Flexible Technologies and Smart Clothing for Citizen Medicine, Home Healthcare, and Disease Prevention

Fabrice Axisa, Pierre Michael Schmitt, Claudine Gehin, Georges Delhomme, Eric McAdams, and André Dittmar

***Abstract*—Improvement of the quality and efficiency of healthcare in medicine, both at home and in hospital, is becoming more and more important for patients and society at large. As many technologies (micro technologies, telecommunication, low-power design, new textiles, and flexible sensors) are now available, new user-friendly devices can be developed to enhance the comfort and security of the patient. As clothes and textiles are in direct contact with about 90% of the skin surface, smart sensors and smart clothes with noninvasive sensors are an attractive solution for home-based and ambulatory health monitoring. Moreover, wearable devices or smart homes with exosensors are also potential solutions. All these systems can provide a safe and comfortable environment for home healthcare, illness prevention, and citizen medicine.**

***Index Terms*—Ambulatory measurement, biomimetic, citizen medicine, flexible sensor, flexible technologies, home care, noninvasive sensors, prevention, skin physiology, smart clothes, smart fabrics.**

I. Introduction

A. Societal Background

As the population is getting progressively older, the need for higher quality and better efficiency in health and medicine, both at home and in hospital, are becoming more important. It is obviously a requirement for the patient in order to increase comfort, but it is also valuable for society in order to increase efficiency and provide cheaper health delivery.

A higher quality of life is now expected by patients, even when suffering from various chronic diseases. Patients generally want to be treated at home and with as little pain and discomfort as possible. Many medical devices can now provide such features. For pain, for example, Baxter has developed a small multitherapy pump for ambulatory applications [1], which is designed with wireless communication and a user-friendly graphic interface. Other devices have been developed to enable home care, like CG-500 PMP4 of CardGuard [2], Micropaq and Wireless Propaq CS of WelchAllyn [3], R TEST Evolution 3 and X-OLTER of Novacor [4], and Cardiocollect12 of Reynolds Medical [5].

As stated above, society needs to reduce the increasing cost of medicine while also improving the quality of health care. This implies a development of alternative solutions to the traditional hospital methods for disease prevention and continuous health monitoring. Cost-efficient access to the best care and illness prevention can empower each individual and enable them to have a longer and healthier life and increased personal performance.

At present, the aging population has resulted in a new, very large market in developed countries. Intelligent biomedical clothes and wearable ambulatory health-monitoring systems can act as a key enabler for lifelong continuous health monitoring for all individuals.

Noninvasive sensors have a huge potential for disease prevention in medicine and for diagnosis. Integration of such sensors into clothing can, therefore, enhance home healthcare, citizen medicine, and disease prevention [6]–[9].

In "citizen medicine," structures and solutions are proposed to allow a patient to take care of his own healthcare at home or anywhere he goes. The aim of such systems is to enhance citizen comfort and the efficiency of healthcare and illness prevention [10]. For healthy subjects, 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 of disease, the system will provide adequate information on how to deal with individual risk factors like hypertension, obesity, diabetes, physical inactivity, and stress through personalized training plans, and will provide motivation to change behavior. Early detection through long-term trend analysis will dramatically reduce the potential damage due to severe events. For postevent patients, this system can significantly improve the rehabilitation process, and can 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 can limit the occurrence of 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 actively involved.

However, as a patient is generally not a medical specialist, these solutions must be designed to be user friendly, and intelligent enough to detect whether the patient uses them correctly. Moreover, the systems should be sufficiently discreet so as not to disturb the normal way of life of the patient, and should permit communication with a specialist if needed.

Systems must monitor the sensors, the various vital parameters, and make the appropriate measurements at the right time. This concept is termed smart sensing.

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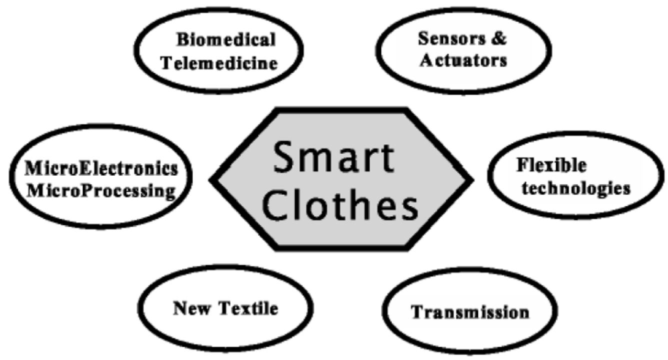

Fig. 1. Main components in the biomedical intelligent clothing.

B. Technological Background

Advances in miniaturization, new sensor, computing science and related technologies have resulted in the emergence of smart clothing (Fig. 1). Surface-mounted components and multilayer printed circuit boards (PCBs) enable the integration of electronic systems into small, light, and discreet devices of various shapes. Integrated circuits, microprocessors, and digital signal processing (DSP) are also key technologies which enable the development of ambulatory leisure systems: MP3 players which can hold hours of music are now integrated in clothes by Infineon [11].

Power management and battery capacity are other key parameters for smart clothes and ambulatory devices. Moreover, if miniaturization can enhance the speed of integrated circuits, it can also reduce the power consumption, size, and price. An example of a low-power microprocessor is one marketed by ARM [12], which provides processors for handheld phones. For most ambulatory devices developed, maximum battery life is about 24 hours, and the power supply takes up about half of the size and weight of the system.

Many novel methods for energy production or conversion are undergoing development. We mention two typical examples of wearable energy sources: the paper battery developed by PowerPaper [13], which is thin and flexible. Power paper cells are made of a special ink that can be printed or pasted on almost any flexible substrate. Another solution is PowerFiber [14], a project by ITN Energy System, Littleton, CO, to make batteries with fibers containing the anode, cathode, and electrolyte. These fibers can be woven together to create a full battery.

Energy recovery is also a method to reduce the size of the battery. Energy-recovery systems can use, for example, body movement or body heat production. However, the efficiency of such systems is still too low. Flexible solar cells, textile coils (RFID tag), or external sources, as Bike's dynamo, are also solutions for supplying energy for smart clothes [15].

Information technologies and systems are yet other key technologies. The Internet can provide a sufficient network anywhere to connect ambulatory devices together or to a specialist center. Vivometric's Lifeshirt [16] uses this strategy to provide services to the patient. All Lifeshirts are connected to a specialist monitoring station where vital parameters are analyzed. On a larger scale, localization systems by satellite are used to retrieve the exact location of the wearer. In the VTAMN project [17], GPS is implemented to watch over Alzheimer patients. Wireless communication and global systems for mobile communications (GSM) are also widely used to ease interconnection when designing user-friendly devices. On a smaller scale, local area networks are used to connect together key components of smart clothing on the same wearer. This is the concept behind personal area network (PAN). PAN's aim is to connect the distributed intelligence of all the items of smart clothing so that they work as a unified whole. Advantages of such concepts are numerous: smart clothes can be independent or communicate together; they can be modular. Intrabody communication is a particular version of PAN: the body is used as a means of communication in itself. Tokyo University [18] has proved that electrical signals can be efficiently transmitted by the human body. Sounds can also be transmitted by bones. An example of intrabone communication is the TS41 phone from Sanyo (Japan) [19].

A fourth key group of technologies for smart clothes is textile and yarns. Yarns or weavable fibers are acquiring very interesting properties: electrical, electronic, mechanical, electrochemical, etc. Conductive yarns can be polyamide coated with a very thin layer of silver on which other metals (Au, Pt, ...) are galvanically deposited [20]. Conductive yarns can also be made of silver or copper threads twisted with natural or artificial fibers [15]. All these conductive yarns can be sewn, embroidered, knitted, and woven using standard machines because of their elastic properties. Some yarns also have electronic and electrochemical properties: International Fashion Machine is developing yarns with anodes, electrolytes, and cathodes to store energy [14]. They have also developed thin metal wires coated with thermal chromic inks that change color when heated [15].

These yarns can be used in the same way as classical yarns to design electro-textile devices or systems in textiles. France Telecom has woven optical fibers with silk to obtain a textile screen, the Wildshirt [21]. The Georgia Institute of Technology has used woven optical fibers as sensors [22], [23]. Keyboards can be implemented using a sandwich layer of organza (silk with twisted gold) and nylon which react to finger pressure [24]. Keyboards can also be created using embroidered electrodes with high impedances which are used as capacitive sensors [24]. Batteries can be woven using electrochemical yarns. Connections and coils have been developed using conductive yarn for RFID Tag, textile antennas, and electromagnetic shields. Textile has been used as a motherboard to connect flexible integrated circuits or flexible sensors together [15].

C. Noninvasive Sensors for Physiological Parameter Measurement in Living Tissue

Many physiological parameters [25] can be measured from skin, using noninvasive sensors. These include thermal, electrical, geometrical, mechanical parameters, etc.

Thermal parameters of interest are mainly body temperature, skin temperature, and body heat flow. From these parameters, we can assess many physiological phenomena, such as metabolism, thermal comfort, skin blood flow, skin hydration, skin thermal conductance, skin infection, core temperature, fever, muscle activity, autonomic nervous system (ANS) activity, and respiration rate.

Electrical parameters involve mainly electrical potential and conductance measurements. From electrical parameters, one can study the electrocardiogram (ECG), heart rate, EMG, ANS activity, electrotomography, vigilance and stress level, and EEG.

Geometrical and mechanical sensors include the plethysmograph, the accelerometer, the goniometer, the interface pressure sensor, the actimetry sensor, and haptic interface sensing. From geometrical parameters, we can obtain respiration rate and amplitude, heart rate, blood pressure, position, detection of falls, monitoring of various daily activities, mobility, circadian rhythm, pressure sore detection, hard point detection, etc.

Mechanical parameters include interface pressure measurement in living tissues. This measurement cannot be carried out with traditional sensors. Indeed, living tissues are mainly constituted of soft matter. This particular state, neither liquid, gas, nor solid, involves complex physical laws. Living tissues are composed of skin, subcutaneous tissue, blood vessels, and bone. All these elements have mechanical behavior very different from each other. For example, skin (epidermis and dermis) is assumed to have hyperelastic and viscoelastic behavior [26].

Interface pressure measurement is achieved through three families of sensors.

- Electronic transducers: the resistance or the capacitance of a sensing element, reported on a deformable body, varies with the force applied. Ashruf [27] gives an overview of the currently available techniques for the measurement of interface pressure or force between soft objects. For example, Tekscan (Boston, MA, USA) supplies the "Flexiforce" sensor based on a pressure-sensitive ink. This device has been evaluated by Ferguson-Pell [28] for beneath bandages applications, compression stockings, and pressure garments. Novel, Xsensor Technology Corporation, and Pressure Profile Systems are suppliers of capacitive sensors.
- Pneumatic transducers: an air cell connected to a pump, or an air reservoir, is inflated until the cell pressure is just above the interface pressure. Bader [29] applied this principle to develop the Talley Pressure Monitor (TPM). Gyi *et al.* [30] have evaluated the performances of the TPM for the automotive industry.
- Electropneumatic transducers: electrical contacts on both sides of the air cell move away when the cell pressure is just above the interface pressure, similar to the pneumatic transducer. An example of electropneumatic transducer is described below (cf. Section II).

II. Smart and Flexible Sensors for Safety and Illness Prevention

In our laboratory, we design and develop smart and flexible sensors for healthcare and illness prevention. The DEPIC (*Détecteur Précoce d'Infection Cutanée pour dialyze péritonéale—Early Detection of Cutaneous Infection in Peritoneal Dialysis*, RNTS Project 2001, French Ministry of Research) is an example of a smart sensor dedicated to citizen medicine.

This noninvasive sensor analyzes the cutaneous thermal parameters around the permanent peritoneal dialysis catheter and can be used at home each morning by the patient himself (Fig. 2).

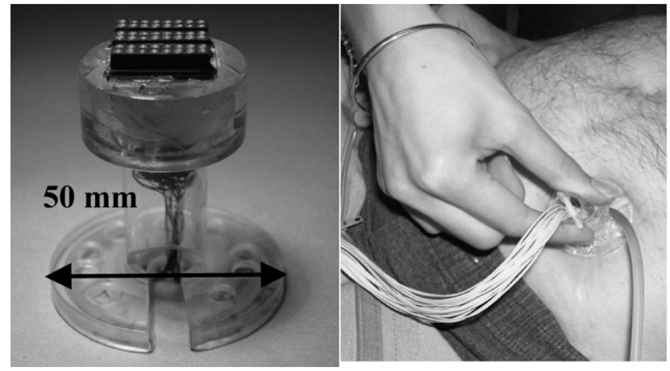

Fig. 2. DEPIC sensor.

The device uses flexible technology (Mylar) for the membrane and 20 sensors to map the skin's thermal parameters.

As it is used by the patient, two automatic processes are performed: the quality of the interface contact sensor/skin is measured, and an analysis of data relevance is carried out.

The associated instrumentation incorporates an automatic alarm in the presence of infection. The alarm (light and sound signals) may be understood and used by the patient. The DEPIC is a portable device, autonomous, and can be used in hospital or at home. It is designed to be connected to the DIATELIC system for the telemonitoring of dialysis at home. If an alarm occurs, the system alerts the nephrologist, the patient, and the presiding general practitioner [31].

Security and illness prevention in healthcare is achieved through the interface pressure measurement with the development of soft-sensor technology.

Interface pressure evaluation requires interaction between the tissue and the sensor, just as when one touches an object with one's fingertip to evaluate the object's compliance. The design of the sensor is thus "bioinspired" [32]. The sensor interacts with the material, but should not modify the phenomenon to be measured.

We have developed a sensor-based mapping methodology based on electropneumatic active cells. The device is intended to measure interface pressure between living tissues and a given object (forceps, chair, bed, ...) or between living organs (patent 0309570, CNRS, September 2003).

Due to the viscoelasticity of the skin, a static measurement is not appropriate. The bioinspired concept is based on the dynamic working principle of the device to evaluate the interface pressure, which is a static pressure.

The device is comprised of numerous cells, connected together. Cells are inflated and deflated periodically using two pumps. When the pressure cell is just above the interface pressure, contacts between the two sides of the cells separate one from each other. A pressure sensor enables the measurement of the corresponding pressure, which is equal to the interface pressure.

The interface pressure measurement is crucial for the prevention of pressure ulcers.

Pressure ulcers are becoming a major issue with the aging population. This is an important concern in older adults with restricted mobility, subjects with C5 quadriplegia, or for burn patients.

Time and pressure are principal factors leading to pressure ulcers. The concentration of localized pressure, in excess of capillary filling pressure, stops blood circulation and can lead to ischemia and necrosis.

These ulcers can lead to distressing complications, and can be used as a quality indicator of the preventive measures taken in healthcare facilities. The recent advent of thin pressure-sensitive materials enables the convenient measurement of interface pressure between the patient and his support.

The exact mechanisms involved, and even the level of pressure required, are unknown. The measurement and comprehension of the effects of interface pressure therefore provides a challenge to medical engineers.

III. Wrist-Wearable Medical Device

To support sensors, a system is generally required which records the data, processes it in some way, and transmits it. This associated instrumentation should be as small, as light, and as easy to wear as possible. Ambulatory systems should be reliable and have sufficient autonomy for the given application [33].

One of the most convenient places to wear an ambulatory device is on the wrist, as it is a very common place to wear watches and other modern devices. The wrist has been used since the dawn of time to wear bracelets and, more recently, for watches, because the attachment of a device onto the wrist is easy and the mobility of the wrist enables good ergonomics and, in the case of watches, easy reading. Wrist-worn devices are, therefore, well accepted by most people; for example, the majority of ambulatory devices for sports applications are worn on the wrist [22]. Moreover, as the skin on the human hand has the highest density of biological sensors and actuators of the whole body, the wrist and the hand are perfect locations for physiological measurements such as skin temperature, skin electrical conductance and potential, actimetry, blood oximetry, and heart rate.

However, wrist devices also have constraints and limitations.

- They must be light and small in order not to inconvenience the user. This implies sophisticated power management, wireless data transmission, and enhanced miniaturization.
- Sensors generally must be placed in a specific location, and wrist devices should be designed accordingly.
- The devices must be user friendly and safe. This will involve ergonomic considerations.

Progress in informatics, signal processing, microelectronics, batteries, and telecommunications is the key to the exciting possibilities for wrist-worn devices, enabling longer battery life, low weight, user-friendly interaction, and wireless networking.

Presented below are three examples corresponding to three separate uses: Actimetry ("Vivago"), vital signs ("Amon"), and sensorial reactivity and vigilance ("Marsian") devices.

Vivago WristCare [34]: The Vivago WristCare is a device that automatically monitors a person's well-being 24 hours a day, and transmits automatically to a station called MultiLink within a range of up to 20 m (Fig. 3). During the first four days

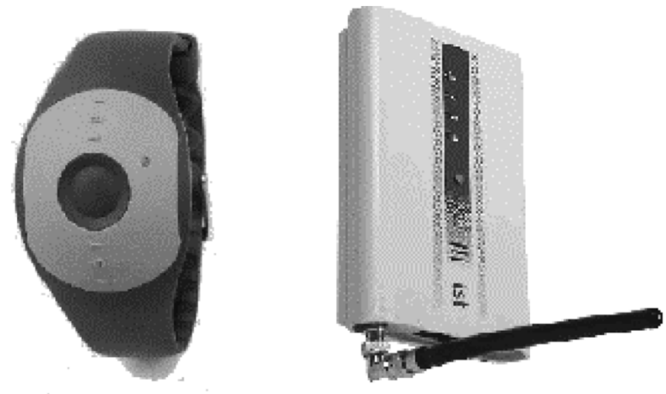

Fig. 3. Vivago WristCare system.

of use, the unit adapts to the user's normal activity level by measuring micro and macro movement, skin temperature, and skin conductivity. The Vivago WristCare device is able to detect hypothermia, activity of the patient, and to determine if the WristCare is being worn or not. These three parameters can determine if the situation of the patient is normal, and if not, can trigger an alarm. Vivago WristCare can also determine the position of the patient inside a building in order to provide access control or to check whether the patient has exited a door or not. This last feature has been designed particularly for users with dementia or mental health problems. 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 appropriate 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 notification when the wrist unit is removed or reattached. The wrist unit continuously monitors its own condition, providing notifications on low batteries and connection problems. The wrist unit can trigger an alarm when the user is unable to do so. Such a situation could arise as a consequence of 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 the user's healthcare needs.

Advanced Care Alert Portable Telemedical MONitor (AMON) European Community IST 2000-25239 [35]: The main objective of the AMON project is to perform the necessary research, development, and validation for an advanced wearable personal health system. The system is designed to monitor and to evaluate human vital signs using advanced biosensors.

The Wrist Monitoring Device (WMD), the wearable component of AMON, will gather vital information from the sensors and analyze it using a built-in expert system. The WMD will transmit the data to a remote telemedicine center for further analysis and emergency care, using GSM/GPRS cellular infrastructure.

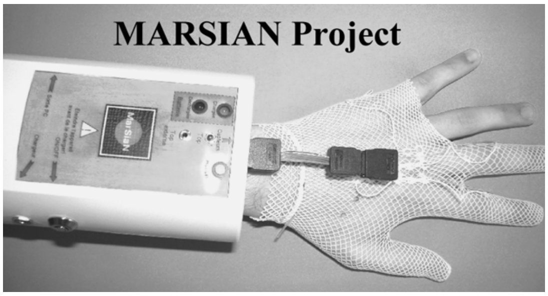

Fig. 4. Marsian, a modular autonomous recording system for measurement of ANS activity, is an ambulatory micro central composed of smart clothing, gloves, and a wrist device.

The WMD will include sensors of key parameters such as: heart rate, heart rhythm, I-lead ECG, blood pressure, O_2 blood saturation, and skin temperature. Future optional sensors may include: 12-lead ECG, EEG, a noninvasive glucose meter, and respiratory peak-flow sensors.

AMON will enable patients who are not confined to a hospital to be monitored, and their vital signs to be continuously analyzed. 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 the freedom of movement and will enhance their quality of life. AMON will ensure continuity of patient care by providing continuous medical monitoring.

The results are as follows.

- A WMD for high-risk patients that is smart enough to be used by the patient, yet small enough to be wearable.
- An expert system that analyzes and diagnoses the condition of the patient and alerts the medical center when there is a need.
- A secured wireless link between the WMD and the medical center.
- A user-friendly, multilingual interface in the WMD display for easy European-wide use.
- Validation of the results in a hospital setting, where it is possible to compare the data generated by the AMON personal health system with data generated by hospital measurements.

The main benefit is that the users will be able to have medical monitoring 24 hours a day, 7 days a week, while having a normal life at home, at work, and at leisure facilities.

MARSIAN: Modular Autonomous Recorder System for Measurement of ANS Activity [36]: The ANS activities (nonconscious) in real and ambulatory conditions are related to emotional, sensorial, and cognitive responses and activities [37]. Developed by our laboratory to measure vital parameters as well as the autonomous nervous system, Marsian is a hybrid device associating the advantages and the specificity of smart clothing with those of wrist devices (Fig. 4). Research is now focusing on smart-clothing solutions to enhance the use and reliability of sensors [38]. The Marsian smart glove has a specific design to ensure a good contact between the skin and the electrodes, in spite of hand motion. Additionally, the glove must not modify the skin's normal physiology.

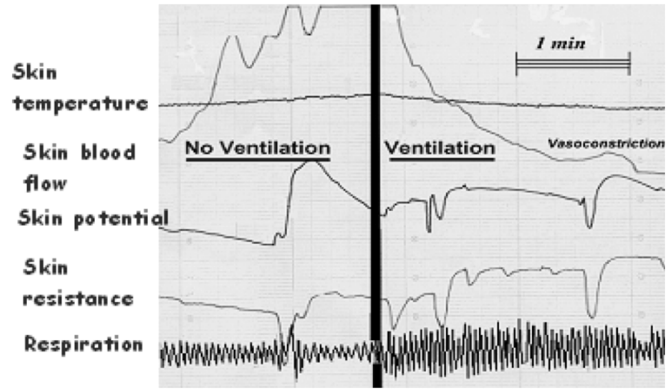

Fig. 5. ANS parameters variation for ventilation stimulation: skin temperature decreases and respiration increases. Skin blood flow also shows a vasoconstriction. ANS parameters should be analyzed with a 10-min time scale for thermal comfort analysis. This ventilation stimulus induces discomfort.

The smart glove includes skin resistance and potential sensors, and a microsensor 0.45 mm for the measurement of skin temperature. Additional sensors are used for the measurement of skin microcirculation of the hand, and smart clothing is used for the measurement of the respiration rate and patterns.

The Marsian wrist device ensures real-time physiological data acquisition, treatment, and wireless transmission, while remaining small in size. Remote software displays and stores data, and provides semiautomatic analysis in order to facilitate the expert's decision making. This wrist device has six hours of battery life when under intensive use.

Experimentation with Marsian has been already carried out. The results have the same quality as laboratory standard devices already developed and tested by A. Dittmar and colleagues (CNRS LPM, INSA, Lyon, France) [39], [40].

The noninvasive multiparametric measurements carried out by Marsian have a large field of applications [41]–[43].

Main research topics include:

- vigilance level and task-related responses (cognitive and physical);
- response to odor, taste, touch, vision (including shape and color), and sound (such as speech) [44];
- research on thermal and environmental comfort responses and states;
- comparison between nonconscious and verbal reaction;
- study under real conditions of the action programming in sport;
- mental imagery training and study for sport;
- study of behavior and stress.

Marsian is equipped both to analyze instantaneous emotional responses which occur almost immediately following stimulation (for example, after an odor stimulation), and the longer responses which characterize a state change (for example, thermal comfort or discomfort, described in Fig. 5).

Marsian's Smart Gloves [36]: A safe and user-friendly solution involving the placement of biomedical sensors on the hand, the Marsian glove includes noninvasive sensors measuring skin temperature, skin electrical conductance, and skin potential. All these sensors are integrated into a smart glove.

Hands do not have a regular shape like the thorax, they involve complex movements and have many functions (including mechanical and sensory). Therefore, the gloves should ensure mechanical support, for sensors should not press too hard on the hand nor modify the physiological parameters under study or the patient's sensation. They should be comfortable, inconspicuous, flexible, and should ensure good operating conditions for the sensors (i.e., electrolyte deposition, thermal contact). Finally, they should ensure good connections from sensors to the data logger. Among the possible solutions (flat structure, ribbon structure, hard glove, etc.), we have designed two solutions for smart gloves: 1) a three-dimensional (3-D) structure based on Kapton and copper foil, with a special structure to enhance flexibility in the articulation areas and rigidity at the sensor areas; and 2) a hairnet glove with polymer electrodes and an electrolyte distribution system.

The 3-D Kapton/copper foil structure is engraved with a microengraving machine, LPKF ProtoMat M60. The Kapton/copper foil's thickness is 150 μm. A flat shape was designed to wrap around the hand and to set sensors correctly in position. Copper connections were used between the wrist device and the sensor. Electrodes were designed in the same manner, and covered with a silver layer. For the thermistor, a folded structure ensures a constant, preset pressure between the thermistor and the skin, which enhances the thermal contact with skin. The copper is then isolated with varnish. The same shape was made in thermoplastic and set on a wooden model of a hand. Kapton was then on the thermoplastic shape, and the structure was heated in an oven. After cooling, the foil becomes a 3-D structure ready to be worn easily on a human hand. To cope with articulation of the hand, some special shapes were designed in Kapton foil and positioned in the articulation areas. These special shapes were flat springs with 15% stretch in the main direction, but very little deformation in the other directions.

The second solution is a hairnet glove with enforced areas at the positions where most movement will be focused, to ensure mechanical support. For this first prototype (Fig. 5), standard Ag/AgCl (Clark Electrodermal Instruments, 30 mm^2) are embroidered into the glove. Unfortunately, electrolyte preset on the electrodes (sponge, paste, or hydrophilic gel) is removed when the glove is slipped on (resulting from the stickiness of the hydrophilic gel or the spreading of the paste). Injection of liquid electrolyte with a syringe under electrodes when the glove is fitted is also difficult. Flexible polymer electrodes were designed to enable electrolyte injection when the glove is already in place on the hand. In our prototype model, injection is centralized; there is a single input for electrolyte into a network of tubes distributing electrolyte to each electrode. Electrodes' electrical connection to the wrist device is facilitated by a very thin copper wire (0.2 mm in diameter) wound around the tubes. To cope with viscosity problems and to reduce as much as possible the volume of the distribution system, the tube network was designed in the form of a vascular tree.

SenseWear Body Armband, Bodymedia: Developed by Bodymedia, Pittsburgh, PA, with partners including Polar, UPMC (Pennsylvania Hospital network), and NASA, the SenseWear Body Armband is a wearable monitoring device for physiological parameter measurement. This armband is composed of polyurethane with an integrated accelerometer, a thermal conductivity sensor, a skin- and ambient-temperature sensor, and a skin electrical-conductivity sensor. It can also be connected to a wireless heart-rate sensor. The dry electrodes used to measure the skin electrical conductance have been patented.

The SenseWear Body Armband can be connected to external sensors and modules using a wireless communication module based on a GSM transceiver. This transceiver can connect the armband to a PC, but also to an external module like a room-heating thermostat.

Software on the PC records the raw data and transmits it to a specialist center in which it can be analyzed.

IV. Ambulatory Devices

Enhanced Personal, Intelligent, and Mobile System for Early Detection and Interpretation of Cardiological Syndrome (Epimedics), European Community IST 2000-26164 [45]: In western countries, heart disease is the main cause of early disability and premature death. Moreover, because of the aging of the population, the number of cardiac deaths is steadily increasing, and almost two-thirds occur before arriving at the hospital.

Despite many attempts to improve the management of cardiac care, only small decreases in the delay between the onset of symptoms and treatment have been reported. Symptoms are often interpreted incorrectly.

Event and transtelephonic ECG 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 patient.

The solution adopted by the Enhanced Personal, Intelligent, and Mobile system for Early Detection and Interpretation of Cardiological Syndrome (EPI-MEDICS) project is to develop and test a novel "intelligent" Personal ECG Monitor (PEM) for the early detection and management of cardiac events (Fig. 6).

The objective is to design an easy-to-use but powerful, professional quality, embedded device that is able to record, store, and synthesize the standard 12-lead ECG, incorporate intelligent self-adaptive data processing and decision-making techniques, generate different levels of alarms, and forward necessary 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 techniques (Bluetooth and GSM/GPRS).

Major alarm messages are automatically transmitted to the nearest emergency call center by means of GSM or GPRS. Data leading to medium or minor alarms is temporarily stored in a central alarm web server, and the health professionals are informed by a text message.

The PEM embeds itself in a web server to facilitate the reviewing and/or update of the EHR during a routine visit to the general practitioner or cardiologist's office.

The first evaluation results for the system demonstrate clearly that progress in science and technology offers, for the first time,

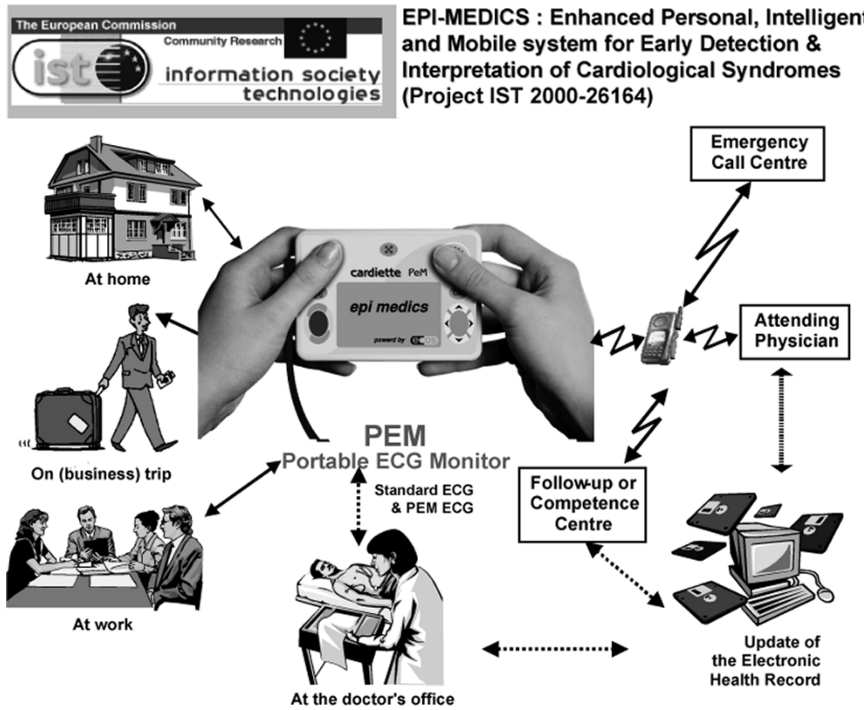

Fig. 6. EPI-MEDICS.

Fig. 7. Melodies is a multichannel ambulatory infusion pump intended for use by out-patients. It is a programmable and portable pump which allows simultaneous and/or sequential administration of more than one drug (up to four).

many new possibilities, bringing intelligence, miniaturization, and sophistication to all at low cost.

Melodies: Programmable and Portable Pump [46]: Melodies enables the physician to program the order, frequency, and timing of administration of given drugs, in exact accordance with the prescribed regimen (continuous, simultaneous, and/or intermittent) (Fig. 7). It ensures all the basic requirements for monitoring the treatment by producing two documents for inclusion into the patient's medical records. While the protocol is being set up, a program report is produced, which ensures that the perfusion can be checked at a later stage. Similarly, at the end of treatment, a perfusion record is produced, which documents all events occurring during treatment. The Melodies pump offers the patient the chance to return home sooner, providing greater independence in their daily lives and the security of knowing that their treatment is being given according to the prescribed protocol, without any need for repeated procedures performed by nursing staff.

It is used for anticancer chemotherapy, to administer antibiotics, or for home pain control. Melodies is a multichannel chrono programmable pump offering:

- the ability to administer more than one drug 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.

Antibiotic therapy is a major indication for the Melodies pump, and the main benefits are as follows:

- 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 perfusion).

The main indications include:

- cystic fibrosis: the Melodies pump permits continuous 24-hr administration, or intermittent administration given during the "long night" period from 18.00 to 8.00;
- osteoarticular infections (osteitis, prosthesis infections);
- super infections (for example, bronchial);
- conditions requiring long-term antibiotic therapy.

The use of the Melodies pump for the management of pain control is directly due to its four channels as well as its patient-controlled analgesia (PCA) 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

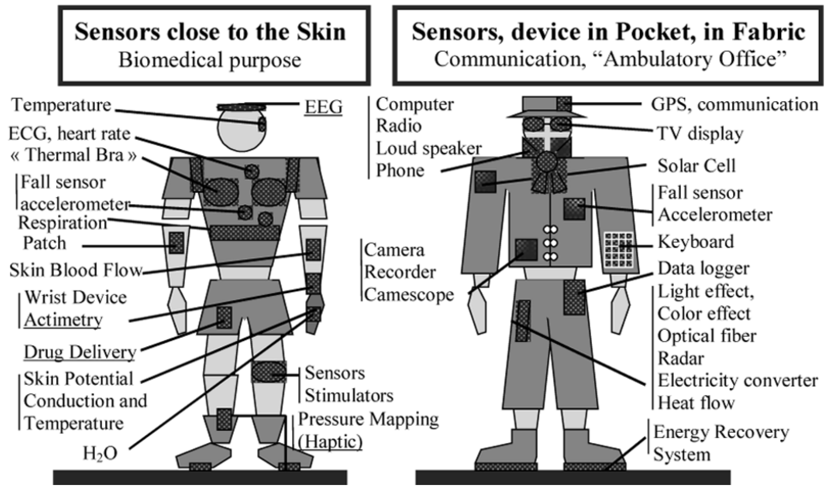

Fig. 8. Two kinds of smart clothes.

patient's pain to be targeted in a more specific fashion (concomitant administration of anti-inflammatory, antidepressant, and analgesic drugs).

V. Biomedical Smart Clothes

There are two main kinds of smart clothing (Fig. 8).

One group involves smart clothing with sensors located in close proximity to the skin, and which are used for biomedical applications. The sensors are generally enclosed in the layers of fabric or on its surface. In some cases, the fabric itself is used for the sensors [47], [48]. Piezo-resistive yarns, optic fibers, and colored multilayers can all be used as sensors.

The biomedical smart clothing has several advantages: it is placed automatically in the correct location (avoiding the necessity of placing the sensors on the patient by a nurse or physician); it is discreet, nonvisible, well protected, and user friendly. It is particularly well adapted for the monitoring of chronic diseases, of the handicapped, and the elderly. They are also used during professional, sport, and military activities.

The second group of smart clothing involves the use of sensors and devices simply housed in pockets and not directly in contact with the skin.

A wide range of exciting new functions can thus be added to clothing, including microradios, microcomputers, flexible TV screens, microcellular phones, solar cells, energy-recovery systems (in shoes, generally), and flexible keyboards.

These devices are used mainly for communication purposes, displaying color and pictures, indicating moods, and sending messages. However, some devices or sensors used for monitoring purposes can also be placed in special pockets (GPS devices, fall detectors, data loggers, accelerometers, and activity detectors).

These two main kinds of smart clothing are compatible and complementary.

Three examples are briefly reviewed below:

- VTAMN project—France;
- WEALTHY project—Europe;
- LifeShirt—USA.

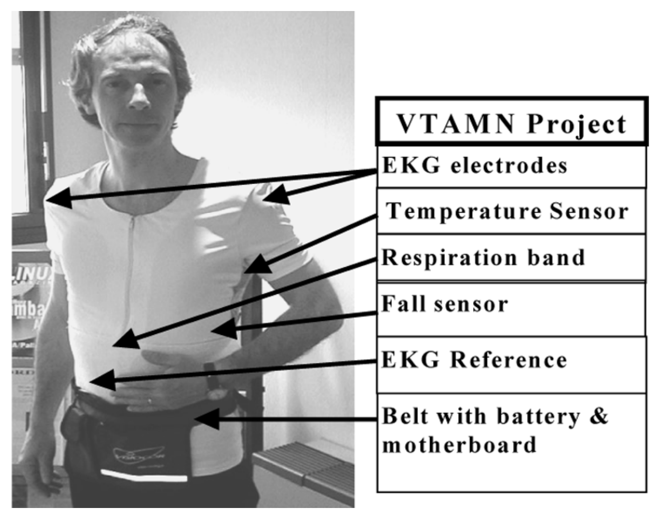

Fig. 9. VTAMN prototype.

The VTAM (clothes for teleassistance in medicine) project began in January 2001 (Fig. 9). It aims at developing generic clothing technology, integrating biosensors and bioactuactors woven into the fabric. The T-shirt incorporates smooth, dry ECG electrodes, a shock/fall sensor, a breathing-rate sensor, two temperature sensors, and a GPS receiver. A GSM/GPRS module is connected to the T-shirt and is used for data transmission and hands-free communication [49]. The VTAM project strives 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 a biocloth, or 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 (Fig. 10). The mother board, the transmission module, and the power supply are mounted 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 includes an ECG reading, a pneumogram, temperature, and fall detection in mobile situations.

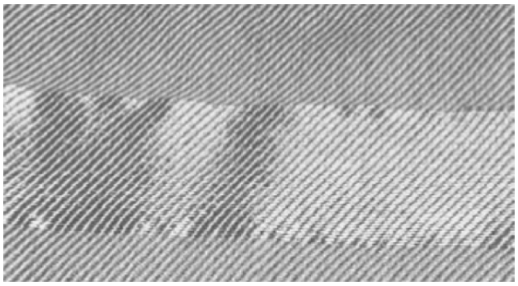

Fig. 10. Stainless-steel wires woven in fabric and used as bus for electronic system.

Wealthy (Wearable Health Care System) European Community IST 2001-33257 [50]–[53].: The goals of the WEALTHY system are to:

- 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, to ensure safety and provide reassurance;
- trigger automatic transmission of physiological or clinically sensitive parameters;
- alert emergency services if a situation becomes critical (absence of patient response, alarming vital signs, etc.);
- allow the interpretation and extrapolation of index related to physiological conditions by considering all data simultaneously;
- guarantee a user-friendly interface for professionals;
- ensure a high degree of freedom and let the user perform his/her normal activities.

LifeShirt: Smart Shirt for Continuous Ambulatory Monitoring, Vivometrics Inc., Ventura, CA 93001 [16]: Since 2002, Vivometrics has been producing and testing a smart shirt called LifeShirt, which records such physiological parameters as:

- electrocardiogram;
- ribcage and abdominal respiration;
- body posture;
- blood oxygen saturation.

LifeShirt is a Lycra shirt which includes embedded textile sensors for plethysmographic respiration monitoring or provides pockets or connectors for additional sensors like ECG electrodes, accelerometers, or commercial sensors for blood oxygen saturation. Made of textile, the basic LifeShirt is therefore washable (Fig. 11).

To record the physiological data, LifeShirt integrates a data logger such as Palm, whose software is able to record raw data and a user diary for more than 24 hours. Raw data can be sent to a remote expert center, which analyzes it and makes a diagnosis.

LifeShirt has been designed for mainly ambulatory, real time, physiological measurements and applications. Main research topics are:

- cough measurement;
- respiration analysis;
- ambulatory monitoring of respiratory and cardiac parameters.

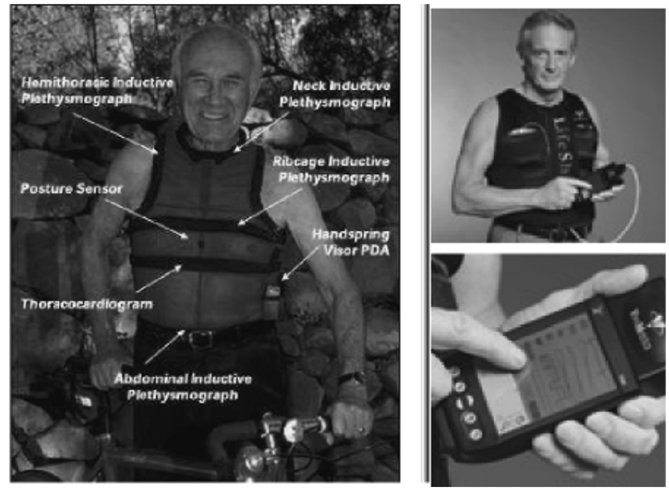

Fig. 11. Vivometric's LifeShirt is a smart shirt designed for ambulatory, but not real time, monitoring. The system is a shirt with embedded sensors and a data logger.

Further development includes the possibility of connecting peripheral devices. This expands the applications to include EEG/EOG, leg activity, pulse oximetry, blood pressure, skin and core temperature, throat microphone, 12-lead ECG, etc. After the data has been analyzed using VivoLogic software, researchers receive a comprehensive, easy-to-interpret report that correlates the data collected by the optional device(s) with the cardiopulmonary data and electronic patient-diary data collected by the LifeShirt system.

VI. Exosensors, Smart Home

The exosensors are not fixed directly on the subject, but in his/her close environment: apartment, place of work, vehicle, sports hall, and sports ground.

Very important advantages: no constraints for the subject, no sensors on the skin, no wires, and the subject is not "constrained."

Limits or disadvantages related to this method: generally only one subject can be monitored by site, and the information collected needs to be supplemented by an ambulatory device for outside monitoring.

The Smart Homes exist in limited numbers and in an experimental state.

The first achievements were based on a lot of sensors, including biochemical sensors. The current trends are based on the use of a limited of highly relevant parameters [25], [54].

The Smart Home concept is based on the integration of the sensors in the structure and fabric of the house (Fig. 12). These sensors measure the activity and the state of a person alone in their apartment. For example, arrays of sensors in the carpet are used for the detection of walking, activity sensors are located in the taps, shutters, and doors, and presence sensors are located on seats, beds, and toilets.

Data processing with neural networks can analyze the activity of the inhabitant and an early detection of functional disorders alerts a nurse or physician.

An example: the Health Integrated Smart Home Information System (HIS^2) has been developed for the remote monitoring

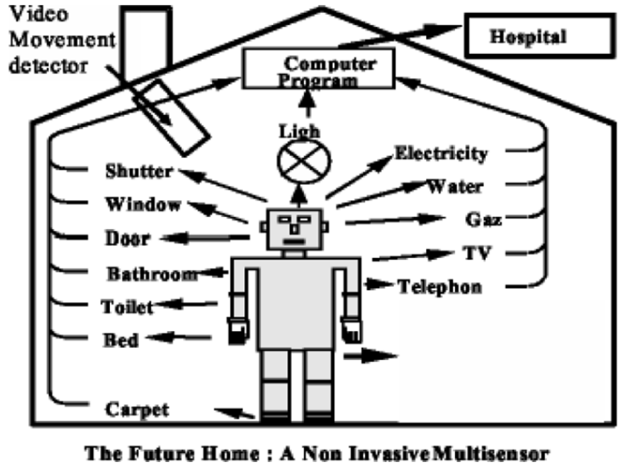

Fig. 12. Smart Home: measurements are taken by exosensors not fixed on the subject.

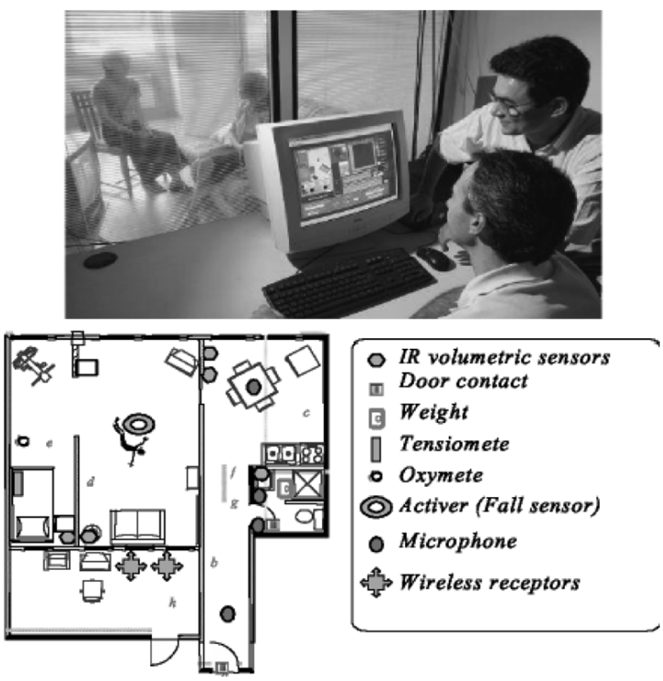

Fig. 13. Experimental platform for telemonitoring the health status of the elderly at home.

of the health status of the elderly at home (Fig. 13). This aims at improving patients' living conditions and avoiding the costs of a long hospitalization. The design of this system is based on a controller area network (CAN) linked to volumetric, physiological, and environment sensors [55]–[58].

The video camera, unacceptable to patients for obvious privacy reasons, was replaced with 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 the incoming data in real time and communicate using a CAN network to display health status.

The experimental platform is a 30 m^2 apartment (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. It integrates smart sensors (volumetric, audio, physiologic, environmental, etc.) 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 successive patient's position and sound activity within the home environment. This system has been well described in the literature [37].

Alerts triggering procedures are divided into two types: short-term 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 latter type uses a buffer to extract some pathological disease scenarios from the database.

VII. Conclusion

The landscape of biomedical technologies has changed with new capabilities to produce miniaturized, low power, communicative, and flexible devices.

For home healthcare and illness prevention, a whole range of user-friendly devices offers new services and promotes a new regime of personal healthcare. Many recent technological improvements, but also new needs and markets, enabled such a growth [8], [59]–[62].

These systems are based on noninvasive sensors, which may be smart, flexible, wearable, and discreet. These sensors are incorporated into ambulatory devices, smart clothing, or smart homes.

All these systems are communicative, from patient to specialist and from specialist to patient, in order to provide the best health service possible.

The contributors in this new medical field are numerous, and each one has an essential role. These include home electronics, health services, security services, biomedical engineering, telecommunications, bioinformatics, and hospitals. The challenge is to obtain from all these new technologies and concepts a coherent and evolutionary cooperation.

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