Wearable electronic systems: Applications to Medical Diagnostics/Monitoring

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Abstract

In this chapter we briefly present the key historical periods in diagnostic medicine, provocatively expressed in terms of their use of sensors, highlighting the dramatic way in which changes in sensing technology have altered the role of the physician, have led to the creation and grow of new professions allied to medicine and have affected the patient healthcare experience. The present need for a further change in healthcare delivery is presented, a change which urgently requires the development of novel ambulatory monitoring systems. After introducing the present and possible clinical applications of ambulatory monitoring, the monitoring constraints and possibilities are discussed. Four groups of monitoring platform are presented (i) "Holter-type" systems with standard sensor designs and locations, (ii) Body-worn sensor patches, (iii) Body-worn bands and harnesses and (vi) "Smart garments" for long-term applications.

Introduction

The combination of an ageing population and the increase in chronic disease has greatly escalated health costs. It has been estimated that up to 75% of healthcare spending is on chronic disease management (mainly cardiovascular disease, cancer, diabetes and obesity) (World Health Organisation 2010). It is now widely recognised that there is a need to radically change the present Healthcare systems, historically based on costly hospital-centred acute care, and make them more appropriate for the continuous home-based management of chronic diseases. The goals of the new approach are the improved management of the chronic disease through encouraging lifestyle changes and the effective early detection and treatment of any problem before it necessitates costly emergency intervention.

The most recent European technology and innovation funding programme initiative using such an approach is termed Ambient Assisted Living (AAL). "*AAL aims to prolong the time people can live in a decent more independent way by increasing their autonomy and self-confidence…by improved monitoring and care of the elderly or ill person…while ultimately saving resources. The main objective is to develop a wearable light device able to measure specific vital signs of the elder or ill person, to detect falls and to communicate autonomously in real time with his/her caregiver in case of an emergency, wherever they are*." (ICT for health 2007) There is therefore an urgent need of novel monitoring systems which include new sensor technologies, mobile technologies, embedded systems, wearable systems, ambient intelligence, etc. which are capable of conveniently, discreetly and robustly monitoring patients in their homes and while performing their daily activities without interfering significantly with their comfort or lifestyle (McAdams et al. 2009; Fayn and Rubel 2010).

In order to develop optimally designed, clinically-viable monitoring systems, it is important to learn the lessons from healthcare innovations in the past, to be aware of the potential clinical applications of such technologies and to fully understand the technical constraints and possibilities which exist.

10.1 Historical Perspective

"Those who cannot learn from history are doomed to repeat it". George Santayana

It can be said that "the history of diagnostic medicine is the history of its tools"- to modify slightly a quote attributed to Lars Leksell. In order to fully appreciate the key factors influencing the successful development of wearable monitoring/diagnostic systems and the resulting changes, desirable or otherwise, to clinical practice and to the roles of the clinicians, hospitals and patients, it is im-

portant to learn lessons from the previous decisive periods in the history of medicine.

The history of diagnostic medicine can be loosely, but rather productively classified into periods characterised by their use of sensors vis-à-vis the use of human senses (Bynum and Porter 1993). Obviously, sensors are not the sole component in a monitoring system, but they do form the problematic first stage in biosignal measurement. The veracity of this comment is evidenced in the present paucity of successful clinical uptake of the many published wearable monitoring systems. Additionally, given the interest of several of the authors in the area of Medical Sensors, this approach to the history of diagnostic medicine is admittedly appealing.

Period in Medical Diagnostic History	Approximate Historical Dates
"Non-Sense"	Earliest times - present
Human Senses	"Hippocrates" - present
Augmented Human Senses	19th Cent.- present
Replaced Human Senses	Mid 19th Cent.- present
Remote Sensors	Late 20th Cent - present
Wearable Sensors	21st Cent

Table 10.1 The history of diagnostic medicine classified according to their use of sensors

The "Non-Sense" period in Diagnostic Medicine (please excuse the deliberate pun)**:** In this classification, the non-use of human senses is generally attributed to earliest man, at any rate before Hippocrates the so-called Father of modern medicine. However, rational use of human senses predates Hippocrates who, along with Galan freely admitted that a large part of their medical knowledge came from earlier Egyptian works. *"Since, then, Egypt and not Greece must be considered the original home of the medical art, we ought not to set up the Greek Aesculapius as the patron genius of medicine, but rather the physician whom the Egyptians gave this dignity, viz Imhotep*." (Cumston 1936) As in the present day, rational "scientific" diagnosis based on astute observation has always co-existed with less rational approaches. In the latter, the cause of disease was considered to exist outside the patient – an evil spirit or an angry god – and hence there was little need to study the patient's body in any great detail. A spiritual leader, such as a priest or shaman, was called upon to use one of a range of divination techniques (observing the stars, flights of birds, animal entrails, etc.) to diagnose the source of the problem and prescribe some cure or gift of appeasement to the offended deity.

The "Human Senses" Period in Diagnostic Medicine: As noted above, the belief that disease has a physical cause that can be diagnosed by careful observation of the patient, his diet, lifestyle etc. is generally, but wrongly, attributed to Hippocrates and his followers. In this approach, a physician was encouraged to employ all of his human senses (sight, hearing, smell, taste, and touch) in making

a prognosis/diagnosis (fig.10.1). He had little or no diagnostic technology and based his diagnosis largely on interview and a visual inspection of the clothed body. He (or more likely his unlucky assistant) would also smell and/or taste wounds, breathe, sweat and urine.

Fig. 10.1 Early Physician using human senses **Fig. 10.2** The introduction of the Stethoscope

In crude engineering terms, human senses are based on a range of human sensor cells which respond to differing inputs by generating an electrical signal which is sent to specialised areas of the brain for interpretation. It is important to grasp the view that the breakthroughs in diagnostic medicine are due to the augmentation and eventual replacement of these human senses, with their inherent limitations, by the development of less subjective and more accurate sensors. Each time a new generation of sensors has been developed, the role of the clinicians and their patients changed and the form of healthcare provision, for example the role of the hospital, changed dramatically – and will continue to do so.

The "Augmented Human Senses" Period in Diagnostic Medicine: This period could most probably be best exemplified by the invention of the stethoscope (fig.10.2) by Laënnec in 1819. Laënnec was able to describe, classify and correlate symptoms detected by his stethoscope with subsequent lesions detected at autopsy. As a result, he was able to present physicians with a complete diagnostic system for pulmonary and cardiac complaints, a key factor in the successful update of any new system. This period involved the developments of a range of other "scopes" including microscopes, ophthalmoscopes and endoscopes enabling the physician to "see into" the patient (before or after death) in ways he was never able to do before. The evolving fields of histology and cytology were made possible through the improvement of microscopes, started in the 1600s, and in the 1860s Pasteur discovered that bacteria cause disease. These advancements in optical techniques lead to an anatomical model of disease, with illness being attributed to defects in body architecture. Much of the advances in this period were made

possible by the improvement in the status of hospitals at the time. With a concentration of patients with the same disease it was possible to specialise, to follow the progression of a disease and to carry out post mortems to locate disease loci.

As a result of these advances, visual and manual examination became more thorough and invasive and there was less emphasis placed on the patient's views. Physicians started to treat diseases not patients. The physician now felt the pulse, sounded the chest, measured blood pressure, peered into eyes, inspected the tongue and throat, etc. and, if necessary, laboratory tests were carried out. Not unsurprisingly, there was considerable resistance to this change from patients, the media and even physician themselves.

Even though these novel sensing systems greatly extending the diagnostic possibilities for the physician, it must be noted that all these tools were still connected at one end with a particular sense of the physician. As such, these measurements remained qualitative, subjective and hard to communicate or teach to others.

The "Replaced Human Senses" Period in Diagnostic Medicine: During this period the physician's senses were progressively replaced by sensors, first by those that measured/recorded the same parameters in a more reliable fashion (such as temperature and pressure) and later by sensors that detected phenomena indiscernible to human senses (such as the Electrocardiogram and X-rays). These innovations resulted in the presence of the physician no longer being needed during a diagnostic measurement and the subsequent creation of new healthcare professionals, such as clinical scientists and radiographers, whose role it was to carry out the ever increasing number of diagnostic measurements. As diagnostic systems such as ECG and X-ray were cumbersome, expensive and difficult to operate, they were initially centred in large teaching hospitals with newly formed medical physics departments, further increasing the status of the hospitals and creating roles for medical physicists and biomedical engineers. A century earlier, hospitals were often places were patients who could not afford the services of a private physician were forced to go and conditions were often very primitive. Throughout the 1900s the health care system's dependence on medical technology grew continuously and the modern hospital emerged as the centre of a sophisticated health care system, serviced by technologically sophisticated staff.

The "Replaced Human Senses" Period was characterised by the development of the study of human physiology and its application to the diagnosis of disease. Claude Bernard, who took nothing for granted, helped established the use of objective scientific measurements in physiology and medicine. Etienne-Jules Marey, a versatile and gifted engineer, was one of the pioneers of the graphic approach, laying much of the foundations of physiology and for Einthoven's later development of the ECG machine. Marey believed that "*in the laboratory, as at the bedside of the patient, the skill of the individual, his practised tact, and the subtlety of his perceptive powers, played too large a part. To render accessible all the phenomena of life-movements which are so light and fleeting, changes of condition so slow or so rapid, that they escape the senses - an objective form must be given to*

them, and they must be fixed under the eye of the observer, in order that he may study them and compare them deliberately. Such is the object of the graphic method." (Reiser 2000).

In the physiological approach to disease diagnosis, illness is evidenced by changes in body function, which may not show up at post mortem. The new physiological techniques were initially introduced into medical schools to help train physicians in the use of their senses. However, eventually the new equipment was wheeled out onto the ward to carry out the measurements/recordings directly. The physician's senses had been replaced by the new sensing systems. Objective data could now be recorded, analysed and compared with those of the past or future thus facilitated training and communication "*Every EKG when and where it may have been recorded, is immediately comparable with every other EKG*" (Bynum and Porter 1993). The successful uptake of the new technology was due to the tenacity of a few key researchers, such as Willem Einthoven, who laboured to improve the devices and establish the clinical usefulness of the measurement techniques.

The "Remote Sensors" period in Diagnostic Medicine: With the widespread introduction of telemetry, it has become common place for a physician to observe and interview a patient located at a distance from the clinic. Such exchanges are often termed "Telemedicine". This term has been defined by the World Health Organisation as the "*practice of medical care using interactive audio visual and data communications. This includes the delivery of medical care, diagnosis, consultation and treatment, as well as health education and the transfer of medical data.*" (Mandil 1996)

Of more interest to the present discussion is Telehealth monitoring (or Telemonitoring) which involves "*the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis and monitoring. ... It includes (amongst other things) a home unit to measure and monitor temperature, blood pressure and other vital signs for clinical review at a remote location (for example, a hospital site) using phone lines or wireless technology.*" (Curry et al. 2003). Many examples of simple home-based, telemonitoring sensor technologies now exist. For example, basic blood pressure cuffs, glucose meters, pulse oximeters and heart monitors are available and patients with heart disease or diabetes, for example, can transmit their 'vital signs' from the comfort of their homes to their health care professional and get feedback or other follow-up, when appropriate. These basic home-based "Telemonitoring" systems are already enabling leading medical centres around the world to more effectively keep patients healthy and out of the hospital – and to decrease costs.

The Present/Future "Wearable Sensors" period in Diagnostic Medicine: For certain medical conditions, it is necessary to monitor a patient "continuously" or "on demand" while going about their everyday business. In such cases, the pe-

riodic use of basic home-based "Telemonitoring" systems is not sufficient and in most cases body-worn sensing systems are required.

It is interesting to note that, in contrast with much of the past, the present evolution is due more to governmental-pull than to (solely) technological-push. Although it is sometimes claimed that the technologies required for this clinical revolution already exist and that it is other aspects such as device interoperability, financial reimbursement and clinical uptake which are holding back progress, the authors, as sensor specialists, firmly believe that the key sensor-related technologies are not as advanced as widely believed. This misconception is probably due to the positive descriptions in the literature of prototype monitoring systems which are clinically untested prototypes. It is one thing to wear a prototype device with all its attached leads and sensors for a few minutes to harvest a suitable, short, artefact-free trace for an attractive publication, it is another for the system to be accepted by a patient and to work robustly for an extended period as they go about their daily lives. This problem is partly due to the difficulty in organising and carrying out clinical trials. As a result, scientists often tend to focus on the use of models, phantoms, patient simulators etc., standard tools of their trade but which ignore the key component in the problem to be solved – the patient, particularly the patient-device interface. The authors firmly believe that when the other aspects are in place, enabling the rigorous real-live assessment of "wearable" systems, many of those published will be found wanting and the apparent complacency concerning the level of the technological readiness, in particular that of the sensors, will evaporate.

If truth be said, academics tend to apply for funding so that they can continue their fundamental research, with often little real understanding of the clinical need they are supposed to be addressing. As a consequence, they tend to continue their on-going fundamental research and successfully publish but rarely reach the stage of clinical transfer of relevant solutions to clinical problems, as hoped for by funding bodies. This is not solely due to the academics' alternative focus or lack of clinical awareness. There is very often a lack of adequate clinical representation in funding body panels and as reviewers. This is probably due to a combination of factors, not least of which is the clinician's workload and lack of motivation at being involved in such "scientific" programmes. Projects are therefore most often assessed by other engineers and scientists who may intuitively think that they are great ideas and are impressed by the quality of academic research and publications. However, they are not best suited at assessing the clinical relevance and feasibility of the work.

The comments made above do not only apply to academics, similar shortcomings exist within industry, especially within small and medium enterprises (SMEs). It has been claimed that 70% to 80% of new products that fail do so, not for lack of sufficiently advanced technology, but because of a failure to understand real users' needs (Von Hippel 2006). There is therefore a great need for a "one-stop-shop" to arrange and manage clinical trials for companies, especially SMEs, and for academics. However, developers need to do more than just bring

new technologies to end-users to ask them what they think. Additionally, clinicians and end-users need to be involved at the very start of the innovation process to suggest, assess and give rapid feedback on the clinical need for a product and the relevance/robustness/etc of the proposed device. The involvement of clinicians (and patients) in the innovation process will sensitise them to the technological possibilities and motivate them to be actively involved in the innovation process rather than being the passive recipients of the latest technological "gadget".

10.2 Present and Possible Clinical Applications

It is often vital to monitor in an ambulatory situation the following parameters: Heart activity (ECG, heart rate, blood pressure, pulse); Lung activity (respiration rate, respiration depth, tidal volume, oxygen saturation); Brain activity (EEG, vigilance, relaxation); Digestion (gastric emptying); Emotions and stress levels; Body characteristics (temperature, posture, position, activity), etc. Some of these parameters are already catered for to some degree, e.g. Holter systems for Cardiac activity have been widely used for many years and, as a result, have greatly increased understanding of heart disease and have led to significant improvements in patient care. Other important physiological functions have not benefited to the same degree due to the difficulties in obtaining accurate measurements outside of a laboratory, for example for assessing breathing or stress. *"One apparent area for application of this new technology is the monitoring of breathing patterns over extended periods in the study of respiratory disorders such as chronic obstructive pulmonary disease, pulmonary emphysema, restrictive lung disease, or asthma"* (Wilhelm et al. 2003). Hitherto unexplored parameters should therefore not be ignored by scientists; however the situation is something of a "catch 22". If the sensor systems do not as yet exist, there is often little clinical demand for them until they do and their relevance established by a pioneer.

The design and relevance of wearable sensing systems will depend on, and will determine, the ambulatory monitoring applications.

10.2.1 "Holter-type" monitoring

In many clinical areas it is important to record measurements on patients over extended periods (generally for a maximum of a few days) as the patient goes about their every-day-life in order to accurately diagnose their condition. Again, the ECG Holter monitor would be the best known example. Often symptoms do not present themselves "on cue" in the doctor's surgery and hence the need for ambulatory monitoring, for example to detect periodic arrhythmias, to detect the location of an epileptic focus, or to study breathing difficulties. Such continuous

recording furnishes clinicians with a much clearer picture than the occasional "snapshot" collected during a patient visit. Multi-parametric continuous ambulatory monitoring helps quantify the number of events, differentiate between several possible causes and helps identify any contributing factors such as stress, sleep, food, medications, activity, etc. For example, emotions and stress can affect a wide range of conditions and hence the concurrent monitoring of the former helps assess their contributions much more effectively than the usual patient diaries or retrospective reports. [An additional advantage of unobtrusive ambulatory monitoring systems is the avoidance of the well known "white coat" syndrome in which patients exhibit elevated blood pressures in clinical settings due to their increased anxiety in a clinic environment.] Multi-parametric monitoring which includes measures of posture and activity also help identify and possibly compensate for the effects of movement-induced artefacts on the other parametric traces.

In "Holter-type" diagnostic recording applications it is not always necessary to transmit the monitored data continuously to a remote monitoring station. Often the recorded data is accessed at the end of the recording period and/or transmitted periodically.

10.2.2 "Post-intervention" monitoring

In post-intervention monitoring, such as that of a heart attack victim recovering in a coronary care unit, there is a role for "Holter-type" monitoring systems to progressively "un-tether" the patient from their bed and to encourage them to take part in some closely-monitored movement and recreation for their physical and mental well-being. In such applications the sensors will be accurately applied by clinical staff and the parameters monitored continuously. Such monitors are vital in assessing the efficacy of ongoing treatment and in the planning of subsequent medication/treatment.

As patients heal, there is a continued need for their monitoring as they gradually re-integrate into normal every-day life. As they do, the design of the monitoring systems, the sensors and positions used and the handling of the data will alter. As part of their rehabilitation, cardiac patients, for example, are encouraged to exercise while still in hospital or later on an out-patient basis. Patients are generally wary of doing so due to the fear of having a further heart attack. Apart from the use of stationary treadmills and exercise bikes, many exercise regimes do not lend themselves to the continuous monitoring of patients and there is therefore a need of ambulatory monitoring systems, if only to reassure the patient. The design of such systems would more optimally be in the form of a suitable wearable "smart garment" or "smart patch" (see next section). It would be preferable, given the vulnerability of the patient, that the measured data be monitored continuously; either remotely by a member of clinical staff or through onboard data processing coupled with the capability of alerting supervising staff.

10.2.3 "On Demand" monitoring

As patients recover and return home, they may still require medical assessment of their condition from time to time. The same applies to those diagnosed with chronic diseases or perhaps to the "worried well" (Continua Health Alliance 2009) with a significant family history of a serious disease. In some cases, "continuous" measurement may be required, for example in the continuous measurement and control of glucose concentrations in diabetics, enabling the provision of better adjustment of insulin dosage. In this case, however, a clinician does not need to be involved, or at least only on an intermittent basis. Regular checks can be arranged with a patient's general practitioner or, more conveniently, can be carried out remotely using home-based monitoring systems. In the next section, for example, a cancer-detecting bra is presented which incorporates temperature sensors to detect cancer-related changes in breast tissue. The question arises, however, does the patient really need to have such a system incorporated into an item of clothing or would in not be more appropriate to simply have some form of monitoring system housed, for example, in the patient's bathroom?

There exists a significant need for "on demand" (rather than continuous) "clinical support" for patients on the move. For example, a recovering heart attack victim may feel the occasional chest twinge and desire urgent medical feedback. "Smart garments" are generally not appropriate for such applications as the patient cannot be expected to wear such a system everyday if the need is only very occasional. However, a small, portable monitoring system, a sort of "professional-in-my-pocket", would be more suitable and patient-compliant, especially if it is integrated into a standard accessory such as a wallet, watch or mobile phone. Depending on the condition, such an "on demand" system could give direct feedback to the patient and/or send the information to a remote monitoring station. Some portable devices already exist, for example the Personal ECG Monitor (PEM) from the European IST EPI-MEDICS project includes a reduced easy to place lead set that allows reconstruction of the standard 12-lead ECG and embeds intelligence that decides when and where to send the ECGs, when needed (Rubel et al. 2005). A further example is SHL Telemedicine's CardioSen'C™ personal cellular-digital 12-lead ECG monitor capable of transmitting to their Telemedicine monitoring centre via any type of phone connection, including regular fixed lines and cellular phones. The healthcare team at the SHL monitoring centre evaluates the transmitted data and provides immediate feedback and reassurance to the patient/subscriber. When necessary, they will instruct the patient on what action to take and/or contact emergency medical services, providing them with all the available medical data, thus saving critical time and ensuring rapid diagnosis and treatment.

The success of such an approach obviously depends on the ability of the patient to apply the sensors in the correct anatomical positions. This will in turn depend on the design of the system and on the circumstances of the patient. From a design

point of view, the accurate location of the sensors for the recording of many "vital sign" parameters is not trivial and warrants much research as misplaced sensors can give rise to mis-diagnoses.

Medical conditions which require the relatively straightforward application of sensors can enable the direct feedback to patients to reassure them or to encourage lifestyle changes. Such direct feedback to patients can be used to empower and motivate them, improve their awareness and potentially allow them to better control their condition.

10.2.4 "Emergency/Disaster" monitoring systems

There also exists a significant market for "victim patches" (Bonfiglio et al. 2007) to be applied by "first responders", such as ambulance staff, fire-fighters, and by a ship's or aircraft's crew, to victims at the scene of an accident, disaster, fire or in a remote location. The parameters monitored by the "victim patch" can be viewed by the staff on site, if appropriate, or by qualified clinicians at a remote monitoring station or a local casualty department with the aim of optimizing their survival management. Potentially suitable, disposable and/or reusable "Smart Glove" systems are marketed by Ineedmd and Commwell containing embedded pre-positioned electrodes, miniaturised electronics and transmitters. Alternatively, Tapuz Medical markets a flexible ECG chest electrode belt which hooks under the arms of the victim and it is claimed that it correctly locates the electrodes irrespective of victim's chest size.

Several "victim patches" are being developed as part of the EU project Proetex, including one based on Intelesens' vital signs patch. The monitoring system is a small, disposable, chest-worn, adhesive sensor patch and a small potentially reusable transmitter module which is clipped on to the patch. The advantage of such a system is that the devices can be rapidly applied by "first responders" to many victims without the need to undress them or to hold the systems in place. By linking the systems to a local hospital, the devices could enable seamless admission of the victims to the causality department and enable triage before, during and following admission.

10.3 Sensing Constraints and Possibilities

The essential characteristic of a biosignal is that of change as a function of time or space. Biosignals can be classified in many ways, for example in terms of their medical application, the transduction mechanism used (e.g. for Temperature Sensors: Thermistors, thermocouples…), etc. Biosignals are associated with various forms of energy and can be thus divided into the six important groups listed in Ta-

ble 1. Some of these biosignals are intrinsic to the body (for example biopotentials emanating from the heart or brain), whereas others are modulated when external energy sources are applied to the body (for example, stress levels detected via changes in the skin's electrical impedance).

Form of Energy	Parameters	Examples of Biosignals
Electrical	voltage, current, resistance, capacitance, inductance…	ECG, EEG, EMG, EOG, ENG
Mechanical	displacement, velocity, acceleration, force, pressure, flow…	Blood pressure, Pulse Wave velocity
Thermal	temperature, heat flow, conduction,…	Body Core Temperature, Skin Temperature
Radiant	visible light, infra-red radio waves…	SpO2, Photoplethysmography
Magnetic	magnetic flux, field strength…	Magnetoencephalography, flow meters
Chemical	chemical composition, pH (derived from several forms of energy)…	Glucose, Cholesterol, Creatine kinase

Table 10.2 Classification of biosignal according to associated form of energy

In a biomedical sensor, a physical quantity that has been found to correspond with a physiological phenomenon of interest to the clinician is detected and transduced into another form of energy, generally an electrical signal that can be transmitted, processed and/or recorded.

The clinical usefulness of such biosignals lies in the historic observation that a given signal measured for example on the skin's surface reflects an inaccessible organ's behaviour, for example, and that certain changes observed in the biosignal indicate a dysfunction in the biological processes involved. It must be remembered that the choice of such signals, the sensors (transduction mechanism) and positions used are not "set in stone" but are often "accidents of history". For example, ECG electrodes are placed on the arms and legs because these were the only body parts that could realistically fit into Einthoven's large saline-filled bucket electrodes, required to decrease the contact impedance as the input impedance of his galvanometer was so low. It was only when the amplifier was improved that the area of electrodes could be decreased and the buckets replaced by limb plates, still in use today in some circles. Further improvements in amplifier design in the 1920s and '30s enabled the miniaturisation and "transportability" of the device and the further decrease in electrode area. The latter point enabled their attachment to the patient's chest and, eventually once the clinical usefulness of such additional measurements was established, the precordial leads V1–V6 were internationally accepted and standardised. "*The monitoring device and amplifier determined the electrode size, design, and location of the electrodes, which in turn determined the*

clinical application and the presentation of the physiological data." (McAdams 2006)

The clinician will therefore have to choose from the evolving possibilities which signal or set of signals is the most appropriate for the physiological phenomenon he/she wishes to study. As a further example, in the monitoring of glucose in diabetes there are a wide range of possible sensing systems including those based on amperometric, potentiometric and impedimetric, measurments on blood, sweat and interstitial fluid, to mention only some of the possibilities vying for clinical and commercial success. Often several signals are necessary to assess the various aspects of, say, an organ's function/dysfunction and thus gain a more complete picture. For example, in assessing the activity of the heart it is possible to measure signals related to bioelectricity, flow, motion, volume, pressure, and/or biochemistry. Each signal will necessarily describe a different aspect of cardiac activity.

Part of the evolving nature of biomedical engineering research and development is the discovery of new sensor transduction mechanisms and associated instruments (Lovell 2007). In order to meet the challenge and to fully harness the potential of wearable health monitoring, it is important to develop a new generation of sensor-driven technologies (Vodjdani 2008).

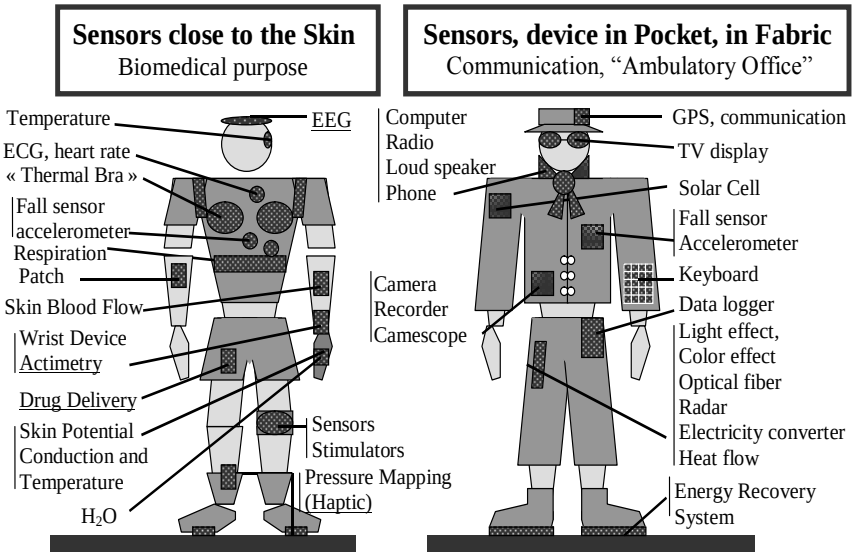


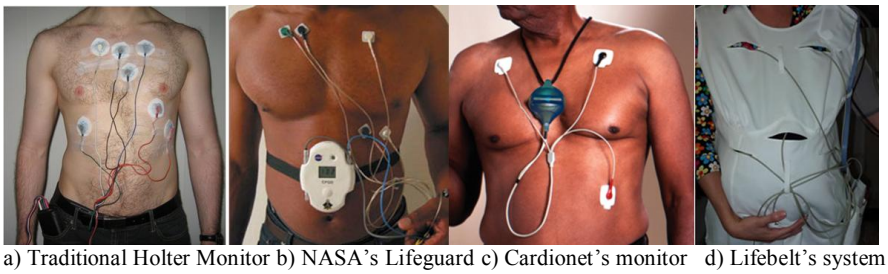
Fig. 10.3 Some sensing possibilities (Dittmar et al. 2005)

The sensor platforms required for approaches such as "wearable" (fig.10.3) Assisted Living can be divided into the following four groups for the purposes of this review:

- "Holter-type" Systems with standard sensor designs and locations
- Body-worn sensor patches and bands
- Body-worn bands and harnesses
- "Smart garments" for long-term applications.

10.3.1 "Holter-type" Systems

Many of the multi-biosignal systems presently envisaged by a range of organisations resemble standard Holter monitoring systems (fig.10.4a). They involve a recording/transmitting device which is attached to the patient's belt, a necklace or located in some form of waistcoat. The device is connected to standard sensors placed in standard locations and thus involves unwieldy leads. Such systems (fig,10.4b,c,d) are best suited for monitoring applications similar to those involving Holter monitoring (for research purposes and/or on concerned and thus motivated patients for a few days to help diagnose their arrhythmias or other health concern) but are generally too obtrusive and cumbersome for elderly patients, especially those with physical disability. The multiple wires connected to the sensors spread across the body will limit the patient's activity and level of comfort to the detriment of patient compliance. In addition, the long connecting wires and traditional sensor designs can give rise to large amounts of motion-induced biosignal artefacts (McAdams et al. 2009).



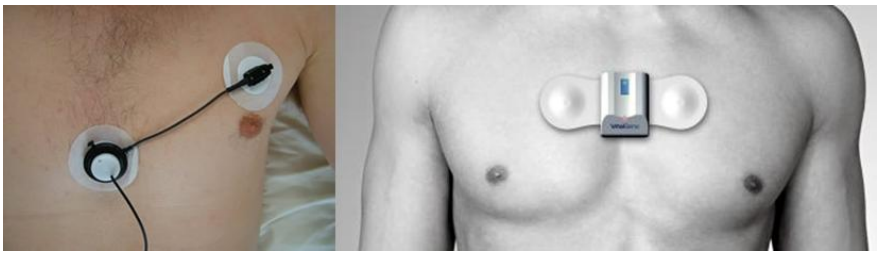
a) Traditional Holter Monitor b) NASA's Lifeguard c) Cardionet's monitor d) Lifebelt's system

Fig. 10.4 Holter-type systems

10.3.2 Sensor Patches and Bands

Adhesive patches (fig.10.5) with totally integrated sensors and a mounted miniaturized telemetry device can be worn by patients for short- to mid-term monitoring applications (up to one week or intermittently over an extended period). In order to develop such monitoring patches for a given patient's condition,

one must be able to monitor, with sufficient accuracy and with a minimum of artefact, the key biosignals and parameters of interest from within the small patch "footprint" located on a discrete, comfortable and convenient site on the body. This will generally require a major change in the transduction mechanisms, the sensor designs and locations traditionally used. One must move away from (literally in this case) the standard anatomical locations and sensor types (McAdams et al. 2009).



a) Actiheart monitor b) Intelesens' Vitalsense

Fig. 10.5 Sensor patches

Intelesens, for example, have developed a range of Wireless Vital Signs body-worn patch systems (see basic system on fig.10.5b). The systems include a miniaturised short range body-worn wireless monitor with on board intelligence to monitor for and trigger on medical events e.g. cardiac arrhythmias; a matching belt-worn device using cellular links to send data immediately to the clinician and an easy to apply, disposable sensor patch for high quality collection of the vital signs which include ECG, respiration, temperature, accelerometers and, it is anticipated, blood oxygen.

There are only a limited number of body sites that lend themselves to the comfortable detection of most key biosignals using an adhesive sensor patch. Suitable sites will most likely be on or near the torso and located on sites which will not experience significant twisting or stretching of the skin, otherwise the patch will cause shearing of the skin layers. Gemperle et al. indentified spaces on the human body where solid and flexible forms could be comfortably and unobtrusively located without interfering significantly with human movement (fig.10.6) (Gemperle et al. 1998). Although they were interested in wearable computing, their guidelines are also relevant to the positioning of sensor patches and bands.

Fig. 10.6 Body sites for comfortable "wearability" (Gemperle et al. 1998)

10.3.3 Body-worn bands and harnesses

Gemperle et al.'s sites for comfortable "wearability" can and have been used to locate devices with sensors integrated into bands strapped around the torso or a limb, thus avoiding, to some extent, the problems of skin irritation associated with adhesive patches. Gloves (not shown on fig.10.6), wrist/forearm bands, arm bands, torso belts and harnesses and head bands/hats (not shown) are all possible areas for sensor attachment.

A "Smart Glove" can readily be envisaged for use in periodic "Home-based" monitoring, in which case the patient simply puts on an appropriately designed sensor-embedded glove to their hand once or twice a day for the measurement and transmission of their vital signs. Sensors can be built not only into the inside of the glove, e.g. to measure skin blood flow, but can also be placed on the outside of the fabric and then held by the patient against their skin in the desired location. In the simplest case, an ECG monitoring electrode can be located, for example, on the inside of the right-handed glove, in contact with the skin, and another electrode be located on the outside of the glove, for example on the palm of the glove. By simply bring the hands together, a one lead (Lead I) ECG can be obtained. If further ECG (and other information) is required, additional sensors can be integrated into the exterior surface of glove and the glove pressed against the chest in the appropriate locations. Several years ago, Ineedmd Inc. patented a glove platform (fig.10.7.a) in which were embedded miniaturised electronics, sensors and transmitters (Ineedmd homepage 2009). Wires and sensors were built into a glove that, once fitted on the right hand, was then positioned on the left chest for registering Vital signs data. Commwell has introduced a similar concept called the "PhysioGlove" which, it is claimed, "*assures the performance of diagnostically accurate*

and reproducible 12 Lead ECG recordings by the patients themselves or by minimally trained personnel, within less than a minute" (Commwell homepage 2005). Such "Smart Gloves", however are less than optimal for "continuous" monitoring applications but could be used for short term monitoring of motivated patients or in professions were the wearing of gloves is acceptable, e.g. military, firemen, pilots, racing car drivers, cyclists.

a) Ineedmd's Glove b) INSA's Emosense c) AMON d) Exmovere's Telepath

Fig. 10.7 Examples of wrist-worn devices

The wrist is a promising location for monitoring systems and tends to benefit from enhanced patient compliance. The Biomedical Sensors Group of the Nanotechnologies Institute of Lyon at INSA Lyon, France initially developed a prototype "smart glove" for neuro-physiological investigations. This has since evolved into a wrist-worn device called Emosense (fig.10.7b). It is an ambulatory monitoring and recording system comprising sensors, amplification and wireless data transmission. The device includes a range of integrated sensors for the measurement of skin blood flow (the Hematron sensor), skin temperature, skin conductance, skin potential and heart rate. These parameters have enabled the monitoring and study of autonomic nervous system activity, providing information on emotional and sensorial reactivity, vigilance and mental state. It has been used to assess the reactions and abilities to cope of car drivers, the elderly, athletes and the visually impaired under a range of conditions.

A similar system is marketed by Exmovere (formerly Exmocare). The bluetooth-enabled biosensor wristwatch service, apparently now called the Telepath (fig.10.7d), monitors its wearer's pulse, heart rate variability, skin conductance and activity level and can send a report regarding the wearer's emotional and physiological state to a loved one or caretaker, via email, SMS, or instant messaging (Exmovere Holding homepage 2010).

Although there has been much research throughout the world aimed at developing an "ambulatory blood pressure" monitoring system for hypertension and similar studies, the basic approach of measuring oscillometric blood pressure with an inflatable arm cuff has hardly changed. The most promising "wearable" monitor to date is the AMON (Advanced care and alert portable telemedical MONitor) system (fig.10.7.c) which effectively incorporates a standard automatic inflation wrist-based blood pressure meter (Anliker et al. 2004). [It also measures pulse rate, oxygen saturation, body temperature and an ECG].

a) Intelesens' Pulse wave velocity sensor

b) BodyMedia's Bodybugg armband

Fig. 10.8 Examples of arm-worn devices

However, an alternative (or preferably, an additional), more convenient continuous measurement is required to assess hypertension in the home or mobile environment. Pulse Wave Velocity (PWV) is a likely candidate and researchers around the world are developing systems based on this biosignal. Arterial stiffness is a major cause of cardiovascular disease and PWV is a well-established technique for obtaining a measure of arterial stiffness between two locations in the arterial tree. Intelesens has been researching a wireless, forearm-mounted PVDF sensor system (fig.10.8.a) for the measurement of Pulse Wave Velocity enabling the reliable and inexpensive measurement of arterial stiffness associated with not only hypertension but also serving as a useful index in assessing atherosclerosis - now regarded as an early warning for cardiac dysfunction and diabetes (Intelesens homepage 2010). It is envisaged that wrist-worn systems can be extended further up the forearm to enable discrete, comfortable monitoring of this vital parameter. Not only is the forearm suitable from a wearability point of view, it is also potentially suitable as a monitoring site for skin temperature, galvanic skin response, accelerometers, etc.

BodyMedia has developed the Bodybugg armband fitness monitoring system (fig.10.8b) for athletes and trainers. The Sensor platform includes a heat flux sensor, galvanic skin response sensor, skin temperature sensor, near body temperature sensor, and a two axis-accelerometer to enable users to gauge the intensity of their workouts and estimate their energy expenditure. Although the present system is designed for the fitness market, BodyMedia are engaged in developing a range of additional sensors to add to their existing platform and thus make their monitoring system suitable for medical applications.

Simple bands/straps around the chest with embedded sensors are already commonly used in sport's monitoring and generally involve heart rate sensing from a basic 1 lead ECG from non-standard locations. Further sensors can be and have been added to chest/limb bands.

Electrode arrays built into straps can be used for Electrical Impedance Tomography (EIT), the imaging of the distribution of the electrical properties throughout the encircled body segment. EIT has been used to study the heart, lungs, gastric emptying, breast cancer, etc. (Josinet 2005). Similar arrays of electrodes built into chest bands can be used for impedance plethysmographic studies of, for ex-

ample, blood volume, cardiac output, lung water content and even body composition. The use of several electrode-embedded bands in parallel around the thorax or a limb can be used for more advanced impedance plethysmographic studies. The extension or deformation of the band can be used to furnish information on respiration. VivoMetrics' LifeShirt System uses inductive plethysmography to measure changes in the cross sectional area of the rib cage and abdomen over time by means of two parallel, "sinusoidal" arrays of insulated wires woven into the garment (see next section). The data is used to calculate the amount of air inhaled/exhaled during respiration.

VivoMetrics recently created a mini, harness-version of their traditional full garment "LifeShirt" called "VivoResponder" (fig.10.9a) to meet the needs of first responders, fire-fighters, etc. It is a lightweight chest harness with a range of embedded sensors that continuously monitor breathing rate, heart rate, activity, posture, and skin temperature. VivoMetrics have developed a similar system called "VivoChampion Trainer" to monitor athletes. The harness makes it possible to ensure firm contact with the torso over a range of promising skin sites. Depending on the designs of the sensors used, the system would appear potentially very well suited to the monitoring of a wide range of parameters over extended periods of time. A similar, bra-like system for women would also be very promising and enable the positioning of many sensors and sensor types in firm contact with the skin. The "cross-your-heart" design of bra would appear be the most appropriate, increasing the contact area with the thorax. A heat-sensing bra was pioneered a decade or so ago by Hugh Simpson, M.D. (Simpson and Griffiths 1989). Chronobra (fig.10.9b), as it was dubbed, measured the deep temperature of the breasts using an array of built-in heat sensors. It was believed that such measurements could detect the early signs of breast cancer and that the bra could become an accurate breast cancer screening technique that women could use at home. A more recent example is the so-called "Cancer bra" being developed by scientists at the University of Bolton (Bolton University news 2007). This smart bra concept will incorporate a microwave antennae system woven into the fabric which will detect temperature changes in breast tissue. It is claimed that the bra will not only detect cancers before tumours develop, but will also be able to assess the effectiveness of ongoing cancer treatment.

a) VivoMetrics' VivoResponder


b) Simpsons' Cronobra (Savage 2008)

Fig. 10.9 Examples of chest harnesses

With the appropriate design of sensors, hats and head-bands could be used for a range of measurements including EEG, EMG, EIT, brain core temperature and perhaps even ECG if necessary.

There are a wide range of applications within the EEG monitoring area for an ambulatory system that includes a suitable hat or cap incorporating electrodes located in Standard '10-20' electrode placement, for example for the study of epilepsy over prolonged periods and during everyday life. Even for routine clinical use, such an electrode system would be highly desirable. Many efforts have been made to develop an electrode "cap", for example *Neuroscan's Quik-Cap* (fig.10.10a), however the correct application of a large number of electrodes on a hairy scalp is exceedingly difficult and still awaits an optimal solution. Nonetheless, there are possible EEG applications for systems involving a reduced number of electrodes, possibly positioned on more convenient sites, and accessible under a simple head band or hair band. These include the study of relaxation, vigilance, sleep patterns and the use of EEG in biofeedback and brain-computer/machine interfaces.

Due to the location of the hypothalamus, the thermoregulatory control centre in the brain, cerebral temperature is one of the most important markers of fever, circadian rhythms and of physical mental activities (Benzinger and Taylor 1972). Unfortunately, it is difficult to measure. The Biomedical Sensors Group at INSA Lyon have developed a brain core thermometer (BCT) sensor (fig.10.10b), for non-invasive ambulatory and non-ambulatory applications, based on the Zero heat flow principle (Fox and Solman 1971; Dittmar et al. 2006) .

a) Neuroscan's Quik-Cap b) INSA's BCT Device

Fig. 10.10 Examples of head bands and caps

10.3.4 Smart Garments

For short monitoring applications, the "Holter-type" systems can be used by highly motivated patients, for example those with a health problem seeking diagnosis and treatment. Longer term monitoring, up to one week of continuous monitoring can be accommodated with an adhesive patch system, obviously with the development of the appropriate sensors. However, patches worn for over a week, even for less with many subjects, will cause skin irritation problems due to the adhesives used. For longer term monitoring applications, suitable wearable "smart garments" are therefore required.

At first glance, "smart garments" appear very promising. The device and leads could be easily integrated into seams and pockets in the clothes. As the body's surface area is relatively large, around 1.5 m², and approximately 90% of it is covered with clothing, the clothing could conceivably contain sensors in close proximity with the skin and thus over the key organs etc. one may wish to monitor (Dittmar et al. 2004). In theory, one could locate sensors almost anywhere on the clothed body, even over body sites traditionally used in standard monitoring, e.g. the sites for standard 12-lead ECG monitoring (McAdams et al. 2009). However, the relative movement between loose fitting clothing and the skin would give rise to problems associated with quality of contact, motion artefacts and patient comfort and hence only a very limited proportion of the body surface is suitable for the application of sensors via tight-fitting clothing or elasticated bands/sections in otherwise "normal" clothing. As a result, it is generally not possible to make firm sensor contact with many traditional monitoring sites and, much like traditional Holter monitoring, sensors have to be repositioned in non-standard sites to enable firm, comfortable contact with the skin which do not give rise to artefacts due to, for example, excessive body hair, muscle noise (i.e. EMG), and body flab (i.e. motion artefacts in ECGs). Novel sensing technologies are therefore required which will enable the monitoring of vital signs from novel locations if the full potential of such wearable garments is to be realised. The "smart garments" available commercially or reported in the literature can be loosely grouped according to the level of integration of the sensors, leads etc into the textiles (Van de Velde 2010).

- Garment level: "Late-stage integration".
- Fabric level: "Integrated sensors"
- Fibre level: "Ubiquitous Sensors"

However, the categorisation of smart garments is not that clear cut. As companies seek to develop multi-sensor garments with completely integrated sensors at a fibre level, inevitably some of their sensors are more integrated than others and their garments tend to straddle the above categories.

In "late-stage" integration, existing sensors and associated hardware are "retrofitted" into "regular" clothes at the garment level. Pockets are formed to hold the various parts of the hardware and thus the garment often resembles a multi-

pocketed waistcoat. Standard sensors or their connectors are anchored on the inside of the garment so that they are held in the appropriate position against the skin once the garment is applied. In many respects these systems resemble the "Holter-like" systems reviewed above, with the same limitations involving patient comfort and compliance. Most "smart garment" projects tend to start with this approach, possibly reflecting the researchers' primary interest in their monitoring and telemetry hardware rather than on the sensor-patient interface. Unfortunately, few projects progress past this stage as it involves solving the thorny patient compliance and signal artefact problems, problems that are not readily solved by the typical electronic engineer and which do not yield a high publication-effort ratio. It could be argued that many of today's inventions fail due to the lack of motivation in the inventors to see the process through to completion. Academics, once they have their publication and an attractive photo or two of the concept for presentations to come, have little inducement to continue developing the system over many years until it is clinically viable.

Early versions of VivoMetrics LifeShirt resembled the "waistcoat" design described above. However, VivoMetrics is one of the few companies that have been in the area for a considerable period of time, over 10 years and the design of their garment and sensors have evolved. At present, the core of the system involves an array of sensors embedded in a lightweight, washable, sleeveless undergarment (fig.10.11a) made of highly stretchable material. Inductance plethysmographic sensors for pulmonary monitoring are woven into the fabric and the system has electrodes for a single channel ECG to measure heart rate and a dual-axis accelerometer to record patient posture and physical activity. Additional peripheral devices can be attached to the shirt to enable the measurement of blood pressure, blood oxygen saturation, core body temperature, skin temperature, etc.

Sadly, VivoMetrics ceased operations in July 2009 and filed for bankruptcy protection in October 2009. The LifeShirt® is currently not being marketed, though their technology portfolio is apparently being offered for sale. Vivometrics was working on a new, remote monitoring version of their system, capable of monitoring the wearer's skin temperature, respiration, activity/posture, and heart rate (ECG) and wirelessly report these parameters to a remote monitoring site via the Internet or directly via GSM wireless. The system consists of ECG and Respirometry (magnetic coils) sensors distributed throughout a shirt that communicate with a central electronics pod that attaches to the garment. Within the pod itself there are actigraphy sensors (3-axis accelerometers) and a temperature sensor, as well as the amplifier etc. Development of the new shirt, sensors and communications network, and system architecture was done by Tronics MedTech, Inc. (Tronics MedTech homepage 2009).

a) VivoMetrics' remote LifeShirt b) WEALTHY Shirt

Fig. 10.11 Examples of "Smart Garments"

Smartex has also been around for over 10 years and is pioneer in the area of electronic textiles; fabrics where sensor function, electronics and interconnections are woven into them using circular and flat bed knitting technologies. They have been involved in numerous EU projects including "WEALTHY", a wearable fully integrated system (fig.10.11b), able to simultaneously monitor ECG, respiration, posture, temperature and a movement index. The stretch garments has integrated fabric ECG electrodes (leads I, II, III, V2 & V5), 4 fabric impedance electrodes (impedance pneumography), 4 piezoresistive fabric sensors (thoracic and abdominal respiration and movement) and embedded temperature sensors. The connecting conductive fibres are woven with stretchable yarns.

Other systems include RBI's Visuresp, Biodevices' Vital Jacket, Sensatex' Smartshirt, and SmartLife's HealthVest

"*The recent and continuous trend toward home-based and ambulatory monitoring for personalized healthcare, although exciting and potentially leading to a revolution in healthcare provision, necessitates even more demanding performance. .... Electrodes must, therefore, (1) require no prepping, (2) be located in the correct location once the smart garment is put on, (3) make good electrical contact with the skin, (4) not give rise to motion artifact problems, (5) not cause discomfort or skin irritation problems, and (6) be reusable and machine-washable. Although much work has been carried out in this novel area, it is not surprising given the above list of required performance criteria that the electrodes/sensors tend to form the bottleneck in the success of the overall monitoring systems.*" (McAdams 2006)

While truly long term monitoring awaits the successful development of totally integrated "smart garments" one potential solution is the use of implanted devices similar to an implantable event (holter) recorder (also known as an implantable loop recorder). The small monitoring device and associated sensors are placed under the skin during a minor operation and are commonly used to monitor heart rhythms for up to a year or more (Medtronic 2010). Such devices are increasingly

embedding additional sensors such as blood pressure and/or accelerometers to improve the monitoring of heart failure and their use for other applications could be envisaged.

10.4 Discussion and Conclusion

History has shown that if a new monitoring system is to be successful, it must be pioneered by a product champion who tenaciously presses on beyond the crude prototype stage, at which most would-be innovators stop, and develop a clinically viable product and firmly establish its clinical relevance through clinical trials and publications in the relevant clinical journals and conferences. The innovator must therefore have knowledge of the clinical needs, environment and procedures which will affect the success of the new system; preferably being a scientifically competent clinician or a scientist working closely with clinicians. In this regards, it would be of great benefit if governments would act to simplify the procedures required to organise and manage the vitally required clinical trials of promising and much needed healthcare products. The creation of "living labs" should also be continued so as to encourage the involvement of clinicians and patients in the earliest phases of the innovation process.

Many of the systems which do not get passed the prototype stage fail because they have not considered the clinical requirements nor those of the patient. It has been pointed out that most new products that fail do so because of a failure to understand real users' needs, not for lack of sufficiently advanced technology. As Abraham Maslow pointed out "to the man who only has a hammer in the toolkit, every problem looks like a nail." Very often, the scientists and engineers involved in the "wearable" monitoring arena, concentrate on the sophistication of their hardware with little attention paid to the less-glamorous, problematic sensor-patient interface, with the "simple" sensors being added on at the end of the project. The problem is compounded by the fact that scientists tend to use bench tests, models, patient simulators, etc., which all ignore the key component in the problem to be solved. Not surprisingly, the devices appear to work well until they are attached to real patients under real life conditions. It must be added that these sensor-related problems will not necessarily be miraculously solved by making sensors smaller, as appears to be widely believed.

The technology must accommodate the needs of the patient, not the other way round. It is therefore important to develop new generations of sensor-driven technologies (Vodjdani 2008). One should therefore start with the (potential) clinical need, identify key biosignals related to the physiological processes of interest and seek to develop a platform of novel sensing technologies capably of monitoring the physiological processes from convenient locations using novel transduction mechanisms. The appropriate hardware should then be developed around these constraints/requirements. This alternative approach should lead to systems which

actually work under real conditions and should lead to novel, patentable innovations.

There are many possible monitoring scenarios, some of them reviewed in this chapter, and it is not possible to optimally address them all with the same "wearable" technologies. It is important to recognize the (present) limitations and advantages of the various approaches. Basic "Holter-type" devices are still often the best compromise for the short term monitoring of a motivated patient to diagnose his/her illness. Adhesive patches appear well suited for "victim patches" and many monitoring applications for up to one week. Sensor belts and harnesses have applications in longer term monitoring situations while truly long term monitoring awaits the successful development of totally integrated "smart garments" or implantable systems. Portable systems exist which are suitable for certain long term "on demand" applications.

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