Implantable Medical Devices: Current status

Currently there are very few implanted, electronically driven medical devices available for citizens in the EU and worldwide. There are a number of reasons for this. From the technology point of view, these include:

- Limited materials available that are suitable for encapsulation in the human body.
- No long life implantable batteries.
- Packaging and interconnect systems have not been developed for flexible 3D micro structures.
- Data and power in body communications are limited.
- Micro-structures, micro-sensors and micro-actuators have not been developed for medical applications.

From the clinical point of view the reasons simply are that:

- The system concepts developed by clinicians often cannot be produced due to lack of resources/access to the relevant technology providers.

And perhaps most importantly from the commercial point of view:

- The volumes are often low for different applications and hence are not of interest to large organisations.
- The time to market due to clinical trials and regulatory approval is long, which puts off large organisations and makes if difficult for SMEs to invest in.
- The regulatory procedure for obtaining approvals requires the highest quality standards within all organisations involved in the development of the product and is ex-

tremely labour intensive. Furthermore, it is often prohibitively expensive, particularly for SMEs.
- The risk is high.

Looking at the available products today most focus on applications relating to the heart and blood system, for example pacemakers. This is because research activities, including clinical research, has been well funded in this area, and the potential market is fairly large. As a result, the main players are large organisations.

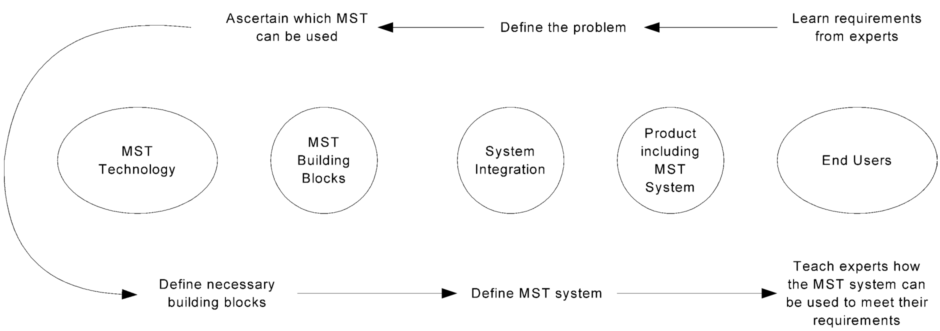
There are also a few other implants available including a cochlear implant for the profoundly deaf, and a bladder stimulator for people with no bladder control. More recently 2 types of artificial urethral sphincters for people with manual dexterity have become available, and most recently a simple 2 channel functional electrical stimulator (FES) implant for ‘Dropped Foot’ sufferers. These are mostly produced by SMEs in Europe, and have demonstrated that smaller high-risk niche markets can be successfully addressed by SMEs.

So how can the number of medical implants developed be increased? This question was put to the NEXUS Medical Devices User Supplier Club (USC) around 18 months ago [1]. This USC comprised at that time of around 100 members. These included academics and design groups with specialist expertise in micro and nano-technology, biomaterial experts, component manufacturers, medical device end user manufacturers and clinicians/surgeons. With this mix of skills and expertise the members were able to:

- Define what the end user, namely citizens in the EU and worldwide, require.
- Determine how the concept could be presented as a system.
- Break the system down into components.
- Design the components.
- Build the components into a system.
- Test the system in labs/animal trials/clinical trials.
- Obtain approvals.
- Market the product.

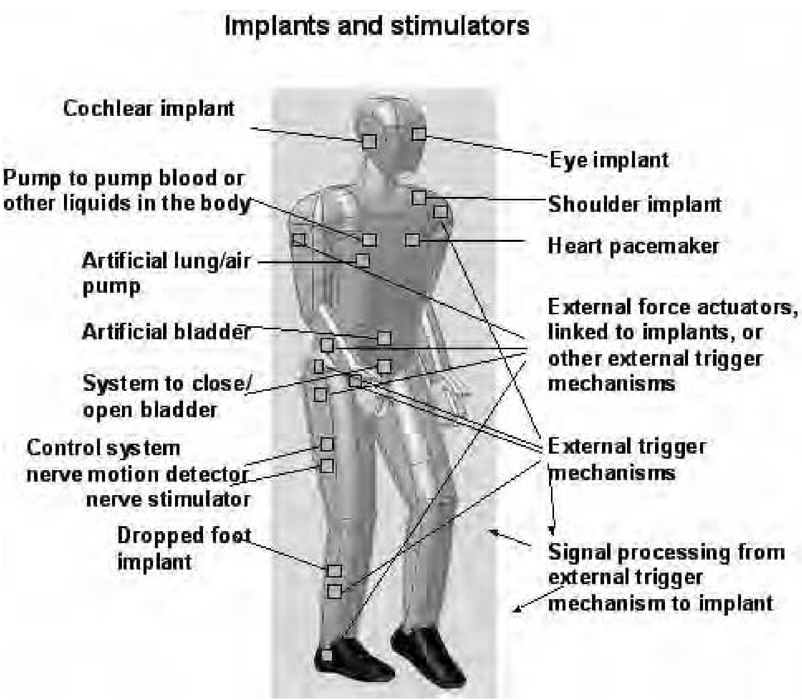
Collectively the network members had the necessary knowledge and expertise to be able to address all of the technical and clinical points defined. The next phase was to bring the members together to discuss the different potential medical implants that are not on the market, and then ascertain which concepts would make most commercial sense to the members.

A number of meetings took place when different concepts were discussed, as shown in the figure below:



During the discussions it became clear that there were a range of electrically driven medical implants that would utilise similar technologies, focusing on the nervous system. As a result it was agreed that a consortium would be put together that would develop the core technologies for a specific range of implants. The core technologies were defined as:

- RF Communications suitable for implanting into the human.
- Implantable power source.
- Biocompatible materials. This would include addressing the problem of maintaining electrical connectivity to the body in a stable manner for extended periods. There is a need for the device to do no harm, and for the body response to do no harm to the device
- Micro-electrodes to connect the power source to the nerves.
- Micro-assembly techniques for 3D, flexible structures requiring coating with biomaterials.
- Sensors and actuators to fit inside the body.



The products chosen were:

- Cochlear (enhancement over existing high cost for resolution system)
- Retina [2]
- FES for upper and lower limbs (enhancement over simple 2 channel ‘Dropped Foot’) [3]
- Artificial intra-urethral sphincter [4,5]
- Sphincter sensor [6]

- Pressure sensor for long term implant (>10 years) [7]
- Glaucoma sensor

The consortium was developed to address the entire project needs from basic research through to clinical trials and subsequent regulation approvals. Complementary skills in the core technologies were included to ensure that the products did not focus on using one technology but would develop a range of methodologies using knowledge from a number of key research areas.

2. The “Healthy Aims” project

The 26-partner consortium from 9 countries was successful in the first IST call under Microsystems. The Healthy Aims project started on 1st December 2003 and will run for 4 years. At the end of the 4 years some of the products will have completed pilot clinical trials whilst others will be ready for trials. It is also anticipated that as the project progresses new products will emerge, using the core technologies developed in the project. It is also anticipated that the Consortium will be able to embrace the process of obtaining regulatory approvals for new electrically operated implants far better than individual companies are able to do at present.

This project is an excellent example of how a well structured partnership, with experts in each of the areas can tackle highly innovative, high-risk topics. The medical sector is one area where the marketplace is well defined, and predictable. With new emerging technologies such as Microsystems, nanotechnology and biomaterials, the opportunities for developing a range of new medical implants is high. The Healthy Aims consortium firmly believes in this goal and 4 years from now will have a range of products to prove it.

The Healthy Aims project is also a prime example of how a network can produce strong partnerships, which will ultimately bring new products to the market. Partnerships like this include SMEs, LEs and academics, with no main driving force from any one sector. It is hoped that the networks developed within other NEXUS USCs including pharmaceutical, household appliances and systems for aerospace and harsh environments will be able to build and strengthen their partnerships to address these other key applications. Other complementary networks such as the UK Medical Devices Faraday Partnership, can also exploit this model for other medical applications, and provide a dissemination vehicle for the Healthy Aims deliverables/outcomes.

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The Role of Implantable Sensors for Management of Heart Failure

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Abstract. Heart failure is a chronic disease with significant morbidity and mortality worldwide. Drugs such as ACE-inhibitors, beta-blockers and diuretics have helped control heart failure but the incidence of hospitalizations remains high. Rigorous continuous monitoring of patients and tailored therapy based on individual clinical and hemodynamic profile has been shown to limit the symptoms of heart failure. Self-monitoring or prescribed frequent in-clinic monitoring is logistically difficult and is fraught with patient non-compliance. Consequently, implantable sensors that can monitor patient's clinical status on a continuous basis are desirable.

The disadvantage with an implantable sensor is obviously that the patient has to undergo an invasive procedure, which in itself has a certain risk, although minimal, associated with it. In addition, the risk of having an implantable device has to be weighed against the benefit of monitoring the patient on a continuous basis. The risk benefit question has been answered in part by the recent success of cardiac resynchronization therapy (CRT) in treating symptoms of heart failure. A recent study has performed a meta analysis on major heart failure trials conducted to date and concluded that CRT reduces mortality and morbidity. The CRT device is a specialized pacemaker with capabilities of continuous heart monitoring and embedded therapeutic decisions. A trend of heart rates offers significant insights into the progression of heart failure and patient status. In addition, using complex algorithms, several of the heart rate variability (HRV) parameters, identified in several studies for risk stratification and prognostication, can also be calculated. Furthermore, in recent devices based on heart rate intervals, autonomic balance (critical measure of progression of heart failure) can be estimated with sophisticated algorithms. Finally, technologies that can monitor patients' activity e.g. accelerometers, can be easily incorporated into the device. Such measures may be used to evaluate the efficacy of a new therapy or simply to provide patient status.

Based on advances in technology, several patient clinical features can be monitored and trended over time. The measured metrics will help form a comprehensive and objective clinical profile of the patient that the physician can act upon. Prospective studies are needed to answer the efficacy of such diagnostic measures in management of heart failure.

Keywords. Heart failure, sensors, cardiac resynchronization, bi-ventricular pacing, heart rate variability

Introduction

Heart failure (HF) affects about 5 million Americans, accounting for more than 550,000 diagnosed cases annually and more than 2 million hospitalizations each year [1]. Recent annual cost estimates range from $10 billion to $40 billion, accounting for approximately 2% to 3% of the national health care budget [2]. Currently, Medicare spends more on HF than it does on all forms of cancer combined. Data from World Health Organization suggest that the prevalence differs little around the world. Up to 50 million of the 1000 million people who inhabit the 47 Nations of the European Society of Cardiology may have a heart failure related problem [3]. HF is one of the few cardiovascular conditions with a clear increase in prevalence. This increase is an end result of an aging population and prevention of premature deaths from ischemic heart disease. The increasing prevalence of overweight, obesity and diabetes is likely to accelerate heart failure incidence. Despite the use of standard pharmacologic therapies, the mortality from HF remains high. Five-year survival after the diagnosis is only 25% in men and 38% in women [4]. In more severe disease, 1-year mortality approaches 30% to 50%.

In patients with mild to moderate HF the goal of the physician is to intervene early and attempt to reverse the process of cardiac remodeling and if possible slow progression of the disease. In addition the objective is to delay as much as possible the onset of the clinically de-compensated syndrome. Hospitalization for heart failure can be minimized by individualized therapy for patients based on their clinical and hemodynamic profile. Rigorous continuous monitoring of patient status through simple direct measures such as weight and symptoms has resulted in better outcome.

Heart failure patient status can be tracked through a variety of external sensors. Cardiac rhythm disturbances and exacerbation of HF during atrial fibrillation can be monitored with 24-hour Holter recorders. In patients with intrinsic heart rates, heart rate variability measures may be used to assess risks and offer prognosis. General patient activity can be recorded with pedometers worn at patient's hip or ankle and quantifies the activity level of HF patients [5]. With 3-axis accelerometers, total energy level expended by subjects can be calculated [6]. Recently, vests and shirts have instrumented with sensors to measure physiological data from ambulatory patients [7].

The disadvantage with external sensors is that they are unreliable, cumbersome and usually limit patient's normal day-to-day life activities. As such, patient compliance is a significant factor resulting in either brief measurement periods or frequently no data at all. Implantable sensors can overcome this limitation but the risk associated with implantation remains. Advances in technology and surgical techniques have minimized the risks with implantable devices. However the risk of surgical procedure and the implant has to be weighed against the benefits of the implantable device.

The risk benefit question has been partly answered by the recent success of cardiac resynchronization therapy (CRT) to treat symptoms of heart failure. CRT has been shown to improve functional status and reduce morbidity and mortality in NYHA class III/IV patients with wide ($\geq$120ms) QRS and systolic dysfunction (EF$\leq$35%) on optimal medical therapy [8]. The CRT device is a modified implantable pacemaker or defibrillator with the ability to stimulate and sense both the ventricles of the heart and restore synchronous contraction. With available microprocessor and memory the CRT device can also compute complex calculations using heart rates. In addition sensors such as accelerometer available in these devices for rate adaptive pacing therapy have potential applications in HF diagnosis.

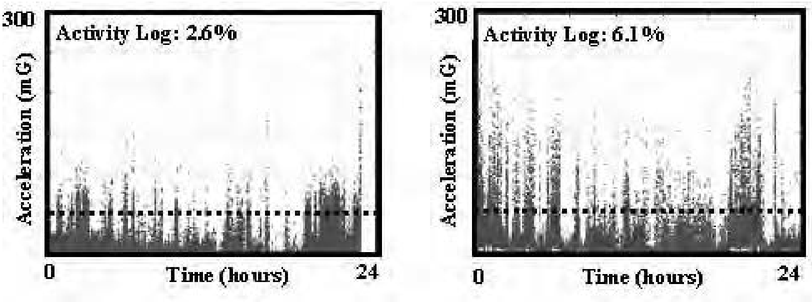

Figure 1. 24-hour acceleration signal recorded on a HF patient before CRT (left panel) and 3 months following CRT (right panel). The dotted line indicates the threshold.

1. Implantable Sensors

1.1. Activity Tracking

A measure of physical activity is an important determinant of patient status. Sub-maximal and maximal exercise capacities of patients have been used frequently to assess patient status. Evaluation of status is useful to assess efficacy of new therapies or help decide whether an intervention is necessary. The 6-minute walk distance (WD) test has been used to assess sub-maximal exercise capacity of patients with heart failure [9]. Although the walked distance has been shown to predict all-cause mortality and hospitalization rates, the WD can only be monitored periodically and is influenced by several factors, including patient motivation, coaching, familiarity with the test, and anatomic limitations.

Accelerometers placed within a CRT device can track patient activity and measure acceleration on a continuous basis. A plot of a 24-hour acceleration suggesting a circadian pattern is evident is shown in Figure 1. The activity log parameter was defined as the percentage of time the acceleration exceeded a certain threshold. To determine the threshold that most accurately identified activity in a HF population, a retrospective analysis of accelerometer data from a subset of patients was performed; a threshold that optimally correlated changes in activity log with changes in WD was selected. This threshold was found at 50 mG (0.49m/s^2), which corresponds to treadmill walk speeds of about 2.0 mph and 2.8 METs. The threshold was then used to test whether activity log can be used to track the changes in HF patients observed with CRT. The sensitivity, specificity, and accuracy of the Percent of Day Active [10] to predict changes in WD were 84%, 73%, and 83%, respectively. The positive and negative predictive values were 95% and 44%, respectively. This activity log is highly sensitive in detecting patients' physical activity, and may be clinically used to continuously monitor the daily activity of patients with heart failure.

1.2. Heart Rate Trending

Heart rate (HR) is a critical vital sign in prognosis of heart failure. Beta-blockers are closely titrated in HF patients to reduce heart rate and thus decrease cardiac energy consumption. Mean heart rate has been shown in several heart failure trials to be of prognostic value. Auricchio et al., [11] reported that CRT produces a long-term improvement in the clinical symptoms of patients with HF who have ventricular conduction delay. In this study which consisted of forty-one patients, CRT treatment resulted in significant decreases in the mean heart rate (from 77 +/- 12 bpm to 73 +/- 12 bpm, p = 0.01) and minimum heart rate (from 63 +/- 14 bpm to 57 +/- 13 bpm, p = 0.003). Consider the 24-hour 1-D histogram of cardiac cycle length for Class I vs. Class III-IV HF. The shortened average cycle length in Class III-IV is apparent as well as the loss of the bimodal structure and lower average 24-hour HR evident in Class I in Figure 2 below.

A continuous trend of a patient's minimum, mean and maximum heart rate can provide the physician an instantaneous snap shot of patient status and help guide therapy as in Figure 3. In order to appreciate both the long and short term effects of the therapy, a weekly averages for 51 weeks and a daily measure for 7 days is presented in CRT devices [10].

1.3. Heart Rate Variability

HF is associated with autonomic dysfunction, which can be quantified by measuring heart rate variability (HRV). Adamson et al. [12] found that CRT positively impacts cardiac autonomic control and results in less sympathetic dominance. In this study, HRV was higher in patients randomized to CRT-on compared with CRT-off. In a prospective study (UK-HEART) Nolan et al., [13] showed that a reduction in HRV parameter (SDNN) identifies patients at high risk of death and is a better predictor of death due to progressive heart failure than other conventional clinical measurements. SDNN is mea-

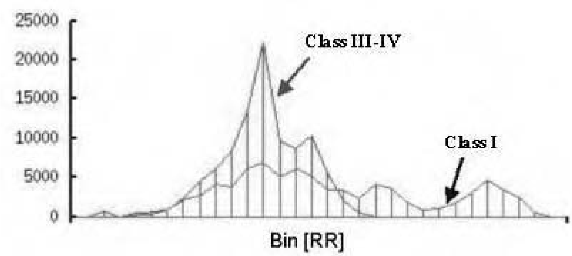

Figure 2. 1-D Histogram of cardiac cycle length for Class I vs. Class III-IV in HF.

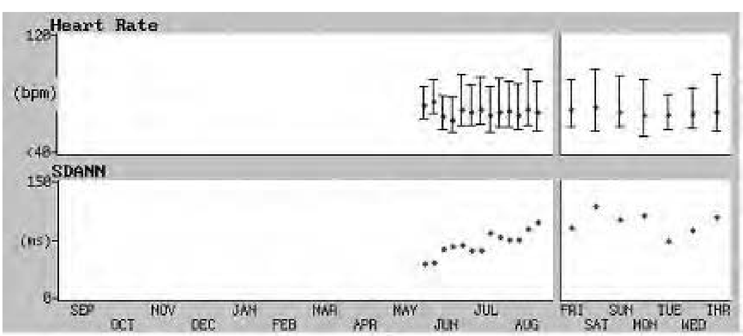

Figure 3. The trend of heart rates and SDANN in a HF patient after 3 months of CRT. The left panel indicates weekly averages and right panel provides daily averages [10].

sured as the standard deviation of all normal-to-normal RR intervals in the entire 24-hour recording. SDANN correlates highly (r^2>0.9) with SDANN- Standard Deviation of Averaged Normal R to R intervals (SDANN). In PATH-CHF [11], significant increases in heart rate variability (SDANN from 90 +/- 29 ms to 117 +/- 35 ms, p = 0.001) were observed. The CRT device monitors electrical activity of the heart and this can easily compute R-R intervals. Unlike an external Holter device, the CRT device can better filter abnormal intervals from premature atrial/ventricular contractions. SDANN is specifically calculated using 288 5-minute segments (24-hours) of intrinsic intervals. The SDANN is the standard deviation of the averages of intrinsic intervals in the 288 5-minute segments. The results for SDANN are presented in a similar manner to heart rate in Figure 3 above.

The results of UK-HEART demonstrate that 24-hour ambulatory ECG with measurement of SDNN and arrhythmias provides important prognostic information when combined with a small number of other simple measurements in symptomatic HF. An SDANN of 100 ms, particularly when associated with renal impairment or hyponatremia, identifies patients at increased risk of death due to progressive heart failure. High-risk subgroups identified by this measurement are candidates for additional therapy after prescription of an ACE inhibitor [13].

1.4. HRV Footprint Histogram

There is benefit to visualizing HR and HRV together in a compact fashion, particularly in HF. By jointly evaluating the structure of HR with HRV, new insights emerge particularly in the area of functional exercise capacity as in Figure 4.

The HRV Footprint Histogram is a rendering of the joint probability density of instantaneous cycle length with associated adjacent cycle length changes calculated over a period of 24 hours. All adjacent normal cardiac cycle interval pairs are mapped into a two-dimensional sample space S. Each event outcome is Ei = (RRi,|ΔRRi|) where ΔRRi = | RRi – RRi-1 | and is binned in a compressed logarithmic fashion. The histogram gen-

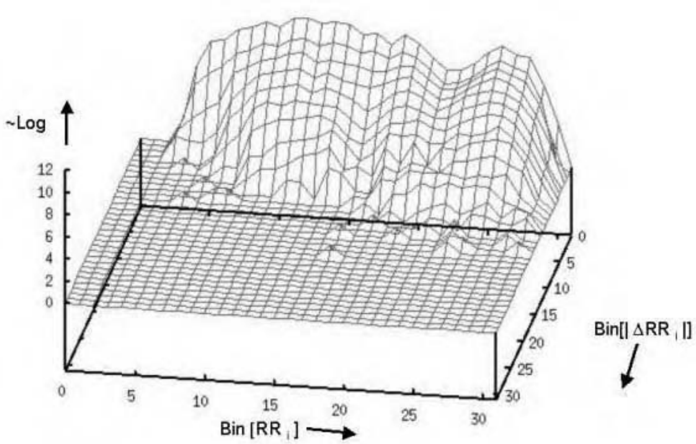

Figure 4. The HRV Footprint Histogram displays the joint density of RR interval vs. |ΔRR| interval. The vertical axis follows a logarithmic mapping.

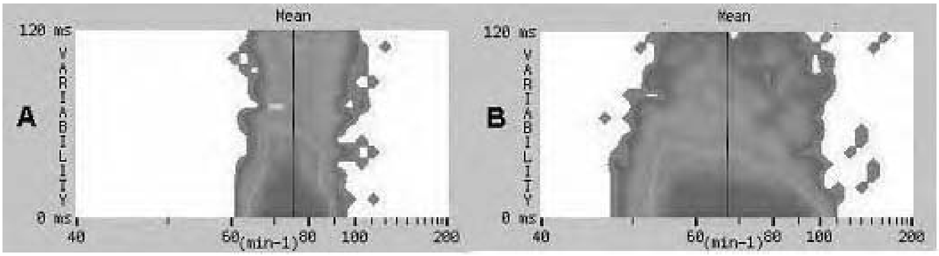

Figure 5. HRV footprint in a patient before CRT therapy (Left Panel) and after 3 months of CRT therapy (Right Panel). Note the decrease in mean and minimum heart rate and the increase in footprint area [10].

erates what is referred to as the HRV Footprint and includes information about SDNN, SDANN, rMSSD as well as minimum mean and maximum heart rate over a 24-hour period. This gives a compact, direct At-A-Glance measure of HRV and reveals a joint structure of HR and HRV. Patients in heart failure exhibit a constrained range of HR over 24 hours with an associated constrained range in sinus HRV overall. Healthier patients show a wider swing in minimum to maximum 24 hour HR with increased HRV overall. Healthier patients and patients responding to CRT present more variability at lower HR. In these same patients, less variability is observed at higher HR. This joint structural relationship between HR and HRV tends to break down in heart failure.

1.5. HRV Footprint

HRV Monitor Footprint, derived from the Footprint Histogram, is an image based rendering of the likelihood of a particular beat-to-beat heart rate (HR) change (variability) occurring at each intrinsic sinus rate during a 24-hour period. The color map depicts the relationship between HR (x-axis) and HR variability (y-axis). The frequency (3rd dimension) of each HR and variability occurrence is indicated by color; red and orange (more frequent), blue and gray (less frequent). HRV Footprint provides compact graphical insight into the frequency and daily values of beat-to-beat variability and maximum, minimum and mean HR values [14] as in Figure 5 [10]. For example, in 1998, Carlson [15] found that changes in the HRV footprint area correlated with changes in peak oxygen uptake (VO_2max), R=0.88, P<0.05. Footprint area is defined as the area occupied by all non-zero pixels in the main lobe of the distribution. This relationship between HRV Footprint and VO_2max was stronger than that for SDNN or rMSSD as has been reported by other researchers such as [16] or [17].

1.6. Autonomic Balance Monitor

Heart Failure is a condition of generalized neuro-hormonal excitation characterized by sympathetic activation and parasympathetic activation [18]. In addition, studies have shown that sympathetic activation is a predictor of survival in heat failure patients. The annual mortality in patients with > 800 pg/ml is in excess of 70% [19].

Spectral analysis of HRV provides insight into the autonomic modulations of heart rate. The high frequency (HF) component is a marker of parasympathetic or vagal activity. The low frequency (LF) component of HRV is influenced by sympathetic and

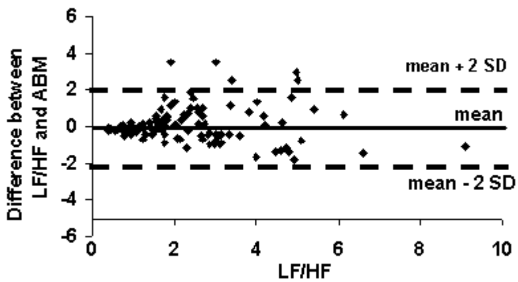

Figure 6. Bland-Altman plot of the difference of LF/HF ratio and ABM.

parasympathetic activity. The ratio of these two components or LF/HF ratio is set to measure of sympatho-vagal balance or sympathetic modulations [20]. Spectral analysis of HRV has been used to characterize the autonomic imbalance in chronic congestive heart failure [21]. While the spectral analysis is beyond the current device technological capabilities, a statistical surrogate of LF/HF ratio has been successfully implemented in implantable devices.

The LF/HF Ratio is defined as σ^2LF/σ^2HF, where σ^2LF is the variance in the 0.04 to 0.15 Hz frequency band and σ^2HF is the variance in the range of0.15 to 0.40 Hz. Cardiac cycle data are input to the autonomic balance monitor (ABM) calculation. The algorithm is implemented as follows: ABM $\cong$ surrogate[σ^2LF]/surrogate[σ^2HF]. The surrogate for σ^2LF is the difference between the 7-second normal cardiac cycle interval variance and the 25-second normal cardiac cycle interval variance. The surrogate for σ^2HF is defined as the familiar rMSSD metric squared.

ABM is the difference between the 7-second normal-RR interval variance and the 25-second normal-RR interval variance divided by the square of rMSSD. This is a new approach to tracking the change in the LF/HF ratio that occurs with a therapeutic intervention such as CRT. Using the Bland Altman plot, the error for the estimation of LF/HF ratio using ABM was found to be less than two standard deviations for most of the points as in Figure 6.

2. Conclusion

Implantable sensors in a CRT device can track several valuable clinical parameters that help assess the status of a HF patient. Prospective studies are necessary to determine whether these simple measurements can be used to guide cost-effective use of therapeutic interventions designed to prevent progression of heart failure and premature death.

Acknowledgements

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EvoCare: A New Standard in Tele-Therapy

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Abstract. The necessity for Integrated Care has been debated controversially and the influence of the legislator and the consequences for the medical device industry discussed sufficiently. In fact, the German health system has been suffering from a lot of problems like cost expansions, but only solutions and not discussions can bring a progress. EvoCare has established a new standard in tele-therapy in Germany. This has been possible because this system maps the clinical therapy process to tele-therapy (and not vice versa), it is extendable for virtually any medical field of application, and the user interface is kept so simple that people inexperienced with computers and even with motor deficits are able to use it. Accompanying the patients from the hospital to their homes, EvoCare allows for shorter hospital stays without loss in treatment quality and more intense training without increasing therapists' average work time per patient. The experiences that have already been made with the described system, especially in the area of neurological rehabilitation and orthopedic prevention, underline its advantages for all involved partners.

1. Integrated Care

The necessity to introduce workable solutions for Integrated Care to the field of healthcare is beyond controversially. Concerning the terms 'Integrated Care', 'Disease Management', 'Homecare' or 'Center of Competence' medical technology agrees on the importance of introduction. Seldom, however, is it possible to find a feasible concept, a commonly recognized approach or even an existing and at the same time profitable example. Instead, a lot of energy has been used to discuss expenses and the medical economy. The influence of the legislator and the supposedly negative consequences for the readiness of the medical device industry to invest has been debated over and over. Only the solutions, the answers to how, what and with what remain unresolved, which still has its dimension that is the quality of medical care and the financial means at its disposal.

1.1. Frequency of Treatments Determines Quality of Care

A discussion about the quality of medical care is certainly a controversy and cannot be the topic at this point. It is a fact that the frequency of treatments is an essential for the increase in quality of medical care in the areas of prevention, rehabilitation and aftercare. Frequency of treatments in this context means the frequency of patient observations with regard to prevention, the frequency of therapy in rehabilitative areas and the frequency of training sessions in aftercare. In this context cost reductions are often equated

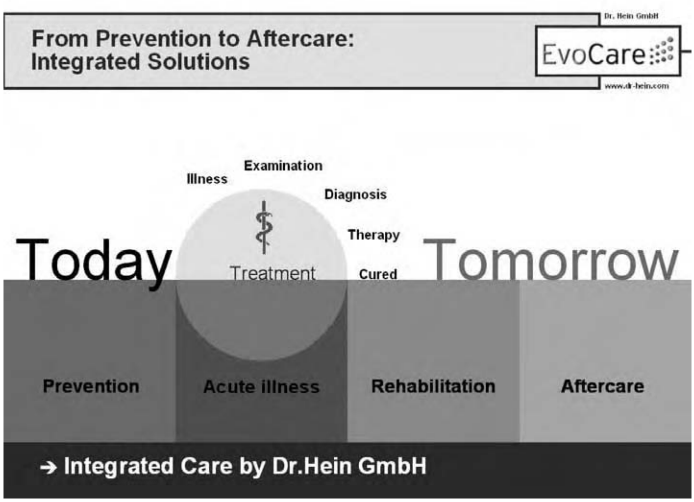

Figure 1. Integrated Care – Categories.

with cutting short a patient's hospital stay and thus seem to impede a better healthcare. But shorter hospital stays do not necessarily have to lead to an impairment of care, on the contrary. Using a sophisticated system of Integrated Care at home, the frequency of treatments can be greatly increased despite a shorter hospital stay.

1.2. What Does Integrated Care Mean?

The meaning of the term 'Integrated Care' in a medical context is explained best by two definitions: When we observe the 'development' of an acute case it is mainly encompassed by the areas of prevention, rehabilitation and aftercare. The Integrated Care ideally combines the phases displayed in Figure 1 around the acute case.

According to this, the integrated care considers the current treatment, whether preventive, acute or rehabilitative, in the complete process of care and consequently integrates all the necessary 'Treatment Phases'. The second, by far more important definition of Integrated Care describes the integration of the patients in the process of the treatment (Figure 2) in their home environment. Within a conventional treatment process the therapist develops an individual training plan with his patient, who exercises in the presence of the therapist. The therapist in turn supervises the patient during the complete workout phase and modifies the exercises if necessary.

2. The EvoCare System

Since 2001, Dr. Hein GmbH has been providing an open tele-therapy platform under the trademark "EvoCare". The underlying concept comprises three main ideas:

First of all, therapy should be mapped to tele-therapy as exactly as possible. This means that the whole treatment circle – consisting of prescription, implementation, evaluation and adaptation – has to be maintained. Secondly, the system must be open, i.e. there must be a common platform, which can be extended by application-specific therapy

Figure 2. Integrated Care – Process.

modules, so called plug-ins. And finally and most importantly, it has to be designed in such a manner that therapists and patients can use it without being computer specialists.

2.1. Phases of the EvoCare Process

Meeting these requirements, the EvoCare platform has become a well-accepted tool for treating inpatients and outpatients as well as patients in their homes. Being used in about 20 medical facilities, EvoCare has established a new standard for tele-therapy in Germany.

This therapy approach can be referred to as a kind of "conveyor belt" as depicted in Figure 3. Starting at an early stage in the hospital, the appropriate therapy plug-ins and training intervals are determined with respect to the patient's anamnesis and diagnosis (phase Ia, see Figure 3). The patient is then instructed and shown how to use the system (phase Ib), enabled to autonomously train later on, asynchronously supervised by the therapist (phase II). Leaving the hospital, the patient does not abort the training abruptly but continues at home, still supervised by the therapist (phase IIIa). This allows for shorter hospital stays and better outcomes. Even if no further treatment is needed, the EvoCare platform can contribute to an improved health care by providing a channel for monitoring and further education of the patients (phase IIIb), e.g. in order to avoid relapses.

2.2. The Application of EvoCare

The described treatment process is divided into different phases and including the integrated system EvoCare:

1) The therapist gets to know the patient and develops an individual workout-program (Figure 4) at his/her therapist-workstation. Doing so, the therapist can choose from a large pool of exercises in the areas of neurology, cardiology and orthopaedics which can easily be modified to meet the patient's individual requirements.

2) The individually created training plan is provided to the patient via a protected network on a secure server. Using a personal check-in card (Figure 5), the patients gain access to their exercises (Figure 6) and thus can execute them on their own. Figure 7

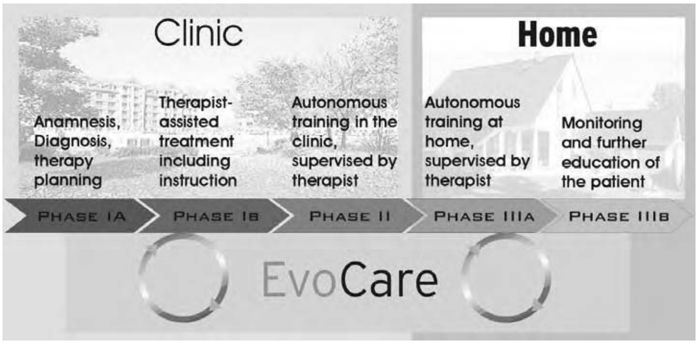

Figure 3. Phases of the Therapy Process.

Figure 4. Creating an individual workout-program.

Figure 5. Check-in.

Figure 6. Individual workout-program.

Figure 7. Example of a linguistic exercise.

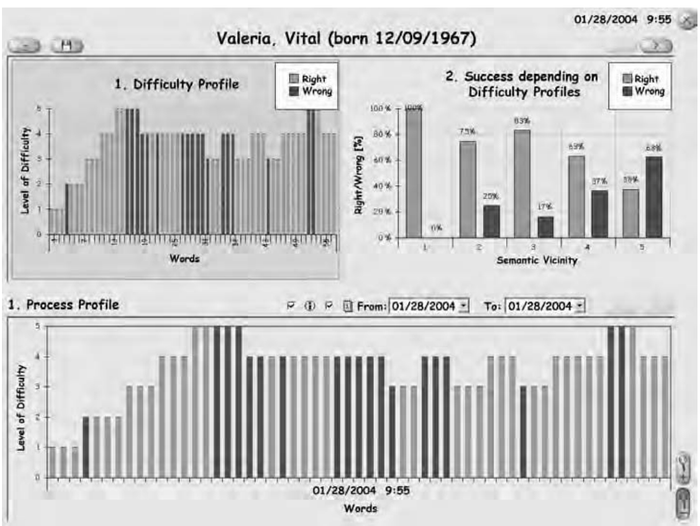

Figure 8. Results.

shows an example of therapy plug-in exercise; it is a linguistic exercise in which a written word is presented and the patient has to find (and click on) the corresponding picture. The button on the top can be used to get acoustical help (so, in this case, ”belt” would be spoken). The bottom-left button sets the system to pause mode (for instance, if the phone is ringing or the patient has to got to toilet), the bottom-right button can be used to abort the exercise before the prescribed exercise time is over (the therapist will be notified about this). In the same way any other exercises, for instance ergometer training, can be executed and monitored, if there’s a corresponding plug-in (software) and suitable sensors (hardware).

Patients cannot do more exercises than prescribed which guarantees a reasonable therapy process always supervised by the therapist.

3) After an autonomous training by the patient the results of the session are automatically transferred to the therapist's computer. The therapist can analyse and evaluate the results (Figure 8) and adjust the training plan.

3. Advantages for All Involved Partners

The experiences that have been made with the described system so far, especially in the area of neurological rehabilitation and orthopedic prevention, underline its advantages for all involved partners.

After the feasibility had been proven these experiences are presently confirmed by scientific studies in regard to their medical effectiveness and economical validity. Patients who have familiarised themselves with the system in the hospital can now train anytime as well as do familiar exercises at home under tele-medical supervision. The contact to the therapist in the hospital that is maintained through the system has a positive effect on the patient's motivation.

Using EvoCare holds another, often underrated advantage for the patients. They are proud to be able to work with such a progressive system and feel "upgraded". The question still remains what advantages hospitals take by the use of such systems. The described system permits the abolishment of the currently predominant 1:1 situation (therapists- patients). Now therapists can attend four or even more patients simultaneously – thus the ratio changes to an at least 1:4 situation. Furthermore the patients can be cared for in their home environments – a stronger bond between patient and hospital is created. In consideration of the above mentioned quality of health care, EvoCare for the first time supplies criteria (measurement results) for the objective evaluation of the patients and their progress of treatment. The billing transparency through detailed presentation of numbers of treatments, intensity, duration and results facilitate retracing and monitoring of the treatment expenditure by the cost bearer. In addition, it is possible to outsource routine tasks and to accelerate rehabilitation procedures.

Patients train independently of the treating physician, while their convalescence makes vital progress in best time. Thus they become 'fitter' within a shorter period of time. The higher frequency of treatments concurs with the simultaneous creation of measurement results, which help as detailed evaluation basics to secure the quality effectively. For the first time the progression of the treatment can be recorded continuously throughout the entire therapy. Evaluations can be based on these data and are confirmable at all times. This is a significant step in the direction of the demand for quality.

4. Conclusion

EvoCare provides a common tele-therapy basis for virtually any field of medical application. While in the fields of neuropsychology and neurolinguistics the computer itself can be used to measure the patient's capabilities, for the fields of cardiology and orthopaedics there's still a need for innovative sensor devices suitable for use at home. Besides tele-therapy, home monitoring is a promising application area of the presented system; in this respect the latest developments in wearable sensors are offering interesting perspectives for the future.

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V. Biomedical Clothing

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Executive Summary

This section provides an overview of the most advanced, global eHealth systems and applications based on biomedical clothing. The papers demonstrate how the integration of multiple disciplines, spanning from textile fibres to biomedical sensors, to wireless and mobile telecommunications and to signal processing and telemedicine, can lead to personalized and ubiquitous health and healthcare management.

Biomedical clothing systems have the capability to provide a safe, effective, patient-centred, timely, efficient and equitable care event cross-border and can be a key enabling technology to meet several healthcare challenges such as reduction of medical errors, prevention through life style monitoring, life saving through early detection and timely intervention.

The wearable motherboard or “SmartShirt” is a pioneer in this field. It is an intelligent garment integrating sensors for monitoring vital signs such as heart rate, electrocardiogram, temperature, pulse oximetry, voice capability, a data controller and a data display and management system. The foreseen applications of SmartShirt in healthcare are sudden infant death syndrome, geriatric care, post-surgery rehabilitation, mental health, drug delivery and pharmaceutical trials

VTAM is based on a similar concept and technology design. It is an underwear t-shirt made from textile with woven wires, incorporating ECG electrodes, breath rate sensor, shock fall detector and temperature sensors, for continuous ambulatory real time monitoring of the patient status. Future developments target a higher level of electronic integration and optimization of power consumption with the objective to design a generic technology for biomedical clothing, which would be at once comfortable, hygienic and resistant.

WEALTHY is pioneering another innovative approach for the development of biomedical clothing. It is based on the use of standard textile industrial processes to realize the sensing elements. Transduction functions are implemented in the same knitted system where movements and vital signs are converted into readable signals, which can be acquired, processed and transmitted. Electrodes and bus structure are integrated in textile material making it possible to perform normal daily activities while the user’s health status is monitored by a specialist in a non-obtrusive manner. WEALTHY’s target groups include chronic patients, post operative rehabilitation and professionals at risk.

Recently, wearable sensing technology and new materials have also been integrated into fabrics for analyzing posture and gesture and monitor body kinematics. The targeted applications are very important, e.g. rehabilitation, sport medicine, ergonomics and falling. Such systems are presented in this section and include a “sensing glove” able to detect the posture and movements of the hand and the “intelligent knee sleeve”, a wearable textile sensor that can provide an immediate biofeedback to the wearer with respect to knee joint motion in the sagittal plan during dynamic tasks. Finally, a system for gait analysis developed for the detection of pathological conditions and well as for the detection and mitigation of falls in the elderly is presented.

Other aspects presented in this section are those related to the use of smart clothing by disabled and elderly people and to the “clothing area networking”, addressing concepts and technologies needed to enable data and power transfer between different modules integrated into the smart clothing system.

The integration of the technologies into a real intelligent biomedical clothing product is at the present stage on the threshold of developing prototype systems. Several issues, technical as well as medical, remain to be solved before the complete clinical validation. Among the most important challenges are the production of higher conductivity textile material according to current industrial processes, as well as the interfacing and protection of electronic components. Along with these challenges, the cleaning and washing issues have to be solved. Further research is required also in signal processing, data interpretation, user acceptance, cost effectiveness, product adaptation, market segmentation and business models.

Wearable eHealth Systems for Personalised Health Management
A. Lymberis and D. de Rossi (Eds.)
IOS Press, 2004

e-Health and Quality of Life: The Role of the Wearable Motherboard

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Abstract. It is hard to place a price tag either on human life or on the quality of life. Technology is the key to enhancing the quality of life for everyone in the continuum of life from newborns to senior citizens – whether it is the safe delivery and care of undernourished premature babies, or extending the life of a senior citizen through exploratory treatments and procedures. Technology has the potential to rapidly transform healthcare and the practice of medicine by improving the quality and safety of patient care and increasing the efficiency of healthcare providers. Moreover, the healthcare industry must meet the challenge of balancing cost containment with maintenance of desired patient outcomes and this can be accomplished through the adoption of technology. Any technology that can minimize the loss of human life and/or enhance the quality of life has a value that is priceless.

An overview of the key challenges facing the practice of medicine today is presented along with the need for technological solutions that can "prevent" problems. The paradigm of "e-Health" is discussed. Then, the development of the Wearable Motherboard as a "platform" for sensors and monitoring devices that can unobtrusively monitor the health and well-being of individuals (directly and/or remotely) is described. This is followed by a discussion of the applications and impact of this technology in the continuum of life – from preventing SIDS to facilitating independent living for senior citizens. Finally, the future advancements in the area of wearable, yet comfortable, systems that can continue the transformation of healthcare and e-Health to *i*-Health (for *interactive* health) – all aimed at enhancing the quality of life for humans – are presented.

Introduction

It is hard to place a price tag either on human life or on the quality of life. Lack of access to affordable and high-quality healthcare is dramatically affecting the quality of life for individuals. According to a recent US Institute of Medicine report, "The uninsured have poorer health and shortened lives. The number of uninsured, 43 million, is as large as the total populations of 26 states combined" [1]. In another study, the Institute of Medicine concluded "The U.S. healthcare delivery system does not provide consistent, high-quality medical care to all people" [2]. In short, this represents a *silent* crisis that is dramatically affecting the quality of life for individuals – *silent*, because it doesn't have the violent and sudden devastation of a terrorist attack. Nevertheless, the long-term implications of lack of quality healthcare on society are significant: The economic vitality

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of a nation is limited by the poorer health, premature death and long-term disability of individuals without proper access to healthcare [1].

1. The Healthcare Challenge

Consider the following facts:

- Healthcare spending in the U.S. increased for the sixth straight year in a row to $1.6 trillion in 2002, representing a 9.3% increase over 2001 figures [3]. In 2000, healthcare spending totaled $1.31 trillion.
- As a percentage of GDP, healthcare spending increased from 13.3% in 2000 to 14.9% in 2002 [3].
- More than 43 million Americans reported being uninsured throughout 2002 and millions more lack coverage for shorter periods. The value in healthy years of life gained by providing coverage to everyone would almost certainly be greater than the additional cost of providing healthcare, at the level of those currently insured, to those who lack coverage [1].
- Experts estimate that as many as 98,000 people die in any given year from medical errors that occur in hospitals. That's more than die from motor vehicle accidents, breast cancer, or AIDS (acquired immune deficiency syndrome) – three causes that receive far more public attention. Indeed, more people die annually from medication errors than from workplace injuries. Add the financial cost to the human tragedy, and medical error easily rises to the top ranks of urgent, widespread public problems [4].
- Seven major diseases accounted for 80% of deaths in the U.S. in 1990: heart disease, cancer, diabetes, arthritis, chronic bronchitis, influenza and asthma [5]. For many of these health conditions, *early, systematic intervention* would be highly beneficial.
- With universal access to information (e.g., through the Web), today's healthcare consumer is demanding more options and taking control in determining the course of healthcare.

Thus, the healthcare industry is facing a set of significant challenges on several fronts, viz., availability (or access), quality, and cost. At the same time, there is a real opportunity for the healthcare industry: According to Andy Grove, the Chairman of Intel Corp., the healthcare industry is facing an Internet-driven "strategic inflection point" or a time in which extreme change forever alters the competitive landscape of an industry, creating new opportunities and challenges [6].

2. Responding to the Healthcare Challenge

To respond successfully to the set of challenges, the healthcare industry must:

- Reduce healthcare costs while maintaining the high quality of care.
- Provide access to care for as many people as possible.
- Provide easy access to specialized professionals *anywhere* and at *anytime*.
- Shift the focus of healthcare expenditures from *treatment* to *prevention* through wellness programs.

- Control length of hospital stay and *decentralize* the provision of healthcare
- Address the increase in the aging population and caring for chronically ill patients.

Thus, the healthcare industry must meet the challenge of balancing cost containment with maintenance of desired patient outcomes.

3. The Need for Improvement and Change

To meet this set of growing challenges, healthcare professionals are trying to provide patient care more efficiently, and whenever possible, in the least expensive setting, throughout the *continuum of care* – be that an ICU (intensive care unit), a hospital general care unit, a skilled nursing facility, an outpatient clinic or a patient's home. This has created a demand for portable, versatile medical devices that can be moved easily from the ICU all the way to a homecare setting [7]. Also, there is a critical need to enhance the physician's abilities to successfully address even the most seemingly desperate of situations whether it is the safe delivery and care of undernourished premature babies, or extending the life of a senior citizen through exploratory treatments and procedures.

3.1. Six Aims for Improving Healthcare

The Institute of Medicine has underscored the need for a "national statement of purpose" for the healthcare system as a whole and has identified six key aims for the improvement of healthcare. These include a healthcare system that is *safe*, *effective*, *patient-centered*, and provides *timely*, *efficient*, and *equitable* care that does not vary in quality across the nation [2]. The healthcare industry must respond, and respond soon, to this call for action to improve the healthcare system in the nation.

3.2. e-Health: The Role of Technology

e-Health has been defined as "an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology" [8]. While other definitions abound, the overarching goal of e-Health is to enhance the quality of healthcare to individuals; the *key* to realizing this goal is the utilization of the state-of-the-art in *technology*.

Technology can enhance the *quality* of life for everyone in the *continuum of life* from newborns to senior citizens. Technology is indeed the catalyst that can rapidly transform healthcare and the practice of medicine by improving the quality and safety of patient care and increasing the efficiency of healthcare providers. Moreover, technology is essential for the healthcare industry to meet its challenges discussed earlier. Finally, technology has the potential to facilitate affordable healthcare to *anyone, anytime, anywhere*. Therefore, any technology to minimize the loss of human life and/or enhance the quality of life has a *value* that is priceless.

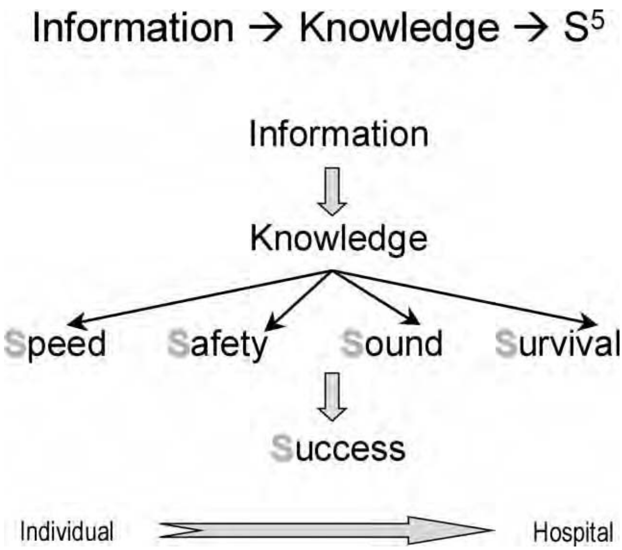

Figure 1. The Information-Knowledge-S^5 Framework.

Information is at the heart of a successful healthcare system, especially in the context of e-Health. As shown in Figure 1, information leads to "knowledge" which, in turn, leads to S^5 or Speed, Safety, Sound, Survival and Success [9]. Armed with the right information, the doctor can provide *speedy* and *safe* treatment that is based on *sound* decision-making which can ensure the *survival* of the patient thereby creating a *successful* healthcare delivery system. Moreover, to realize a healthcare system with the six key aims identified by the Institute of Medicine, there is a need for an effective and mobile information infrastructure or monitoring system that can be tailored to the individual's requirements to take advantage of the advancements in telemedicine and information processing. And, if this information infrastructure can be realized in the form of a *wearable garment* that can collect, process, store and transmit (and receive) information about the wearer, e.g., body vital signs, to (and from) any remote location, say via the Internet, it would go a long way towards:

1. Addressing the Healthcare Challenge;
2. Realizing the Healthcare System called for by the National Institute of Medicine;
3. Contributing to the paradigm of e-Health; and
4. Enhancing the Quality of Life for everyone in the continuum of life throughout the continuum of care.

The remainder of the paper is organized as follows: In Section 2 details of the Wearable Motherboard or Smart Shirt developed at Georgia Tech, which represents the first attempt at realizing an unobtrusive, mobile and easy-to-use vital signs monitoring system, are discussed. In Section 3, the key applications of the Smart Shirt technology along with its impact on the practice of medicine are presented; in Section 4, key opportunities to create the next generation of truly "adaptive and responsive" medical systems for the realization of *i*-Health are covered. Concluding remarks are presented in Section 5.

4. The Wearable Motherboard (Smart Shirt) Technology

Research at Georgia Tech – funded initially in October 1996 by DARPA through the US Department of the Navy – has led to the realization of the world's first Wearable Motherboard™ or an "intelligent" garment for the 21st Century [10]. The Georgia Tech Wearable Motherboard (GTWM) or the Smart Shirt uses optical fibers to detect bullet wounds, and special sensors and interconnects to monitor the body vital signs during combat conditions. However, as the research progressed, new vistas emerged for the deployment of the resulting technology including civilian medical applications and the new paradigm of personalized mobile information processing using the flexible information infrastructure, and that led to the concept of a "wearable motherboard." Just as special purpose chips and processors can be plugged into a computer motherboard to obtain the desired information processing capability, the Smart Shirt provides an extremely versatile framework for the incorporation of sensing, monitoring and information processing devices. The principal advantage of the Smart Shirt is that it provides, for the first time, a very systematic way of monitoring the vital signs of humans in an *unobtrusive* manner.

4.1. An Overview of the Smart Shirt Technology

Since the objective has been to create a comfortable and wearable information infrastructure, user requirements for the Wearable Motherboard have been identified. As shown in Figure 2, these include factors such as Functionality, Wearability, Durability,

Manufacturability, Maintainability, Connectivity, and Affordability. For example, Wearability implies that the Wearable Motherboard should be lightweight, breathable, comfortable (form-fitting), easy to wear and take-off, and provide easy access to wounds. These are critical requirements in combat conditions so that the soldier's performance is not hampered by the protective garment. The durability of the GTWM is another impor-

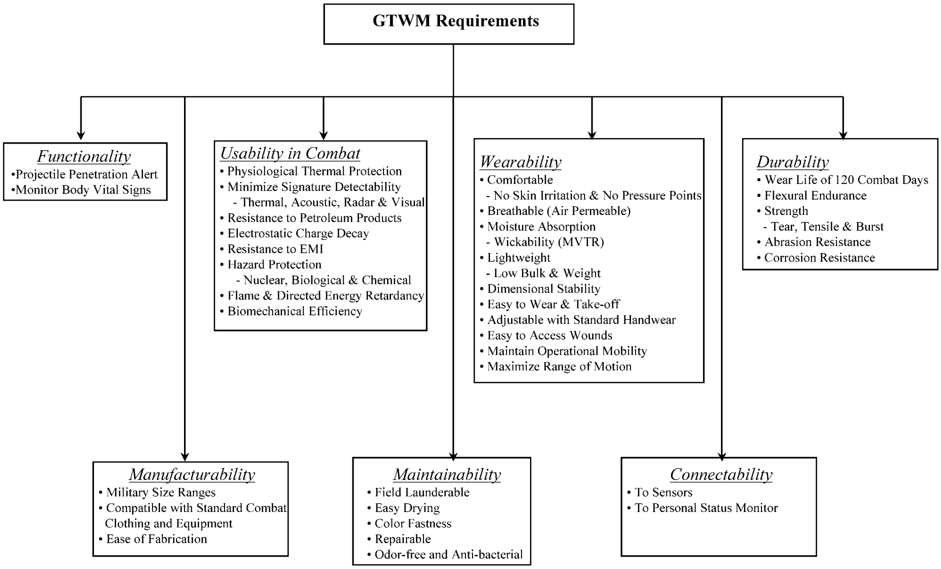

Figure 2. Performance Requirements for the Smart Shirt.

tant performance requirement. It should have a wear life of 120 combat days and should withstand repeated flexure and abrasion – both of which are characteristic of combat conditions. Manufacturability is another key requirement since the design (garment) should be eventually produced in large quantities over the size range for the soldiers; moreover, it should be compatible with standard issue clothing and equipment. Maintainability of the GTWM is an important requirement for the hygiene of the soldiers in combat conditions; it should withstand field laundering, should dry easily and be easily repairable (for minor damages). The developed GTWM should be easily connectable to sensors and the communications module on the soldier, known as the Personal Status Monitor (PSM). Finally, affordability of the Smart Shirt is another major requirement so that the garment can be made widely available to all combat soldiers to help ensure their personal survival, thereby directly contributing to the military mission as force enhancers. The details of the design methodology can be found elsewhere [11]. Several versions of the Smart Shirt have been produced and with each succeeding version, the garment has been continually enhanced from all perspectives – functionality, capabilities, comfort, ease of use and aesthetics.

Figure 3 shows the architecture of the Wearable Motherboard intended for medical applications. The comfort or base fabric (woven, knitted, nonwoven, etc.) provides the necessary physical infrastructure for the Wearable Motherboard. The base fabric is made from typical textile fibers (e.g., cotton, polyester, blends) where the choice of fibers is dictated by the intended application. The developed interconnection technology has been used to create a flexible and wearable framework to plug in sensors for monitoring a

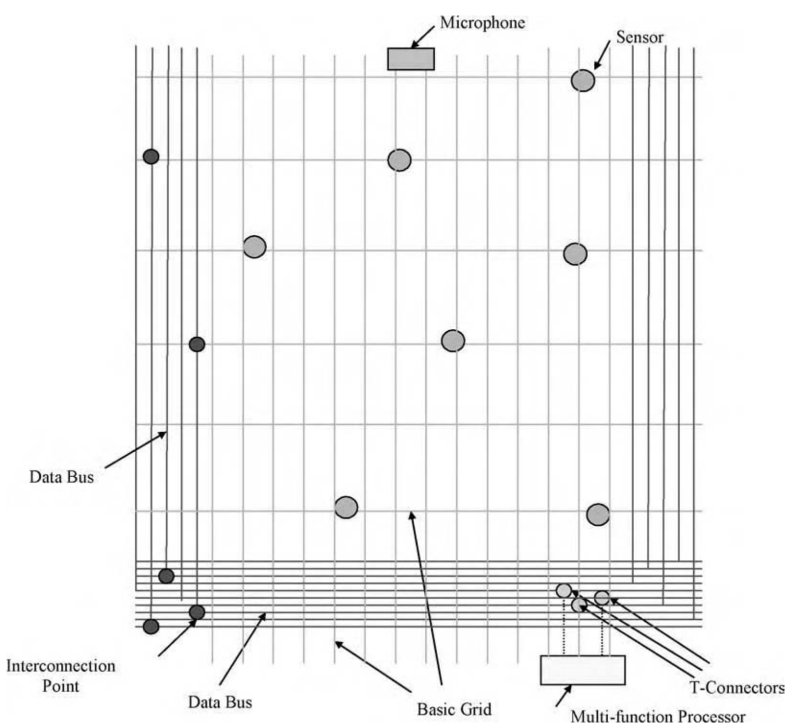

Figure 3. The Wearable Motherboard Architecture.

variety of vital signs e.g. heart rate, respiration rate, ECG, body temperature and pulse oximetry (SpO_2). In addition, voice can be recorded by plugging in a microphone into the Shirt.

These sensors can be positioned in desired locations on the body and will plug into the Smart Shirt. The flexible data *bus* integrated into the structure transmits the information from the suite of sensors to the multifunction processor known as the Smart Shirt Controller. This Controller, in turn, processes the signals and transmits them wirelessly (using an appropriate communication protocol such as Bluetooth, 802.11b) to desired locations (e.g., doctor's office, hospital, battlefield triage station). The *bus* also carries information *to* the sensors (and hence, the wearer) from external sources, thus making the Smart Shirt a valuable information infrastructure.

The motherboard or "plug and play" concept means other sensors can be easily integrated into the structure. For instance, a sensor to detect oxygen levels or hazardous gases can be integrated into a variation of the Smart Shirt that will be used by firefighters. This information along with the vital signs can be transmitted to the command center or fire station where personnel can continuously monitor the firefighter's condition and provide appropriate instructions including ordering the individual to evacuate the scene, if necessary.

4.2. Testing of the Smart Shirt

The vital signs monitoring capability has been tested by a subject wearing the garment and measuring the heart rate, respiration rate, electrocardiogram (EKG) and body temperature using commercial off-the-shelf sensors that "plug" into the Smart Shirt.

The data is wirelessly transmitted to a personal computer. Figure 4 shows the display of the key vital signs including the EKG waveform on the computer illustrating the successful realization of the Wearable Motherboard concept. The garment is also comfortable and easy to wear and take-off similar to a typical undershirt. For monitoring acutely ill patients who may not be able to wear the garment over the head (like a typical undershirt), Velcro® and zipper fasteners are used to attach the front and back of the garment creating a garment with full monitoring functionality that is also easy to use.

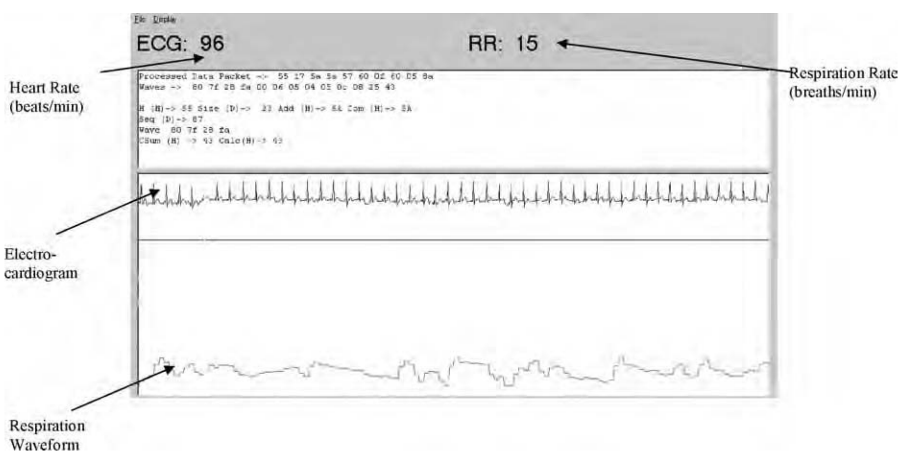

Figure 4. The Display of Key Vital Signs from the Smart Shirt.

5. Applications and Impact of the Smart Shirt

The realization of the Smart Shirt has opened up new frontiers in personalized information processing, healthcare and telemedicine, and space exploration, to name a few [12]. Until now, it has not been possible to create a personal information processor that was customizable, wearable and comfortable; neither has there been a garment that could be used for unobtrusive monitoring of the vital signs of humans on earth or in space.

5.1. Applications of the Smart Shirt

Figure 5 illustrates the use of the Smart Shirt in a variety of applications – battlefield, public safety, health monitoring, sports, and fitness, among others. The vital signs information gathered by the various sensors on the body travels through the Smart Shirt to the Smart Shirt Controller for processing; from there, the computed vital signs are wirelessly transmitted using the "communications information infrastructure" in place in that application, e.g., the firefighters' communications system, the battlefield communications infrastructure, the hospital network, the Wi-Fi (Wireless Fidelity) network at home, to the respective monitoring station. There, the back-end Data Display and Management System – with a built-in knowledge-based decision support system – can receive this vital signs data in real-time and provide the right response to the situation.

Table 1 summarizes the broad range of applications of the Smart Shirt technology [7]. The table also shows the application type and the target population that can utilize the technology.

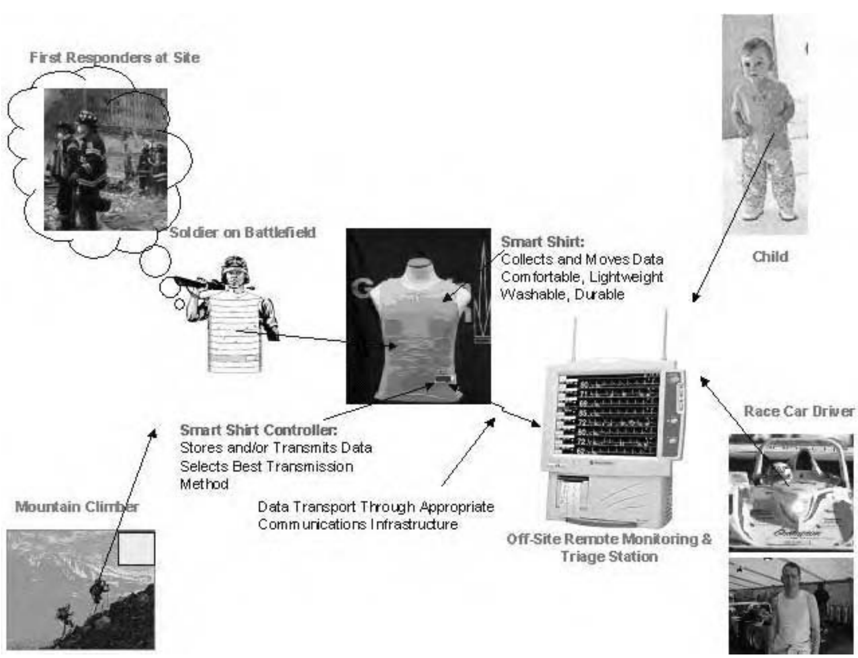

Figure 5. Smart Shirt in Various Fields of Application.

Table 1. The Wearable Motherboard / Smart Shirt: Potential Applications

Segment	Application Type	Target Customer Base
Military	Combat Casualty Care	Soldiers and Support Personnel in Battlefield
Civilian	Medical Monitoring	Patients: Surgical Recovery, Psychiatric Care
		Senior Citizens: Geriatric Care, Nursing Homes
		Infants: SIDS prevention
		Teaching Hospitals and Medical Research Institutions
	Sports / Performance Monitoring	Athletes: Individuals/Teams
		Scuba Diving, Mountaineering, Hiking
Space	Space Experiments	Astronauts
Specialized	Mission Critical / Hazardous Applications	Mining, Mass Transportation
Public Safety	Fire-fighting	Firefighters
	Law Enforcement	Police
Universal	Wearable Mobile Information Infrastructure	All Information Processing Applications

5.2. *Impact of the Smart Shirt*

The Smart Shirt will have a significant impact on the practice of medicine since it fulfills the critical need for a technology that can enhance the quality of life while reducing healthcare costs across the continuum of life, viz., from newborns to senior citizens and across the continuum of medical care, viz., from homes to hospitals and everywhere in-between (Figure 6). The six aims for an improved healthcare system identified by the Institute of Medicine are also shown in the outer ring of the figure and illustrate the potential of the Smart Shirt technology in facilitating the realization of the desired healthcare system.

Clothing, the most universal of interfaces, is probably the only "constant" that is an integral part of the individual throughout the twin continua shown in the figure. By having a technology that is not only ubiquitous but also has the ability and intelligence to respond to the changes in the needs of the wearer, the quality of preventive care can be significantly enhanced, thus reinforcing the paradigm that "investment in prevention is significantly less than the cost of treatment." For instance, when an infant version of the Smart Shirt is used for monitoring babies prone to SIDS (sudden infant death syndrome), it can shift the focus from the treatment of infants who have suffered brain damage due to apnea to the prevention of the damage in the first place. The relative costs of the two scenarios (prevention vs. treatment) are only too well-known to be elaborated upon here.

The Smart Shirt can contribute to reductions in healthcare costs while enhancing the quality of life. For instance, patients could wear the Smart Shirt at home and be monitored by a monitoring station (similar to home security monitoring companies), thereby avoiding hospital stay costs and reducing the overall cost of healthcare. At the same time, a home setting can contribute to faster recovery. For example, if the patient recovering at home from heart surgery is wearing the Smart Shirt, the EKG can be transmitted wirelessly (through a mobile phone, Internet, etc.) to the hospital on a regular basis. This

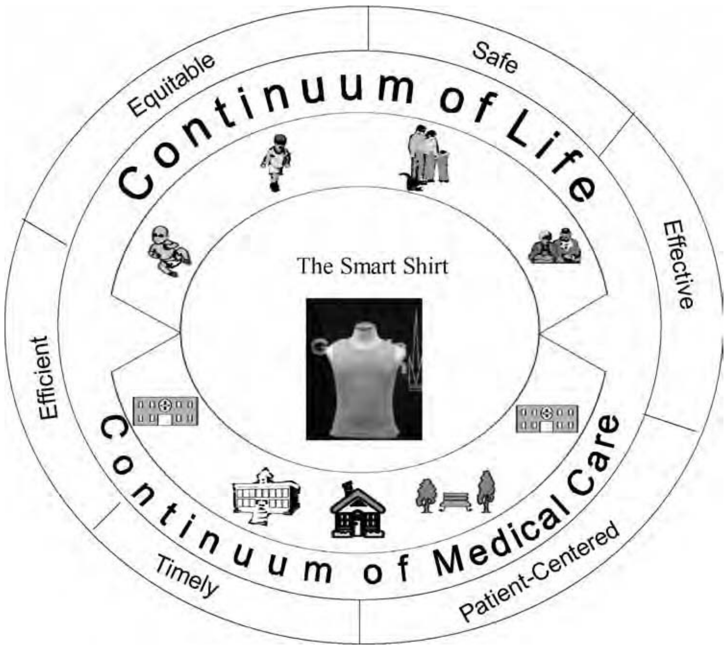

Figure 6. Six Aims for Improvement in Healthcare and the Twin Continua of Life and Medical Care.

monitoring will help the patient feel more "secure" and will facilitate the recuperation while simultaneously reducing the cost and time associated with recovery. Moreover, in the event of an emergency, the doctor can be notified instantaneously. Using the online medical records (available over the Web), the physician can administer the *right* treatment at the *right* time at the *right* cost, and indeed save a life thereby realizing the full potential of the Smart Shirt technology!

Furthermore, persons who have known disorders can wear the Smart Shirt and be under *constant* monitoring of their physical conditions by medical personnel. For example, it can be used to monitor mentally ill patients (e.g., those suffering from manic depression) or even kids suspected of ADD (Attention Deficit Disorder) on a regular basis to gain a better understanding of the relationship between their vital signs and their behavioral patterns so that their treatments (e.g., medication) could be suitably modified. Other potential applications include the treatment of anxieties and phobias. Such medical monitoring of individuals is critical for the successful practice of telemedicine that is becoming economically viable in the context of advancements in computing and telecommunications, especially the Internet.

Yet another potential impact of the Smart Shirt technology is the eventual disappearance of geographical/physical boundaries as barriers for individuals seeking the best in healthcare worldwide. For example, patients in remote/rural areas served by general family practitioners can have convenient and easy access to healthcare specialists without having to travel, thereby minimizing overall healthcare costs. In the future, the physical boundaries and distances that limit a specialist's healing area could potentially disappear and patients can indeed access *any* specialist they desire in *any* part of the world. In fact, taken one step further, this approach could potentially lead to a network of "specialty" centers around the world where each hospital could focus on a particular area of medicine rather than attempt to excel in *all* the specialties – a new paradigm of medicine and healthcare delivery.

The Smart Shirt technology has the means to provide unobtrusive monitoring for individuals and can therefore play a critical role in disease management for the large numbers of individuals at risk for blood pressure, heart disease, diabetes, chronic bronchitis and depression by enabling *early*, *systematic intervention*.

The mail below shows an example of a letter received from a parent that underscores the need for the Smart Shirt technology for medical applications such as SIDS. This indeed is the "value" that the technology provides. It is extremely hard to "quantify" this value. However, this type of response is not only gratifying to the authors, but also serves as an impetus to make further contributions aimed at enhancing the quality of life for individuals.

From: xxxxxxx@aol.com
Date: Sat, 19 Feb 2000 12:57:39 EST
Subject: Heart monitor t-shirt
To: sundaresan.jayaraman@textiles.gatech.edu
X-Mailer: AOL 5.0 for Windows sub 47

Dr. Jayaraman,

Hello. I recently read about your heart rate and breathing monitor t-shirt and wanted more information about it.

Will it be possible to purchase this equipment this Spring. We lost a son to SIDS and are expecting a second child near May. We have been told that the monitors available have a high false alarm rate and are not effective when the baby becomes mobile. We are petrified that we will not have a reliable system to monitor our second child to catch her in time to administer CPR.

We also wanted to know is the shirt adjustable? Will it grow with the baby. Our son was 10 months old, much older than the projected SIDS rate. Obviously the newborn shirt would not fit an older infant. Finally, how is it cleaned?

Thank you for you time. Your immediate response would be greatly appreciated.

Sincerely,

Mrs. xxxxxxxxx

xxxxxxx@aol.com

5.3. Smart Shirt Technology and the Six Aims of the Healthcare System

The Smart Shirt technology can facilitate the realization of the six key aims for a healthcare system identified by the Institute of Medicine (see Figure 6). By focusing on the human or individual as an "information node," the Smart Shirt technology creates a "*patient-centered*" environment while collecting information from the wearer in a *timely* (and unobtrusive) manner; this information can be used to administer a treatment regimen that is *effective*, and the whole diagnosis-treatment-recover process will be more *efficient* – cost- and time-wise. By making the Smart Shirt technology easy-to-use and affordable, the healthcare system can indeed be made *equitable*. In other words, the Smart Shirt is a valuable information infrastructure that can facilitate the transformation of *information* to *knowledge* leading up to S^5 (Figure 1) and enhancing the quality of life for everyone.

6. Looking Ahead: From e-Health to *i*-Health

By providing a "platform" for a suite of sensors that can be utilized to monitor an individual unobtrusively, the Smart Shirt technology opens up exciting opportunities to develop "adaptive and responsive" systems that can "think" and "act" based on the user's condition, stimuli and environment [13]. Thus, the rich vital signs data stream (and resulting knowledge) from the Smart Shirt can be used to design and implement "real-time" feedback mechanisms (as part of the Smart Shirt System) to enhance the quality of care for the individual by providing appropriate and timely medical "intervention." This will facilitate the transformation of e-Health to *i*-Health or *interactive* healthcare to the individual.

6.1. The Smart Shirt and Integrated Feedback Systems

Certain individuals are susceptible to *anaphylaxis* reaction (an allergic reaction) when stung by a bee or spider and need a shot of *epinephrine* (adrenaline) immediately to prevent serious illness or even fatalities. By applying advancements in MEMS (micro-electro mechanical systems) technology, a feedback system – including a drug delivery system – can be integrated into the Smart Shirt. Of course, mechanisms to guard against inadvertent administration of the drug can be built as part of the control system.

Likewise, the Smart Shirt's data acquisition capabilities can be used to detect the condition when an individual is lapsing into a diabetes shock and the integrated feedback mechanism can provide the appropriate response to prevent a fatality. Thus, the Smart Shirt represents yet another significant milestone in the endeavor to save and enhance the quality of human life through the use of advanced technologies.

6.2. Smart Shirt, Knowledge Banks and Personal Privacy

As with any advanced information technology, invasion of personal privacy becomes a very big concern and the Smart Shirt is no exception. However, since the technology is in the form of a "garment," the user (or the caregiver, in the event the user is unable to make the choice due to age or mental incapacitation) must make the "deliberate" choice to put on the garment and only then can the data be monitored [14]. In other words, the user has *control* over personal privacy. Advances in telecommunications technology are addressing other across-the-board issues such as data integrity, data latency, data security and these will not be unique to the use of the Smart Shirt technology. The user (i.e., the patient) will have the right to grant access to the appropriate individuals such as physicians, hospitals and insurance companies.

The ease with which personal data can be collected in real-time using the Smart Shirt will result in the creation of "knowledge banks" of human performance; this knowledge base can be used in clinical and pharmaceutical research potentially leading to new treatments, drugs and drug delivery systems. These benefits should be weighed in the context of potential invasion of personal privacy. Similar issues arise with the Human Genome project. Therefore, there is a critical need for a major initiative that brings together experts from the medical, insurance and legal communities to address this important facet of advanced technologies so that society can harness the benefits from technological advancements and enhance the quality of life without sacrificing an individual's most prized possession, viz., personal privacy.

7. Concluding Remarks

The Smart Shirt is an effective, comfortable and mobile information infrastructure that can be *tailored* to the individual's requirements to take advantage of the advancements in telemedicine and information processing. Just as special purpose chips and processors can be plugged into a computer motherboard to obtain the required information processing capability, the Smart Shirt is an information infrastructure into which the wearer can "plug in" the desired sensors and devices thereby creating a system for monitoring vital signs in an efficient and cost-effective manner with the "universal" interface of clothing. This "fabric is the computer" paradigm – exemplified by the Smart Shirt – demonstrates the feasibility of realizing personalized mobile information processing (PMIP) and sets the stage for transforming healthcare in this new millennium through the e-Health paradigm.

Advanced technologies such as the Smart Shirt have the potential to dramatically alter the landscape of healthcare delivery and the practice of medicine – as we know them today. By enhancing the quality of life, minimizing "medical" errors, and reducing healthcare costs, the patient-centric wearable information infrastructure can play a critical role in realizing the future healthcare system envisioned by the Institute of Medicine. Just as the spreadsheet pioneered the field of information processing that brought "computing to the masses," it is anticipated that the Smart Shirt will bring personalized healthcare monitoring to the population-at-large thus leading to the realization of "*Affordable and Interactive Healthcare, Anyplace, Anytime, Anyone*."

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Wearable System for Vital Signs Monitoring

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Abstract. A new concept in healthcare, aimed at providing continuous remote monitoring of user's vital signs, is emerging. An innovative system named WEALTHY is presented, where conducting and piezoresistive materials in the form of fiber and yarn are integrated and used as sensor and electrode elements. The simultaneous recording of vital signs allows parameter extrapolation and inter-signal elaboration that contribute to producing alert messages and synoptic patient tables. Cardiac patients in the rehabilitation phase can be continuously monitored during selected time intervals, such as during physical activity or occurrence of symptoms, to discover potential threats and generate appropriate alerts to the patient and/or to an emergency center. The core of the system sensing is a textile interface, in which the sensing components are elements of the fabric: the sensorized garment is comfortable like a common article of clothing and is made with knitting machines; furthermore, the position of the electrodes and sensors is fixed and the elasticity of the fabric allows a good fitting to the body. The system is provided with a portable electronic unit, where signals are acquired, elaborated and transmitted. A monitoring system allows extrapolation of a new physiological index and data flow coordination as well as alarm management and database creation.

Keywords. Wearable, healthcare, fabric sensors, integration

Introduction

An emerging need of our society is continuous contact with an external supervisor system during normal daily activity as well as during extreme and risky activities. This need is both socially-driven (the rising cost of assistance, the need to improve early illness detection and medical intervention) and technologically-driven. In particular, advances in sensor technology, as well as in communication technology and treatment of data, constitute the basis on which a new generation of health care systems can consolidate. Monitoring systems designed to be minimally-invasive, based on flexible technologies conformable to the human body, easy to use and endowed with a monitoring system customizable to the specific user, represent the latest generation of healthcare instruments. They are also cost-effective in providing assistance, for example in rehabilitation from cardiac disease or in the prevention of acute crisis, and for the monitoring of professional workers engaged in extreme environmental conditions. Finally, by providing direct feedback to the users, they improve their awareness and allow better control of their own condition. In these systems the electrophysical properties of materials in fiber and yarn form are used to implement woven or knitted fabrics possessing distributed sensor and logic functions. Conductive and piezoresistive yarns are integrated and used as sensors, tracks and electrode elements. The simultaneous recording of vital signs allows parameter extrapolation and inter-signal elaboration that contribute to making alert messages and personalized synoptic tables of patients' health.

1. The WEALTHY System

Strain fabric sensors based on piezoresistive yarns, and fabric electrodes realized with metal-based yarns, enable the realization of wearable and wireless instrumented garments capable of recording physiological signals and to be used during everyday activities. Respiration, electrocardiograms, electromyograms, activity sensors and temperature can be listed as physiological variables to be monitored through the proposed system.

A miniaturized short-range wireless system can be integrated in the sensitive garment and used to transfer the signals to WEALTHY boxes/PCs, PDAs and mobile phones. An "intelligent" monitoring system for the alert functions, able to deliver the appropriate information for the target professional, is the complementary function to be implemented. The system addresses the monitoring of patients with heart disease during and after their rehabilitation and of professional personnel at risk (working alone, working in a dangerous environment, etc.).

2. WEALTHY Functions

The WEALTHY system has been developed as the integration of several function modules. The main functions of the wearable modules are shown in Figure 1, namely: sensing, conditioning, pre-processing and data transmission.

The garment interface is connected with the portable WEALTHY device where the local processing as well as the communication with the network is performed. A knit-

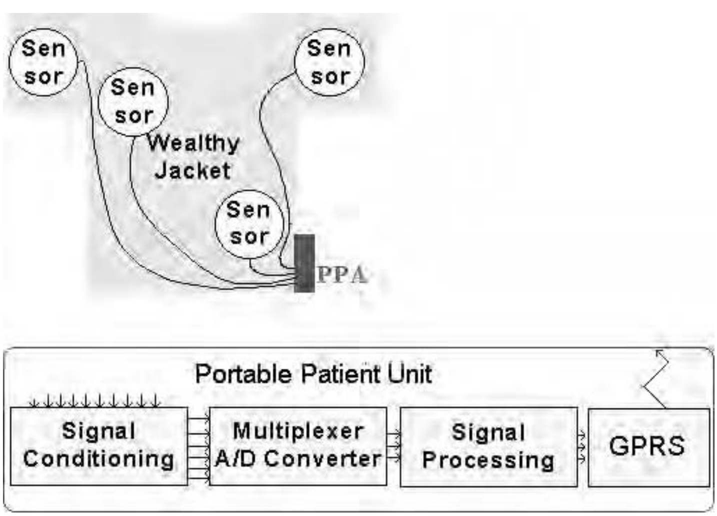

Figure 1. Overview of wearable WEALTHY's modules.

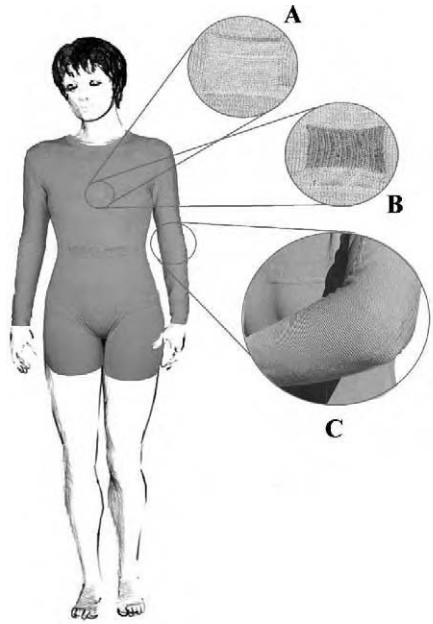

Figure 2. Textile prototype: (A) close-up of the external view of electrode and track, (B) internal view of electrode and track, (C) close-up of moving sensor.

ted fabric platform containing insulated conductive tracks connected with sensors and electrodes is implemented in the garment.

The textile prototype is shown in Figure 2. In windows A and B are shown the electrode and the related track on the face and back side of the cloth; the conductive yarn is visible only on the back side where the fabric is in contact with the body. In window B the piezoresistive sensor is visible.

The body is achieved using knitting technology. As can be observed from the figure, specific yarns are confined in a predefined insulated region by means of an intarsia technique. The elasticity is increased by coupling an elastomer to the other yarns during the working process; high elasticity allows freedom of movement and comfort as well as preventing formation of pleats and crumples. The goal is to find the right compromise between the thinness and handling of the cloth and the sensitivity of the yarn, on which the sensor features depend. The prototype is made with flat-knitting machines.

Most signals are transmitted unprocessed to the monitoring system where they can be analyzed off-line. In order to reduce the required data capacity of the wireless link to the central monitoring system, some sensor signals are processed by the portable patient unit (PPU) to extract essential parameters.

Local pre-processing of signals is applied to the ECG signal in order to extract the heart rate value. Off-line processing, depending on the application, will also be done at the monitoring center. A preliminary list includes:

- RR distance and tachogram
- QRS duration
- Level of the T wave with respect to the R wave
- T wave area

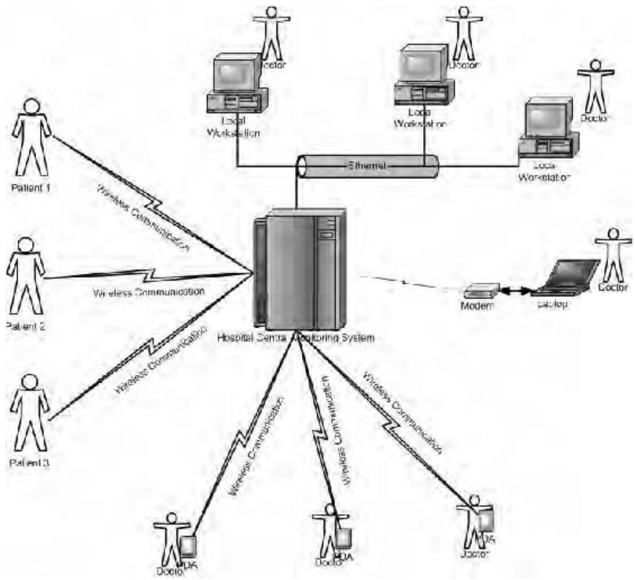

Figure 3. Overall view of the WEALTHY monitoring system.

The PPU is designed to have a simple user interface with two LEDs and a buzzer for user-warning purposes and a button to let him manually trigger an alarm.

The final action is to classify those parameters to detect an event. Several statistical tools based on a multifunctional analysis, such as PCA or IDA, may be used for this purpose.

In order to offer full mobility to the patient or the user, acquired signals are wirelessly transmitted from the PPU to the remote monitoring system. The communication is based on the TCP/IP that is the standard protocol for GPRS communication. All signals are sent in quasi-real-time to the remote monitoring centre. The central monitoring system is organized into the following modules:

- Web server
- Database server
- Client application module
    - Central control module
    - Doctor's desktop/laptop module
    - Doctor's PDA module

All the above modules are able to run on a single computer without the need of dedicated high-end servers. Figure 3 below shows the overall view of the WEALTHY monitoring system.

The WEALTHY platform offers the possibility of monitoring and assisting patients through a remote medical advice service. The use of intelligent systems provides physicians with data to timely detect and manage health risks, make early diagnosis of illness or injury, recommend treatment that would prevent further deterioration and, finally, make confident professional decisions based on objective information - all in a reasonably short time.

2.1. Signals Analysis and Results

The WEALTHY system is an innovative device able to provide improved healthcare to users. The integration of multiple parameters and their continuous transmission to a monitoring clinical center makes the system quite unique and different from currently used medical devices.

Standard Holter ECG (24-hour continuous recording of 2-3 ECG leads) or ambulatory blood pressure devices are actually simple recorders that need to be put on and then removed in hospital or clinics. Data analysis is off-line and only a delayed medical response can be provided when abnormalities are detected. These systems are therefore used to reach a non-urgent diagnosis (for example to verify that palpitations reported by a patient are due to cardiac arrhythmias) or to obtain a spot check on the efficacy of therapy (for example of a drug that lowers blood pressure), yet they are not practical when medical data have to be obtained more frequently.

WEALTHY more closely resembles a monitoring device, like those used in intensive care units, that continuously transmits ECG, respiratory trace, etc. and that are extensively used for the management of critically ill patients. The experience gained with these devices can be used for some of the features of WEALTHY: automated ECG analysis and alarm generation, monitoring of respiratory function, etc. Moreover the transmission of the ECG by freely moving subjects will be close to the situations encountered in clinical ECG stress testing where detection of ECG signs of myocardial ischemia is possible. Figure 4 shows a typical set of ECG and respiration activity signals recorded simultaneously with the textile prototype.

3. Discussion

The most innovative aspect of this system consists of the use of functionalized materials in the form of fibers and yarns which can be knitted or woven into a multifunctional sensing fabric. The achieved results [1] show that the basic sensing features on which vital sign recording is based can be implemented using integrated knitted sensors and electrodes. The possibility of knitting sensors, electrodes and tracks in the same textile material allows the design of an interactive platform that is manufactured in an unconventional way. Nevertheless, a material to be processed using textile machinery must satisfy very strict requirements in terms of mechanical and chemical properties, and, for our purposes, also in terms of electrical properties.

The potential for using textile facilities is linked to the realization of fibers and yarns suitable for use in the most sophisticated knitting machinery; the fineness, the composition, the mechano-elastic properties of yarns play key roles in this process. The final characteristics of the integrated textile structure are modulated by a series of factors, starting from the material, the combination of yarns, the textile processes, up to the final finishing step. An efficient, wearable, comfortable sensing system is the result of a balance between performance, number and position of the active elements, and lightness, comfort and conformability of the final cloth.

Previous authors' works [2–4] have shown that low-frequency mechanical signals of cardiopulmonary origin (respiratory signals, ballistogram) or generated by the relative motion of body segments (kinesthesia) have been recorded by textile strain gauges. Finally, bioelectric potentials related to cardiac or skeletal muscle activity (ECG, EMC) have been faithfully recorded by metal-based fabric electrodes.

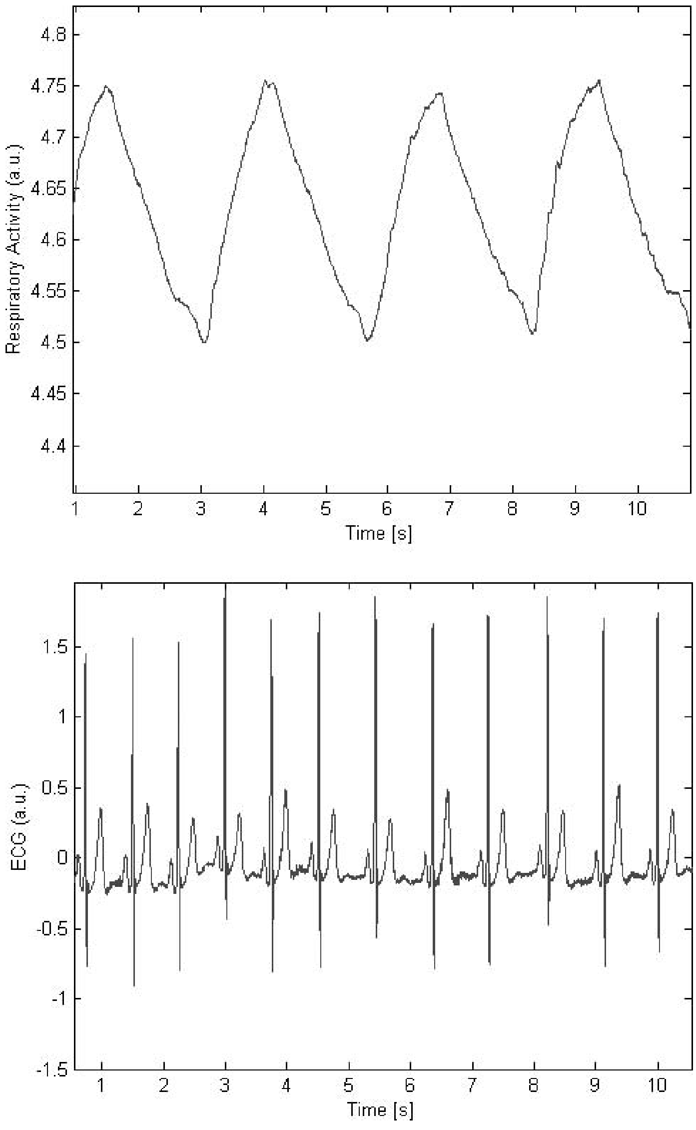

Figure 4. Respiration activity and ECG trace.

The integration of these different components with appropriate elastic electrical conductors and properly-designed connectors to the wearable electronic unit leads to a comfortable, wearable cloth that has no counterpart in any existing monitoring system.

These new integrated knitted systems enable applications extending even beyond the clinical area and open up new possible applications in sport, ergonomics and monitoring of operators exposed to harsh or risky conditions (firemen, soldiers etc.).

The possibility of simultaneously recording different physiological signals provides an integrated view of normal and abnormal pattern of activity which could be otherwise impossible to detect by recording each signal at different times.

Finally it must be outlined that the possibility of recording physiological variables in a more "natural" environment may help to identify the influence of the psychoemotional state of the subject in the performance of a physical activity. This is not easily detectable when recording is done within a protected (medical) environment.

A further innovation is the in-context data interpretation. While a simple telemonitoring system would just transmit or record real-time physiological signs, the WEALTHY system will be able to process physiological parameters in context, so that appropriate feedback can be given to the patient.

4. Conclusions

The innovative approach of this work is based on the use of standard textile industrial processes to realize the sensing elements. Transduction functions are implemented in the same knitted system, where movements and vital signs are converted into readable signals, which can be acquired and teletransmitted.

In this system, electrodes and bus structure are integrated in textile material, making it possible to perform normal daily activities while the user's clinical status is monitored by a specialist, without any discomfort.

Acknowledgments

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Telemonitoring of Vital Parameters with Newly Designed Biomedical Clothing

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Abstract. The paper describes the development of biomedical clothing for ambulatory telemonitoring of human vital parameters. VTAM (Vêtement de Télé-Assistance Médicale) presents a T-shirt made from textile with woven wires and incorporating four smooth dry ECG electrodes, a breath rate sensor, a shock/fall detector and two temperature sensors. The garment is equipped for the signal pre-computing and transmission through a miniature GSM/GPRS module kept on a belt together with the power supply. Three VTAM prototypes have been tested on persons in a normal state of health using a medical protocol to assess the biomedical data that include an ECG reading, a pneumogram, temperature and fall detection in mobile situations.

Keywords. Telemedicine, e-health care, wearable surveillance system, integrated sensors

Introduction

The rising R&D effort in the field of biomedical clothes witnesses of a need to get new solutions for the healthcare delivery. Garments integrating sensors that measure and transmit vital personal data could provide a powerful tool for personal health monitoring. Up to now a few examples exist for this issue. Among the most cited there is LifeShirt-Continuous Ambulatory Monitoring System (VivoMetrics, USA) [1], an advanced, non-invasive, ambulatory monitoring system that collects, analyses and reports on clinically relevant parameters, with a focus on respiratory pattern measures. Verhaert (Belgium) has developed another product under the brand name Mamagoose-Pyjama for the detection of Sudden Infant Death Syndrome [2]. The clothes have five stitched-in sensors - three for the heartbeat and two for the respiration survey. The pyjamas monitor infants during sleep and sound an alarm if symptoms of sudden infant death syndrome arise.

Other research and development activities in real time personal care wearable systems are ongoing in Europe and worldwide, e.g. Wealthy (Wearable Health Care System) [3] and Lifebelt (wearable device for health monitoring during pregnancy) [3] or Sensatex (wearable motherboard Smart Shirt) [4].

The VTAM (Vêtement de Télé-Assistance Médicale) is a French research project that has been run from January 2001 [5–10] and that aims to integrate several physiological sensors into a T-shirt in order to have a continuous ambulatory real-time monitoring of a patient. The VTAM challenges to reach a higher level of electronic integration with the objective to design a generic technology for biomedical clothing, which would be at once comfortable, hygienic and resistant.

1. Methods

The fabric with woven wires and design of the clothing itself has been made by ITECH Enterprise. Breath rate sensor together with its signal treatment module was from RBI; shock/fall detector from TIMC-IMAG; electrocardiogram amplifier was supplied by MEDIAG. Database and distant platform application were developed by SPIM. Electronic integration (sensors + bus + treatment modules), GSM/GPRS, GPS, power supply, antennas and data transmission have been provided by TAM-Télésanté.

The VTAM clothing was conceived as a T-shirt to fit a person like a second skin. It incorporates four smooth dry ECG electrodes in its back part and on the shoulders as shown in the Figure 1. The breath rate sensor wraps the abdomen region. The two

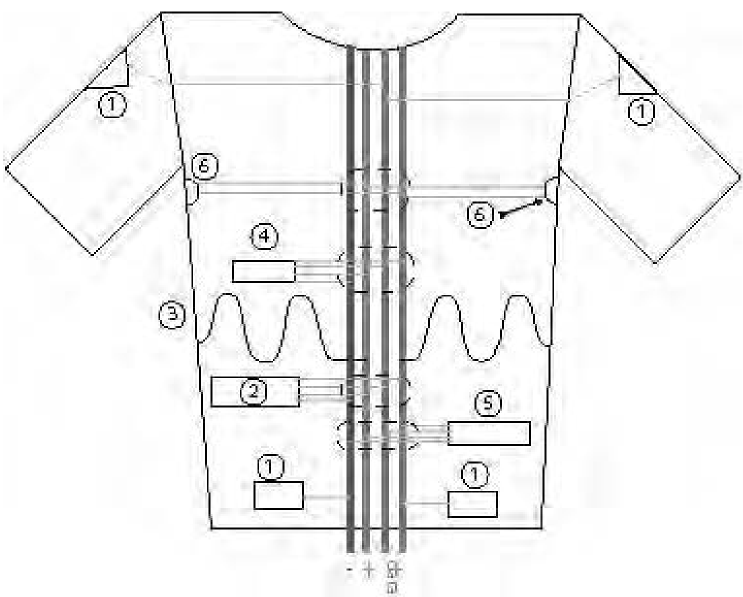

Figure 1. Schematic diagram of the VTAM clothing shows the location of electrodes (1) and treatment module (2) for the ECG recordings; breath rate sensor (3) and its signal processor (4); the shock/fall detector (5) and the temperature sensors (6). The dotted lines indicate supple silicon-embedded connections of the components to the woven I2C bus.

temperature sensors are placed in the armpits, one of them is protected with an adiabatic shell from the outer side of the clothing. The shock/fall detector and flexible treatment modules are sewn between two layers of textile. The components communicate via an I2C bus. A motherboard situated inside a belt manages the power supply, the sensors response and the communication module.

2. Results and Discussion

Three VTAM prototypes like the one in the Figure 2 have been made and tested on persons in a normal state of health. The T-shirt combines extensible and non-extensible textiles and tight enough to flatten the sensors against the skin.

Sensors recordings can be immediately sent to a distant platform, for example in case of a fall, a press alarm button or a low body temperature. The platform can communicate at any time with the VTAM through a miniature GSM/GPRS module in the belt connected to the T-shirt. Certain readings like breath rate or shock/fall detection are pre-computed before being sent to the platform in order to minimise the transmitted data size. The distant platform can transmit a new configuration to VTAM or ask for a sensors records reception. All recordings are stored in a database for further processing.

Figure 2. Photograph of a VTAM prototype.

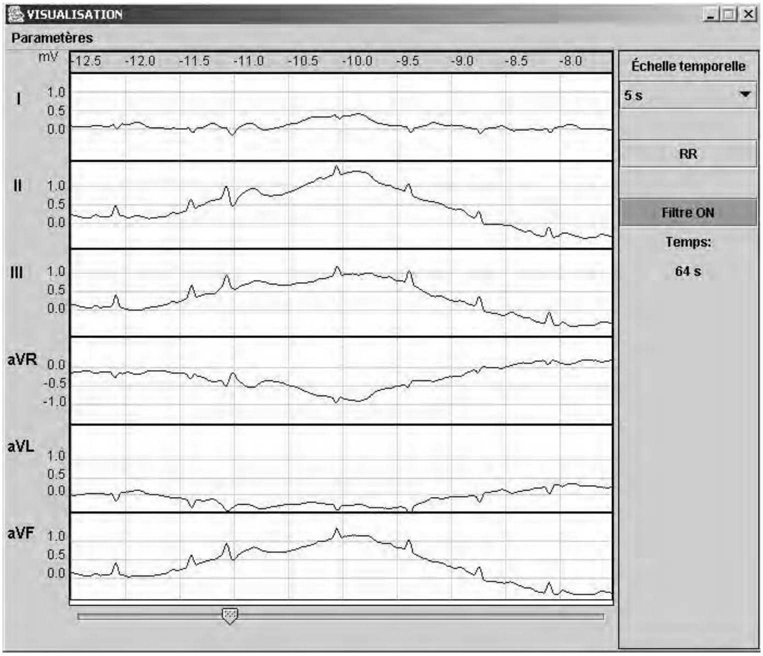

Figure 3. Monitor capture of an ECG recorded with VTAM. The time scale is of 5 seconds per window; the traces present a Heart block.

A medical protocol has been applied to assess the biomedical data that include an ECG reading, a respiration frequency, temperature values and fall detection in mobile situations. The tests also exploited geo-localisation data supplied by GSM.

Electrocardiograms recorded with VTAM (Figure 3) were well interpretable except for intensive wearer's movements. Graphic visualisation allowed distinguishing the main Arrhythmias such as irregular ventricular rhythm, early beats or pause, P wave presence of *flutter or fibrillatory waves.*

Signals from breath rate sensor were transmitted to the database as a succession of the breath frequency values. The latter were in agreement with visual observations during the test procedure.

Use of the temperature sensor cushioned against the body heat loss aimed the eventuality to measure a value that is representative of the body central temperature. Such a parameter when compared to the surface body temperature could be valuable to estimate the body's thermal regulation capability. The temperature difference measured by the two sensors was about 2°C taking into account the baseline gap.

The shock-fall detector is based on an analysis of the 3-D signature of the fall down accelerations associated to the 3-D components of the shock. Fall-down has been tested by healthy people, which simulate either smooth or hard falls. When fall is detected by the VTAM, it transmits automatically the whole physiologic and geolocalisation parameters to the distant station (Figure 4).

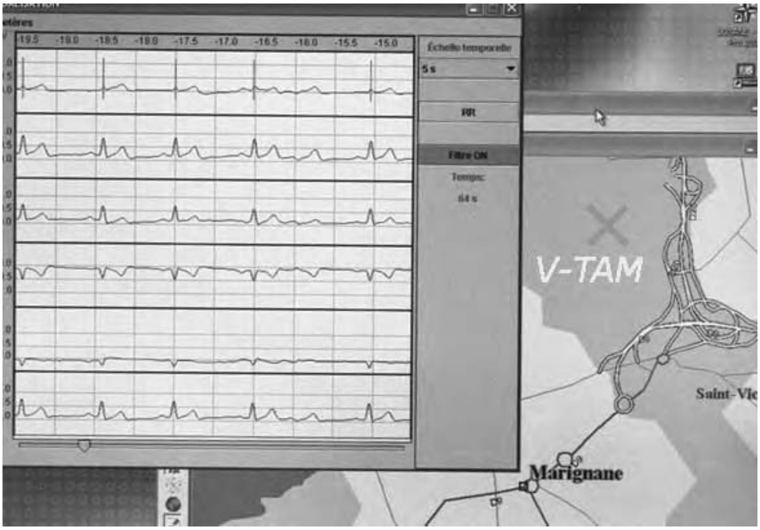

Figure 4. Localisation of a VTAM wearer after a data transmission set on by the shock/fall detector.

3. Conclusion

The biomedical clothing developed in the VTAM project demonstrates the large possibilities offered by the sensors integration into a daily-life garment. The data transmitted by the VTAM wearable system allow a physician at the distant platform to take a survey of patient's vital parameters and possibly set on an emergency action. Use of the VTAM clothing might be adapted for active seniors, professional sportsmen or high-risk professions such as firemen, police or the military.

Further effort should be given to reach a higher level of the electronic integration and minimise the system power consumption with more adapted energy sources, the final goal being the creation of a real second electronic skin.

Acknowledgements

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Wearable eHealth Systems for Personalised Health Management
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Strain Sensing Fabric for Hand Posture and Gesture Monitoring

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Abstract. Monitoring body kinematics and analyzing posture and gesture is an area of major importance in bioengineering and several other connected disciplines such as rehabilitation, sport medicine and ergonomics. Recent developments of new smart materials consent the realization of a new generation of garments with distributed sensors. What we present here is a sensing glove able to detect the posture and movements of the hand.

Introduction

The main disadvantages of sensing gloves available on the market are their weight, the rigidity of the fabric, the dimension of the sensors used, and all the other properties which make them obtrusive. All these undesired characteristics can be avoided by using a new technology to realize the sensing glove we present. The lightness and the adherence of the garments are fundamental requirements for the unobtrusivity of the device. Moreover, using conventional sensors to evaluate the posture of the hand, requires the application of complicated and uncomfortable mechanical plug to interface the garment with the sensors. We have chosen to realize a glove made of Lycra® which satisfies the requirements of lightness, elasticity and adherence.

1. Sensorized garments

The very innovative goal we have obtained consists in printing the set of sensors and the connecting wires directly on the fabric by using a carbon filled silicone rubber. This mixture does not change the mechanical properties of the fabric and maintains the wearability of the garment. Moreover, it shows piezoresistive properties and can be used both as sensors and as wires. By using this technology, no external cables are necessary to interconnect the sensors on the glove. The mixture we use is produced by WACKER Ltd (ELASTOSIL LR 3162 A/B) and is available on the market. WACKER Ltd guarantees the non toxicity of the material we have used:

"Postcured parts can be used for applications in the pharmaceutical and food industries and comply with the recommendations "XV. Silicone" of the BgVV and FDA § 177.2600" [1].

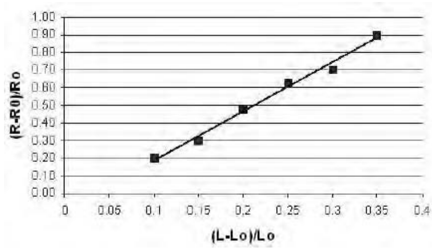

Figure 1. Quasistatic response in terms of percent change in electrical resistance versus strain for a CFR based sensor.

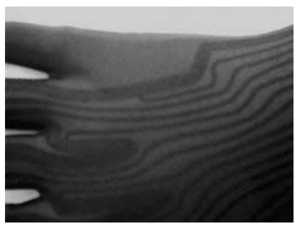

Figure 2. Fabric treated with ELASTOSIL.

Treated fabrics have been characterized in terms of their electromechanical transduction properties (in Figure 1 the gauge factor, Gf=(R-R0)L0/(L-L0)R0 is reported), thermal transduction properties and aging [2].

To obtain a sensorized fabric, the ELASTOSIL mixture is smeared on the fabric previously covered by an adhesive mask cut by a laser milling machine. The mask is designed according to the shape and the dimension desired for sensors and wires. After smearing the solution, the mask is removed. Then, the treated fabric is placed in an oven at a temperature of about 130 degrees centigrade. During this phase the cross-linking of the solution speeds up and in about 10 minutes the sensing fabric is ready to be employed. Since the mixture is soluble in trichroethylene before process, to verify that cross-linking process has completely happened and that the deposed material results inert, the solvent is rubbed on sensors and wires. After this test, the fabric is ready to be used to manufacture the glove (Figure 2).

2. Glove for gesture recognition

Sensing fabrics described can be employed to realize wearable sensing systems able to record human posture and gesture, which could be worn for a long time with no discomfort. We integrated sensors into a glove (Figure 3) linked to an electronic unit which treats the pre-filtered obtained data. As mentioned above, both sensors and interconnections are realized by galley proofs of the same mixture (in early prototypes the interconnections, made by metallic wire, bounded certain movements, and they was fixed to the garment by metallic snap fasteners which was too large to be placed on a glove).

The bold black track (Figure 4) represents the set of sensors connected in series and covers the most important joints of the hand. The thin tracks represent the connection between sensors and the electronic acquisition system.

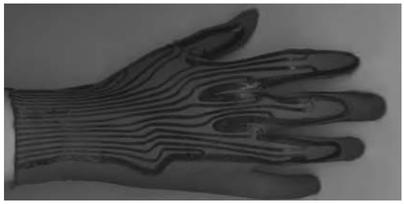

Figure 3. The sensorised glove.

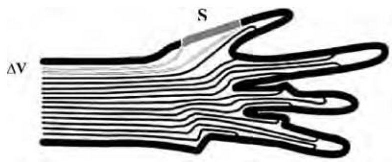

Figure 4. The mask used for the sensorised glove. The segment S represent a sensor, while ΔV represents the voltage read by the thin tracks.

The electronic unit is designed to compensate the resistance variation of the thin track during the deformations of the fabric due to the movements of the hand, and the galley proofs perfectly substitute the traditional metallic wires. Practically, a sensor consists in segments of the bold track between two thin tracks and can be smeared in any position to record the movements of a particular joint.

All the advantages deriving from the technology employed give rise to some problems, respect to conventional gloves, which have been solved by the electronic acquisition devices and by the acquisition and interpretation algorithm. Our main aim consisted in realizing an universal garment, i.e. a garment which works independently on the structure of the hand of the subject which wears it. Another problem we had to solve was the cross-talk phenomenon between sensors which inevitably occurs when an elastic substrate is used. The interpretation algorithm, which is the core of the good capabilities of this technology, as reported in [2], has been developed to address these problems. In the following, two methodologies of employment of the sensing garment are presented.

3. The sensing glove as posture and movements recorder

When the glove is worn by a hand which holds a certain position, the set of sensors assumes a certain value strictly related to the position. If the number of sensors is large enough, the values presented are unique for the position considered. The glove has performed good capabilities of repeatability, even if it is removed from the hand and re-worn (by the same subject). In this way, it is possible to detect if two postures are the same or not, and it is possible to record a certain set of postures coded by the status of the sensors. In the same way, movements, can be recorded as transition from a posture to another, and are coded by an evolution of the sensor values. In particular, we have tested this capability on a set of functionally relevant postures, the basic hand grip. An ad-hoc software devoted to recognize recorded posture has been developed. Although this working mode for the glove is quite simple, it seems to be very promising for several applications in

Figure 5. The sensing glove and the electrogoniometers for the calibration phase.

rehabilitation therapies and medicine. In particular the sensing device is going to be applied in a tricky surgical operation devoted to implant a neural electrostimulator whose electrodes will be positioned on nerves, directly. The operation is aimed to recover some pre-defined basic functional grasps in a tetraplegic. patient and the glove will be used in the following steps.

In the preimplant phase, the glove can monitor the range of grip generated by a Prostigm. These grips are then memorized. In the perimplant phase, during surgery, it is necessary to verify the range of the stimulus obtained during the preparation of the implant. After positioning the electrodes adequately, by activating the neuroprosthesis, a control is performed through the memory of the glove to verify that the gestuality obtained is the same as that set up in the preimplant phase. In the postimplant period it is also possible to use the glove extemporaneously to re-calibrate the hardware (stimulator).

4. The sensing glove as posture detector

Some of the basic positions acquired during the posture recorder mode can be used to construct a continuous function which maps position into sensor values. This map, obtained as an interpolation of the discrete function which recognizes recorded posture, can be used to detect any position of the hand, even if it has never been hold. In fact, the identification algorithm is able to construct a model of the hand expressed in terms of sensor values. If the basic position recorded are associate to a set of angle deviations for the joints of the hand, for example by using in a calibration phase a set of electrogoniometers (Figure 5), the inversion algorithm reconstructs position (in terms of angles) which never have been assumed by the subject.

5. Results

The glove, used as a posture recorder, requires to verify only the hypothesis of repeatability. In the test we have performed (on a set of 32 different postures, the basic grip and the sign of the American sign language), the glove has recognized the 100% of the postures previously recorded if it was not removed from the hand, and the 98% when it has been re-worn. The percentage grow up to 100% if the wearing is re-adjusted when the first error occurs.

In order to test the prototype of the glove in (unknown) posture reconstruction, a set of positions different from the ones used in the identification phase has been chosen. The electrical values of the sensors have been acquired and the positions have been estimated

Table 1. Real angle values estimated angle values for the metacarpo-phalangeal joint (in flexion-extension), the proximal interphalangeal joints and the distal interphalalgeal joint of the forefinger different test points. The real and estimated angles are expressed in degrees. In the last column the number of steps necessary to reconstruct the values is reported

	Met-Fal	Int-proxs	Int-Dist	N° step
Real	45	45	0	34
Estimated	45	45	0	
Real	45	22.5	22.5	25
Estimated	45	25.3125	15.468	
Real	45	45	45	3
Estimated	45	42.1875	45	
Real	75	75	25	26
Estimated	80.1563	67.5	32.3438	
Real	60	0	0	33
Estimated	60.4688	0	8.4375	
Real	22.5	22.5	22.5	17
Estimated	22.5	22.5	45	

by an iterative methods (Newton) which employ the pseudo-inverse of the interpolated function. Then these points have been compared with the real ones. Some of these data are collected in Table 1.

Acknowledgement

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Wearable Textile Biofeedback Systems: Are They Too Intelligent for the Wearer?

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Abstract. The Intelligent Knee Sleeve is a device capable of providing immediate audible feedback to the wearer pertaining to knee flexion angle during human movement. The Intelligent Knee Sleeve was used in a landing training program to determine whether providing subjects with this form of feedback was able to effect a change in knee flexion angle during dynamic landing tasks. Preliminary results suggest that the feedback modality is effective in correcting landing technique. However, advancements in the Intelligent Knee Sleeve design would produce a more robust system leading to more effective biofeedback for the athlete.

Introduction

One of the most disabling injuries an athlete can sustain is non-contact rupture of the anterior cruciate ligament (ACL) which, when ruptured, predisposes the knee joint to episodes of giving way, meniscal damage, loss of proprioception, recurrent pain and likely knee joint degeneration. Unfortunately, these injuries most commonly occur in the world's most popular participation sports, such as soccer and volleyball, predominantly during movements involving rapid deceleration, quick changes in direction and/or abrupt landings and are often accompanied by poor landing technique. It has been estimated that 66% to 78% of ACL injuries occur via non-contact mechanisms, with a staggering 22% of all non-contact ACL injuries resulting when landing from a jump [1]. Compared to contact injuries that have mainly been attributed to chance, non-contact ACL injuries are more related to characteristics of the injured individual, such as the degree of muscular weakness or muscular coordination and, therefore, the movement pattern performed at the time of injury [2]. For example, most non-contact ACL injuries occur when the knee is flexed less than 30° [3] where quadriceps contraction, which is activated to prevent the lower limb from "collapsing", increases ACL strain by increasing anterior tibial translation [4]. Furthermore, with the knee extended, the hamstring muscles are less effective in protecting the ACL by counteracting the quadriceps contraction due to their inefficient line of action [5]. For this reason, it is strongly advocated that individuals should bend their knees when landing from a jump to enable the hamstring muscles to more effectively protect against high ACL strain [3]. Increased knee flexion can also "cushion" the forces generated at foot-ground contact, reducing the jarring effects of landing as well as lowering an individual's centre of gravity, in turn, enhancing their stability [6]. In fact, research has advocated a knee flexion angle of approximately 17^{o} at initial foot-ground contact and 40^{o} at peak resultant ground reaction force as being protective to the ACL [7]. Therefore, it would appear feasible that teaching athletes to increase their knee flexion when landing from a jump, via appropriate intervention programs may prevent these non-contact ACL injuries. However, the challenge is to actually achieve this desired change in landing technique.

Past research has found that providing verbal feedback to subjects before they performed a vertical drop jump resulted in the subjects generating greater knee flexion and, consequently, lower ground reaction forces upon landing [8]. That is, subjects were able to quickly and effectively assimilate verbal instructions so as to modify their lower limb alignment to generate less force upon ground impact. Based on these findings it was suggested that subjects could be trained to modify the kinematics of their landing technique to reduce their risk of injury. Although the benefits of landing programs in reducing ACL injuries are readily acknowledged [9–11], participants in such programs have no method to ensure they are actually bending their knees sufficiently during training to gain the protective effect. That is, dynamic landings occur so abruptly that it is not feasible for coaches or trainers to "eyeball" the knee flexion angles displayed by their athletes during a landing training program to ensure they are learning to flex their knees appropriately. A method to provide athletes with instantaneous feedback pertaining to their lower limb alignment during landing training programs is therefore urgently required.

Recent advances in polymer science have now provided the opportunity to develop such an instantaneous feedback device. That is, inherently conducting polymers can now be integrated into textiles, creating new novel non-rigid biomonitoring options in the form of textile sensors, which have strain gauge-like properties with a wide dynamic range [12]. These unique textile sensors are ideal as wearable systems capable of direct biomonitoring and instantaneous feedback with respect to human motion as, when integrated with conventional but wearable electronics, they can be incorporated directly into existing clothing and equipment without changing the material properties or functions of these items and without interfering with normal human motion. One such device, the Intelligent Knee Sleeve, has been developed to provide audible feedback with respect to changes in knee flexion angle during human motion. The Intelligent Knee Sleeve consists of a simple, inexpensive sleeve of lycra-like material; incorporating a disposable polypyrrole coated nylon-lycra fabric sensor that is placed over the patella (kneecap; see Figure 1). The fabric sensor, integrated into an electronic circuit (3 V), acts as a strain gauge whereby as the sensor is stretched when the wearer bends their knee, resistance within the sensor decreases. At a predetermined threshold resistance, which can be varied, an audible tone is emitted to alert the wearer that the desired knee flexion angle has been achieved. The Intelligent Knee Sleeve therefore is a unique example of a wearable textile sensor system that can provide immediate, individualised and objective biofeedback to the wearer with respect to knee joint motion in the sagittal plane during dynamic tasks, allowing them to adjust their technique accordingly. Validity and reliability trials have confirmed knee angle data obtained using the Intelligent Knee Sleeve to be valid and highly reliable (R_1 = 0.903-0.988) [13]. As such, use of the Intelligent Knee Sleeve should be able to train athletes to flex their knees through a desirable range of motion throughout the landing action and, in turn, reduce the risk of injury. However, although

Figure 1. The Intelligent Knee Sleeve.

theoretically feasible, it is unknown whether using the Intelligent Knee Sleeve during landing training activities does in fact assist the wearer to alter their landing mechanics, both in practice and in match situations. Therefore, the purpose of this study was to determine whether a simple, inexpensive knee sleeve (Figure 1), which can provide audible feedback with respect to knee angle, could be used by athletes to learn how to land correctly.

1. Methods

1.1. Subjects

Thirty-seven subjects who were skilled in sports that require landings and with no history of knee joint disease or trauma participated in the study. Subjects were randomly assigned to one of three groups:

1) *Knee sleeve trained group* - subjects who participated in a landing training program using the Intelligent Knee Sleeve;
2) *Landing trained group* - subjects who participated in a landing training program using a placebo Intelligent Knee Sleeve (that is, the sensor was not functional and no audible feedback was provided to the wearer); and
3) *Control group* - subjects who did not participate in a landing training program.

Subjects were matched for age, height, mass, sports experience and athletic ability. Written informed consent was obtained from all subjects, and all testing was conducted according to the National Health & Medical Research Committee Statement on Human Experimentation. The subject characteristics are reported in Table 1.

Table 1. Subject characteristics

Subject	Knee Sleeve Trained	Landing Trained	Control
Age (yrs)	22.9 ± 4.0	22.7 ± 4.3	23.7 ± 3.9
Height (m)	1.81 ± 0.12	1.76 ± 0.08	1.75 ± 0.11
Mass (kg)	74.2 ± 14.3	71.1 ± 7.7	73.6 ± 17.6

1.2. Experimental Protocol

Pre- and post-intervention, the athletes from all subject groups performed a vertical and a horizontal landing task whereby they landed on their dominant limb with their foot centrally located on a force platform whilst catching a football. Data from five successful trials were collected for each landing task for further analysis.

1.3. Kinematic Data

During the landing tasks, each subject's three-dimensional landing motion was captured (200 Hz) using an OPTOTRAK 3020 motion analysis system located approximately 3 m from a calibrated landing zone. Standard data collection procedures were followed before each trial to enable later computation of the marker coordinates located on each subject's test limb. Orientation and motion of the leg and thigh of the landing limb were calculated during each trial from the frame representing initial foot-ground contact until the frame representing the peak resultant ground reaction force during each landing task.

1.4. Kinetic Data

The three orthogonal components of the ground reaction forces generated at landing during each trial were quantified using a Kistler Multichannel force platform. Force data were sampled (1000 Hz) over 4 s for all successful trials (that is, landing in the middle of the force platform). The four vertical channels, two anteroposterior channels and two mediolateral channels were then summed and scaled to obtain force-time curves as input for calculating the force-time history of the peak resultant ground reaction force.

1.5. Electromyographic Data

The activation patterns of eight lower limb muscles that control motion of the lower limb were collected (1000 Hz) using the Noraxon Telemyo electromyography (EMG) system for 4 s during each landing task. These muscles included rectus femoris, vastus lateralis, tibialis anterior, peroneus longus, biceps femoris, semimembranosus, gastrocnemius and gracilis. Following zero offset removal, raw EMG signals were processed to obtain linear envelopes and a threshold detector was then used to determine the temporal aspects of each muscle burst with respect to initial foot-ground contact and peak resultant ground reaction force. Filtered EMGs were then integrated over the duration of each burst of interest to determine the muscle intensity required to perform the landing task.

1.6. Knee Sleeve Intervention Program

Subjects in the "knee sleeve trained" and "landing trained" groups participated in a 6-week [8–10] progressive landing training program to learn correct landing mechanics, completing 3 x 30 minute training sessions per week. The landing training program improved the ability of the subjects e.g. from general to specific landing movements and incorporated ball skills, surface and footwear changes, gymnasium- and field-based activities, open and closed skills, and fatigued and non-fatigued conditions [2]. Advice on how to land correctly was given to all subjects participating in landing training [8,9]. However, no specific feedback, other than the audible feedback from the Intelligent Knee Sleeve, set to respond at approximately 35^{o} knee flexion, for the knee sleeve trained group, was given to subjects. Extensive pilot testing was completed when designing the landing training program to ensure the landing tasks replicated movements performed by players in both competition and training in the popular sports of football, basketball, netball and volleyball. Activity diaries were kept by all subjects throughout the 6-week intervention and monitored weekly in order to determine any changes in activity level, health or injury status of the subjects.

1.7. Statistical Analyses

Means and standard deviations for the kinematic, kinetic and EMG data were calculated to establish the landing mechanics of each subject before and after the 6-week training program. Data were then analysed using an ANOVA design with one between factor (subject group: knee sleeve trained, landing trained, control) and one within factor (test time: pre- and post-training). The purpose of this design was to determine if there were any significant differences ($p \leq 0.05$) in the kinematic, kinetic and EMG data because of the feedback provided by the Intelligent Knee Sleeve and/or the 6-week landing training program.

2. Results

During the 6-week intervention, two subjects in the landing trained group and three subjects in the knee sleeve trained group sustained injuries during their usual sporting pursuits, unrelated to the study, and withdrew from the study. Therefore, the results reported are from the remaining subjects in each group who completed the study.

Preliminary knee flexion angle results suggest that the Intelligent Knee Sleeve provided an effective biofeedback modality for subjects in the present study as subjects in the knee sleeve trained group successfully increased their knee flexion angle during the dynamic landing movements after completing the landing training program. For example, when performing the vertical marking movement, the knee sleeve trained subjects increased their maximum knee flexion angle at initial foot-ground contact from 12.6^{o} flexion pre-landing training to 14.5^{o} flexion post-landing training. In comparison, subjects in the landing trained group did not display differences in knee flexion angle (pre-training = 8.0^{o} flexion and post-training = 8.2^{o} flexion) and subjects in the control group actually recorded less knee flexion after the 6-week intervention compared to before the intervention (pre-intervention = 12.6^{o} flexion and post-intervention = 10.7^{o} flexion). Furthermore, anecdotally, whereas subjects in the landing trained group indicated that they felt improvements in muscle strength may have helped their landing movements, subjects in the knee sleeve trained group indicated that they felt they bent their knees more and had improved postural alignment when landing from a jump which made them feel more stable and at less risk of injury. Specific feedback from knee sleeve trained subjects with respect to the Intelligent Knee Sleeve as a training device was positive, in that they supported the idea and the assistance that it provided to them during the landing training program. However, as the training sessions were quite vigorous, performance of the fabric sensor was compromised by factors such as mechanical degradation, temperature, humidity and sweat and therefore at times the sensor needed replacement during a session.

3. Discussion

Polypyrrole-coated nylon-lycra was found to be a suitable fabric substrate to integrate into the Intelligent Knee Sleeve as a sensor as it exhibited a wide linear dynamic range (e.g. 30-70% strain), with good sensitivity [14]. However, as the sensitivity, linearity and dynamic range of these fabric strain gauges are dependent upon numerous factors, including the uniformity and nature of the polymer coating itself in combination with the material properties and knit pattern of the fabric base substrate, further research is recommended to optimise these characteristics so they can accurately characterise human performance. Furthermore, enhancement of the sensor to allow for methods by which the sensors can be calibrated to replicate the functional demands of monitoring human performance, innovative sensor-electronics connection techniques and knowledge pertaining to the effects of variations in temperature, humidity, machine washing and sweat resistance are required to ensure such sensor systems are robust enough to withstand the rigours of physical activity likely to be encountered in activities of daily living, work, and recreation.

Previous research has suggested that when landing from a jump, athletes should generate knee angles of approximately 17^o flexion at initial foot-ground contact and approximately 40^o flexion at peak resultant ground reaction force to provide optimal protection against ACL injury [7]. Based on the results of the present study, following a landing training program using the Intelligent Knee Sleeve, on average athletes displayed

greater knee flexion when landing from a jump which, in turn, should decrease the forces of landing and place the hamstring muscles in a better position to protect the ACL. However, the recommended value of 17^o knee flexion was derived from one specific landing task, that being landing after leaping forward to catch a chest level pass. Therefore, the clinical relevance of a 3^o difference in knee flexion angle between tasks is unknown and requires further investigation.

4. Conclusion

In conclusion, the Intelligent Knee Sleeve appears effective in providing immediate feedback with respect to uniplanar knee joint motion, that can be used by athletes to learn correct landing technique, a device that is NOT “too intelligent” for the wearer.

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Potential Applications of Smart Clothing Solutions in Health Care and Personal Protection

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Abstract. The rapid development in the fields of sensor and telecommunication technologies has created completely new possibilities also for the textile and clothing field. New smart textile and clothing systems can be developed by integrating sensors in the textile constructions. Application fields for these added-value products are e.g. protective clothing for extreme environments, garments for the health care sector, technical textiles, sport and leisure wear. Some products have already been introduced on the markets, but generally it can be stated that the development is only in its starting phase, and the expectations for the future are big.

Many different aspects have to be considered in the development of the wearable technology products for the health care sector: medical problems and their diagnosis, sensor choice, data processing and telecommunication solutions, clothing requirements. A functional product can be achieved only if all aspects work together, and therefore experts from all fields should participate in the RTD projects.

In the EC-funded project DE3002 Easytex clothing and textiles for disabled and elderly people were investigated. Some recommendations concerning durability, appearance, comfort, service and safety of products for different special user groups were defined, based on user questionnaires and seminars, general textile and clothing requirements and on laboratory test series.

"Clothing Area Network - Clan" is a research project aiming to develop a technical concept and technology needed in enabling both wired and wireless data and power transfer between different intelligent modules (user interfaces, sensors, CPU's, batteries etc.) integrated into a smart clothing system. Fire-fighters clothing system is chosen as the development platform, being a very challenging application from which the developed technology can be transferred to other protective clothing systems.

Introduction

Clothing forms the medium between the human skin and the environment, being in direct and continuous contact with the skin and giving protection (thermal, moisture, mechanical, etc.) against discomfort and risks. The total clothing system is in most cases containing several layers with different properties: underwear and hosiery close to the body, middle layers to provide insulation, and outer layers for appearance and protection.

As clothing is continuously worn, it forms an ideal platform to incorporate sensors for measuring the human vital signs on one side and the environmental risk factors on the other side. However several factors have to be considered when developing technical solutions of this so called wearable technology. The clothing material and design must be correct for the sensing but also provide comfort for the user and be serviceable. The sensors must, in addition to performing the measurements reliably, either be easily removable or withstand repeated washing or dry-cleaning. The measured signal must be transmitted to a processing unit, preferably by wireless communication. And a system for analysis of the data must exist. Therefore many different skills have to be united for the development of wearable technology: medical, textile/clothing, sensor and signal processing.

Two apparent application fields for wearable technology are the health care and the protective clothing sectors.

1. Health care – the EASYTEX project

In the health care sector, a continuous monitoring through wearable technology solutions of vital signs (heart rate, breathing, blood pressure, mobility, etc.) of patients and risk groups has the potential benefits of increasing patients' safety, decreasing the work load of nurses and doctors, and make independent living possibilities better. Some prototype garments have already been developed, but much remains still to do.

In the European EASYTEX project concerning clothing and other textiles for disabled and elderly people, one of the objectives was to define the functional requirements on products for end-user groups with special needs. The results have been published in [1] and can in many respects be taken as a base for future wearable technology solutions of these products.

1.1. Function vs. comfort

Different functional characteristics can be integrated in clothing systems. However it always has to be remembered that a basic requirement for clothing is that it should be comfortable to the user. Severe and prolonged discomfort might lead to unbearable suffering and health risks. Clothing comfort is affected by several factors:

- Thermal comfort: the heat production of the body has to be equal to the heat loss, in order to maintain thermal balance. In a warm environment the resistance to dry heat loss, i.e. the thermal insulation, should be low, and the breathability (transmission of water vapour) should be high. In a cold environment and particularly if the physical activity is low, a high thermal insulation of the clothing is needed.
- Tactile comfort or mechanical contact between the textile products and the skin is always important but particularly for persons sitting or lying for long periods. The tactile comfort depends on the mechanical fabric properties (surface smoothness, protruding course fibres, friction, elasticity, etc.) as well as on possible hard seams and sharp fabric wrinkles. A continuous high moisture level makes the skin more sensitive to mechanical irritation. Persons with supersensitive skin caused by e.g. diabetes have to be extremely careful when choosing particularly underwear and bed textiles.

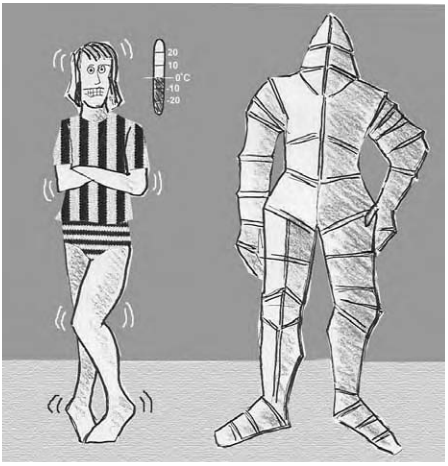


Figure 1. Compromises between function and comfort have to be done in many situations.

– True allergies caused by textiles are not very common, and the possible problems are highly individual. Impurities in the fabrics might however cause problems (finishing agents, dyestuffs, accessories like metal buttons, rests of detergents, dirt, etc.). Protein fibres (wool, raw silk) and rubber are known to give allergic reactions.
– Static charges in the clothing cause clinging to the body, attraction of dust particles, and sparkling when undressing or getting out of a car. The problem occurs particularly in dry environments and synthetic fibre products are problematic.

The psychological aspect of comfort is also very important. The clothing has to be aesthetically attractive and fashionable, in harmony with the user's personality, and appropriate for the wear situation in order not to cause psychological discomfort and aversion against the use of it.

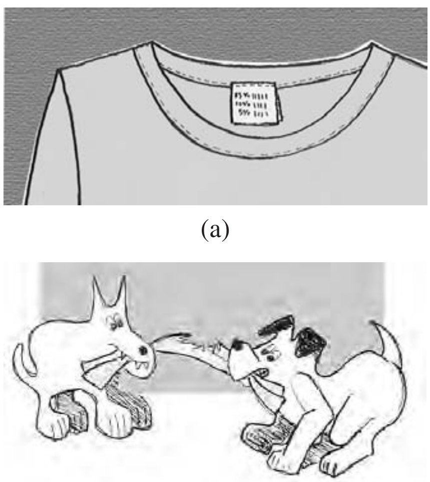
The functional requirements can in many cases be in conflict with the comfort requirements, and compromises between the two have to be done, Figure 1. If sensors are integrated in the underwear to measure e.g. blood pressure, this might need a firm contact between the garment and the body and therefore a relatively rigid underwear material and tight fitting design. From the comfort point of view, a continuous use of that type of garment particularly in warm conditions can be very stressing.

1.2. Bed textiles and diapers

In the healthcare sector, a large proportion of the most severe cases spend most of their time in bed, either in home or in institutional care. The bed textiles are therefore an apparent potential application field for the integration of sensors to monitor the signs of the patient, Figure 2. Many different textiles are used in the bed: nighties, sheets, blankets, mattresses / mattress covers, cushions / pillows. Similarly as with the clothing solutions, the comfort aspects have to be considered in addition to the functions.

Incontinence is a well known problem among elderly and some disabled groups, and diapers have to be used. If the diapers do not function properly or get oversaturated, leakage will occur which is very embarrassing and causes discomfort. Moisture sensors, either in the bed textiles, in the clothing or in the diaper, which give a signal either when

Figure 2. The hospital or home bed provides a potential platform for monitoring patients' health.



(a)

(b)

Figure 3. Care and mechanical properties of the textiles products have to be considered.

the diaper surface gets too wet or when leakage occurs, could decrease the patients' suffering and the work load of the carers.

1.3. Care, durability, usability

General requirements on consumer textiles have to be specifically considered when choosing them for wearable technology solutions. The price of the product will be higher than for normal products, and therefore it should also meet all possible user requirements.

Clothing and bed textiles are normally not disposable after single use but should withstand a number of washing or dry cleaning, drying and ironing cycles, according to the care label, Figure 3a. The sensors and other wearable technology elements must therefore either comply with these or be easily removable and re-connectable.

The mechanical durability (abrasion, tear, breaking, bursting and seam strength) as well as the appearance persistency (colours, smoothness, drape, pilling, etc.) are general requirements, and information can be provided by the producers, Figure 3b.

If the product is not planned to be disposable, the total costs and the expected life cycle should be considered when making the purchase decision. The purchase price is generally only a small part of the costs, and service, distribution and other costs should also be calculated.

The products should be easy to dress and undress, should not restrict the movements of the user, or otherwise be ergonomically difficult. This is particularly important in home use, where the user himself has to ensure the continuous use of the wearable technology product.

2. Protective clothing - Clothing Area Network project

In many working tasks, an intelligent clothing system could be very useful. Especially if clothing is capable of monitoring both the working environment and the wearer's well-being and also capable of transmitting this measured data, or any information related to the work itself, to it's operative control. This kind of clothing can be especially useful when working alone in environments of high risks.

When thinking of valuable applications on social benefits, suitable areas for pilot research are found from the clothing used for example in fire & rescue operation, elderly people's home monitoring or patient monitoring, water industry's field work etc. Fire-fighter's clothing offers a good and challenging R&D platform, because specific parts of the fire-fighter's gear can "act" as those less demanding clothing applications, which usually have less pieces of clothing. The wholeness of the fire-fighter's gear contains at least underwear, outerwear, footwear, gloves, helmet and compressed-air bottles, and all those pieces should have their own intelligence in future. The working environment in fire & rescue operations is also very challenging and varies from extreme hot and smoky fires to often less demanding rescue operations like traffic accidents, searching lost persons etc.

Firemen are equipped with special protective apparel made of multi-layer high tech fabrics (like meta-aramids or laminated fabrics of aramids with breathable waterproof membranes). On one hand the modern fire suit protects fireman longer when exposed to a raging flames, but on the other hand, the suits prevent them from sensing the dangerous intense heat of a fire. Today fire-fighters still use their raised hands when trying to sense temperature during smoke diving. Their suits retain radiant heat perhaps too well; fire-fighters can walk into situations where they start burning from the inside and have no return from flames. Sensors detecting temperature outside and inside the suit can provide this lack of temperature sensing information. The moisture in the microclimate inside the suit is another important quantity to have information on. What about fire-fighter's vital signs? Are his necessary equipments working properly? Is there still air enough is his bottles for the final attack? How is his partner doing, and where is he? Can others find us if we'll be trapped?

How to make reliable measurements on quantities giving answers to those questions? How to send all that measured information to the operative control and how to utilise it? What kind of technology is available today to give answers to these questions? Finally, how to make things wearable and reliable to get the best usage?

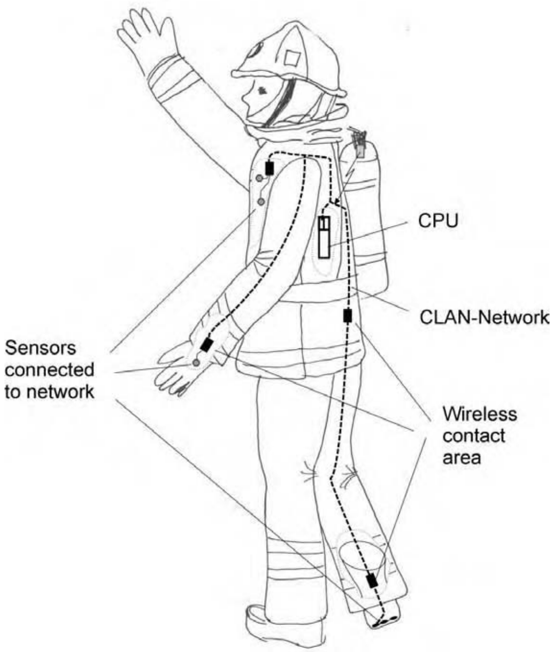


Figure 4. Clan concept in fire-fighter's gear.

"Clothing Area Network - Clan" is a research project aiming to develop a technical concept and technology needed in enabling both wired and wireless data and power transfer between different intelligent modules (user interfaces, sensors, CPU's, batteries etc.) integrated into a smart clothing system, Figure 4.

The first phase of the project contains the preliminary definition of the Clan concept and certain research and development work for specific techniques needed in piloting and verifying the future benefits of Clan.

2.1. State-of-the-art, workshops

The Project will start with a state-of-the-art research and brainstorming workshops in close co-operation between fire & rescue professionals and researchers of all special areas of technology needed. The workshops will clarify the current situation in fire & rescue field and give estimation about the future within next ten years. Clan's first stage focus and priorization of the potential intelligent features will be determined according to the results of the workshops.

2.2. User interfaces and usability

Designing the user interface for the smart clothing is a challenging task. Parts, which have not any clothing-kind of features, should be avoided. On the other hand, a user interface should perform complex controlling functions like locating and communication tasks. The extremely hard demands must be set for the user interface because it has to operate in unpredictable conditions of extreme environment. The special conditions (heat, moisture, noise and varying lighting conditions) of the work environment create special challenges for developing and studying the usability of smart clothing and chosen user interface. The planning and estimation process of the usability consists of sectors, which supplement each other. These sectors are: use context determination, target group determination, user demands methods, planning usability estimations. Stage 1 of the Clan project aims only to examine, not yet to develop any intelligent user interface, which is suitable for clothing used in fire & rescue operations.

2.3. Sensors

The sensor technology to be built into the prototype clothing will be decided according the prioritization. The sensors must be suitable for their size or for their form to be integrated into the clothing. The functionality of the prototype sensors is tested in conditions (temperature, moisture and mechanical stress, machine wash), which correspond to the use of the clothing. In next stages of Clan, if necessary, the encapsulation, protection and the signal transmission of the sensors will be modified.

An interesting area for research will be the electrodes integrated into the garment. These electrodes will function a part of the clothing itself. New conducting and flexible materials (conductive elastomers, conducting fibres) can be used to produce wide electrode areas in the underwear. This improves the contact to the skin and therefore decreases the impact of persons moving on the accuracy of the EKG monitoring.

2.4. Instrumentation, signal and power transfer inside and between garments

The signal and power can be transferred along one wire inside a piece of clothing by a new, patented instrumentation solution. The possibility to simply branching allows a significant reduction of the number of cables and because wide bandwidth signals may be transferred through the isolation a full networking capabilities may also be implemented.

Because the basis of the system is a wireless system, the concept allows borderless shift from cables to wireless communication. This may be done essentially at any suitable stage of the signal transfer.

2.5. Measuring of vital signs and environment

The prototype suit is meant for the fire & rescue tasks where the environment and the working conditions set extremely high demands to the equipment. On the other hand, the monitoring of vital functions brings a considerable addition to the safety of the work. In fire and rescue operation the working environment and hardness and intensivity of the work itself cause many elements of danger. The perception of those dangers early enough is the key factor to maintain health and working ability. Today the protection, which is based only on ones own senses and on working norms, does not give a comprehensive protection in the changing conditions of fire and rescue tasks. The intelligence of the smart suit, the integrated sensors and data communication methods would make the online monitoring of vital functions possible. The projects background research will clarify furthermore what are the physiologic quantities of the vital functions to be measured in different types of tasks and the priorities of various measuring. Beside the pulsation of the heart and temperature of the skin other measured quantities could be the depth and frequency of the breathing, breathing gases, EKG, monitoring the amount of blood pumped by the heart, monitoring unconsciousness and activity and vigour state etc.

2.6. Piloting and testing

The sensors and other technology used in Clan prototype are chosen according to the information gained via workshops and the prioritizations. The clothing to be tested is either designed and manufactured specially for the project or modified by the garments available in the markets and suitable for the purpose. The whole prototype outfit will include underwear, station wear, fire tunic and trousers and other PPE (personal protective equipment).

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Body Motion Capture for Activity Monitoring

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Abstract. CEA-LETI has developed a 3D orientation tracker based on accelerometers and magnetometers. Owing to an efficient data fusion algorithm, the tracker provides accurate 3D orientation angles. The tracker is small enough to be used as a wearable device and therefore is an interesting tool for body motion capture. Investigations are being performed to analyse how activity of a person can be monitored from body motion measured with the tracker. In the domain of healthcare monitoring, many applications are envisaged such as rehabilitation with 3D body motion capture, elderly dependency evaluation, context acquisition for physiological monitoring.

Introduction

There is a growing interest and demand for healthcare monitoring systems due to two main factors: one is the availability of smart devices and associated NTIC (New Technologies for Information and Communication), the other is the society evolution where the population lives longer, where the health costs need to be reduced, and where the citizens are concerned with the quality of life, fitness and health. The general trend is to adapt and simplify hospital tools to provide the citizen with wearable means to monitor his health status, for instance heart rate monitoring, e.g. POLAR [1], instead of 12-lead ECG, optical oxygen partial pressure measurement, e.g. NONIN [2], instead of blood gas analysis.

Activity is one of the key parameter to acquire in order to monitor health because motion is directly related to life. A series of systems have been developed in this area, usually based on MEMS accelerometers. Some devices are attached to the wrist (Actiwatch [3], Vivago [4]) others on the chest or back [5,6].

In that environment CEA-LETI has developed a motion capture device which allows making fine measurements in the 3 degrees of freedom of space [7]. The approach consists in taking benefits from the microsensor technologies to design new motion tracking microsystems which do not require any artificial external sources. The sensors issued from the LETI technologies, or which are available on the market (accelerometers and magnetometers), enable to design a three degrees of freedom orientation tracking system.

In the following we first present the orientation tracker device, developed by LETI, then we go through different usages of system such as a wearable tool in the medical

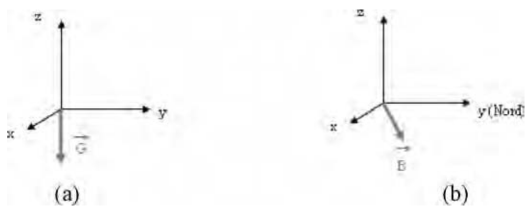

Figure 1. Gravitational and magnetic fields in the reference coordinate system.

domain: human body motion capture, activity classification or monitoring, and context measurement related to physiological parameter monitoring.

1. Orientation tracking microsystem developed by CEA-LETI

1.1. Giving Orientation without sources nor integration

The principle of orientation estimation is based on three axes sensing of Earth gravitational and magnetic fields. The gravitational field, G, has always the same direction and value (Figure 1(a)), so three orthogonal accelerometers attached to a static object will give us the direction of the local vertical.

The magnetic field, B, is oriented to the north with an angle depending of our position on the Earth. (Figure 1(b)). Three orthogonal magnetometers provide the direction of the magnetic field. Both fields are necessary because G alone does not give the rotation around the z axis. The three axes measurements are needed to get the three rotation angles in full 360°. This solution doesn't integrate gyrometer unlike other devices based on the same principle [8,9], which reduces considerably the cost and the dimensions of the tracker. One limitation is that the accelerometers are sensitive to gravity as well as linear accelerations. In a system which accelerates, the three linear accelerometers produce an output vector which doesn't give the direction of the vertical. The other limitation is that the Earth magnetic field is perturbed by any ferromagnetic object. Because of these limitations, sensors used independently cannot reach a very high accuracy, but the combination of the six sensors (3 accelerometers and 3 magnetometers) reduces the errors: when a sensor gives erroneous information another sensor compensates by giving good information, for example, the accelerometers is perturbed by an acceleration due to displacement and the magnetometers are not. Therefore, an efficient data fusion algorithm has been developed to obtain a tracker providing accurate 3D orientation angles.

1.2. Hardware structure

Surface micromachined acceleration sensors have been commercially available for some years now, with the automotive sector being the largest market. Initial applications include crash sensors for airbags. These devices resolve acceleration down to the milli-g level (1g=9.8m/sec2). Miniaturization and precision enlarged the applications to inertial navigation coupled with GPS navigation. The accelerometers mounted in our tracker have a dynamic range of $\pm$1g or $\pm$2g. We use the Analog Device and STMicroeletronics accelerometers, which include on chip signal conditioning.

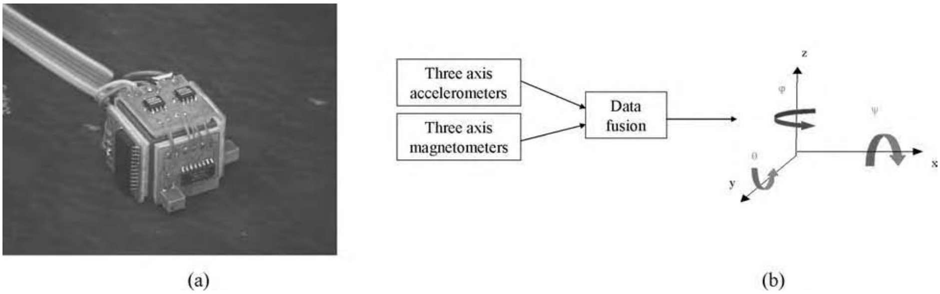

Figure 2. (a) cubic structure of the tracker, (b) principle for angle computation.

The micro fluxgate magnetometers have been designed in the LETI Laboratories. It consists of two coils wrapped around a common high-permeability ferromagnetic core whose magnetic induction changes in the presence of an external magnetic field. A drive signal must be applied to the primary winding and the signal is detected to retrieve the magnetic field value. They benefit from performances required in space applications. The low cost alternative is the magnetometer based on giant magneto-resistance. To improve their performance characteristics they need compensation circuits for drift correction. But in applications such as navigation for general public, such elaborated compensations are not need.

Only few sensors are available in 3D package, so we need at least two orthogonal planes to have the third dimension for the 3D mounting of the sensors. The solution used for our first prototype is a cube where the 6 sensors are mounted on three of the faces (Figure 2). The new design is a 1.5 cm cube.

1.3. A tracking device

The end-up result is a generic tracking device which combines a hardware sensor and a data fusion processing to provide the three rotation angles of a solid.

The orientation sensing is very efficient in the static mode, i.e. when the movements are quite slow. When the movements are fast, the initial and final orientation are well found but not during the movement. The resolution is about 0.5° and the precision is better than 1° in the static mode. Actual researches tend to improve the dynamic response using elaborated algorithms like adaptive filtering.

Developed originally as an interface to navigate and interact with the 3D virtual worlds, it is a generic tool on which many applications can be built, including healthcare. Many different analysis of the 3D angle information (and raw data sensors as well) can be developed depending of the specific needs. That is what we present below with some examples of activity monitoring for personal health monitoring.

For these applications, the trackers are clearly not textile sensors but small enough to be integrated in a cloth or stitch to the skin to make it wearable. The present size of the sensor is a 1.5cm cube, but further integration is planned. 3D packages are almost available for Honeywell GMR, but are rare for accelerometers. It will change in the near future and the system will be mounted on one plane reducing the manufacturing cost and the dimensions. On the other hand, the progress in micromachining and the heterogeneous assembling of materials make possible the mounting of the six sensors on a single chip with the conditioning electronics.

Figure 3. (a) tracker position on the body, (b) body tracking experimentation with 3D visualization.

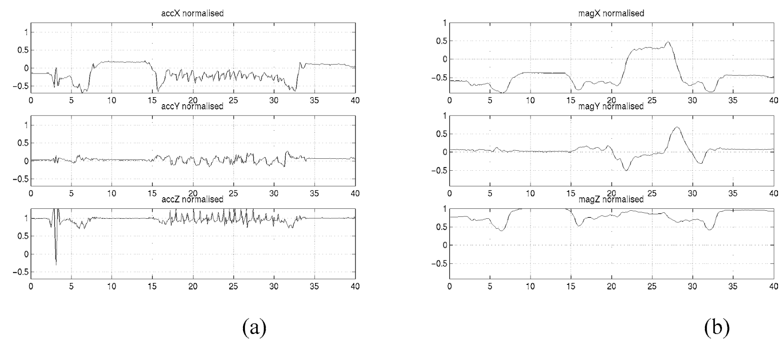

Figure 4. accelerometer and magnetometer signals acquired on the chest of a patient.

2. Medical / health applications

2.1. 3D human body motion capture

The idea in that application is to develop a whole body tracking system. The system is based on a simplified skeleton modelling, which describes main bones and joints with rotation constraints, and the use of multiple sensors attached to the body. Owing to the skeleton model, it is possible to capture a whole body motion from limited number of trackers depending on the application. The minimum number is ten trackers but fifteen is much better (see Figure 3(a)). Afterward it becomes possible, from the tracker acquisitions, to have a global motion model of the user. The model can be used for an animation, such as presented on Figure 3(b), but also to trigger off action by computer from body posture detection, and for motion and behaviour analysis. For the medical point of view, this tool could be used for rehabilitation in order to help users to visualize their movements, and to compare them with reference ones.

2.2. Activity monitoring

For some daily life applications, we have to use only one tracker in order to have device acceptable for the user. However, from one sensor, it is already possible to acquire lots of information on the activity of the person. For example on Figure 4, we present the accelerometer and magnetometer signals acquired on a person who jumped, sat on chair, stood up, walked around and sat back on a chair.

From these signals, and the associated computed angles, it is possible to analyse the posture of the person, but more generally his activity. It has been used in the ACTIDOM project. The project is funded by France Telecom R&D, and also involves TIMC and LI2G-GPSP university laboratories and TEAMLOG. The goal of the project is to monitor activity in frail elderly in their daily life. It shows how the miniaturized device can represent elementary activities such as walking, transfers between postures, confinement to bed with good intra and inter subject reproducibility. The final goal is to detect a dependency increase, by trend analysis on activity.

2.3. Activity classification

In addition to accurate activity analysis to detect subtle change in behaviour, it can be interesting for some other application to classify the activity of a person: for example walking, running, sleeping, sitting. This can be useful when it is necessary to adapt your life style after a health problem such as cardiac surgery, or to have a healthier way of life for obesity problem. By analysing the signal of the tracking device, accelerometer, magnetometer and 3D estimated angles, it will become possible to classify the current activity and to build a history of activity of the user. This can be compared with an expected activity level in order to give automatically advice to the user.

2.4. Context acquisition for physiological monitoring

Physiological measurements in a medical environment are acquired with a strict protocol in order to have a good diagnosis. Physiological monitoring (ECG, blood pressure…) in daily life does not respect this protocol and is highly dependent on the context or activity of the user. Therefore it is very important to add a sensor to acquire this context. For example OMRON has added an accelerometer to a wrist blood pressure sensor in order to know when the forearm is in good position to get accurate pressure measurement. This is a very specific case, and we plan to use our sensor as a general history context related to physiological monitoring. The corresponding activity measurement can be use either to correct the physiological measurement from artefacts, or more generally as input to be used in parallel to physiological measurement for data interpretation and diagnosis. This automatic history acquisition will make an easier life for the user of cardiac holter for example who has, so far, to write on a paper his activities during day. In addition the diagnosis will be better and simpler.

3. Conclusion

LETI has developed a 3D orientation tracking system based on accelerometer and magnetometer MEMS. Based on a low cost technology, it is however possible to compute accurate 3D orientation angle owing to a dedicated data fusion algorithm.

This tracker can be used as a wearable device to monitor motion of a human and consequently its activity. This activity monitoring can be very useful for many personal health monitoring applications such as rehabilitation, elderly dependency evaluation, context acquisition for physiological monitoring. This tracker could also be used as a diagnostic tool for quantitative motion measurement which is done by eye usually.

Acknowledgments

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An e-Textile System for Motion Analysis

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Abstract. Electronic textiles (e-textiles) offer the promise of home health care devices that integrate seamlessly into the wearer's everyday lifestyle while providing a higher level of functionality than current devices. Existing gait analysis systems are cumbersome laboratory-based systems that, while providing valuable information, would be difficult or impossible to deploy in the home. Yet gait analysis systems offer the promise of preventing and/or mitigating the serious effects of falls in the elderly population. This paper proposes an e-textile solution to this problem along with a design approach for realizing a solution that is inexpensive and usable across the elderly population. Preliminary results are given to demonstrate the promise of the proposed system.

Introduction

An ideal home health care technology should be easy to use, reliable, and cost-effective, should blend in with the home environment, and should provide accurate medical information to the patient and/or caregivers. Wearable medical devices should be small, lightweight, and simple to attach, while medical devices that are used in the home should be easy to install and permit normal movement about the living space. A patient should be able to go about a daily routine without interference or distraction. Devices that do not have these characteristics will not be widely adopted or effective. In usability studies of health monitoring devices used by the elderly population, participants were apprehensive and lacked confidence in the devices due to the size, non-functionality when moving about, and lack of training [3]. An emerging technology, electronic textiles (e-textiles), holds the promise of creating home health care devices that will be more accepted and usable. In this paper, we outline an approach to investigating the use of e-textiles for monitoring and analyzing problems with an elderly person's gait, thereby reducing the risk of falling, a leading cause of mortality and nursing home placement.

E-textiles, fabrics that have electronics and interconnections woven into them, have the potential to provide home health monitoring and assessment that is small, lightweight, easy to use, and cost-effective. E-textiles allow the creation of systems with a physical flexibility and size that cannot be achieved with currently available electronic manufacturing techniques. Using standard techniques and machinery from the textile and garment industries, large e-textiles can be produced quickly and inexpensively, benefiting from the economies of scale of those industries.

Because e-textiles do not have wiring harnesses between discrete components, they have a distinct advantage over conventional electronics for home health care. Both the wires and the components are a part of the fabric and thus are much less visible and, more importantly, not susceptible to becoming tangled together or snagged by the surroundings.

Consequently, e-textiles can be worn in everyday situations where currently available electronic devices would hinder or perhaps embarrass the user.

While we foresee numerous home health care uses for e-textiles, our focus in this paper is on using e-textiles to monitor and assess a patient's gait. An elderly person's gait is a good indicator of a number of medical conditions, including muscle weakness, strokes, and Parkinson's disease. A person with gait problems has a greatly increased risk for falling, which in the elderly population is a major cause of mortality and nursing home placement. In the U.S., accidents are the fifth leading cause of death in the older population (aged 65 and older), and falls make up the largest percentage of accidents (over 65%) for this age group [4]. Approximately 33% of the elderly population living at home will fall each year, and about 1 in 40 of them will be hospitalized. Of those admitted to the hospital after a fall, only about 50% will be alive one year later [5]. Additionally, falls and hip fractures among older individuals rank as one of the most serious public health problems in the U.S., with annual costs expected to exceed $16 billion by the year 2040 [6].

Being able to analyze a person's gait easily, reliably, and cost-effectively would allow the medical community to reduce the incidence of falling in the elderly. However, with current technology, it is not feasible to assess a person's gait on a regular basis or in the patient's home. This paper addresses the problem through the design of e-textiles that can be worn by a patient or placed in the patient's home, allowing the patient's gait to be monitored and analyzed without interfering with a normal daily routine. In addition to monitoring and analyzing gait, this research will outline methods for reducing the severity of a fall as well as helping patients improve their gait.

In this paper, the authors outline the research issues associated with designing an e-textile system for gait analysis. The goal is to create an e-textile system that can provide the same level of accuracy as a video-based laboratory system, while being cost-effective and easy to use. An important aspect of the project is to quantitatively assess the accuracy of the e-textile system by comparing it to a video-based laboratory system. The measures that must be compared are kinematic and kinetic parameters of gait (i.e., stride length, stride width, lower extremity joint angles, friction demand, and joint torques), movement patterns associated with whole body Center-of-Mass (COM), and slip parameters (i.e., heel slip distances, and sliding heel velocity.) By creating an inexpensive gait analysis system that can be used in the home or in the doctor's office, other researchers will be able to more easily study gait-related problems at home and to use gait analysis as a diagnostic tool for predicting and mitigating fall accidents among the elderly.

In addition to being accurate, the e-textile must tolerate a range of faults, operate on a small energy budget, and be cost-effective to manufacture on existing textile equipment. By using a design process that incorporates high-fidelity simulation and prototype manufacturing [2], we will construct a weave pattern (including wire, sensor, and processor placement), textile network design, and sensor/processor activity level assignment that provides the required level of application accuracy, fault tolerance, and energy consumption. It is expected that the resulting experience and process will enable the construction of a wide range of e-textiles for home health care.

1. Gait Analysis

A review of the biomechanical literature indicates that there are several differences in the gaits of older and younger adults. Older adults tend to walk slower, have a shorter stride length, and a broader walking base. This results in a gait cycle with a longer stance or double support time [7]. On slippery floor surfaces, people of all ages tend to shorten their stride length to reduce horizontal foot forces and reduce the likelihood of slipping [8]. It is generally believed that the shorter step length and the slower walking velocity of older adults result in a more stable or safer gait pattern, but these gait changes may also have some important implications for the initiation of slip-induced falls.

Initiation of a slip occurs whenever the frictional force ($F\mu$) opposing the movement of the foot is less than the horizontal shear force (Fh) at the foot during the heel contact phase of gait [9]. Specifically, at the time of the heel contact, there is a forward thrust component of force on the swing foot against the floor. This results in a forward horizontal shear force (Fh) of the ground against the heel. Additionally, a vertical force (Fv) occurs as the body weight and the downward momentum of the swing foot (and leg) make contact against the ground.

Lockhart et al. [10] conducted a laboratory study to examine the gait changes associated with aging and the effect of those changes on initiation of slips, initial friction demand, and frequency of falls. The results indicated that older participants' horizontal heel contact velocity was significantly faster, and transitional velocity of the whole body COM (velocity changes between heel contact to shortly after heel contact phase of the gait cycle) was significantly slower than their younger counterparts. Slower transitional speed of the whole body COM increased horizontal foot force at heel contact, and increased friction demand at shoe/floor interface. As a result, older subjects slipped longer and faster, and fell more often than younger subjects.

At present, gait analysis is performed using a video-based locomotion laboratory. Retroreflectors are attached to anatomically significant body positions on the patient, as shown in Figure 1. The patient is videotaped as he or she walks, and then the video is processed offline to compute an array of dependent measures used to characterize the

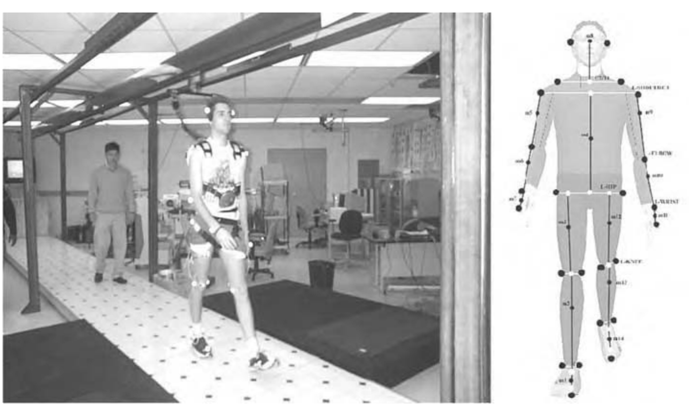

Figure 1. Picture from the VT Locomotion Research Laboratory showing a typical gait analysis apparatus. The field layout of the experiment includes a fall arresting harness and moveable force plates. Twenty-six reflective marker positions (two heel markers hidden on the illustration) are also illustrated.

gait. With currently available technology, this processing requires about 30 minutes for each five seconds of video. Donning a full set of retro-reflectors is in itself a lengthy process, requiring approximately 30-60 minutes for a healthy young adult; more time may be required for an elderly patient. The amount of time required and the complexity of the equipment make this a very expensive process, and a completely natural analysis is not possible in a laboratory. Consequently, locomotion laboratories are not commonly used as a diagnostic tool.

2. The Proposed System

Our aim to design an e-textile that is capable of computing the array of dependent measures associated with gait analysis with the same accuracy as computed by video-based gait analysis systems. This e-textile will consist of pants and either shoes or socks. Because of its simplicity, such an e-textile can be worn by the user in the home to provide for more realistic data for analysis as well as provide feedback to the user on improving gait. In addition, the system can detect the initiation of a fall and deploy a hip airbag designed in the Virginia Tech Locomotion Laboratory to mitigate the effects of a fall. Current hip protector technology utilizing soft and hard shell hip pads offer some reduction in the peak impact forces, but in most of the studies on hip protectors, compliance has been the biggest problem, with an average compliance rate range from 24% to 45%. Major reasons for not wearing hip protectors were: readily conspicuous, too unattractive and, too bulky and cumbersome to wear. A compact airbag activated during fall will provide better force reduction and, we hope, better compliance.

In addition to fall detection and mitigation, gait analysis can be used to detect a number of health problems. Many studies suggest that age-related changes in muscle strength have an important effect on fall accidents and physical performance capacities [14], and muscle strength degradation can be observed in gait. A frequent cause of difficulty in mobility in the elderly is an unreported or undetected cerebrovascular accident. The effects of severe loss of proprioception following a stroke on potential for recovery have recently been recognized [11]. A patient with significantly impaired proprioception after a stroke has marked muscular incoordination resulting in a disturbance of gait such as "wide-base-gait." The clinical features of Parkinsonism in the elderly are akinesia, rigidity, tremor, postural impairment, and autonomic dysfunction, including dysphagia. Abnormalities of gait in Parkinsonism probably result from associated akinesia, rigidity, and effects in posture [11]. In addition to the above conditions, a number of other conditions may result in an impaired gait. These include dementia, peripheral neuropathy caused by diabetes or neoplasms, normal pressure hydrocephalu, undiagnosed foot problems, and unsuspected fractures of the hip.

To design an e-textile with these capabilities, several questions must be addressed.

- What is the level of accuracy that we can achieve with e-textiles and what are the engineering trade-offs between accuracy, cost, and ease-of-use?
- How does the accuracy of e-textiles compare to more expensive and more difficult to use laboratory set-ups?
- How does accuracy vary with fitting devices to an individual, i.e. this approach will be less feasible if the device has to be custom-fit to the patient, but it will be more feasible if we can provide a set of standard sizes.

- What is an appropriate design for the woven bolts of fabric that will allow the placement of sensors, actuators, and computing devices across a variety of garment sizes? Design for cost-effective manufacture is of significant importance.
- What steps can be taken to improve the time between battery recharge of these e-textiles? Are there domain-specific characteristics that we can exploit to reduce power consumption? Can new fiber batteries be used to improve energy storage capacity in the garment?
- How do we ensure continued functionality over the lifetime of the garment? Small tears and wearing of localized areas is expected in any long-worn garment and should not lead to a failure, particularly an unidentified failure, of the sensing and computing capability of the fabric.
- How do we evaluate usability? Patients will not use the devices if they are difficult to put on or if the devices require training sessions to be accurate.

To answer these questions and construct our proposed e-textile, our approach is to use the Tailor-Made modeling and simulation environment [2] to explore the selection and placement of sensors on the human body for the gait analysis application, and then to create a set of prototype garments. The Tailor-Made modeling and simulation environment allows for detailed, accurate simulation of many aspects of e-textile operation, including sensor input, energy consumption, fault tolerance, and application behavior. In preliminary work, this environment has been used to develop an e-textile capable of extracting dependent measures such as acceleration of a joint, angular velocity of a joint, or stride length, and then using those dependent measures to classify the wearer's activity into categories such as walking, running, or sitting [2]. Developing this application requires making design choices such as the number, type, and position of sensors, the choice of dependent measure, and the frequency of sampling such measures. Designing a general garment requires making these choices in such a way as to be applicable to a large class of users rather than custom-designing a garment for a single user. Further, the classification algorithms should be trained to operate across a range of users as well. Using a database of body position data from a wide range of users and user activities [1], accurate models of different sensor types are used to generate simulated sensor time series data. For example, we constructed a mathematical model for the electrical response of a piezoelectric film when excited by the motion of the joint to which it is attached. After training the system on a range of simulated users, we then constructed a prototype garment and used the unmodified system to classify user activity based on the physical readings from the garment. Without re-training the classification algorithms, we were able to obtain 94% accuracy on classifying actual user activity using the prototype garment. This indicates a close match between simulation and physical behavior.

The pants constructed for this project will be based on the current context-awareness pants prototype developed by the VT e-textiles group. This prototype, shown in Figure 2, has wires woven into the fabric to carry power and data around the textile. The weave pattern is designed such that different sizes of pants can be cut from the same bolt of cloth while still retaining the capability to place sensors, processors, and communication elements where required. The textile has "floating" wires at regular locations across the fabric (see Figure 2a) to allow for attachment of e-tags, electronic attached gadgets [13] (see Figure 2b). An e-tag is a small printed circuit board with connectors specifically designed for attachment to textiles. A variety of e-tags have been designed and constructed by the VT e-textiles group; these e-tags use the wires in the fabric to draw power

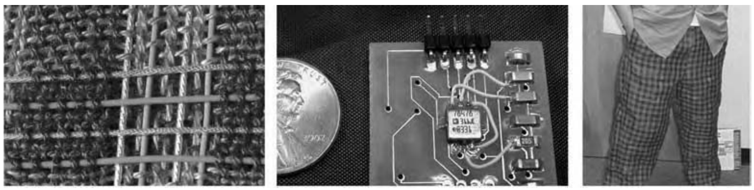

Figure 2. Virginia Tech shape-sensing pants: (a) orange and silver wires woven into the fabric, (b) prototype "e-tag" for attaching electronics to fabric, (c) final garment.

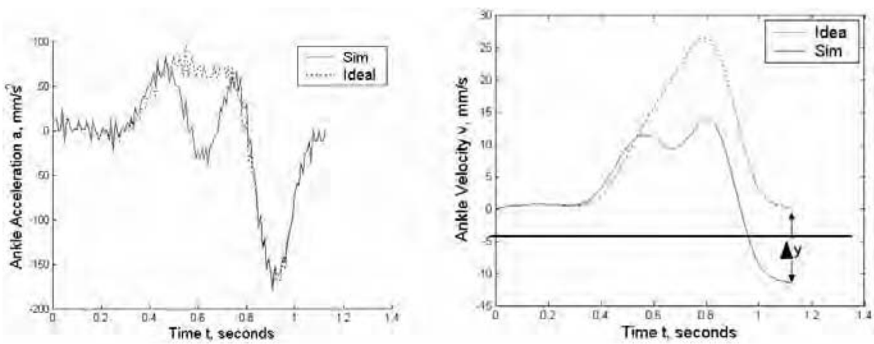

Figure 3. (a) Acceleration curves calculated using both position data and the simulated accelerometer incorporating the change in orientation of the sensor during walking. (b) Velocity curves calculated via integration from (a).

and communicate amongst themselves [12,13]. We are currently considering three basic types of sensors for use in the pants to compute the dependent measures associated with gait analysis. Piezoelectric fibers can be used to measure angular velocity at a joint [2] as well as a significant range of force values applied to an area. Accelerometers can be strategically placed (e.g., hips and heel) to directly compute acceleration and, by integrating the results, indirectly compute velocity and distance traveled [2]. Finally, gyroscopes can be used to compute the attitude of thigh, calf, and foot. In addition to the pants, we will be designing socks that incorporate the piezoelectric fibers to measure force applied at the heel and the ball of the foot, two measures critical to gait analysis.

3. Simulation Results

In this section, we use simulation to investigate the use of accelerometers placed on each ankle to compute the stride length of the user. While stride length is only one of the dependent measures, accurate computation of this will allow for other measures such as stride onset and completion as well as velocity at any point during the stride. Using motion capture data from several individuals [1], the Tailor-Made simulation environment was used to predict the accuracy of stride length computed by integrating the data from accelerometers placed on the ankles.

The results of the simulation indicate a significant difference in the true (ideal) acceleration and the acceleration measured by the simulated accelerometer (see Figure 3a).

Table 1. Step lengths for four subjects (two steps per subject) in simulation. Values are shown for the true distance as measured from position data, the values calculated from a simulated accelerometer, and the values calculated from the fitted curve used to correct the accelerometer. The percentage error in computed stride length from the simulated and fitted (corrected) accelerometer data is given

	Actual	Sim	Fit	Sim Err	Fit Err
(subject)	(mm)	(mm)	(mm)	%	%
Step 1 (1)	1097.4	341.2	1175.2	68.9	-7.1
Step 2 (1)	1084.4	413.6	1159.7	61.9	-6.9
Step 1 (2)	1180.6	271.3	1251.2	77.0	-6.0
Step 2 (2)	1172.4	318.7	1267.8	72.8	-8.1
Step 1 (3)	1220.8	312.5	1323.0	74.4	-8.4
Step 2 (3)	1234.1	303.6	1343.2	75.4	-8.8
Step 1 (4)	1410.3	299.6	1524.9	78.8	-8.1
Step 2 (4)	1411.3	512.2	1489.4	63.7	-5.5

When the velocity is calculated based on the ideal and simulated acceleration in Figure 3b, a significant error is introduced. When step length is computed based on this velocity (see Table 1) errors of approximately seventy percent are recorded. Closer examination of Figure 3a, however, shows that the deviation in true and measured acceleration is limited to a small portion of the step. In order to calculate accurate gait metrics, it is necessary to compensate for the deviant acceleration. Fortunately, the deviation is generally constrained to a single, small interval of the step and can be explained by the inherent biomechanics. The video data reveals that during this interval, the ankle is changing its angle with respect to the ground. This change in ankle angle is reflected in the accelerometer, causing it to no longer sense acceleration in a purely horizontal direction.

To compute a correction, we examine the biomechanics of a walking step. The basic biomechanics of a step dictate that the initial velocity and terminal velocity of a step must be approximately zero. The velocity curve calculated using the simulated accelerometer data shown in Figure 3b has a terminal velocity that is non-zero. Given that we know the terminal velocity must be zero, we can correct for this error. The region of inaccuracy in acceleration is nearly identical in shape across all of the subjects in the motion capture data.

By identifying this region and applying a correction to the acceleration that results in a terminal velocity of zero, we can closely match the correct acceleration. The correction is made by applying a three-point piecewise, linear fit across the affected interval of the ankle acceleration as shown in Figure 4a. The beginning, *x1*, and end, *x2*, of the affected interval are identified as peaks in the data. The height of the midpoint, *x3*, is chosen such that the terminal velocity computed from the acceleration is approximately zero. This piecewise linear data replaces the recorded acceleration in the deviant interval; the remainder of the acceleration data is retained unchanged.

This new curve, when integrated to find velocity and step difference, is far more accurate as shown in Figure 4b. The step lengths for four subjects (two steps per subject) were calculated via simulation using the ideal motion capture position data, simulated accelerometer, and the accelerometer data corrected by the three-point piecewise linear fit method.

The resulting calculations, shown in Figure 1, using the fitted curve had an average error of 7% from the ideal value calculated from position data. Uncorrected acceleration data had an average error of 71%.

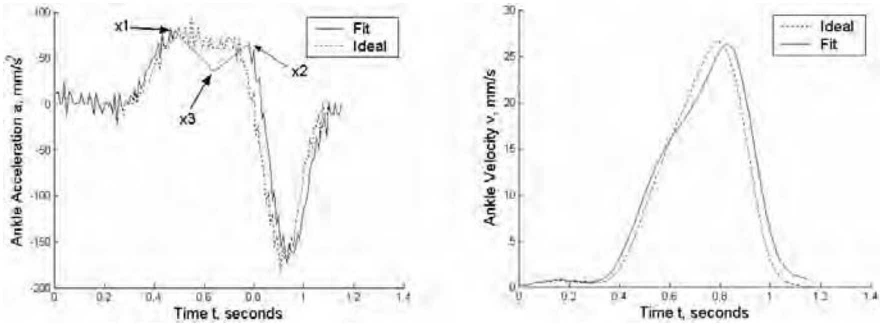

Figure 4. (a) Typical acceleration curves, both ideal and fitted using the described method above. (b) Typical acceleration curves, both ideal and calculated from the fitted velocity in (a).

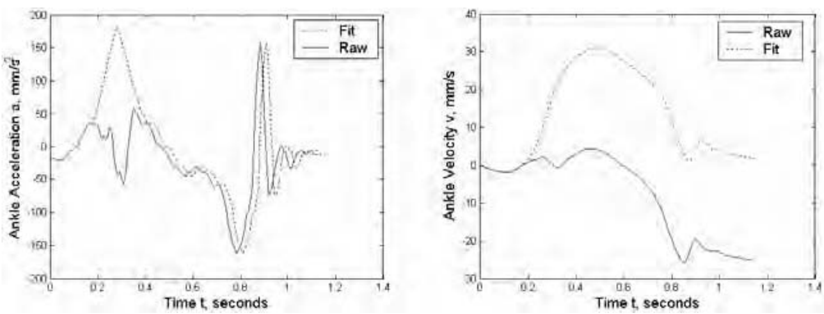

Figure 5. (a) Acceleration curves calculated from both actual accelerometer data and fitted accelerometer data using the method described above. (b) Velocity curves calculated from the actual accelerometer and from the fitted accelerometer data in (a).

4. Experimental Setup and Results

To verify these simulation results, the e-textile prototype pants used to compute context awareness were modified to compute stride length. A single user wore the pants during a videotaped motion capture session and the data from each recording system was calibrated. The experimental setup consisted of two dual-axis accelerometers located on the ankles and piezoelectric strips affixed to the heels on the exterior of the subject's shoes. The accelerometers were oriented such that, in a standing position, they measure the horizontal and vertical components of acceleration. The piezoelectric films affixed to the heels were utilized to determine the precise step interval. Retro reflectors were placed on the hips, knees, heels, and toes. Two data sets (four steps) for a single subject were analyzed in the same manner used for the simulation data; the ideal step length was calculated using the position data from the video system and the fitted accelerometer data. The fitted accelerometer data was computed using the correction method described in the previous section.

The acceleration and velocity curves from the raw and fitted accelerometer are shown in Figure 5a and Figure 5b. The resulting step lengths for the first set of data exhibited error similar to that found with the simulation results, roughly 7%. The second set of step lengths averaged 0.85% error. The results for the measurements can be found in Table 2.

Table 2. Stride length and associated error calculations using the e-textile pants as a data source

	Actual	Fit	Err
(subject)	(mm)	(mm)	%
Step 1 (1)	1308	1407	-7.57
Step 2 (1)	1408	1311	6.89
Step 1 (1)	1333	1316	1.28
Step 2 (1)	1393	1383	0.72

5. Conclusions and Future Work

E-textiles offer a promising platform for a range of e-health applications. Advantages of e-textiles systems include increased user comfort, ease-of-use, ample surface area for sensors and communication devices, and cost-effective construction. This paper described a system for gait analysis constructed with the intention of detecting pathological conditions as well as detecting and mitigating falls in the elderly. Results from an e-textile simulation environment were used to develop an initial prototype system for measuring one aspect of gait. Preliminary experimental results indicate that the resulting prototype system has a high accuracy.

Several challenges remain to be overcome before such a system is ready for field use. The next step in this process is computing a wider range of dependent measures including the force applied by different parts of the foot during a step and the velocity immediately preceding a step. In addition to computing a wider range of measures, the quality of the measurements must be assessed across a wide range of users, including those with pathological conditions and abnormal gaits.

Acknowledgements

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VI. Round Table Debate

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A. Lymberis and D. de Rossi (Eds.)
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New Solutions for Personalised Health Management: Citizens' Needs, Healthcare Changes, and Market Perspectives Round Table Debate

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Abstract. The aim with the round table was to give additional inputs and views to the specific technology oriented presentations focusing on issues dealing with the need, patients' view, the use and the business opportunities relating to wearable eHealth systems for personalised health management.

Wearable eHealth systems for personalised health management are targeting citizens, patients at health risks and patients enrolled in open care or home care for monitoring, treatment or follow up. The developments so far show promises for these group categories, and in addition, could support developments in health care organisations and systems. However, the ethical issues and data privacy nature have to be seriously taken into account.

The market is not yet developed, and this is the situation both in Europe and in the US. To be able to give the customers solid product information a standardised test bed for new equipment and services might speed up the market development. In the round table discussion it was highlighted that one has to differ between needs

[1]The views developed in this paper are that of the author and do not reflect necessarily the position of the European Commission

and demands. Needs are related to the prevalence of the diseases, the health risks, etc. Demands are more related to market developments and customers' willingness to pay for the new products and services. Further, technical interoperability was seen as a fundamental prerequisite for market acceptance. As wearable eHealth systems for personalised health management differ completely from traditional way of deliver healthcare, new reimbursement systems have to be developed and implemented.

Introduction

The developments and use of eHealth systems have already gone through several phases. Firstly, up to first half of the 1990th, applied research focused mainly on the needs in the sector of specialised health care e.g. to facilitate remotely consultations between health professionals. Thereafter, eHealth developments turned to gradually include also the primary health care and home care taking advantage of emerging technologies such as mobile telecommunication and Internet. This progress has given new possibilities for patients to be taken care on an outside hospital basis and for health professionals to work in mobile teams in pre hospital emergency care as well as in home care settings. Achievements in regional and national eHealth networks have been the recent backbone developments for broader use of e.g. e-referrals, e-lab-reports, e-prescriptions and e-health records. Now, eHealth also includes tools for supporting changes and development of working methods, organisations and health systems.

The round table focused on issues dealing with the need, the use and the business opportunities relating to wearable eHealth systems for personalised health management. In particular, the presentations have addressed the following topics:

- Patients' view and ethical considerations related to personal healthcare technologies
- Developments in integrated open care and the need of personalised health systems
- Market challenges and perspectives
- Test beds and added value for users

Based on the presentations, a panel discussion has taken place touching the user and business points of view but also other intermediate aspects e.g. interoperability.

Interestingly and challenging, the new generation of wearable eHealth systems is in a way a "melting pot" where the "eHealth community" will meet and collaborate with other business sectors like the whole process chain of textiles. In textiles, a highly research orientation is ongoing to explore new market segments including health. The results of this "marriage" will be seen in the coming years.

1. The patient's view and ethical considerations of medical technology

Medical technology is changing at an extraordinary pace and is having a positive effect on people's health. New drugs alleviate arthritis; new forms of IT for doctors reduce side effects and the duplication of diagnostic examinations and treatments; better means of transmitting healthcare information helps patients become informed. But, despite the advances, patients and the public regard healthcare technology with some degree of suspicion. The heady days of the 1960s promised medical miracles. The decades that followed often showed hope to be mere hype and hubris. Now, public scepticism is ingrained, and today's patients question even the most promising of scientific revolutions.

A host of new factors bolster patient misgivings, including: greater patient self-determinism; a changing balance of power in doctor-patient relationships in favour of patients; and the shifting of more medical responsibility onto the shoulders of the citizens through the decentralisation of healthcare. Nor are patients the only individuals who are important. Carers, families, relatives and friends all play an important part in framing the attitudes of patients toward the treatments they receive. These groups can be even more hesitant at accepting new technologies.

Finally, personal health management systems obviously involve a number of ethical issues e.g. misuse of data collected.

2. Developments in integrated open care and the need of personalised health systems

Globally, chronic conditions are on the rise and will increasingly present a major health care challenge in the 21st century. Unfortunately, there is a fundamental mismatch between the kinds of problems that are presenting in health care, on one hand, and providers' abilities to successfully manage these problems, on the other hand.

Whereas successful outcomes for acute health problems can occur with a single health care provider using a biomedical intervention (classical evidenced based intervention), positive outcomes for chronic conditions are achieved only when patients and families, community supporters, and health care teams are informed, motivated, prepared, and working together to shape the goals of health care.

Health care educational curricula have evolved around the predominance of acute, infectious disease, and as a result they "create" health care professionals who perform best when addressing patients' acute and urgent symptoms. Without reform, health care systems will grow increasingly inefficient and ineffective as the prevalence of chronic conditions rises. Health care expenditures will continue to escalate, but improvements in populations' health status will not. As long as the acute care model dominates health care education, it will effectively undermine health outcomes that could otherwise be achieved.

To be able to implement effective health care for chronic conditions, professional education and patient's perception need to evolve beyond traditional biomedical management. While biomedical management will always be essential, health care providers of tomorrow also need to be able to:

- emphasize the patient's central role in caring for themselves
- assess patient knowledge, skills, behaviors, confidence and barriers
- provide effective behavior change interventions
- assure collaborative care-planning and problem-solving
- provide ongoing follow-up and support via peers and professionals

To facilitate this transformation, a change in mentality is also required. Around the world, health care providers are trained and socialized in provider-centered practices, where interventions are chosen by providers and patients are expected to accept and

”comply” with these self-management recommendations. Many professionals struggle to give up compliance-based approaches even though these are incompatible with good chronic illness care.

While changes in health care educational curricula have an important role to play in fostering a paradigm shift towards more patient-centered approaches, it is accepted that information & communication technologies (ICT) constitute key enabling tools to facilitate the developments towards the new model of personalized care aiming not only to enhance patient outcomes, but also to improve wellness of the citizens.

3. Market challenges and perspectives

3.1. Personalised healthcare in Europe: market developments

Since few years the growing perception of health as one of the most significant asset for the person, is changing the approach of individuals to the management of their personal care.

In particular prevention is becoming a more and more normal attitude for a very significant part of the population and, beside prevention itself, the monitoring of few physiological parameters is acquiring importance too. This is true especially for the growing well being elderly population: a sort of *young elder class* often with good financial availability. This at the moment is pushing a number of investors in putting attention to few areas of medical applications almost neglected in the past. The establishment of new Service Companies in the area of Telemedicine is an example.

These companies are able to deliver personal assistance to people in different medical areas by mean of telephone conversation and using specific hardware developed to acquire and transmit biological signals performed directly by the user/customer. Most of these experiences are in the cardiology area. This is essentially due to the importance of cardiovascular pathologies in western world and also because of the abundance of telecardio equipment available. The market addressed is quite inhomogeneous. It includes both healthy and pathological subjects.

The market of “worried well” users is small, but increasing, following the increment of the “young elder” population, which requires a friendly and non-intrusive approach. This would lead to develop new tools, both in terms of equipment as well as “style of service”. The market segment related to the pathological subjects is often related to various kinds of health organisations (hospitals, health insurance, patient association etc.) with a more traditional approach. As a partial example in this segment we find subjects with a history of arrhythmia or ischemia, possibly coming out from some medical/surgical treatment as well as chronically ill patients, like CHF (Congestive Heart Failure) patients. For all of them new acquisition approaches are very important. Particularly the CHF population is an interesting target for the personal healthcare remote services due to the fast growing number of them: as an example in Lombardia region in Italy, the number of CHF patients has doubled in 6 years, passing from about 15,000 in 1995 to 30,000 in 2001. For these people a multiple parameters acquisition gear can be a quantum leap in quality of life.

3.2. Market challenges of personalised eHealth systems in the United States

Marketing personalised eHealth systems in the United States is not for the faint of heart. The structure of the market does not lend itself to easy adoption of new technologies, even when they offer apparently “compelling” value to patients and society. This is because the economic incentives required for innovation are misalign.

Innovation, even cost-saving innovation, has to be paid for by somebody. In the United States, that “somebody” is the payer community, a group of private insurance companies, and state and federal agencies whose immediate agendas drive what goods and services will be reimbursed. The people who bear the prospective cost of innovation are not the same people who stand to reap the benefits from it, and that’s where the problem lies. Private insurers “own” a life for a year at a time and many health problems (for instance, the results of undiagnosed sleep apnea), don’t show up for many years. There is an attitude among private insurers of “why should we invest in saving Medicare money?” (Medicare is the federal health program that applies to retired people.)

The current set of rules for Medicare reimbursement constitutes 130,000 pages of documents, compared with 10,000 pages for the Internal Revenue Service. These rules are often in contradiction with each other. For instance, Medicare will reimburse a hospital for a cardiopulmonary sleep study (i.e. one that does not include EEG readings but is sufficient to diagnose obstructive sleep apnea), but will not reimburse for any subsequent therapy that is based on a diagnosis from such a study. Getting Medicare to change its reimbursement rules takes years of political lobbying. Introducing a new category (such as personalised eHealth systems) requires the prior acquisition of a practice code from a subcommittee of the American Medical Association which owns the codes, and then a submission to Medicare. The process is longer than the life cycle of most entrepreneurial organisations.

This means that innovation in US healthcare is best undertaken in collaboration with a marketing partner with the requisite resources to see it through - a model similar to the pharmaceutical industry in which small biotechnology companies provide new product opportunities to the immense marketing engines of big pharma. As Baxter Healthcare chairman and CEO Harry M. Kraemer pointed out at the Medical Innovation Summit sponsored by the Cleveland Clinic this year, in 1980, the thousand largest companies in the United States derived less than 5% of their revenue from alliances and partnerships; in 2002, 35% of those companies’ revenues came that way.

An alternative approach is to go directly to consumers. In 1997, US consumers made more than double the number of visits to complementary and alternative practitioners than they did to primary care physicians. Their out-of-pocket costs in doing so were more than double their total out-of-pocket costs for participation in conventional healthcare. Consumers are leading with their feet and their dollars. They have the most to gain from better healthcare technologies and there are ways in which their needs can be addressed directly. There are large constituencies interested in wellness and athletic performance. They can be used to launch new wearable technologies. In the intermediate term, it is likely that better informed consumers will become more central decision-makers in their healthcare as the current delivery system fails to meet their needs.

4. Test beds and added value for users: A unified test bed for remote medical applications

The lack of an open test bed to verify, demonstrate and operate pilot operations across organisational borders has led to projects not being able to practically demonstrate their values or that projects have not reached demonstration status at all. Important prerequisites for a common test bed environment that would allow for a higher rate of projects to reach pilot status is an open test bed specification which could be adopted across Europe and lead to a broader application verification market and a broader group of pilots to verify the medical usability and rationality of the tested application/device.

The common test bed has to be able to handle manual integration of data from wearable censors and instrument, have docking capabilities (physical or wireless) to transfer data from the wearable device to a local test bed integration device, allow for wide area wireless transfer of data to the central management point directly from the wearable device or from the local test bed integration device. Important functions of the central management centre will be to control the status of the device to be tested (authorisation of equipment and version criteria, authorisation of person who introduces the instrument and assigns the identity of the patient/person using the equipment), to provide logistics for monitoring the status of reports from the remote device and to allow for integration of information of data from the remote device into existing medical applications.

The test bed should also allow for automatic and transparent encryption of all data communication between the wearable medical devices to the central management centre. This generic test bed environment should be openly published and available for suppliers and/or health care organisations to use as open source software (e.g. according to the GPL). The existence of an open test bed environment will make it easier for R&D projects to have their findings demonstrated and tested in live medical environments, and will allow for “real life” testing of devices to verify the medical and economic feasibility of the devices operating in live medical environments.

5. Discussion

The Round Table discussion, after the presentations, covered themes including:

- technology development vs. market development
- needs and demands
- long time to market, reimbursement issues, lack of infrastructure
- patient technology relationships
- interoperability and standardisation

The discussion topics are summarised below.

Technology developments vs. market developments were discussed and the conclusion was that technology R&D are highly predictable compared to market acceptance and development for wearable eHealth systems. Many, at the moment, unknown factors will influence the growth of the market. These factors include adoption of new business models in healthcare to comply with the nature of eHealth, reimbursement regulations, uptake and willingness to pay by the patients themselves, and reorganisation of delivery of care models to offer the patients and relatives the benefits inherent in wearable eHealth systems.

One has to differ between needs and demands. There are several needs demonstrated for introducing eHealth e.g.:

- to transfer part of care delivery from hospitals to primary and open care settings
- to integrate care from different specialities to mach the need of the patients
- to enhance the quality of life for chronic ill persons, and also
- to support home care services e.g. for the growing sector of elderly people.

To address those needs with real solutions and the corresponding necessary infrastructure, the needs have to be transferred into demands. Somebody has to demand and pay for the services. This is the crucial situation at the moment. Probably, we will see a more differentiated market in the future with different payers, e.g. the public, insurance companies, companies as staff benefits, and, and the patients seem willing to pay more, out of pocket, for their personal health services in the future.

Due to the situation discussed above, there is a long way to the market for the companies involved in developing wearable eHealth products and systems. This is a critical situation for many small companies having products very much fitting to the needs of large groups of patients but see week demands. And large companies hesitate to allocate major investments into wearable eHealth products and systems - currently they say “where is the demand and the market?” Since the market for information and communication technologies in the healthcare sector in Europe will continue to develop, the demand for wearable health devices will grow, however with a delay due to factors like reimbursements issues and need of change in the system of delivery of care when introducing disruptive health technologies.

The situation in the US and Europe are quite different. In US small companies have to find their way in the maze of reimbursements regulations. At the moment, many of the products find the market in the “test and research sector” of the health and healthcare. The real market has still to show up in US. In Europe, in some countries like Germany and Italy, dedicated service companies are now offering eHealth solutions directly to patients. However, as in the US, the real market has still to show up.

Relationship between patients and technologies is also a key issue for further development and deployment. Generally the patients are in favour to new technologies. The trend is that patients will be more responsible for their own care and health. However, the doctor-patient relationship is important. With new technologies new ethical issues might arise, like privacy, and must be seriously taken into account.

Technical interoperability in the eHealth domain is a prerequisite for market acceptance, growth and cost containment. This highlights the importance of widely adopted technical standards. In the hospital sector, an initiative “Integrating the Healthcare Enterprise (IHE)” founded by users and industry is an initiative for integrating medical technology from different vendors based on available technical standards. IHE had its origin in the US and has currently 10 national affiliates. This could be an example how to speed up and accomplish interoperability. Vital user interest and demand is required. Interoperability is crucial, not the least for small companies, to be able to enter into the market. There was a general concern in the discussions that the standardisation process is too slow which hamper the market developments. To speed up the validation procedure of new products and services, and to be able to proof interoperability for the purchasers of eHealth systems, the solution might be to set up a European recognised test bed for this purpose.

The very vivid discussion can be seen as a commitment to the firm interest and belief in the developments of wearable eHealth systems for personalised health management. However, many unsolved challenges remain before a real sizeable market can be developed to the benefits of the actors involved, predominantly the patients.

VII. Smart Fibers and Fabrics: The Challenges to Wearable Health

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Executive Summary

This session focuses on the latest technological advances in new materials and devices enabling full textile solutions to wearable systems. Intrinsic conducting polymers, organic semiconductors, shape memory alloys and fibre optics have been reported in their early stage of integrated design into clothing to provide sensing, actuation, processing and communication.

Although most of the reported work still needs considerable development and validation to go into real application, the perspective of using smart materials in fibre form looks promising, offering additional fuelling to the emerging concept of bio-clothing.

Integrated fibre optic sensors and information networks incorporated into textiles provide an efficient platform for intelligence embedded into large area, flexible substrates. Although the reported work essentially deals with military applications its extension to other fields more closed to societal needs is not difficult to foresee. This might occur in ambient intelligence platforms or more strictly eHealth related realizations.

The processing function based on silicon devices has revolutionised our lifestyles through the extensive use of microelectronic devices. More recently polymer electronics, flexible displays and e-ink are also providing more handy and ergonomic ways to microelectronic yet. Yarn and fibres with annexed electronic functions offer intriguing clues onto textile as substrate for computation and processing. The real world feasibility of this approach has yet to be demonstrated. However, the potential gains of this realisation look high.

Actuation onto wearable is really difficult, but it would represent at the end the true outcome of interactive wearable interfaces. Shape memory alloys incorporated into garments are reported and demonstrated into experimental devices. Although possibly not representing the most appropriate actuating solution they have the great merit, anyway, to represent a first step into this direction.

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Wearable eHealth Systems for Personalised Health Management
A. Lymberis and D. de Rossi (Eds.)
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Smart Fabrics: Integrating Fiber Optic Sensors and Information Networks

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Abstract. "Smart Fabrics" are defined as fabrics capable of monitoring their own "health", and sensing environmental conditions. They consist of special type of sensors, signal processing, and communication network embedded into textile substrate. Available conventional sensors and networking systems are not fully technologically mature for such applications. New classes of miniature sensors, signal processing and networking systems are urgently needed for such application. Also, the methodology for integration into textile structures has to be developed. In this paper, the development of smart fabrics with embedded fiber optic systems is presented for applications in health monitoring and diagnostics. Successful development of such smart fabrics with embedded sensors and networks is mainly dependent on the development of the proper miniature sensors technology, and on the integration of these sensors into textile structures. The developed smart fabrics will be discussed and samples of the results will be presented.

Introduction

Available conventional devices and systems are not technologically mature for smart fabric applications, which require miniature and flexible devices/structures. Fiber optic technologies are compatible for this type of applications and they present the best choice for the time being. The development of smart textiles with embedded fiber optic sensors and information networks will form the basis for innovative biomedical applications such as Smart Shirts and Uniforms, for health monitoring and diagnostics. These shirts and uniforms will have the ability to contact the patient's physician, through wireless communication systems. Novel flexible opto-electronic systems will be developed to take the advantage of smart fabrics, which can fit any shape of any structures on ground, in space, or under water.

Along with the challenges on development of smart fabrics, a highly qualified multidisciplinary team was organized in the middle 1990s at Drexel University, in collaboration with Photonics Laboratories, Inc., focusing on development of a new class of smart textiles with embedded fiber optic sensors and electro-optic networks. Two examples of the successful work achieved so far on the development of smart fabrics will be

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presented in this paper. The first one is based on the development of a smart parachute canopy, for measuring stresses/strain induced in the canopy during airdrop and canopy inflation. The developed technology is based on using embedded fiber optic sensors for strain measurement, and wireless transmission of the information to a ground station. The second one is based on the development of Smart Uniforms, integrating fiber optic chemical sensors, for sensing environmental conditions and monitoring the field for any toxic substances. These two applications are ready for integration in a health care shirt "Smart Shirt" for health monitoring and diagnostics. Successful development of such smart fabrics with embedded fiber optic sensors and networks is mainly dependent on the development of the proper miniature sensor technology, and on the integration of these sensors into textile structures, which will be also discussed in this paper.

1. Fiber Optic Sensor Technology

In sensor technology, sensors based on intensity modulation are simple and cost effective. However, they provide limited sensitivity. On the other hand, sensors based on phase and polarization modulation type provide much better sensitivity but they are bulky and require laser sources and expensive techniques for detection. To overcome these limitations, a novel technique, based on monitoring the Modal Power Distribution (MPD) in multimode fibers, was developed. This technique provides a sensitive and inexpensive methodology for miniature sensors applications [1].

The principle of operation of the developed technique is based on modal power modulation. Within a multimode optical fiber, optical signals propagate according to the modal structure of the fiber and the boundary conditions. Altering the boundary conditions of an optical fiber induces modal coupling and results in Modal Power Distribution (MPD) modulation. The Coupled-Mode-Theory can be employed for the analysis of the MPD modulation [2]. Deforming the fiber by mechanical stresses or other forms of perturbation, results in modal power modulation, which can be exploited in sensing the applied signals. The measurements of the distribution and the subsequent redistribution of the modal power can be accomplished by scanning the far-field pattern at the fiber end using a CCD camera, or by using one or measurements of the distribution and the subsequent redistribution of the modal power can be accomplished by scanning the far-field pattern at the fiber end using a CCD camera, or by using one or more photo-detectors positioned at a specific location in the far-filed zone, as shown in Figure 1. The modal launcher is a single LED, used to excite a limited group of modes within the optical fiber, and the modal analyzer is the detection system of the modal power positioned at the output end of the optical fiber, in the far-field zone.

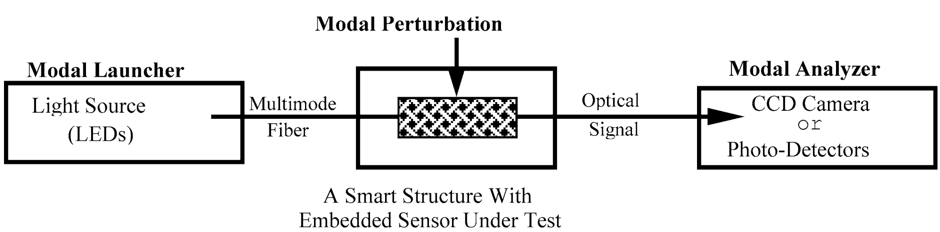

Figure 1. The general block diagram of the developed characterization method.

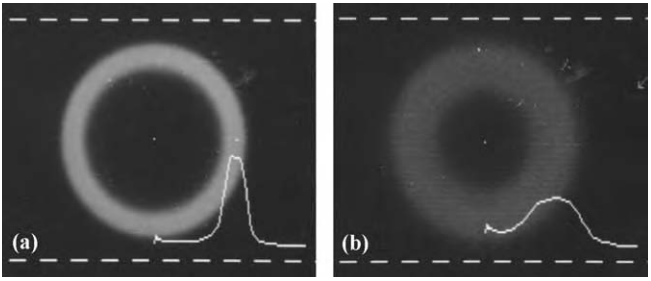

Figure 2. The 2-D image and the horizontal intensity profile of the far-field pattern measured at the Center before (a) and after (b) the presence of perturbation.

As an example, a step index silica fiber of 100μm fiber diameter was excited at 10 degrees off-axis. The 2-D far-field pattern (MPD) and intensity profile were scanned and recorded by a CCD camera as shown in Figure 2a. When the fiber was under stress, the recorded far-field pattern shows inter-modal coupling and redistribution of the modal power (Figure 2b). As the applied stress was increased, considerable rearrangement of the modal power was recorded in a similar way. These two figures indicate that continuous variation of the applied perturbation will result in a respective change in the MPD, in a very sensitive manner. For a cost effective and miniature sensor configuration, the CCD camera can be replaced by a single photo-detector located at key positions in the far-field, to indicate the variation in the optical signal. Using a light emitting diode as the optical source and a regular photodiode for detection will provide a miniature and inexpensive technique compared to the phase or polarization modulation techniques.

2. Smart Fabrics

In accordance with the advancement of the health monitoring and diagnostic systems, this section presents a novel approach on the development of a “Smart Shirt” for health monitoring and diagnostics applications. Three major R&D programs were conducted, in collaboration with the Department of Defense, on the development of smart textile/fabrics for various applications, which can be transformed for health monitoring and diagnostics. The first program was on the development of the methodology for integration of optical fibers and electronic wire into textile fabrics during the regular manufacturing process, using commercially available textile machines. The optical fibers and the electric wires will be used for building sensors and devices within the textile fabrics, and for transmission of the information. The developed methodology can be used for processing and manufacturing the Smart Shirt. The second program was on the development of Smart Soldier’s Uniforms with embedded fiber optic chemical/biological sensors for early warning on existences of toxic or biological substances in the space surrounding the soldier [3]. This can be modified to analyze the patient’s breath and check for the quality of the environmental conditions, such as oxygen level. The third program was on the development of smart parachute integrating fiber optic stain/stress sensors for measuring actual stresses and vibrations induced in the parachute canopy during the airdrop and the inflation of the canopy [4]. The Smart Parachute includes electronics and a RF transmitter/receiver for signals processing, multiplexing and transmission of the sensors

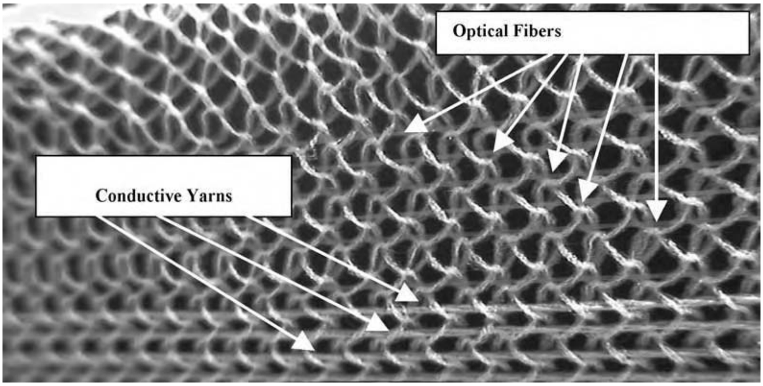

Figure 3. Knitted textile fabric with embedded optical fibers and conductive yarns.

output to a ground station. This type of smart fabrics can be transformed to checking heartbeat measurement or monitoring other similar mechanical motion or vibration, such as chest motion under various breath conditions. The developed remote sensor system can be used to transmit the information instantaneously to the patient physician.

2.1. Integration of Optical Fibers and Wires into Textiles

The development of textile fabrics with embedded optical fibers and electric wires requires a full understanding of textile structural behavior and geometry. For proper integration of optical fibers, the processing parameters and final shape conditions of the textile structures should be carefully identified. Three types of basic textile structures (knitted, woven and non-woven) were under consideration for development as smart textiles. In knitted textiles, the yarns are in the form of inter-loops that are subjected to very tight bends at a very small radius of curvature. Therefore, the idea of replacing one of the yarns with optical fiber is not acceptable for these structures. However, optical fibers and electric wires can be integrated in a straight line, interlacing with the loops, as shown in Figures 3. In woven textiles, there are three forms of woven structures: plain, twill, and satin. The yarns are interlaced and subjected to various bending conditions based on the type of the woven structure. In general, in woven textiles, the optical fiber can be integrated during the regular manufacturing process by replacing one of the textile yarns with the optical fiber. For non-woven textiles, they are basically made up of layers of sheet materials, each composed of more or less randomly oriented fiber segments bonded together. Thus, the only way for optical fibers and electric wires to be integrated into non-woven structures is by placing them between the sheets (or layers). The fibers/wires orientation can be in a straight line or with minimum bending curvature. Therefore, the integration of optical fibers in non-woven structures is much easier than in knitted or woven structures.

2.2. Integration of Sensors and Networks

The successful integration of optical fibers and fine electric wires into textile structures has led to the integration of sensors and networks for a number of applications. One of these applications is the "Smart Parachute", which has the ability to predict the opening forces and to measure the strains induced in the parachute canopy during airdrop [5]. Another developed application of smart textiles is the "Smart Uniform", which has the ability to sense environmental conditions. The detection of environmental substances is based on the concept of modifying the passive optical fibers to be chemically sensitive fibers. This modification is achieved by replacing the passive cladding material in a small section of the optical fiber with a chemically sensitive agent [6]. When these sensors are incorporated into clothing, such as uniforms for soldiers, fire fighters, security guards, and special mission personnel, they would provide instantaneous early warning of the presence of chemical or toxins in the ambient environment. A large number of technical reports and papers were published, recording the progress achieved so far on these two applications. These applications will form the basis for the development of the "Biomedical Smart Shirt" for health monitoring and diagnostics. This shirt can be used to monitor heart conditions, heartbeat, breath, blood analysis and circulation, injury conditions, and other health issues, using the principles developed through the smart parachutes and the smart uniforms projects. The application of smart fabrics in self-monitoring of induced stresses and vibrations within the structure as well as a chemical sensor were successfully conducted, using the MPD technique as a sensitive, simple and inexpensive method. Samples of the developed the results achieved are presented next.

2.3. Experimental Results

In the parachute project, Experimental work was carried out for the validation of the MPD technique in measuring quasi-static and dynamic strains in processed smart fabrics. Strands of optical fibers were embedded into small pieces of the canopy fabrics and tested. The quasi-static tests were carried out in a uniform, systematic way. Each sample is mounted on the tensile tester, and the optical fiber is connected from one end to a light source and from the other end to a photodetector and a wireless RF transmitter. The tensile tester pulled the fabric a certain amount, and then the output data was recorded for the load, elongation and the sensor output. This process was continued until the fabric starts to tear. Figure 4 shows the sensor output (volt vs. time) and the tensile tester output (elongation vs. time) for two tested samples. The tensile tester will give the relation between the loads and the elongation of the fabric structure. It can be seen that the sensor output was in full agreement with the tensile tester output. The quasi-static test results are used to build the relationship between the optical signal and the mechanical behavior of the fabric and thus to predict the external perturbation on the fabrics during dynamic application [5].

For the chemical sensor application, the modified fiber cladding used for detection of and dimethyl methylphosphonate (DMMP) was the conducting polymer "polypyrrole". As the modified cladding is exposed to DMMP, the polypyrrole cladding index and absorption coefficient change and therefore changes the light intensity at the end of the fiber. The optical fibers coated with the polypyrrole were integrated with a light source and a photo-detector for testing the developed chemical sensor. The fiber was exposed to DMMP vapor for about 2 minutes. The sensor output is shown in Figure 5. The figure shows a step change in the intensity output as a function of time from about 2 seconds of the start of the DMMP exposure. The delay in the response times can be attributed to the natural structure of the film and its porosity.

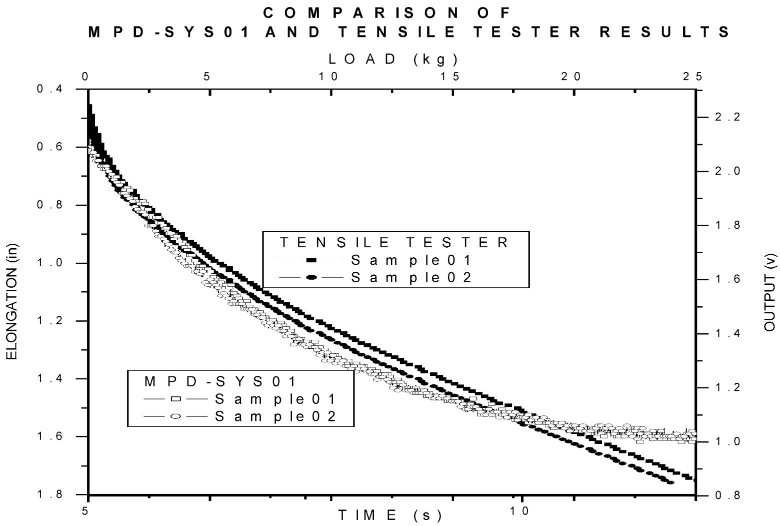

Figure 4. Comparison between Results of the MPD and Tensile Tester.

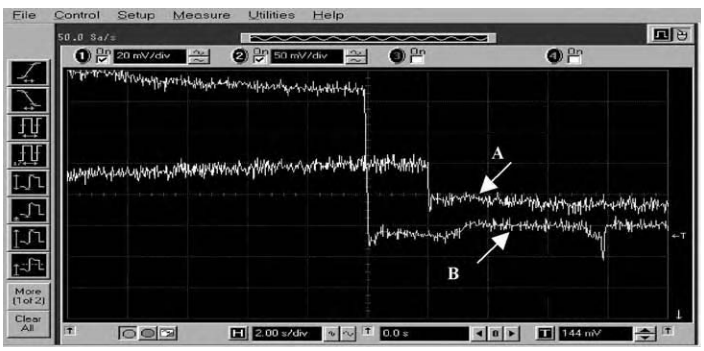

Figure 5. Optical sensors output (A) and the trigger signal (B) for exposure time.

3. Conclusion

In conclusion, the idea of using smart fabrics in biomedical applications will have a strong impact on the advancement of health monitoring and diagnostics systems. The developed remote sensory systems, embedded into textile structures, have been proven to operate successfully in monitoring any perturbation induced in the smart fabrics, as well as monitoring environmental conditions. Furthermore, the value of the MPD technique in smart structures applications, where the requirement of miniature structures and sensitivity are of great importance, has been successfully demonstrated.

Acknowledgment

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Wearable eHealth Systems for Personalised Health Management
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A Feasibility Study of Yarns and Fibers with Annexed Electronic Functions: The ARIANNE Project

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Abstract. In this paper several issues concerning the development of fibers endowed with electronic functions will be presented and discussed. In particular, issues concerning materials, structures, electronic models and the mechanical constraints due to textile technologies will be detailed. All these aspects have been studied in the framework of the project Arianne, funded by the European Community during the V Frame Programme.

Introduction

In the last few years, wearable electronics has become one of the hottest topics in Electronics and there are indications that this topic will sign a step of the next electronic revolution. The issues concerning the development of a textile fiber having the function of a transistor have been considered in a recently funded European Project named ARIANNE.

The main objective of ARIANNE is to obtain an initial assessment of a very innovative research idea, which consists in building a yarn with endowed electronic functions which can be thought as an "extended transistor". Such yarns should then be knitted, woven or processed by means of textile techniques to produce fabrics which can then be seen as complex wearable electronic networks.

The project aims to assess several points which all together will contribute to the final goal: the possibility of building up a yarn, therefore materials and technologies which are best suitable to this aim (including the possibility of developing new fibers with tunable levels of electrical conductance); the electronic model of the yarn, seen as a "textile transistor"; the electronic model of the fabric, to evaluate its possible distributed digital or analog functions depending on the topology of the yarns; the mechanical constraints that must be considered in order to obtain a textile component, suitable to be processed by means of textile technologies. In the following, we will address each issue, and show the main results obtained during the project.

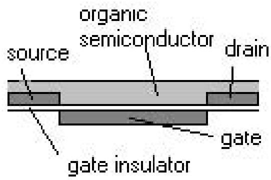

Figure 1. General scheme of a Thin Film Transistor.

1. A structure for textile transistors

A textile structure has very strict mechanical constraints: therefore the choice of materials is crucial for obtaining a suitable device. Traditional inorganic crystalline materials, as silicon, do not have the requested features. Organic semiconductors (polymers and oligomers), having the electrical properties of semiconductors and the mechanical properties of plastics, are good candidates for realizing flexible transistors, suitable to be transferred on unconventional substrates as textiles.

Transistors based on organic semiconductor are a special type of field effect transistors, named Thin Film Transistor (TFT): source and drain are simply ohmic contacts formed by a metal (that can be substituted by a conductive polymer) on the organic semiconductor while the channel between source and drain is formed through a charge accumulation induced by the gate.

Recently [1], a completely flexible structure assembled starting from a transparent insulating film has been realized that seems to be the ideal candidate for realizing a textile transistor. In fact, the whole procedure for obtaining such structure (shown in Figure 1) is realized without inserting a substrate whose mechanical properties determine the flexibility of the whole structure. In this way, the substrate can be added to the structure only after its assembly, therefore allowing employing unconventional substrates as paper, 3-dimensional surfaces and textiles.

2. Materials for textile transistors

As shown, a TFT independently by its geometry is made by three main layers: the insulator, the gate metal and the organic semiconductor.

The insulating layer must have a proper dielectric constant (for comparison, the value for silicon oxide is 3.9) and should be as thin as possible (in order to ensure a suitable value of the dielectric capacitance per unit area). In addition, it must have mechanical properties similar to fabric, in order to allow the possibility of bending and stretching as it is necessary during a weaving process.

For these reasons we selected Mylar (commercial trademark for Poly-Ethylene Therephtalate film, produced by Du Pont) as a material that perfectly fulfills the previous requirements. It has a dielectric constant of 3.0, a minimum thickness of 900 nm, and it is completely flexible, more than a fabric ribbon.

The gate metal layer must be a conductive layer, typically a metal or an organic conductor. There is no particular requirement for this layer, and then gold or aluminum layers can be thermally evaporated or alternatively, PEDOT (Poly(3,4-ethylenedioxythiophene)) layers can be spin-coated on mylar.

As organic semiconductor, many semiconductor organic materials can be used to realize the device with high charge carrier mobility. Unfortunately they are not easily processable materials and they need complex and expensive deposition techniques [2,3]. Usually conductive polymers also are poorly processable materials, but the synthesis of new monomers yields soluble materials in common organic solvents. Synthesis of regioregular poly-3-alkyl-thiophenes using the method developed by Mc. Collough et al. overcomes this problem enhancing conjugation between thiophene rings; a better ordering in the solid state occurs [4,5].

We used three different semiconducting polymers, namely regioregular poly-3-exilthiophene (supplied by Sigma-Aldrich, Milano), regioregular 3.3”-didocel-2,2’:5,’2”-terthiophene [6] (supplied by Prof. M.C. Gallazzi, Politecnico di Milano) and Pentacene (Sigma Aldrich, Milano),

The first two polymers were deposited by casting from concentrated solutions of polymers in pure chloroform and in chloro-benzene, at a concentration in the range 0.8 - 0.5 % weight, the last instead was be deposited by thermal evaporation.

3. The electronic model of textile transistors

As can be seen in fig. 1, in the TFT structure the gate is electrically insulated from the organic semiconductor (as in all FET structures) and the source and drain contacts are simply ohmic (differently than most FET structures). Differently than in Silicon MOSFETs, in such device, an inversion channel does not form. As source and drain are ohmic contact, the channel is confined to the surface of the semiconductor where majority carriers (generally holes) accumulate due to the field effect induced by the gate. Therefore the TFT is an accumulation device. This also means that a small current can flow even when an accumulation layer is not formed (OFF state) but this current is very low because of the intrinsic low conductivity of the organic materials. The equations that describe the behaviour of an organic TFT can be directly derived from those of inorganic FETs providing to consider that the OTFT is an accumulation device. For a TFT, the relations that link the current I_d to the applied voltages are:

$$I_d = (Z/L)^* \mu^* C_i^* [(V_g - V_t)^* V_d - V_d^2/2] \quad \text{in linear region} \quad (1.1)$$

$$I_{dsat} = (Z/2L)^* \mu^* C_i^* (V_g - V_t)^2 \quad \text{in saturation region} \quad (1.2)$$

Z and L are, respectively, width and length of the channel, μ is the carrier mobility, C_i the insulating layer capacitance (per area unit), V_g and V_t are respectively the gate and the threshold voltages and V_d is the drain voltage. The threshold voltage is the value of gate voltage necessary to increase the conductivity of the surface channel with respect to the rest of the semiconductor (for low values of the drain voltage).

4. The yarn topology of the electronic fabric model

Building reliable transistors with well-defined electrical properties using conductive and semi-conductive yarn implies small and stable geometrical structures of the fabric and within the fabric. Therefore, a woven structure emerges as a possible manufacturing

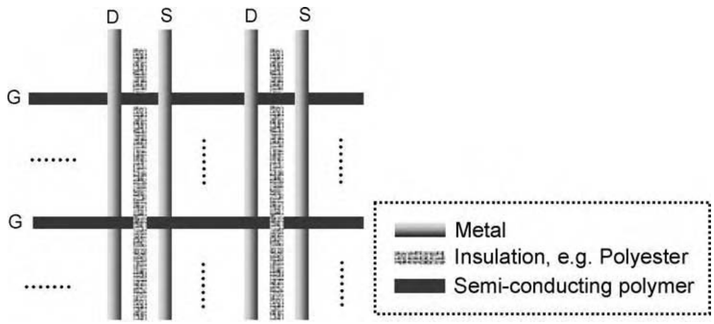

Figure 2. Polymer Transistor Structure.

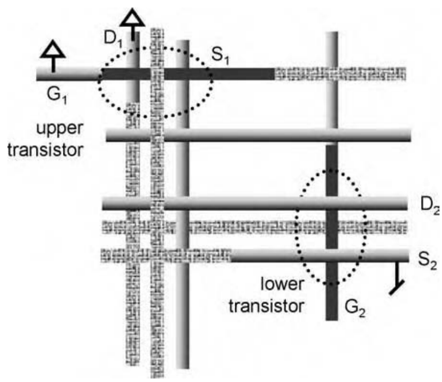

Figure 3. Circuit Structure in Textile.

technology since the smallest mesh lies in the range of 100 microns by weaving single fiber and since it is more rigid compared to a knitted structure.

For simplicity, a polymer transistor can be regarded as P-MOS FET at a first stage. Therefore, when inserted in a fabric, it can be seen as an elementary network where 'Drain' (D) and 'Source' (S) are purely metallic wires that cross the yarn-like transistor indicated with 'Gate' (G) (Figure 2). Since reliable connections of electrical contacts among threads seem difficult to achieve due to the drapability of textiles and mechanical stresses, redundancy by parallel connection of transistors improves functionality.

A structure as in Figure 2 cannot suffice diverse electrical functions since the transistors are arranged in columns. Connecting transistors between different columns would lead to shorts of the Drains and Sources because they are metallic. To our knowledge, applications of such an array mainly lie in the sensing field where external interferences partially change the electrical characteristics of the textile since polymer transistor are rather sensitive to geometrical, temperature or even light variations.

In order to establish a self-contained device within the textile, piece-wise (semi-) conductivity and non-conductivity of threads are necessary avoiding shorts, multiple excitations of transistor gates and unwanted parallel connection of transistors. Figure 3 shows a section of such a circuit. Since distances between transistors can be large, manufacturing methods for section-wise plating need not to be precise.

5. Mechanical constraints for textile structures

Textile industries have used metal yarns for years. Usually a single metal fibre is avoided, because of problems due to flexibility, resistance to stretching and friction, lower than other natural or artificial yarns, preventing its use with standard weaving machines. Possible solutions are: a) production of a yarn with a core made of common textile yarn and with spiralled metal filament; b) use of pure metal yarns made of several metal fibres, prepared as long filaments or from staples; c) a yarn made by twisting metal fibres around a filament or a previous spun yarn, thus concealing the core. With these techniques, metal yarns can be used with commercial weaving machines and have technical properties comparable with traditional yarns. It must be underlined that a new trend is observable in textile domain, as indicated by the presence, in the last ITMA fair, of several new circular knitting machineries able to process pure metallic and technical yarns. Alternatively, a textile ribbon can be knitted or woven like a yarn. As an example, a ribbon can be used as substrate of a transistor made on an insulating film with a width (average) of 3.5 mm: technical details are described in Table 1 below.

It can be processed by means of two fabric weaving processes in order to realize woven fabric and knitted fabric. Woven fabrics are generally composed with two sets of yarns, made by interlacing them at right angles. The knitted fabric is made by interlocking series of loops of one or more yarns, a scheme of both the fabric is shown in Figure 4.

The fundamental difference in topology between these two processes is that for the woven fabric the yarn are organised in a network scheme, while for the knitted fabric there is only a continuous yarn that is running up and down on weft direction.

Off course, such differences in topology reflect on the global properties of the fabric in terms of elastic properties but, in case of a ribbon with electronic properties, also on the global "transfer function" of the fabric.

Table 1. Mechanical Specification of the ribbon

Composition: *Cotton 100% CO*					
Structure: *Tubular, subject to squashing*					
Ave. Nm	***Variance coeff.***	***Breaking force***	***Variance coeff.***	***Elongation at break***	***Toughness***
2.21	*4.0%*	*5.1 gr*	*>7.2%*	*>7.0%*	*11.0 gr/tex*
		UNI EN ISO 2062		*UNI EN ISO 2062*	

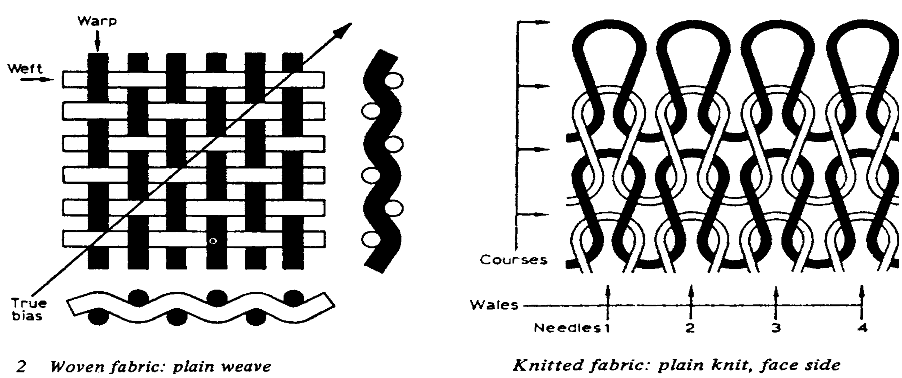

Figure 4. Scheme of woven fabric on the left and knitted fabric on the right.

6. Conclusions

A transistor with a form factor suitable to be employed in a textile process has been studied in the frame of a feasibility analysis project named Arianne. This study has demonstrated that several complicated points must be taken into account when designing and realizing a textile system with an electronic function. Not only questions concerning the electronic properties of materials are important as in conventional circuits but also issues concerning the mechanical properties and the topology of the yarns in the fabric; furthermore, these issues are often cross-correlated. Nevertheless, the employment of such devices for the realization of "smart" fabrics seems to be affordable for a class of recently developed devices based on organic semiconductors. The electronic properties of such materials, together with their mechanical features (many of them are polymers and can be organized in form of flexible thin films) make them the ideal candidates for the final goal of obtaining an electronic yarn.

7. Acknowledgement

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Development of Textile-Based High–Tech Products: The New Challenge

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Abstract. The new generation of smart textiles is represented by fibers, yarns, fabrics and other resulting products that have special properties, regarding mechanical, chemical, electrical and thermal performances.

These high-tech products, being able to respond to external *stimuli* through the integration of electronic components, phase change materials, shape memory materials or nano materials, enabled the development of different active and functional products. These products when combining the functions of medium, carrier and interface for micro-systems applications represent the ideal connecting channel between humans and the environment.

This is a field of innovation that broadened the scope of the traditional textile and apparel products to high-tech textiles, designed to meet specific needs, involving different technologies and produced according to required properties, like personal protection, safety, leisure or health wear.

The development of smart wear is a new challenge for the textile and clothing industry: it has to develop products based not only on design, fashion and comfort concepts but also in terms of functions. Moreover these products must be easy to care and durable.

Introduction

The development of textile-based high-tech products, also defined as smart or intelligent textiles, represent a novel and interdisciplinary approach to the production of *active* and *functional* products that are able to sense and/or measure and respond to body and external *stimuli* (movement, pressure, temperature, acceleration) in order to fulfill a pre-specified function (insulation, protection, safety , health).

These highly engineered products, resulting from the merging of different technologies and techniques, opened up new fields of application for the traditional textile and clothing products and are becoming increasingly prominent, for example, as biomedical materials.

Different types of smart or intelligent textiles can be defined using the characteristic response behavior or mechanism to assess product's level of *intelligence*:

– Reactive *(open loop response)*– the effects are developed by active substances fixed into or onto the textile substrates, stimulated from body or external sources (e.g. biofunctional textiles);

– Active *(adaptive response)* – the effects result from the interaction between body and external *stimuli* and are adapted to these conditions based on the use of active materials with special properties (phase change materials, shape memory polymers or alloys, bi-material film laminates, bi-gels) incorporated into or onto the textile substrates (e.g. thermal regulating fibers);

– Interactive *(controllable response)*– the effects result from a permanent interaction with the user/environment and are regulated according to body and external conditions by monitoring different parameters through micro-systems devices integrated in the textile substrates (e.g. *e*- textiles or electronic textiles). This type of smart or intelligent textiles, representing a revolutionary approach to produce flexible electronic devices and systems on unconventional substrates, led to new concepts for product development and involve a potential breakthrough in innovation as it is on the verge to transform everyday products (fabrics or garments) into interactive interfaces between the human and environment - a new generation of *wearable* systems or *intelligent wear/clothing*.

1. Properties Requirements for *e*-Textiles

A structured methodology is essential to design and develop a complex textile-based product such as an *e*-textile regardless the foreseen application (health, leisure, military, etc). The definition of product performance requirements is the first step of the approach and comprehends product general objectives description. In health or wellness applications, for example, the assessment of an individual's vital signs is one of the main objectives.

Based on these general requirements, product properties (such as sensing and comfort) are then specified and define product design.

1.1. Electrically Conductive/Resistive Substrates

The electrical conductivity (or electrical resistivity) of a substrate is one of the main properties requirements of an *e*-textile structure and determine the applications of the conductive textile. The resistivity defines the intrinsic nature of the material and one can distinguish three types according to the shape of the material: linear (for filiform elements, like yarns or threads), surface (for flat materials, such as fabrics) or volume resistivity. Normally, for applications such as electrical data transport, the resistivity levels are relatively low (less than 103 Ω/cm^2).

Although more difficult to engineer in textile substrates due to their specific attributes (such as softness and flexibility), electrical properties are being increasingly demanded in technical applications to perform functions as heating, electromagnetic interference shielding, electrical data transportation or signals detection.

An electro-conductive textile substrate may be obtained through the integration in or on a textile structure of (1) intrinsically conductive fibers or yarns (metallic fibers or metallic alloys); (2) polymer-base fibers or yarns (e.g. polyester, polyamide) grafted with a conductive function or through the (3) finishing or coating of the textile substrates with conductive products (metallic or conductor polymers).

Currently, there are many commercial electrically conducting yarns made from metals (intrinsically conductive) or from polymers grafted with metals (extrinsically conductive) that can be processed in textile machinery to produce an electrically conductive textile substrate. Some examples are staple and filament steel yarns, copper yarns or steel-grafted polyester yarns.

1.2. Networking and Microelectronic-systems Interconnection and Integration

The use of metallic yarns on textile goods is not new for the textile and clothing sectors, but the purposes are now significantly different. Initially targeted to decorative effects they became increasingly focused on industrial applications (e.g. special fabrics for filters) and more recently on active and functional products involving textile circuitry build up- *sensing fabrics*. This new function (sensing system) added more requisites to material properties (e.g. electrical behavior, electrical insulation) and led to several constraints and incompatibilities with the available textile and clothing technologies, especially related to the interconnection and integration of micro-electronic systems in the textile structures [1,2].

The production of an embedded network of conductive yarns within a textile structure may be obtained through textile fabrication techniques (weaving, knitting) and clothing manufacturing techniques (seaming, embroidery).

Woven fabrics may be used as, selective, anisotropic electrical conductive substrates (using conductive yarns interwoven in one direction and non-conductive running along the opposite direction) or as isotropic electrical conductive substrates (using conductive yarns interwoven in both directions).The conductive yarns, may be continuous or arranged in lanes, and act as intrinsic electrical conduits capable of carrying data signals and/or power. Moreover fabric structure may be multi-layered enabling space to accommodate electronic devices.

The formation of woven circuits requires the interconnection of yarns at selected crossover points and the cutting of other yarns to integrate microelectronic circuits. These interconnection/disconnection operations are made, manually, after weaving.

Knitted fabrics (warp or weft) may be used as conductive substrates in the same way as woven fabrics. However, as the process of fabric formation involves yarn bending care must be taken when selecting the materials, especially in terms of mechanical and electrical performances.

One of the most interesting characteristics of knitting technology relies on the possibility of producing seamless 3D structures which enables the production of shaped products in one stage, eliminating the need for posterior cutting and sewing. This feature may improve the interconnection and integration of micro-electronic devices.

Seaming or sewing and embroidery are clothing manufacture technologies. Basically they use threads (or yarns) to join several plies of fabrics or to finish garments. The use of these techniques to manufacture a textile circuitry is based on seaming or embroidering a base fabric or garment with conductive threads and attaching the electronic devices. These technologies do not enable embedding these devices, but they allow the design and production of flexible multilayer electronic circuitry on fabric substrates [3].

2. Sensory Systems

Nowadays, the developments in textile and clothing technologies enable the integration of conductive yarns in a textile structure or the addition of a conductive function to a fabric. This allows the introduction of electronic components, such as sensors and actuators and computational devices on the fabrics.

The conductivity of the available electro-conductive materials and substrates is, in most cases, insufficient to build up electrodes, sensors or electronic devices. To enhance conductivity, a possibility is to prepare electro-conductive textile structures using special coating procedures or finishing techniques [4]. Generally the base fabric is submitted to electrochemical or galvanic deposition processes in order to coat or modify the base structure's conduction properties. However, these treatments normally impair comfort related properties such as bending, handle and flexibility, degrading *wearability* and thus restraining the application fields.

Textile printing techniques, such as ink jet printing is also a solution that is being adopted and developed to apply conducting, semi-conducting or non-conductive polymers to different surfaces for printed low-cost electronic components and devices. Till now the conductivity of the commercially available inks is not sufficient for sensor structures.

A more fundamental approach that is being followed by researchers relies on a sensing technology based on electro-active response fibers, such as conducting polymer composite (CPC) materials that utilize carbon nanotubes (CNT) as the electrically conductive phase [5]. These environmentally responsive materials, still under development may lead, in a near future, to the development of fiber-based textile sensors and actuators that can be fully embedded in textile substrates.

Other research works aim the incorporation of piezoelectric materials within the electro conductive textile structures to act as a sensing system [6]. The functionality demonstrated by these materials may lead to the integration, within the textile structure, of several discrete components that, until now, are extrinsic to the substrate (e.g. microphones).

These research approaches have a common goal: the development of textile-based structures that are able to sense and respond to different *stimuli* as an inherent property of the substrate.

One of the primary challenges in *e*-textiles is to select materials and devices that provide the desired functionality and that can be easily embedded into hybrid materials using available technologies [7]. It is the degree of integration of these microelectronic components in the textile structure that characterizes the *wearability* of *e*-textiles.

Presently, electronic systems are typically characterized as hard and rigid structures that are not able to conform to other forms or semi-rigid structures with flexibility constraints. These materials are merged with textiles that are soft, pliable and flexible structures that can be shaped to other forms to produce an *e*-textile substrate. These disparate materials characteristics are limiting factors for the integration of electronic devices inside textile structures. In the case of *intelligent clothing* this limitation is even more acute as clothing relies on lightweight, flexible and comfortable products, fashionable, durable and washable.

3. Intelligent Clothing / *i*-Wear

Comfort related properties are of utmost importance when the end-product is intended for clothing: flexibility, handle, design and fashion play a determinant role on consumer's acceptance, as well as, product's durability and ease-care. In the development of *intelligent wear/clothing* these textile attributes are specific product properties requirements.

Clothing is normally worn in layers: the inner layer, the closest to the skin, is intended for comfort and support and is characterized by underwear products; the outer layers, represented by outerwear products, are normally used to add comfort (e.g. warmth) and protection from the surrounding environment. These end-uses influence product specification in terms of materials selection, structure's geometry and construction method and determine garment design and fit.

In garment development, the physiological effects upon the wearer (normally assessed by monitoring changes in body and skin temperature, heart rate and sweat evaporation) must be taken into account to assure product's *breathability* and *wearability*.

A critical aspect when considering *i-wear/clothing* to be used in daily life is the integration and interconnection of textiles and electronics. Due to the different material characteristics, embedding electronic components is still limited.

The majority of the existing solutions for *i-wear* are based on attaching electronic devices to textile substrates in order to fulfill a pre-determined function, disregarding comfort and fashion issues. This limits consumer acceptance of the product to a *need* level: health wear for patients or uniforms for soldiers. The step forward relies on the production of *intelligent clothing* where function design, fashion and comfort concepts are integrated.

4. Conclusion

The adequate selection of materials, structure's geometry and fabrication technologies are determinant to achieve the expected properties requirements and the key factor for the success of textile-based high tech products, namely *e*-textiles and intelligent clothing/*i*-wear.

Researchers still have to overcome many technological challenges in merging electronics with textiles and other flexible materials. The development of materials able to be embedded into textile structures and the improvement of available technologies compatibility to cope with this new generation of textile-based products represent the major challenge to produce comfortable, easy-to-wear, fashionable, cost-effective and added-value consumer goods.

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Smart and Hybrid Materials: Perspectives for Their Use in Textile Structures for Better Health Care

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Abstract. High tech materials such as Shape Memory Alloys can be effectively integrated in textiles, thus providing multifunctional garments with potential application to the health care industry or for simply improving the quality of life. The objective of the present paper is to describe the development of a novel hybrid fabric with embedded shape memory (Nitinol) wires, and the related clothing application with the capability of recovering any shape depending upon the environment and becoming superelastic. The use of these smart garments for biomedical applications will be illustrated, thus opening new perspectives for enhanced health care provision.

Introduction

Fiber and fabric technological developments have created a whole range of smart and modern textiles for many applications. These textiles have been used in functional fashion clothing, sportswear, medical and safety-wear [1–3]. Smart fabrics have been developed to create temperature adaptable clothing with thermal management capabilities [4]. Fabrics or garments embedding Shape Memory Alloys (SMAs) have been developed to provide protection against heat, and increase comfort. The two-way effect in shape memory alloys was generally exploited, which can produce the reversible variation needed for protection from variable weather conditions, or reacting to temperature changes brought about by variations in physical activity levels [5].

A survey of patent databases highlighted that clothing with variable insulation has been conceived, where shape memory materials are activated to increase the air gaps between adjacent textile layers, for example using SMA springs [6,7]. In some concepts, SMA strips have been sandwiched between two enclosing fabrics. In the passive state, the Nitinol strip lies flat and the fabric is about 1 mm thick. When exposed to intense heat, the fabric thickness is rapidly increased to 8 mm. This doubles the escape time available to firefighters or operators working in very harsh environments. This concept can play a role in thermal physiology, increasing or decreasing the insulation of the garment. Other interesting applications are brassiere cups and other deformable, inflatable fabrics to be used for thermal insulation and increased perspiration [8]. Nitinol fibers can be also used to transmit discomfort signals (stress-strain) due to swelling and coupled with other electronic textile components to monitor bio-signals.

Because of the price barrier that imposes limitations to the launch of such products, currently the most promising sector for SMA technology seems to be bio-medical clothing where higher value is added by the technology. An interesting application, recently patented, concerns the application of a flat composite fabric incorporating SMA wires that provide a massaging effect [9]. Such effect is induced by the tensile stress due to shape recovery. The contraction of the fabric is selectively initiated using a two-way memory effect to perform a massage via tensioning and untensioning. This device has been used for the treatment of edemas exerting a pressure action perpendicular to the skin surface of the arm.

The self-ironing shirt with woven shape memory yarns, manufactured by Grado Zero Espace S.r.l., is an example of the possible construction of fabrics and clothing using interwoven Nitinol wires [10,11].

1. Development of a Hybrid Fabric

Work was initiated to develop a hybrid fabric able to combine shape memory properties and superelastic effect for fashion applications. The overall target of the development work was the possibility of weaving nylon and Nitinol yarns to provide travelers with an innovative fabric for shirts that are self-ironing and sensitive to environmental changes.

Nitinol belongs to the class of Shape Memory Alloys, which are a class of alloys that have the ability to undergo reversible micromechanical phase transition processes changing their crystallographic structure over a temperature variation. This capacity results in two major features at the macroscopic level which are the superelasticity and the shape-memory effect.

These peculiar shape memory and superelastic properties are due to a reversible phase transformation, either thermal-induced or stress-induced, which consists of a solid-to-solid diffusionless process between a crystallographically more-ordered phase, the austenite, and a crystallographically less-ordered phase, the martensite. At relatively high temperatures SMAs are in the austenitic state. They undergo a transformation to the martensitic state when cooled [12].

When a unidirectional stress is applied to a martensitic specimen, there is a critical value whereupon the detwinning process of the martensitic variants takes place. The detwinning process in crystalline solids is a unique microstructural deformation mechanism, during which martensite passes from its twinned (self-accommodated) state to its detwinned state upon loading. Specifically, the process consists of a spatial re-orientation of original martensitic variants, characterized by great motion of multiple interfaces occurring at stress levels far lower than the plastic yield limit, thus not generating dislocation, but also lower than the elastic deformation limit. During this process the stress remains practically constant, until the martensite is fully detwinned. Further straining causes the elastic loading of the detwinned martensite. Upon unloading, a large residual strain remains. However, by heating, martensite transforms into the crystallographically more-ordered austenite and the specimen recovers its initial undeformed shape. This shape is kept during cooling, when the material re-transforms into twinned martensite. This phenomenon is generally named as shape-memory effect [12].

When a unidirectional stress is applied to an austenitic specimen, there is a critical value whereupon a transformation from austenite to detwinned martensite occurs. As deformation proceeds in isothermal conditions, the stress remains almost constant until the material is fully transformed. Further straining causes the elastic loading of the detwinned martensite. Upon unloading, a reverse transformation takes place, but at a lower stress level than during loading so that a hysteretic effect is produced. This remarkable process gives rise to an energy absorption capacity with zero residual strain, which is termed superelasticity (or pseudoelasticity) [12].

Discussions with representatives of the textile sector revealed that several attempts to integrate micrometric metallic yarns into textile structures had been widely carried out by considering a pragmatic approach. Indeed, the current practice within the textile sector is to make empirical adjustments in weaving conditions in order to obtain new products with specified properties that will meet market demands. Since the objective of the project was to create a fabric with specific recovery behaviour, a systematic approach was attempted to control the fabric properties. Specific fibres and a hybrid fabric structure were considered in order to achieve the target deformability and recovery. The Nitinol fibres were co-woven with Nylon. An estimate of the fibre volume fraction needed to achieve the required recovery was performed since the recovery should be activated by a controlled amount of Nitinol wire actuators. The percentage of Nitinol was optimised during manufacturing trials in order to reduce disadvantages as sensitivity to actuator – nylon interface, and relatively high rate of actuator breakage during manufacturing because of sensitivity to stress concentrations at the mechanical restraints.

1.1. Fabric Development

A preliminary qualitative analysis permitted to conclude that the deformation of the fabric during the shape recovery of the Nitinol wire is dependent on two major factors. One is the amount of Nitinol used and the other is the stretching percentage of undulated fibre yarns of the fabric. A woven fabric was thought to be able to accommodate extension of undulated fibres in the fibre direction and deformation of square units in the diagonal directions reducing possible wrinkling of fabric. Woven fabrics are normally constructed from fibre yarns, and the movement of each fibre yarn is restricted by friction between crossing fibre yarns during the shear deformation process. According to existing studies on micromechanics which link the fibre properties and their arrangement within the structure to the basic mechanical properties of yarns and fabrics, the deformation behaviour of the plain woven fabric may guarantee a good recovery behaviour [13,14].

The ability of a fabric to recover from wrinkling depends to a certain extent on the recovery from deformation of the individual fibres. This property of the fibre is also imparted to yarns and to fabric made from them. The improved properties of recovery from deformation of Nylon yarns depend on the peculiar crystallised structure resulting in aligned molecules closely packed in some areas, which stabilise the fibre and improve the recovery properties. While the areas relatively unaligned (amorphous areas where the molecules are loosely held together by secondary forces) permit flexibility of movement.

Considering the typical recovery stress for Nitinol ($\geq$200MPa) and assuming that the recovery stress will be transmitted uniformly to the fabric, the fraction of the fibre, necessary for recovery, was estimated in the range 5-25% [15]. An analysis, which links fabric properties to the complex deformations involved in drape, handle, and other commercially important attributes of fabrics linked to the subjective impressions of consumers, was also performed during the manufacturing trials in order to further optimise the required amount of Nitinol.

A Nitinol alloy in a wire form was selected as the actuator material. The temperatures necessary to trigger the shape memory effect, were near body temperatures and the transformation start was fixed above 37°C. A Nitinol alloy was specified with an appropriate composition to give a martensite finish temperature in the range 38-45°C and a wrinkled shape, for providing the sleeves with rolling up. Nitinol wires with an austenite peak temperature above 66°C, were used to provide the shirt with ironing properties.

1.2. Weaving Trials

A “rapier” weaving loom was used. The rapier system provides the means to interlace warp and weft yarns according the weave patterns. Warp yarns (namely ends), in the fabric lengthwise direction, were supplied to the weaving machine on the loom beam. The yarns crossing the warp referred to as weft were inserted in the fabric by means of a weft feeder. Nitinol fibers were interwoven as weft filament, while nylon yarns were woven as warp. The interweaving of Nitinol fibres as weft permitted to avoid rewinding and irregular movement of the fibres. Furthermore, this technique could permit to manufacture different woven structures as Twill or Satin. In the Twill structure, one or more warp fibres alternately weave over and under two or more weft fibres in a regular repeated manner, while in Satin weaves are fundamentally twill weaves modified to produce fewer intersections of warp and weft.

The loom was modified to achieve a uniform and smooth surface on the fabric. Two servomotors and a disc-cam operated mechanism controlled individual thread selection and movement. Control techniques were set up based on understanding of the material structure and behaviour in order to relate fabric properties with design and control specifications. Multiple thread feeders were used with the weft rapier accelerator. The weft thread rapier was accelerated hydraulically to a speed of up to 40m/sec. The incoming high-speed rapier was stopped and ejected from the brake by a disc cam operated mechanism. Each device feeded up to 1 threads of weft. A weft insertion speed of 4000 yarns per minute was used. The Nitinol yarn tension was controlled during manufacturing in order to prevent stress-induced transformation. Since there are few ways to assess tension on-line, hand held tension-meters were used to test individually each yarn one after the other to guarantee a uniform textile. The size of the Nitinol filament was selected in order to facilitate the weaving process as 76μm, and the final percentage of Nitinol fibres was 10%. The final weight of the fabric was approximately 200g/m^2. Fibres with shape recovery above 45°C were interwoven in the sleeves, while fibres with shape recovery above 66°C were interwoven for the manufacturing of the other parts of the shirt.

The developed fabric and related manufacturing process was optimized to meet the typical requirements of clothing processing and wearing. The whole fabric and the Nitinol wire have to withstand textile typical handling requirements, for example, for washing and wrinkling without damage of the wires. In addition fibers that are used for clothing have to be fine and to some extent elastic in order to achieve a high comfort of wearing.

Several weaving trials were performed in order to achieve the typical quality requirements of the fashion industry. One of the intrinsic limitations of first trials was the in-

Figure 1. Self ironing shirt.

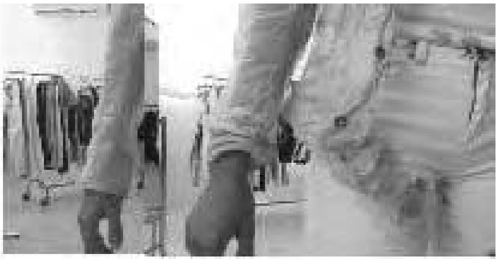

Figure 2. Thermal Memory Effect during wearing.

homogeneity (not uniform surface) of the textile due to several irregularities or variations, such as variations in diameters and density from thread to thread. At the level of the fabrics the distance between yarns varied. Another important issue was the intrinsic viscoelasticity of nylon fabric, the tension induced by weaving released during time and the geometry changed. But several trials resulted in achieving a satisfying quality and fabric uniformity. The final prototype shirt is shown in Figure 1.

One of the main features of the shirt is that sleeves roll up when it becomes too warm, as shown in Figure 2 and 3. The sleeve was developed to shorten as soon as the room temperature becomes a few degrees hotter, behaving like a thermostat strip when it's heated and cooled. The shirt will never need ironing, indeed even if the fabric is rolled up into a ball, pleated and creased, a blast from a hairdryer pops it back to its former shape. This means the shirt can be ironed while wearing it. The partial self recovery of the fabric is depicted in Figure 4. Furthermore the fabric is washable and non-allergenic.

Unlike the conventional perma-press or wrinkle-free shirts (100% cotton, rayon and linen) available on the market, the shape-memory shirt maintains natural soft texture, while holding their functional effects semi-permanently.

Further developments will investigate the possibility to design a hybrid weft knitted fabric considering different structures. Particularly, the possibility to develop a plain

Figure 3. Thermal Memory Effect.

Figure 4. Fabric self shape recovery.

stitch in one direction and two directions using an in-laying technique will be considered. The in-laying technique consists in introducing the SMA filaments into a non-stitch forming feeder system in such a way that it is picked up by every second-third-fourth needle only (Figure 5 – A and B). The SMA inlay density will depend on the number of feeder systems: for example, in a hosiery machine with four feeder systems, the threads

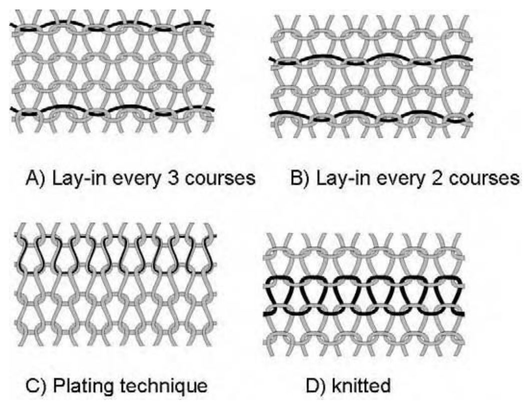

Figure 5. Knitted fabric with Nitinol inlay.

float in every third course. A plating technique will be investigated too, to form one stitch out of two filaments: one nylon filament and one SMA filament (Figure 5 – C). Finally the direct knitting of the SMA filament will be considered (see Figure 5 – D).

2. Perspectives in Biomedical Applications

Based on the experience with the smart shirt, D'Appolonia is currently investigating the possibility to exploit the Shape Memory fabrics for biomedical applications. One of the investigated applications is the opportunity to apply Shape Memory Alloys for the development of bras with embedded superelastic fibers to help sustain the reduction in swelling and discomfort which is due to lymphedema or chest or breast post surgical conditions. In fact, the problem with conventional bras is that the under-wires and the thin elastic straps and bands "dig in" at the shoulders, the rib cage, and especially under the breast and armpit, which are sensitive post surgical areas, thus they do not address lymphedema, and are often very uncomfortable (and may even exacerbate pain) for women suffering from those conditions.

A second interesting investigation regards the possibility to exploit superelastic and shape memory properties of Nitinol for the development of textile structures which have the capability of controlling compression through the application of physical stimuli, thus offering a great opportunity for the application within graduate compressive devices for addressing venous disorders or, again, lymphedema.

One of the major applications of Shape Memory Alloys today consists of their use as actuators. Some attempts have been also performed in using Shape Memory Alloy sensors for civil engineering applications. Damage sensing of a structural member, using electric resistance characteristics of Shape Memory Alloys has been investigated [16]. This suggested the possibility to use shape memory wires or fibers as strain sensing elements for the development of textile superelastic bands capable of real time bio-signal acquisition (and eventual actuation) thus exploiting the superelastic effect to detect, for instance, breathing and heart rate signals at both chest and abdomen. Indeed, the electrical resistance of Shape Memory Alloys was first used to detect their transformation temperatures and it was observed that in particular conditions and alloys, the electrical resistance could be related to the strain of the alloy linearly, thus stimulating a new application-oriented research [17].

Although this research is still at an early stage, the basic concepts rely on the fact that the electrical resistance is a linear function of strain for some NiTi-based alloys [17]. The result is that the electrical resistance R of some SMA-wires changes during transformation and retransformation. This proportionality suggested those Shape Memory Alloys to offer potential applications as very simple strain sensors or as actuators with built-in sensor capabilities also for acquiring bio-signals. Furthermore, the successful achievements in weaving of Nitinol fibers let presume the possibility to develop biomedical clothes with interwoven SMA sensors for the effective acquisition of data during wearing conditions.

3. Conclusions

The outcome of the research performed to date highlighted the successful feasibility of constructing fabrics and clothing using interwoven Nitinol wires. The development of a self-ironing fabric has been demonstrated, highlighting areas of further improvements that need to be addressed to have a commercially viable product. The overall idea is to move towards knitted structures. Considering the typical crimped structure of the hosiery knitted textile, the embedding of the Nitinol filaments will be investigated considering different possible configurations: interlacing of an inlay of Nitinol, or directly knitting the Nitinol filaments with the Nylon yarns. Different knitted fabric structures will be considered as shown in Figure 5. Initial work with knitted structures showed promising perspectives, demonstrating a huge exploitation potential in the near future also considering applications in the area of biomedical clothes, where fundamental and applied research work will be necessary to accomplish the desired objectives.

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Smart Textiles

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Abstract. After technical textiles and functional textiles, also smart textiles came into force a few years ago. The term ‘smart textiles’ covers a broad range. The application possibilities are only limited by our imagination and creativity. In this presentation, it is further explored what smart textiles precisely mean. In a second part, an analysis is made of the possibilities, the state of affairs and the needs for further research.

Introduction

The term ‘smart textiles’ is derived from intelligent or smart materials. The concept ‘Intelligent Material’ was for the first time defined in Japan in 1989. The first textile material that, in retroaction, was labelled as a ‘smart textile’ was silk thread having a shape memory effect (by analogy with the better known shape memory alloys which will be discussed later in this article).

The continual shrinkage of the textile industry in the Western world has amply raised the interest in intelligent textiles. Smart textile products meet all criteria of high-added value technology allowing a transformation to a competitive high-tech industry:

- from resource-based towards knowledge-based,
- from quantity to quality,
- from mass-produced single-use products to manufactured-on-demand, multi-use and upgradable product-services,
- from “material and tangible” to “intangible” value-added products, processes and services.

1. Definition of intelligent clothing

What does it mean exactly, ‘smart textiles’?
Textiles that are able to sense stimuli from the environment, to react to them and adapt to them by integration of functionalities in the textile structure. The stimulus as well as the response can have an electrical, thermal, chemical, magnetic or other origin.

Advanced materials, such as breathing, fire-resistant or ultrastrong fabrics, are according to this definition not considered as intelligent, no matter how high-technological they might be.

The extent of intelligence can be divided in three subgroups [1]:
passive smart textiles can only sense the environment, they are sensors;
active smart textiles can sense the stimuli from the environment and also react to them, besides the sensing function, they also act as actuators;
finally, *very smart textiles* take a step further, having the gift to adapt their behaviour to the circumstances.

On principle, two components need to be present in the textile structure in order to bear the full mark of smart textiles: a sensor and an actuator, possibly completed with a processing unit which drives the actuator on the basis of the signals from the sensor.

Although smart textiles find and will find applications in numerous fields, this presentation is limited to clothing. However, clothing can be interpreted in a broad sense. It involves for example wearable smart textiles meant for medical applications, designed to fulfil certain functions, but apart from that without any fringes. Also casual clothing is possible, which is expected to be functional as well as fashionable. It also embraces sports clothing, where the comfort factor is even more critical. Finally, smart textiles could be sold as a gadget, where the intelligent character will be more accessory (Spielerei) than useful but in any case extremely visible.

Initially, smart clothing will find applications in those fields where the need for monitoring and actuation can be of vital importance, such as a medical environment, and with vulnerable population groups, in space travel and the military. However, as experience and familiarity will increase and hence breaking down barriers, the field of application will in the long term definitely widen to more daily applications such as sports and leisure, the work environment and so on.

2. State of the art

The first generation of intelligent clothes uses conventional materials and components and tries to adapt the textile design in order to fit in the external elements. They can be considered as e-apparel, where electronics are added to the textile. A first successful step towards wearability was the ICD+ line at the end of the 90ies, which was the result of co-operation between Levi's and Philips. This line's coat architecture was adapted in such a way that existing devices could be put away in the coat: a microphone, an earphone, a remote control, a mobile phone and an MP3 player. The coat construction at that time did require that all these components, including the wiring, were carefully removed from the coat before it went into the washing machine. The limitation as to maintenance caused a high need for further integration.

The most obvious thing to do was integrating the connection wires of the different components into the textile. To this end, conductive textile materials are appealed to. Infineon has developed a miniaturised MP3 player which can easily be incorporated in a garment. The complete concept consists of a central microchip, an earphone, a battery, a download card for the music and an interconnection of all these components through woven conductive textiles. The different components are protected by a robust and wash-proof packing.

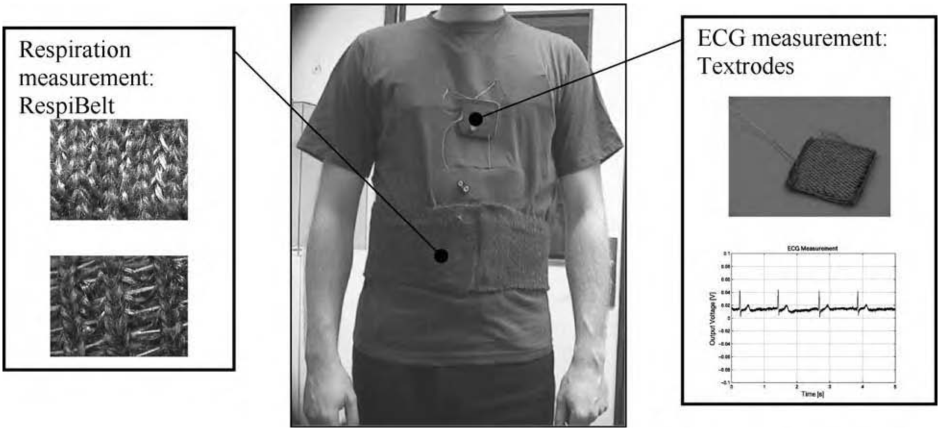

Figure 1. Full textile components.

No matter how strongly integrated, the functional components remain non-textile elements, meaning that maintenance and durability are still important problems.

In the second generation, the components themselves are transformed into full textile materials, as illustrated by Figure 1.

Basically, 5 functions can be distinguished in an intelligent suit, namely:

- Sensors
- Data processing
- Actuators
- Storage
- Communication

They all have a clear role, although not all intelligent suits will contain all functions. The functions may be quite apparent, or may be an intrinsic property of the material or structure. They all require appropriate materials and structures, and they must be compatible with the function of clothing: comfortable, durable, resistant to regular textile maintenance processes and so on.

3. A closer look at the different components

3.1. Sensors

The basis of a sensor is that it transforms one signal into another signal that can be read and understood by a predefined reader, which can be a real device or a person. The senses of a person are well known: sight, hearing, smell, taste, touch.

The sensors can consist of 3 elements that are combined in a smart way: a selective intelligent *barrier/interface/filter* (e.g. selectivity by blocking signals by for instance membranes, (selective) absorption, Bragg effect, permeability triggered by the signal to be detected), *conversion* of the signal into another signal (sensor systems use several conversions, even an optical sensor eventually provides an electrical signal as output, and actuators and energy "generation" systems for instance, also convert signals or energy (e.g. into motion or electricity)), and the actual *detector*. Careful selection of conversion steps between parameter to be detected and available textile sensors at any point in research, allows a huge number of sensor systems. As for real devices, ultimately most signals are being transformed into electric ones. Some examples of conversion:

From/to	**Thermal**	**EM**	**Chem./ biol.**	**Optical**	**Mechanical**	**Acoustic**
Thermal		Seebeck	thermal reaction	thermo-luminescence	shape memory material	
Electromagnetic	resistance/ Peltier			electro-luminescence	electroactive polymers	speaker
Chemical/ biological	thermal reaction	ion/electron reaction		chemo-luminescence	active gels	
Optical	absorption	photovoltaic	dyes	dyes		
Mechanical (kinetic, elastic..)	friction	piezo electric			elastic, intertia	vibration
Acoustic	friction	piezo electric				

Electroconductive materials are consequently of utmost importance with respect to intelligent textiles.

When designing new textile sensors, the art will be to specify the concepts of transformation that make it possible to turn the signal one wants to measure into (the variation of) a signal one can measure (in most cases the latter will be an electric signal). Possibly, intermediate transformations may be necessary, although these must be minimised. Of course, apart from technical considerations, concepts, materials, structures and treatments must be focusing on the appropriateness for use in or as a textile material. This includes criteria like flexibility, water (laundry) resistance, durability against deformation, radiation etc.

Nevertheless, when looking at possibilities of transformation, e.g. from optical to electrical, from thermal to mechanical, from mechanical to electrical, from thermal to optical, and combinations of subsequent transformations, it will be clear that there is an enormous potential of sensors that are just waiting to be developed for a huge range of textile applications.

Materials that have the capacity of such a transformation are for instance :

- Thermocouple: from thermal to electrical
- The **Softswitch** technology [2]: from mechanical (pressure) to electrical
  The so-called ‘Quantum Tunnelling Composite (QTC)’ is used. This composite has the remarkable characteristic to be an isolator in its normal condition and to change in a metal-like conductor when pressure is being exercised on it. Depending on the application, the pressure sensitivity can be adapted. Through the existing production methods, the active polymer layer can be applied on every textile structure, a knitted fabric, a woven fabric or a nonwoven. The pressure sensitive textile material can be connected to existing electronics.
- Fibre Bragg Grating (FBG) sensors [3]: from mechanical through optical to electrical. This is a type of optical sensors receiving a lot of attention the latest years. They are used for the monitoring of the structural condition of fibre-reinforced composites, concrete constructions or other construction materials. At the Hong Kong Polytechnic University, several important applications of optical fibres have been

developed for the measurement of tension and temperature in composite materials and other textile structures. FBG sensors look like normal optical fibres, but inside they contain at a certain place a diffraction grid which reflects the incident light at a certain wavelength (principle of Bragg diffraction) in the direction where the light is coming from. The value of this wavelength linearly relates to a possible elongation or contraction of the fibre. In this way, the Bragg sensor can function as a sensor for deformation.

3.2. Data processing

Data processing is one of the components that are required only when active processing is necessary. So far, no textile materials are available that can perform this task. Pieces of electronics are still necessary. However, they are available in miniaturised and even in a flexible form.

Research is going on to fix the active components on fibres (Ficom project [4]). Many practical problems need to be overcome before real computing fibres will be on the market: fastness to washing, deformation, interconnections, etc.

3.3. Actuators

Actuators respond to an impulse resulting from the sensor function, possibly after data processing.

In a sense, actuators are similar to sensors in that they also transform the impulse signal into a response signal.

Actuators make things move, they release substances, make noise, and many others. Shape memory materials are the best-known examples in this area. They transform thermal energy into motion. In a cold state, or beneath the transition temperature, a shape memory alloy can easily be deformed and the material will keep this shape. If the material is heated again above the transition temperature, it will return to its original shape. The material so to speak has 'memorised' this shape. Because of its ability to react to a temperature change, a shape memory alloy can be used as an actuator and links up perfectly with the requirements imposed to smart textiles. A common shape memory alloy is Nitinol. It consists of a mixture of nickel and titanium.

Shape memory alloys exist in the form of threads, which makes them compatible with textile materials.

Although shape memory polymers are cheaper, they are less frequently applied. This is due to the fact that they cannot be loaded very heavily during the recovery cycle.

Until now, few textile applications of shape memory alloys are known. The Italian firm, Corpo Nove, in co-operation with d'Appolonia, developed the Oricalco Smart Shirt [5]. The shape memory alloy is woven with traditional textile material resulting into a fabric with a pure textile aspect. The trained memory shape is a straight thread. When heating, all the creases in the fabric disappear. This means that the shirt can be ironed with a hair dryer.

Real challenges in this area are the development of very strong mechanical actuators that can act as artificial muscles. Performant muscle-like materials, however, are not yet within reach.

Materials that release substances already have several commercial applications. However, actively controlled release is not obvious.

Chemical products (in the widest sense) can be released in a controlled way using two main principles:

- products are chemically bound to the substrate, these bonds are broken down by a predetermined factor, or
- the textile material contains one or many tanks (massive fibre, micro or nanocapsules, micro or nanopores,...) whereby release is controlled by an intelligent barrier. Micro-encapsulation is a well-known example of this category.

Obviously, controlled release opens up a huge number of applications as drug supply systems in intelligent suits that can also make an adequate diagnosis.
Mechanical and chemical actuators are clear examples, but of course one can think of many other types, again for a huge number of applications.

3.4. Storage

All smart suits will need some storage capacity. Storage of data or energy is most common.
Sensing, data processing, actuation, communication, they usually need energy, mostly electrical power. Efficient energy management will consist of an appropriate combination of energy supply and energy storage capacity.
Energy supply is also based on transformation, in this case of one type of energy into another one.

Sources of energy that are available to a garment are for instance body heat, mechanical (elastic from deformation of the fabrics, kinetic from body motion), radiation, etc.
Infineon had the idea to transform the temperature difference between the human body and the environment into electrical energy by means of thermogenerators [6]. The prototype is a rigid, thin micromodule which is discretely incorporated in the clothing . The module itself is not manufactured out of textile material. However, the line of thought is introduced. The Infineon thermogenerator delivers 1.6 microwatt/cm^2 and is washable thanks to the plastic packing.

The use of solar energy for energy supply is also thought of. At the University of California, Berkley, a flexible solar cell is developed which can be applied to any surface [7].

As mentioned before, energy supply must be combined with energy storage. When hearing this, one thinks of batteries. Batteries are becoming increasingly smaller and lighter. Even flexible versions are available, although less performant. Currently, the lithium-ion batteries are found in many applications.

For some applications where large temperature variations occur, it may be useful to store the thermal energy as well:

Phase change materials are materials whose state of aggregation changes within a determined and limited temperature interval [8]. When comparing the melting process of a material and in particular of a PCM with a normal heating process, it is seen that a PCM can absorb a much larger quantity of warmth without observing a considerable increase of its temperature. A paraffin PCM, for example, will absorb during the melting process until 200 kilojoules per kilogram warmth. When a textile material would absorb the same amount of warmth, its temperature would increase with 200 °C! During the coagulation process, the PCM will return the same amount of warmth to the environment, without its temperature changing a lot. Because of this characteristic, PCMs are very suitable for warmth supply in a textile material. To prevent the paraffins from flowing away during the liquid phase, it is necessary that they are captured in a microcapsule (1-10 micron). These microcapsules are integrated in a textile material The concept of micro-encapsulation of PCMs was developed by NASA in the 60ies in order to be able to protect the delicate instruments against extreme temperature variations in space.

3.5. Communication

For intelligent textiles, communication has many faces: communication may be required

- within one element of a suit,
- between the individual elements within the suit,
- from the wearer to the suit to pass instructions,
- from the suit to the wearer or his environment to pass information.

Within the suit, communication is currently realised by either optical fibres, either conductive yarns. They both clearly have a textile nature and can be built in the textile seamlessly. The advantages and disadvantages of both carriers are well known: optical fibres are light and insensitive to EM radiation. The transport does not cause production of heat. On the other hand, the signals have to be transformed into electrical ones at least at one point.

Communication with the wearer is possible for instance by the following technologies: For the development of a flexible textile screen, the use of optical fibres is obvious as well. France Telecom has managed to realise some prototypes (a sweater and a backpack) [9]. At certain points, the light from the fibre can come out and a pixel is formed on the textile surface. The textile screen can emit static and dynamic colour images. The resolution is extremely low however. Nevertheless, in this way, these clothes are uplifted to a first generation of graphical communication means.

Pressure sensitive textile materials (Softswitch, Eleksen [10] and Tactex [11]) allow putting in information, provided a processing unit can interpret the commands.

Communication with the wider environment does not allow direct contact, so wireless connections are required. This can be achieved by integrating an antenna. The step was also taken to manufacture this antenna in textile material. The advantage of integrating antennas in clothing is that a large surface can be used without the user being aware of it. In the summer of 2002, a prototype was presented by Philips Research Laboratories, UK and Foster Miller, USA on the International Interactive Textiles for the Warrior Conference (Boston, USA). The researchers made use of conductive yarn on the basis of copper and nylon. Moreover, existing production methods were appealed to to construct the textile antenna.

4. Need for further research

The potential of intelligent textiles is huge. One can think of many applications for each of the examples given above. The other way around, starting from an application, the basic concepts have to be defined and evaluated for their use in or as a textile product. Selection of materials, structure and production technology are the first step in the design. The actual research phase will be long and hard for many cases.

Basic items that need to be addressed to come to a real breakthrough and to innovation are:

transformation and conversion mechanisms
new materials and
new structures that can offer the requested functions

Conductive materials, and more specifically inherently conducting polymers or ICPs, are already being used in many applications: antistatic working, EMI shielding, heating, transport of electrical signals, ... These are fascinating, dynamic, molecular systems suitable for applications in many domains of intelligent clothing: polymer batteries, solar energy conversion, biomechanical sensors, ... Some materials are already available, be it at laboratory level. Some substantial disadvantages which have to be overcome are the instability of the polymer in the air, the weak mechanical properties and the difficult processing. However, in the United States one has managed to spin the first polyaniline fibre [12].

Another class of materials that will without any doubt play a major role in many intelligent clothes are optical fibres. They are well known from applications in electronics, but the range of deformations to deal with in textile applications is of a different order and causes problems that restrict the number of applications at present.

5. Conclusion

Textiles are present everywhere and any time. No one ever leaves his house without having been occupied with textiles. The economical value and impact of textiles is gigantic. The advent of smart textiles makes it possible to bring the traditional textile sector to a level of high-technological industry. Moreover, it appears that this is only possible by intense co-operation between people from various backgrounds and disciplines. Technology domains such as biotechnology, computer science, microelectronics, polymer chemistry, material science ... look at textile possibilities from another point of view.

The development of smart textiles starts to come at cruise speed. A part of the new materials and structures have already reached the stage of commercialisation, a much larger part however is still in full development or still has to be invented even. This applies especially for the very smart textiles. This phase is not to be reached in the near future.

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