Advanced Wearable Health Systems and Applications

Research and Development Efforts in the European Union

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Medicine has traditionally focused on treatment using molecules, drugs, mechanics, prosthesis, and surgery. More recently, the healthcare community's investments and expectations have shifted more toward early detection of diseases, health status monitoring, healthy lifestyle, and overall quality of life. Healthcare providers are looking for cheaper and more responsive ways of delivering services than through large centralized institutions [1]. Healthcare and health services have to be accessible to everyone, at low cost, whenever and wherever they need them.

The evolution that is underway in healthcare and health delivery in Europe and worldwide is mainly driven by:

- demographic changes [1], including the increase of the aging population and chronic diseases and the need for further integration of handicapped
- steadily increasing healthcare costs [2]
- cultural changes; e.g., people becoming more eager to participate actively in their own health management
- the remarkable progress in sciences and technologies, like biomedicine and micro/nano technologies (MNT), offering new solutions based on integrated, smart, cost-efficient systems. In particular, the strong market demand for microsystems and nanotechnologies in medical applications has significantly contributed to the continuous technological innovation [3].

Europe has driven substantial developments in medical technology and eHealth since the early 1990s. In particular, research & development support under the Information Society Technologies (IST) activities of the Fifth Research and Development Framework Program (FP5, 1999–2002) of the European Commission (EC) has achieved significant results in integrated ICT systems and applications to support mobile and personal health. Special research and development effort was placed on smart wearable health systems and applications (SWHSA) [4]. This work was further advanced in FP6 (2002–2006) with more integrated multifunctional wearable systems like smart textiles, body sensor networks, and context-aware sensor systems enabling physiological, biochemical, and physical monitoring of the individual. Research and development projects in SWHSA face several common issues, technological and nontechnological, which are usually addressed in the user-requirements phase of a project. This article discusses these aspects as well as the major achievements and ongoing research and development on SWHSA in Europe (and worldwide) and future challenges.

User Requirements for Wearable Health Systems and Applications

Communicative wearable health systems [4]–[6] are recognized as one of the most promising platforms for minimally obtrusive and individualized health services at the point of need. In addition to improving the quality of life, the strong interest in developing and implementing such solutions is guided by the considerable direct and indirect annual medical costs [2]. SWHSA could contribute to a significant reduction of the total healthcare expenditure by, for example, avoiding unnecessary hospitalizations and ensuring that those who need the urgent care get it sooner, and reducing medical errors by enabling interaction between patient and health professional any time it is needed.

One of the most important development phases of a SWHSA is the analysis of the user needs. The experience acquired within the European project research activities shows that these issues are numerous and complex [4]; e.g., usability and wearability, data storage, embedded decision support, power supply (i.e., power scavenging and storage), telecommunication, and interoperability and eHealth service.

Sensing capabilities and biomedical sensors play a key role in the design, performance, and acceptance of SWHS. The new generation of biomedical sensors presents a large spectrum bandwidth allowing new measurements on humans and new approaches for diagnosis, ambulatory healthcare, and care at the point of need, any time [7]. The non-invasive sensors are particularly suitable for humans (offering painless measurement, no risk for infection, and user-friendliness) but present usually a high complexity of principle and system design, due to the difficulty to measure deep phenomenon from the surface of the skin. The choice of the localization of noninvasive devices has to satisfy several criteria and limitations (e.g., obtaining the best signal/noise ratio, fixing, and ergonomics) but also unobtrusiveness. Several solutions are available such as independent sensors and devices, perimetric fixing using the body segments and the circular body parts (e.g., head, arm,

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wrist, leg and ankle) as well as networked body sensors. However, the limited number of available sensors and the long life cycle of development and validation constitute a bottleneck for further progress of wearable biomedical devices.

Other major issues to be addressed in the user requirements analysis are:

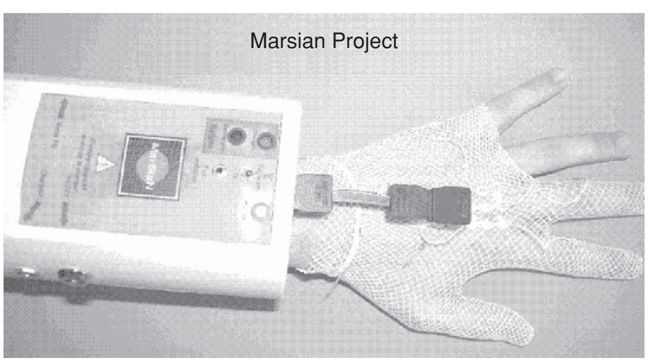
- *clinical validation planning;* e.g., possible clinical scenarios that have to be tested with respect to normal and abnormal medical values (diagnostic and screening tests)
- *legal and ethical issues;* e.g., personal medical data protection, user confidentiality measures, and risk analysis
- *manufacturability, maintainability, and connectivity,* which are particularly important for smart fabrics technology.

Achievements In Wearable (Nontextile) Health Systems

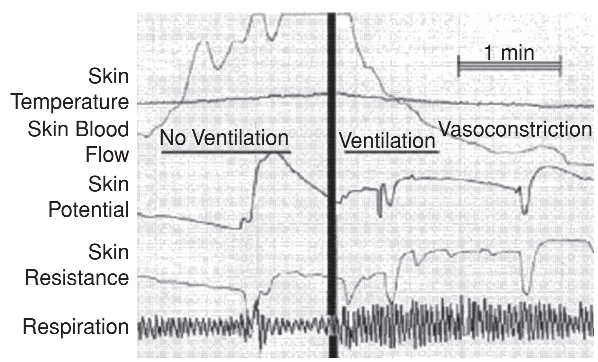
Remote monitoring of multiple vital signs has been too complicated to achieve either because the required specialized measurement devices were unavailable or too expensive or too unfriendly to be employed. Therefore, almost all past and current commercial portable/wearable applications of health monitoring have been limited to the registration of a single physiological parameter, resulting in incomplete information about other relevant physiological and environmental factors likely to contribute to the wearer's health status. The reluctance of health professionals to include the analysis of the (large amount of) transmitted data in their daily practice has been another barrier to the expansion of ambulatory health monitoring.

One of the main objectives of recent and ongoing research in SWHSA, in Europe and worldwide, is to increase system functionality and autonomy with embedded decision support, as well as to enhance user-friendliness and multiparameter monitoring capabilities. More than 35 EC projects with an approximate total funding of €60 million were supported from 1999 until 2002 in the area of ambulatory and wearable Information and Communication Technologies (ICT)-based health monitoring systems and medical devices [8]–[12]. Projects contributed to these results mainly by following two complementary approaches: the "application pull" approach (supported by the "eHealth" sector) and the "technology push" approach (supported by the "micro and nanosystems" sector). Representative examples of such prototype systems and applications include:

- continuous measurement and control of glucose concentration in subjects with type 1 diabetes, enabling the provision of better adjustment of insulin dosage [8]
- personal ECG monitoring [9] for early detection and management of cardiac events, including recording, storage, and synthesis of standard 12-lead ECGs, self-adaptive data processing, decision support, and alarm generation
- a wrist multisensor device for continuous monitoring of health status and alert, integrating biomedical sensors for heart rate, 1-lead ECG, blood pressure, oxygen blood saturation, and skin temperature measurement [10]
- a personal mobile health service platform for vital signs monitoring based on a body area network, utilizing the next generation of public wireless networks [11]
- an ambulatory bio-sensing microsystem for continuous evaluation of organ feasibility both during transport and during the initial postoperative period [12].



(a)



(b)

Fig. 1. (a) Marsian: An ambulatory instrumentation composed of clothes, gloves, and wrist device. (b) Autonomic nervous system reaction to ventilation stimulation. The ventilation localized on the face of the subject induces a thermal and sensorial discomfort. The decrease of skin microcirculation, the increase in respiration rate and amplitude, and the pattern of skin resistance and potential are related to a negative stimulation (thermal discomfort).

There are also other approaches that aim at developing biosensing patches, adapted to different body fluids (e.g., sweat, blood), where the textile itself is the sensor.

Other relevant prototype systems developed in Europe during the same period include:

- a wrist system providing continuous monitoring of physiological signs, changes in the user's normal activity [13], and overall well-being by measuring skin temperature, heart pulse and rate, micro/macro movement, and fall detection [14]
- a smart glove [15] for noninvasive multiparametric measurements of the autonomous nervous system, enabling the study of cognitive and physical status; the response to odor, speech, and vision; and the comparison with conscious and verbal indications as well as mental training (Figure 1)
- a multichannel portable chrono-programmable pump based on the principle of chrono-adapted administration of drugs; i.e., adaptation to the changes of the pharmacological effect of a drug according to the biorhythms [16].

New promising research recently emerged from the miniaturization of electronics and materials processing, making possible the integration of multiple smart functions into textiles without being a burden. The advantages of this integration are obvious: first, about 90% of the skin can be in contact with textile, which is the most "natural" interface to the body, and, second, fabrics are flexible and fit well with the human body and they are also cheap and disposable. Intelligent biomedical clothing (IBC), presented below, is a special example of SWHS.

Intelligent Biomedical Clothing: State of the Art and Ongoing Research

Intelligent biomedical clothing [17] refers usually to clothes with sensors that are close to or in contact with the skin. The sensors are enclosed in the layers of fabric, or it is the fabric itself that is used as the sensors [18]–[25]. Such sensors can be piezo-resistive yarns, optic fibers, and colored multiple layers. IBCs have several advantages, starting with removing the task of placing the sensors by a nurse or a physician, providing a "natural" interface with the body. Commonly, IBC is understood as the integration, into textile, of sensors, actuators, computing, and power source, with the whole being part of an interactive communication network. Such systems could only be conceived through a combination of recent advances in fields as diverse as polymer and fiber research, advanced material processing, microelectronics, sensors, nanotechnologies, telecommunication, informatics, biochemistry, and medicine.

The fist results in IBC have been achieved recently mainly by research teams in Europe and the United States. Five major prototypes are presented below: VTAMN, WEALTHY, magIC (Europe), and the SmartShirt and LifeShirt (USA).

- VTAM is a t-shirt made from textile with woven wires, incorporating four smooth, dry ECG electrodes; a breath rate sensor; a shock/fall detector; and two temperature sensors [18].
- WEALTHY (EC, FP5 Project) is a wireless-enabled garment with embedded textile sensors for simultaneous acquisition and continuous monitoring of biomedical signs like ECG, respiration, EMG, and physical activity [19]. The "smart cloth" embeds a strain fabric sensor based on piezo-resistive yarns and fabric electrodes realized with metal-based yarns (Figure 2). The project terminated in March 2005, and the prototype has since been further validated; market exploitation effort is under way.
- MagIC [20], is a sensorized vest including fully woven textile sensors for ECG and respiratory frequency detection and a portable electronic board for motion assessment, signal preprocessing, and Bluetooth connection for data transmission.
- SmartShirt [21] is a wearable sensorized garment that measures human heart rhythm and respiration using a three-lead ECG shirt. The conductive fiber grid and sensors are fully integrated (knitted) in the garment.
- LifeShirt [22] is a miniaturized, ambulatory version of respiratory inductance plethysmography. The garment is a lightweight, machine washable, form-fitting shirt with embedded sensors to measure respiration. A modified limb two-lead ECG quantifies cardiac performance and a three-axis accelerometer measures posture and activity. The above prototype systems have reached a mature technological status and currently pursue (without an EU or other public funding) either further performance validation in healthcare and other applications or a commercialization route.

Several other research activities are in progress at the European and national levels. Within the FP6, a cluster of projects dealing with *smart fabrics, interactive textile, and flexible systems* regroups research and development activities from the following sectors:

1) "micro & nano systems": the projects' main objective is the full integration of sensors/actuators, energy sources, processing and communication within the clothes enabling health applications but also personal protection and disaster situation management
2) "ICT for health": the projects aim at personal health management through integration, validation, and use of smart wearable systems/solutions; i.e., smart clothing and other networked mobile devices.

In the first category, the projects focus more on research and development and integration of advanced fibers and materials at the fiber core (microelectronics components, user interfaces, power sources, and embedded software) toward more functionalized, user-friendly, and autonomous wearable systems. These projects are biosensing textiles to support

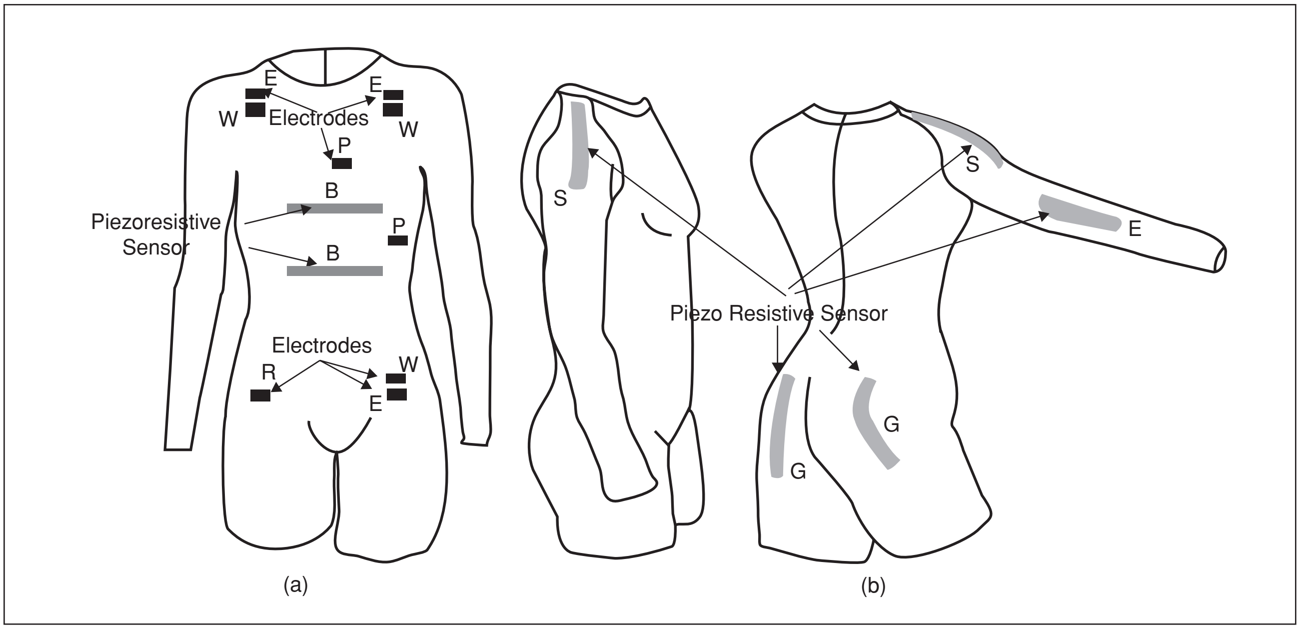


Fig. 2. (a) Wealthy prototype model: E = Einthoven, W = Wilson, R = referee, P = precordial leads, B = breathing sensors. (b) Wealthy movement sensors.

health management (BIOTEX), contactless sensors for body monitoring incorporated in textiles (CONTEXT), protection e-textiles: micro/nanostructured fiber systems for emergency disaster wear (PROETEX) and stretchable electronics for large area applications (STELLA).

Examples of projects in the second category are MyHeart [23], aiming at the systematic fighting of the origin of cardiovascular diseases (i.e., sedentary lifestyle, sleep disorders, stress, weight, and acute events) by developing and validating specific wearable applications, and OFSETH (aiming at the integration of optical fiber-based sensors into functional textiles for extending the capabilities of wearable solutions for health monitoring).

One of the major challenges today for this rapidly growing field is to fuse the research work and consumer insights on smart clothing and create multidisciplinary teams of product designers and engineers.

Future Challenges and Conclusions

Research and development on SWHSA was motivated by the need to respond successfully to the healthcare challenges of reducing healthcare costs while maintaining a high quality of care, providing ubiquitous easy access to care, and shifting the focus of healthcare expenditure from treatment to prevention through wellness programs. It goes without saying that this final objective raises great challenges.

Physiological monitoring with SWHS has so far dealt mostly with measurement of vital signs like ECG, heart rate, respiratory rate, skin temperature, and posture. There is a trend to extend monitoring capabilities toward biochemical variables. Sampling body fluid analytes, like glucose, lactate, and other proteins, will enable more thorough assessment of a person's health status, the state of his/her immune system, stress condition, etc. There are several promising techniques for achieving this type of monitoring in a purely noninvasive, painless way. One could thus envisage the integration of noninvasive transdermal biosensors in SWHS; e.g., in biomedical clothes [24]. There are also other approaches that aim at developing biosensing patches, adapted to different body fluids (e.g., sweat, blood), where the textile itself is the sensor; e.g., the BIOTEX project mentioned earlier.

The future development of IBC based on full integration of sensors/actuators, energy sources, processing, and communication within the clothes could overcome barriers to existing wearable health systems.

Among the most important challenges are the production of higher conductivity textile materials according to current industrial processes, as well as skin interfacing and packaging. Along with these challenges, cleaning and washing issues have to be solved. Further research is required also in signal processing and improvement of signal quality during the wearer's physical activity and data interpretation. Also, business models for network services as well as standardization at all levels and personalization are widely considered as criteria for success. Finally, clinical validation as well as cost-effectiveness have to be further assessed in order to provide a critical mass of data that would convince decision makers, third-party payers, health providers, and citizens.

The international community recognizes the huge development of wearable health technology and its potential role in the new healthcare-delivering landscape. For example, the IEEE Engineering in Medicine and Biology Society established a technical committee for wearable biomedical sensors and systems (WBSS) in 2004. The purpose is to raise awareness of the community in this subject and to encourage collaboration to progress research and development.

The area of SWHSA is further developed in FP6 of the EC, through significant support of new functionalized systems based on the integration of several technologies and disciplines such as micro/nanotechnologies, textile materials, physiology, biology/biochemistry, and ICT as well as data integration and decision support (see cluster of EC-funded projects on Smart fabrics, interactive Textile) [25]. This area is expected also to be further developed within FP7.

Andreas Lymberis was born in Patras and graduated with a B.Sc. in Applied Physics from Paris VI, in 1985. After a postgraduate degree (D.E.A.) on Magnetic Resonance Imaging in 1987, he obtained his Ph.D. in biomedical sciences with thesis on human tissues characterisation by ultrasounds in 1990. After completing his military service, he worked in France as a post-doc engineer on the applications of ultrasounds for health monitoring in space. From 1993–1999 he worked in the biomedical technology area, especially in management and assessment of biomedical equipment, in R&D on diagnostic techniques and in Health telematics, as R&D manager in IT companies. In 1999 he joined the European Commission, Directorate General Information Society and Media, in Brussels, Belgium, as a Scientific Officer in the eHealth sector where he coordinated a group of R&D activities on "smart wearable health management systems and biomedical clothing." Since 2004 he is appointed as scientific officer to the "Integrated Micro-Nano Systems" sector where he is mainly involved in the R&D activities relating to the integration of micro-nano systems and smart textile and to the interaction of micro-nano systems with the living world. He is visiting faculty in several graduate and post-graduate courses on Biomedical Engineering and has published over 30 articles in journals and conference proceedings. He has co-edited two books on wearable e-Health systems and one book on mobile Health.

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