Wearable Medical Systems for p-Health

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Methodological Review

Abstract—Driven by the growing aging population, prevalence of chronic diseases, and continuously rising healthcare costs, the healthcare system is undergoing a fundamental transformation, from the conventional hospital-centered system to an individualcentered system. Current and emerging developments in wearable medical systems will have a radical impact on this paradigm shift. Advances in wearable medical systems will enable the accessibility and affordability of healthcare, so that physiological conditions can be monitored not only at sporadic snapshots but also continuously for extended periods of time, making early disease detection and timely response to health threats possible. This paper reviews recent developments in the area of wearable medical systems for p-Health. Enabling technologies for continuous and noninvasive measurements of vital signs and biochemical variables, advances in intelligent biomedical clothing and body area networks, approaches for motion artifact reduction, strategies for wearable energy harvesting, and the establishment of standard protocols for the evaluation of wearable medical devices are presented in this paper with examples of clinical applications of these technologies.

Index Terms—Energy scavenging, intelligent biomedical clothing, motion artifact, pervasive computing, wearable healthcare systems.

I. INTRODUCTION

GING of the population is a global phenomenon. The elderly population aged 65 and above numbered 500 million in 2006. By 2030, the number will be almost doubled to around 1 billion [1]. While global aging represents a triumph of medical, social and economic advances over disease, it also presents tremendous challenges to the society and healthcare systems all over the world. The global health spending continues

Manuscript received August 27, 2008; revised October 07, 2008. Current version published December 12, 2008. This work was supported in part by the Hong Kong Innovation and Technology Fund (ITF) and in part by the following industrial sponsors: Standard Telecommunications Ltd., Jetfly Technology Ltd., Golden Meditech Company Ltd., Bird International Ltd., and Bright Step Corporation.

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Digital Object Identifier 10.1109/RBME.2008.2008248

to outpace economic growth. Per capita health spending has increased by more than 80% from 1990 to 2005, exceeding the 37% rise in gross domestic product [2]. The proportion of deaths due to age-related chronic diseases is projected to rise from 59% in 2002 to 69% in 2030 [3]. If not carefully prevented and managed, chronic diseases will become the most expensive financial burden on our society [4]. For example, it is anticipated that China will lose \$558 billion in foregone national income over the next ten years due to premature deaths caused by heart disease, stroke and diabetes, according to the World Health Organization's global report in 2005 [5].

The growing aging population, skyrocketing healthcare costs, and prevalence of chronic diseases are the main driving forces to propel the fundamental transformation of the current healthcare systems [6]. Health providers are looking for more cost-effective and responsive ways to deliver healthcare services [7]. The conventional hospital-centered healthcare system, which focuses on diagnosis and treatment, is shifting its focus towards an individual-centered healthcare system with emphasis on early detection of risk factors, early diagnosis, and early treatment [8]-[10]. The new paradigm of p-Health aims to "encourage the participation of the whole nation in the **prevention** of illnesses or early **prediction** of diseases such that pre-emptive treatment can be delivered thus achieving a pervasive and personalized healthcare [11]." In this paradigm shift, wearable medical systems have been recognized as an enabling technology for monitoring an individual's health condition on a continuous basis, feeding relevant information back to the users and/or medical professionals, and firing an alarm signal when an adverse condition occurs [8], [12]–[14].

The work that has been carried out so far in the area of wearable medical systems has been mainly focused on noninvasive monitoring of vital signs, like the electrocardiogram (ECG), heart rate (HR), blood pressure (BP), respiratory rate and blood oxygen saturation (SpO2), in an attempt to collect information that may lead to the prediction or prevention of diseases. Some other systems have been designed utilizing inertial sensors, e.g., accelerometer, and generally sensors to detect movement and movement characteristics with the aim of identifying certain features of human posture and kinematic activity [15], [16]. To assess a person's health status, biochemical measurements on body fluids (blood, sweat, urine) may be sometimes needed and several methods have been recently proposed to address this issue [17], [18]. In most prototypes of wearable systems, microelectronics and electrical sensors are integrated in body-worn devices, e.g., gloves [19], wrist-worn devices [20], finger rings [21], [22], earlobe devices [23] and patches [24]. An alternative approach is the development of intelligent biomedical clothing (IBC) with embedded sensing capability[25], [26].

This paper summarizes the state-of-the-art of wearable medical systems for p-Health. Recently developed enabling technologies are reviewed in the areas of continuous and noninvasive measurements of physiological parameters and biochemical variables, IBC, and body area networks. Examples of related research projects are also provided. Three critical issues in the development of wearable medical systems are thoroughly discussed, i.e., the need for minimizing motion artifacts, the need for developing ways to achieve energy harvesting, and the urgency to establish standard protocols for the evaluation of newly developed wearable medical systems. In addition, several application scenarios are presented.

II. WEARABLE SENSING OF PHYSIOLOGICAL PARAMETERS AND BIOCHEMICAL VARIABLES

A. Cardiac Activity

There are numerous well-known signals and related parameters that capture the main characteristics of the cardiac activity. Among them, HR is one of the simplest and most informative cardiovascular parameters. Besides HR, heart rate variability (HRV) has also gained increasing attention as an indicator of the health status of the cardiovascular system [27]. Moreover, various physiological signals can be derived from recordings of the cardiac activity by using different models. In this respect, Tröster [9] has proposed the following viewpoints:

When considering the heart as an electrical generator, the electrical activity of the heart can be measured by placing electrodes directly in contact with the skin. Although wet silver/silver-chloride electrodes are widely used for measuring the ECG in a conventional clinical setting, recent developments in smart fabrics allow flexible conductive yarns made by metal glad aramid fibers, soft polymers or conductive rubber to be woven into clothes as dry electrodes to provide a convenient and unobtrusive means to measure the ECG [28], [29]. In a prototype developed by Philips Research, the electrodes are integrated in a belt, which has been proven to be suitable for long-term use [30].

When considering the heart as a moving muscle, the measurement of cardiac activity is possible without having electrodes directly in contact with the skin. This is achieved by means of microwave sensors on the basis of the Doppler effect to detect movements of the heart [31], [32]. This approach is well suited for home monitoring because of its unobtrusiveness. A single-chip implementation of this technology has been presented in a recent paper by Droitcour *et al.* [33]. A system of this type provides information about the rhythmic activity of the heart but not the detailed morphology of ECG.

When considering the heart as a pump, the changing blood volume can be measured by sensing changes in the electrical resistance of the body via sensors positioned on the skin. This technique is known as impedance plethysmography [34] or as photoplethysmography [35] according to the way the measurement is implemented. The impedance plethysmography technique is based on measuring the electrical resistance of parts of the body such as the chest, calf, *etc* to estimate blood volume

changes. The photoplethysmography technique utilizes a light emitting diode (LED) placed at peripheral sites, e. g. the fingertip or earlobe, to measure transmitted or reflective light via a photodiode as light absorption changes according to Beer–Lambert Law as blood flow changes.

When considering the heart as a noisy pump, HR can also be monitored by a phonocardiographic (PCG) sensor mounted on the chest [36], [37]. In a paper by Tanaka *et al.* [38], a simple system was proposed to measure HR and respiration rate. This was achieved by setting an accelerometer on a water-mat or air-mat to measure the vibration of the mat caused by the activity of the heart and the movements associated with respiration. By calculating the autocorrelation function of the fully rectified sensor output or by local pattern matching between the rectified output and a reference signal (prememorized for each subject), the system measured the average heart rate and respiratory rate as well as the instantaneous interpulse interval [38].

B. Blood Pressure

Among different vital signs, BP is one that requires attention even in asymptomatic subjects. In fact, the majority of the individuals with hypertension experience no symptoms. Consequently, most of the individuals with hypertension have no apparent reason to consult a doctor and thus often overlook their ailments. Recent studies also demonstrated that BP variability (BPV) is an independent indicator of morbidity and mortality due to a cardiovascular disease [39], [40].

A number of wearable systems for BP measurement have been developed based on conventional measurement techniques such as the oscillometric method. Instead of measuring on the brachial artery though, these systems are modified into wearable watch-type ambulatory BP monitors that can be applied to measure BP over the radial artery at the wrist. Another watch type BP monitor, called MediWatch, uses arterial tonometry to capture the radial pulse waveform and yields BP measures after the waveform is calibrated [41]. Vasotrac (Medwave, Arden Hills, MN) is also a wrist type BP monitor, which provides BP measurements approximately every 12–15 beats via analysis of the waveform obtained from the radial artery at the condition of zero load [42].

Although no cuff is needed in the MediWatch and Vasotrac systems, an external pressure is still required to exert on the wrist and the reliability and accuracy of the BP measures is location-sensitive. Other problems include the disruption of sleep and other activities of daily living, and irritation of the skin underneath the cuff/sensor. These systems provide only sporadic readings and are not fully wearable and unobtrusive. Therefore various approaches have been undertaken to design cuffless blood pressure monitors.

The cuffless BP measurement technique, which can be implemented on wearable systems, is based on estimating BP from the transit time of a pulse travelling along an artery and other related parameters [43]–[45]. The pulse transit time (PTT) is sometimes measured as the time interval between the R-peak of the ECG and the characteristic point of photoplethysmogram (PPG). To use the system measuring BP regularly or continuously over extensive periods of time, the electrodes and photo detector can be incorporated into a watch [46] or a module that is wirelessly

connected with a mobile phone or Personal Digital Assistants (PDAs) [6]. The first PTT-based watch-typed blood pressure monitor was produced by Casio and it was on sale in 1992. Although Casio discontinued its efforts in this area, the endeavor to develop cuffless blood pressure monitor has never been stopped. Zhang and his group have investigated the effect of several factors, i.e., finger temperature [47], sensor contact force [48], and pre-ejection period [49] on the accuracy of BP estimation. Comparable estimation accuracy has been achieved taking the readings from a sphygmomanometer as in [50]. Recently, the research group led by Prof. Asada at Massachusetts Institute of Technology, proposed a motion-based adaptive blood pressure estimation, which allows complete calibration of PTT to BP without the use of an oscillometric blood pressure cuff or external pressure sensor [51], [52].

C. Blood Oxygen Saturation

Optical transducers applied directly to the skin can determine the percentage of hemoglobin bound with oxygen. Blood oxygen saturation is a vital indicator of a patient's health considering that a human being cannot survive for a prolonged time without a constant oxygen supply to the brain. The first prototype of a wearable reflectance pulse oximeter including a radio frequency (RF) data transmission unit was miniaturized in a finger-ring configuration [21], [53]. This pulse oximeter allows one to continuously monitor HR and SpO₂ in a totally unobtrusive way since the device is shaped like a ring, it can be comfortably worn by a subject for long periods of time. The ring sensor is equipped with a low-power transceiver that accomplishes bidirectional communication with a base station, thus allowing one to reconfigure the sensor when necessary and to upload data at any point in time.

The oxygenation state of the capillary bed of the muscles is of particular interest for measuring aerobic efficiency of a person undertaking an exercise routine. In addition to monitoring and maximizing athletic performance, information pertaining to the delivery of oxygen to the limbs and the brain is important in military and space applications where changes in gravity and other sources of stress may result in fatigue, and ultimately, blackouts. A wearable system for noninvasively determining the oxygenation state of tissue located beneath the surface of the skin, such as muscle tissue, of an exercising person or a person at rest led to a first patent covering this line of work in 1992 [54]. In such system, a wearable detector array, placed on the leg, used near-infrared radiation to collect oxygenation data. Data could be displayed by a wristband indicator of a telemetry device for remote monitoring. A separate, user-wearable battery pack, preferably designed to provide power for the duration of the activity being monitored, was also envisioned.

Forehead is another location for measuring blood oxygenation using wearable devices [55], [56]. Researchers at Drexel University and the University of Pennsylvania are developing a wearable neuro-imaging device that enables continuous, noninvasive, and minimally obtrusive monitoring of changes in blood oxygenation and blood volume related to human brain function [57]. Positive correlation between a participant's performance and oxygenation responses as a function of task load has been found. Functional optical imaging of the prefrontal

cortex using near infrared is an emerging affordable and wearable sensing modality able to monitor physiological changes that occur during cognitive tasks.

D. Respiration

Respiration is an important physiologic function that is multidimensional in nature. A detailed quantification of volume, timing and shape of the respiratory waveform can map into different physiological states. Respiration is associated with the kinematics of the chest thereby bringing about changes of the thoracic volume. The inductive plethysmography (IP) method is the gold standard for unobtrusive respiratory monitoring and has been used widely in clinical and research settings. A respiratory IP sensor consists of two conductive wires, one around the ribcage and the other around the abdomen [58]. Motions of the chest wall cause changes in the self inductance of the two loops. Magnetometers or linear-displacement sensors can detect changes in the chest diameter and perimeter. For example, strain gauges wrapped around the torso are suited for systems that rely on embedding sensors into clothing items such as undergarment [59]. Recently, a wearable yarn-based piezo-resistive sensor has been developed [60]. This yarn-based sensor was fabricated by using piezo-resistive fibers, elastic, and regular polyester fibers. Single and double wrapping methods were employed to fabricate the yarn-based sensors. Due to the symmetric structure of the sensor, the double wrapping yarn could resist the slippage and higher linearity in the resistance curve was achieved. Sensing techniques based on the operating principle underlying the Doppler effect are also under investigation as discussed in Section II-A.

E. Biochemical Measurements

Several methods, such as iontophoresis, electrophoresis and sonophoresis, have demonstrated potential for enhancing the efficiency of the "extraction" of body fluids through the skin [18]. As our largest "organ," the skin enables noninvasive/mini-invasive measurements of several analytes including blood glucose, lactate, immunoglobulins, amino acids, and small proteins. Taking blood glucose as an example, methods that have the potential to be applied in the development of wearable systems [61] are introduced in the following.

The method of iontophoresis, which has been used for many decades, utilizes electrical current to deliver charged drug compounds through the skin. Noninvasive monitoring, however, uses transport of glucose in the opposite direction to that of drug compounds (i.e., from the skin outward); therefore this process has been called "reverse iontophoresis" [62]. The GlucoWatch monitor developed by Animas Technologies is a wristwatch device that utilizes such technique with two independent potentiostat circuits [63]. This measurement is possible because neutral molecules, such as glucose, are extracted through the epidermis surface via this electro-osmotic flow to the iontophoretic cathode, along with Na⁺ ions. The system can read glucose levels every 10 min for up to 13 h. Reverse iontophoresis is not the only method of extracting noninvasive glucose molecules from the skin. Sonophoresis, using piezoelectric transducer to create 20 kHz sound waves (i.e., ultrasound) that increases cutaneous permittivity to interstitial fluid can also serve this propose [64]. Analyte concentrations can be determined with standard electrochemical glucose sensors. Initial *in vivo* laboratory results have been reported in [65]. Electrophoresis involves the application of low current levels at the skin surface, triggering a transdermal flux of molecules from the underlying blood vessels, in to extracellular fluid and to the skin [66]. Other methods with the potential for leading to a wearable system are the bioimpedance spectroscope, which was firstly published by Caduff's group in 2003 [67], [68] and the near-infrared spectroscopy method [69].

Recently, a miniaturized "all-in-one" glucose enzyme fuel cell, which represents a compartmentless fuel cell that is based on the direct electron transfer principle, has been developed [70]. This project involved the combination of a wireless transmitter system and a simple and miniaturized continuous glucose monitoring system, which operated continuously for about three days with stable response. This is the first demonstration of an enzyme-based direct electron transfer-type enzyme fuel cell and fuel cell-type glucose sensor which can be utilized as a subcutaneously implantable system for continuous glucose monitoring.

In the case of transdermal monitoring, several factors affect the accuracy and reliability of the measures such as sweating, skin color, surface roughness, tissue thickness, breathing artifacts, blood flow, body movements, ambient temperature, pressure and sample duration [61], [71], [72]. Furthermore, multisensory arrays are required for continuous multianalyte measurements.

III. WEARABLE MEDICAL SYSTEMS

The early prototypes of wearable medical systems are mainly based on body-worn devices, which are designed to be miniaturized, integrated, networked, digitalized, and smart (MINDS) for p-Health application [11]. Body-worn medical systems can typically gather data from sensors located only in a specific and usually relatively small body area and cannot fulfill, alone, all the needs for sensing, actuating, displaying, and interacting with the user. An alternative approach to achieve wearable monitoring is to integrate sensors in clothing items. Intelligent biomedical clothing [25] refers usually to clothes with sensors that are close to or in contact with the skin [73]. The sensors are either embedded in the fabric of the garment, or it is the fabric itself that is used as a sensor or a sensor suite [74], [75]. Several prototypes of wearable medical devices/systems are shown in Fig. 1.

Several prototypes of IBC systems have been developed over the past few years. *LifeShirt* system is a noninvasive, continuous ambulatory monitoring system that can collect data during a person's daily routine [77], [78], However, it is unsuitable for lengthy continuous monitoring due to the cumbersome recorder and peripheral attachment to be carried around. To address the limitations of the first prototype developed in the area of sensorized garments, researchers shifted their focus on smart textiles. Smart textiles have become one of the thriving areas of application for materials and nanotechnology research for the purpose of health monitoring. The smart textile approach of Sensatex, i.e., the *Smartshirt*, originally developed and patented by researchers at Georgia Institute of Technology, collects analog signals through conductive fiber sensors and transfers them through a conductive fiber grid knitted in the



Fig. 1. Examples of wearable medical devices/system prototype. From the upper left corner clockwise are an earlobe device [23], a watch (provided by Jetfly Technology Ltd.), a finger ring [21], a glove [19], a wrist-worn device AMON [20], a jacket, and a smart textile cloth [76].

T-shirt [79]. Another example is *VTAMN*, which aims at reaching a higher level of electronic integration in clothing than previous prototypes [80]. The objective is to obtain a biocloth, or second skin, both comfortable and washable. The T-shirt incorporates four smooth, dry ECG electrodes, a shock/fall sensor, a respiration rate sensor, and two temperature sensors. The electronic I²C bus is also part of the textile. The motherboard, the transmission module, and the power supply are mounted on a belt and connected to the *VTAMN* T-shirt through a microconnector.

Up-to-date, sensing body movements or physiological signals, particularly the ECG and respiration, remains the main function of an IBC. The measurement of BP is still a challenge for IBC because of the conventional cuff-based principle utilized for BP measurement. In a recent manuscript by Zhang et al. [81] a Health-Shirt (h-Shirt) that can monitor BP cufflessly and continuously has been proposed. The h-Shirt is designed to simultaneously record ECG and PPG and uses them to estimate BP with the PTT-based method. ECG is captured from the two wrists, with a reference electrode placed on the forearm to avoid respiration-induced noise. The electrodes were made of e-textile materials. A photo reflective sensor is mounted on a PCB to capture PPG from the fingertip. Male side fasten snap buttons are soldered to the PCB copper pads for connection and signal transmission. Fig. 2 shows the frontal view of the shirt when the user is measuring BP and ECG continuously. The performance of continuous and long-term BP monitoring by using the h-Shirt has been evaluated [82].

Other studies performed in the area of IBC include: a wearable physiological monitoring system for space and terrestrial applications named *Life Guard* [83]; the *Armband SenseWear* (BodyMedia Inc., Pittsburgh, PA) wearable body monitor that



Fig. 2. *h-shirt* prototype [81].

has been used to study body movement and energy expenditure in healthy as well as subjects with chronic obstructive pulmonary disease [84]; the WEALTHY system that is made up of a sensorized cotton or lycra shirt that integrates carbon-loaded elastomer strain sensors and fabric bio-electrodes, enabling the monitoring of respiration, ECG, electromyogram (EMG), body posture and movement [85]; a textile based wearable system, called MagIC designed for unobtrusively recording cardiorespiratory and motion signals during daily life and in a clinical environment on patients with different cardiovascular conditions [86]; and the MyHeart wearable monitoring system that focuses on integration of unobtrusive sensors into everyday garments and miniaturized on-body electronic modules for data processing and storage with dedicated software for data analysis like ECG preprocessing and motion artifact detection, computation of HR and HRV [87], [88].

The approach of ongoing research and development is to integrate monitoring, diagnosis, treatment and communication functions into fabrics. Several issues, technical as well as clinical, remain to be solved before a clinical trial can be performed. Among the most important challenges are the production of higher conductivity textile material according to current industrial processes, as well as the interfacing and protection of electronic components.

IV. BODY AREA NETWORK

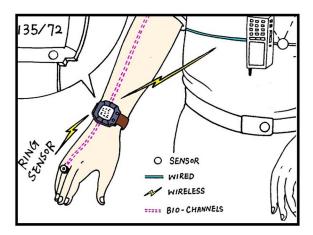
The need to develop a network is driven by the increase in the number of wearable or implanted biosensors or devices to be placed on users. In particular, for many applications in which long-term and continuous collection of health information is needed, multiple sensors or devices are often required to be placed at different body parts. Since this network is setup around a human body to interconnect sensors worn on or implanted in the body, it is named body area network (BAN). It is also sometimes referred as body sensor network (BSN) when used in a

medical or health application where each node of the network comprises a biosensor or a medical device with a sensing unit.

Setting up a BAN to connect on-body or in-body sensors or devices helps to optimize the use of resources in order to satisfy the stringent constraints in the terminals. For example, health information collected from different sensors can be centralized before being passed on to external networks for remote analysis, diagnosis, or treatment. In addition, the presence of a BAN can also enhance the control, scheduling, and programming of the overall system such that it is adaptive to body condition and external environment. For example, some sensors or devices may have to be reprogrammed from time to time (e.g., a device for drug delivery).

From the user's point-of-view, intra-BAN communication should be via connections that are as unobtrusive as possible. Technological advances in microtechnologies and nanotechnologies, application-specific integrated circuits, wireless networking, and embedded microcontrollers and radio interfaces on a single chip [89] have enabled wireless connectivity of individual sensors into a wireless BAN (WBAN) [90] that uses RF techniques [90], [91] such as ultrawideband (UWB) radio technology [92]-[94], Bluetooth [43], [95] and ZigBee [96]. Bluetooth is a mature technology that has been integrated in many cell phones and PDAs. It allows high communication bandwidth of up to 720 kb/s. Despite Bluetooth can be set into a low-power mode, power consumption and complexity of protocol stack implementation is still a limiting factor for most WBAN applications. ZigBee is an emerging wireless standard for low data rate, very low-power applications, with potential applications in WBAN. The maximum data rate provided by ZigBee (250 kb/s) is sufficient for most of the health and medical applications using wearable systems [97]. Among different wireless communication technologies, UWB is of particular interest. Its operation is based on the use of narrow pulses of extremely short duration (a few nanoseconds) instead of continuous RF waves. These narrow pulses are essentially responsible for a signal bandwidth in the gigahertz range. UWB is a very low power communication protocol, which is very important as far as power management of wearable systems is concerned. UWB supports very high data transmission rates, hundreds of Mb/s, for short ranges up to a few meters. UWB applications are not only restricted to wireless communication but extend to detect heart and respiratory rate, as we discussed above. Finally, it is worth mentioning that UWB is the only wireless RF technology that can determine the position of an object with an accuracy of a few centimeters.

While wireless RF techniques are still a main research area for BAN, the unique characteristics of BAN open up the opportunity of connecting sensing nodes through other means. For example, nodes that are close to each other could be connected through "wires," provided that the appearance of the user is not too adversely affected and his mobility not impaired. In this respect, a research group from Georgia Institute of Technology [98]–[100] proposed the concept of wearable motherboard, where fabric made of e-textiles is developed into a computer and served as a framework for personalized mobile information processing.



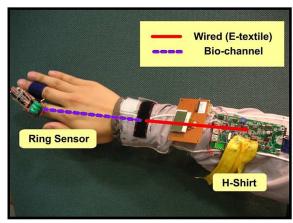


Fig. 3. Example of setting up a hybrid body area network to acquire multiple physiological signals and parameters.

Even more uniquely, since nodes of BAN are placed in or on the human body, they are inherently linked by pathways which we name biological channels (bio-channels) [101]. Bio-channels are commonly referred to the voltage-gated channels that allow the exchange of selected ions across the otherwise impermeable cell membrane. In this context, we use bio-channel to denote any biological conduit that is part of the human body and enables the transfer either exogenous or endogenous information. Signals transmitted via bio-channels could be either processed information or biological data. As some of the biological data are unique to individuals, they could potentially be an identifier of the owner of BAN. Thus, a biometrics approach using bio-channels could be used to secure wireless communications in BAN [101]. Another example of the use of bio-channels is to transmit the arrival time of a pulse at the finger tip to a processing unit worn on the wrist of the users [102].

The different communication means discussed in this section should be viewed as the complement of each other. In future, depending on the application, one or more communication means should be used in a BAN to connect the various sensors and to communicate with the external world, i.e., the concept of hybrid BAN (h-BAN). As illustrated in Fig. 3, the design of a BAN may include using e-textile materials wove in a jacket to connect e-textile-based electrodes that capture ECG from the two arms of the user, using bio-channel to transmit information from a ring senor that detects the pulse to another sensor node that contains a processing unit and using wireless RF techniques to send information to an external device or terminal for analysis and storage.

V. STANDARDS AND OTHER ENABLING TECHNOLOGIES

In order to develop a wearable medical system for p-Health, different enabling technologies and standard protocols are needed to meet the unique requirements of MINDS devices and the BAN that connects them. We will discuss a number of them in this section.

A. Motion Artifact Reduction

The presence of motion artifacts is a major limitation in most practical implementations of wearable medical systems. In a recent position paper, the IEEE Engineering in Medicine and Biology Society technical committee on Wearable Biomedical Sensors and Systems (WBSS) identified sensing of biomedical signals and the estimation of related parameters as a core function of WBSS [103]. However, there are conflicting design targets, i.e., for comfort and ease of use, that make it impossible to reach the clinically required signal quality in ambulatory patients while enabling acceptable comfort level for the user/patient when long-term, continuous monitoring is required [104].

Methods to reduce motion artifacts can be implemented at different levels, including a proper design of the sensor package, selection of the transducer, design of the signal conditioning circuitry and development of signal processing methods [105]. At present, a majority of the studies were performed in PPG. Commercially available pulse oximeter often reduce artifact-related errors by frequency domain heuristic methods [106] or a specific transformation known as Discrete Saturation TransformTM (DST) [107]–[109]. DST extracts the true signal from one that was contaminated by artifacts due to motion and low perfusion and utilizes a proprietary technique to establish a "noise reference" in the detected signal such that adaptive filters can be applied to real-time physiological monitoring. Recent studies also focus on optimizing the mechanical design of the system and incorporating signal processing techniques based on: 1) an independent measure of motion, 2) an optical model, 3) features recognized from analysis of the corrupted signal, or 4) time-frequency analysis such as the wavelet transform and smoothed pseudo Wigner-Ville distribution [110], [111].

For techniques based on an independent measure of motion, one or more transducers (e.g., accelerometers or optical sensors) are employed to record the user's motion. By assuming that the artifact is a linear addition to the PPG, the original signal can be reconstructed from the corrupted signal [112], [113]. This hypothesis is however often questioned when inspecting PPG under typical artifact-producing forces [114]. This observation has been driving researchers to develop more realistic models for the PPG or the artifact [115].

Minimum correlation discrete saturation transform (MCDST) is a recently proposed algorithm based on an optical model derived from photon diffusion analysis [116]. The simulation results show that MCDST is more robust under

low signal-to-noise ratios (SNRs) than the clinically verified motion-resistant algorithm DST. Furthermore, the experiment with different severity of motions demonstrates that MCDST performs slightly better than DST. MCDST is also computationally more efficient than the DST method because the former uses linear algebra instead of the time-consuming adaptive filter used by the latter, which indicates that MCDST can reduce the required power consumption and complexity of the circuit needed for the implementation of the artifact reduction procedure.

Techniques based on feature analysis often utilize some predetermined criteria to separate regions of corrupted and uncorrupted PPG and estimate the desired parameter values (i.e., the values corresponding to recordings that are not contaminated by any motion artifacts) from the uncorrupted portion of it [117], [118].

B. Energy Harvesting

Wearable medical systems need to be lightweight, small in size and have long battery life [119]. Therefore, a critical issue for their design and system integration is to keep power consumption as low as possible. While it is important to design MINDS devices and BAN communication protocols with low power consumption, the frequency of which the battery is changed or recharged can also be reduced by using externally powered sensors [120], [89] or employing techniques to scavenge energy from the environment. For example, a thermo-electric module produced roughly 60 $\mu W/cm^2$ from the temperature gradient between the human body and the ambient [121]. The efficiency of these methods however heavily depends on the condition of the surrounding environment. A solar cell mounted on the shoulder generated around 100 mW/cm² when the user is under a bright sun but produced a thousand times less when the user is in an illuminated office [121].

In view of this, researchers looked into methods that are less dependent on the environment but rely more on the user's activity such as arm motion and walking [122]. Magnetic generators that were embedded into a sneaker's sole or added as a strap-on to an overshoe produced an average of 60 mW and 250 mW, respectively, during standard walking. [121]. Donelan *et al.* [123] recently proposed a new approach to generate electricity with minimal user effort, where a mechanical generator coupled to leg motion was selectively engaged only during the deceleration phase of each stride cycle. This type of "generative braking" produced electricity at a metabolic cost similar to that for normal walking, resulting in a much lower cost of harvesting than conventional generation approaches [123].

Since these energy harvesting techniques are designed to generate power intermittently, a storage mechanism is often needed to ensure stable power supply, particularly in between two power generation cycles, so that sufficient power is available to the wearable system. A direct solution is to store power in an electrical form by charging capacitors that can be utilized to provide power supply during periods of no power generation. However, simply charging a capacitor results in losing half of the available power [124]. Moreover, a purely capacitive solution to the problem is also restricted by size. In such cases,

rechargeable batteries may be employed. Mechanical energy storage may be more attractive for some of the generation mechanisms described above. For example, with walking as a source of power generation, flywheels, pneumatic pumps, and clock springs may prove more convenient in storing power than solutions based on electrical components.

Although walking is an extremely useful activity for scavenging energy, it is impractical to use it continuously for extensive periods of time. In contrary, since a person breathes all the time, it becomes an attractive activity from which energy are harvested. An emerging direction of research uses fabrics made from piezoelectric nanowires grown radially around textile fibers to convert low-frequency vibration or frictional energy from breathing or even heartbeats into electrical energy [125].

C. Standard Protocols for Evaluation and Development

Establishment of a standard protocol is important for the validation and comparison of the performance of medical and health devices as well as the communication of these devices in BAN.

Noticing the importance of establishing international standards for various aspects of wearable medical systems, the IEEE has begun their work in January 2007 on the standard IEEE P1708, which is the first independent standard for the validation and comparison of wearable and cuffless BP measuring devices. Although there are existing evaluation standards for conventional BP measurement devices used with an occluding cuff, these standards are not suitable to be used directly for the evaluation of wearable and cuffless BP devices which rely on a different measurement principle involving an individual calibration procedure [126]. Based on a model on measurement differences between BP test devices and their references, an evaluation scale for assessing the accuracy of wearable BP devices will be proposed in this standard.

In November of the same year, the IEEE 802.15 working group for Wide Personal Area Networks (WPANs) has formed a new task group (Task Group 6) to develop an international wireless communication standard optimized for ultra low power devices and operation on, in or around the human body. IEEE 802.15.6 aims to define BAN into one that works at a range even shorter than other wireless technologies that are already available in the market, such as Bluetooth. Ideally, the short-range design of BAN should reduce the chances of interference and eavesdropping but the need for security in BAN is also prevalent, especially when it is used for collecting and transmitting sensitive health and medical information in p-Health. This new standard is proposed for medical and nonmedical applications, where the medical applications are further divided into wearable BAN or implanted BAN to be used in hospital or outside hospital.

VI. APPLICATIONS OF WEARABLE MEDICAL SYSTEMS FOR P-HEALTH

Optimal management of many diseases, particularly chronic noncommunicable diseases like cardiovascular and neurological diseases, such as congestive heart failure and Parkinson's disease, relies on the early detection of and prompt response to some warning signs of worsening of the patient status or subtle symptoms that are indicative of inappropriate management of

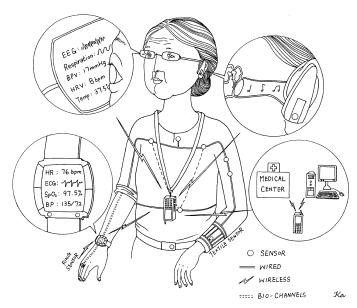


Fig. 4. Illustration of the Wearable Intelligent Sensors and Systems for p-Health with the *h-Shirt*. (Artwork courtesy of J. K. Y. Leung, The Chinese University of Hong Kong) [81].

the condition affecting the patient. In the p-Health paradigm, appropriate clinical measures should be implemented at all the different stages of the disease according to the patient's response. The use of wearable medical devices could reduce incident rates by 1) predicting acute events by long term monitoring and analysis, 2) providing instant diagnosis of acute events and links to health care provider/emergency system, and 3) reducing the time of treatment by the implementation of telemedicine interventions. Rehabilitation in the home setting can be provided to maximize functional outcomes in patients with mobility-limiting conditions [25].

A. Management of Personal Health Conditions

Wearable Intelligent Sensors and Systems for p-Health (WISSH) is comprised of a collection of miniature biomedical sensors and devices, which are embodied in or integrated with wearable nodes (such as watches, finger rings, or clothing), and use BSN as the communication infrastructure [81]. The *h-Shirt* can be considered a device of WISSH. It is worth emphasizing that it is also possible to connect the *h-Shirt* with external peripherals. In the schematic representation shown in Fig. 4, we illustrate the use of the *h-Shirt* in WISSH. Sensors on the *h-Shirt* are connected to a watch worn by the user and utilized for display purposes, which is a convenient way for users to read the monitored physiological parameters and be alerted if signs of a worsening of the patient status are detected.

At this stage, ECG and BP measures have been gathered using a system relying on the h-Shirt [81], [82]. In the future, we envision that WISSH will be extended to measure other physiological parameters such as respiration and SpO_2 . It is also of interest to examine possibilities to broaden the functions of devices of WISSH, e.g., not just to monitor health status but also to deliver therapeutic interventions. Recent reports suggested music as a non-pharmaceutical alternative to regulate BP [127] or reduce BP [128], in certain conditions. A personal therapeutic

device to lower BP using music and paced breathing has already been on the market [129]. Since it has been reported that a digital music player system can be integrated onto e-textile [9], [74], [130], in future, it is envisaged that existing technologies could be modified and integrated into WISSH to provide real-time BP management services based on bio-feedback mechanisms.

B. Management of Cardiovascular Conditions

Several multimillion-dollar projects have been conducted in Europe to develop innovative wearable monitoring systems. These projects include companies such as Philips, Nokia, and Ericsson in a leading position. Andreas Lymberis, scientific officer of the European Commission's Information Society directorate believes that "this new means for health monitoring has the potential to significantly reshape the provision of health care, assigning new responsibilities for the medical-device maker, the health practitioner and the patient" [131]. Following Smartex's WEALTHY project while focusing on developing a garment for physiological monitoring, Philips initiated a project named MyHeart aimed at farther developing technologies for remote monitoring of patients via wearable sensors and systems. MyHeart is one of the largest projects supported by the European Commission in the field of personal healthcare aiming to use wearable systems to monitor, diagnose and treat cardiac ailments such as arrhythmias. Shortly after completion of the EUR 33 millions project, Philips launched another project entitled HeartCycle in March 2008 [132] that represents a further step in the direction of developing wearable systems for clinical applications.

HeartCycle will provide a closed-loop disease management solution being able to serve patients with congestive heart failure and/or chronic heart disease, including possible comorbidities such as hypertension, diabetes and arrhythmias. This will be achieved by multiparametric monitoring and analysis of vital signs and other measurements. The system will contain a patient in-the-loop schema by which the system will "interact" directly with the patient to support daily treatment. The system will monitor several aspects of the response to different interventions, including treatment adherence and effectiveness. Based on the feedback provided by the system, researchers expect that compliance will increase, and health status in patients utilizing this system will improve. The system will also contain a professional in-the-loop schema by which medical professionals will be involved in reviewing patient's data. The system will automatically alert medical personnel in cases in which diagnosis or treatment is required. The system is connected with the hospital information system, to ensure optimal and personalized care via access to extensive medical information.

C. Management of Neurological Conditions

Since wearable technology provides the opportunity for long-term patients' monitoring, this technology has gained a great deal of interest in physical medicine and rehabilitation [133]. In fact, physiatrists and therapists largely see patients with chronic conditions whose management is the main concern of the clinical personnel (because these are conditions for which a cure does not exist or has not been identified).

An example of clinical application of wearable technology in the context summarized above is the one of monitoring patients with Parkinson's disease. An interest for long-term monitoring of patients with Parkinson's disease is clearly originated by the nature of the disease that requires assessing the severity of symptoms at different points during the day and over different days in order to capture the variability in severity of symptoms experienced by patients over time. Several authors demonstrated an interest for long term monitoring of symptoms in patients with Parkinson's disease since the mid nineties [134], [135]. As wearable technology developed, other authors started focusing their attention on the possibility of relying upon inertial sensors to assess the severity of tremor, dyskinesia, and bradykinesia. Seminal work by Keijser *et al.* [136], [137] and Hoff *et al.* [138] opened the way to automatically predict the severity of Parkinsonian symptoms and facilitate medication titration.

The potential for facilitating medication titration is a very attractive feature of wearable technology. In the management of Parkinsonian symptoms, this feature of wearable technology is particularly attractive as it could improve the management of patients showing severe motor fluctuations [139]. Motor fluctuations are changes in the severity of symptoms observed in association with medication intake. Motor fluctuations span a time interval of several hours. Patients often do not recollect accurately the severity of their symptoms. Therefore, the use of wearable sensors such as accelerometers and gyroscopes is very appealing. Such monitoring technique needs then to be combined with processing techniques that allow one to explore the relationship between characteristics of the outputs of the inertial sensors attached to the body segments of interest (i.e., those affected by the symptoms) and the actual severity of symptoms as observed via clinical examination of the patient. The process of identifying such relationship is very complex and some authors have leveraged upon data mining techniques to determine this relationship [140]. This technique has been recently expanded upon application to patients undergoing Parkinson's control therapy via stimulation of the subthalamic nucleus [141].

Another example of application of wearable systems of interest in neurology is the one of monitoring subjects with epilepsy [142]. The overall objective of long-term monitoring in these patients is the assessment of pharmacological interventions in this patient population that address the occurrence of seizures, hopefully decreasing their frequency, duration, and severity. One way to approach this problem is to develop an ambulatory electroencephalogram (EEG) system and then identify ways to detect or even predict the occurrence of a seizure [143]. The other way to approach the detection of seizures is the one of focusing on seizures accompanied by motor symptoms. In this case, seizures are detected because of the abnormal movements associated with them. Movement patterns would be captured via wireless straps of miniaturized sensors [144].

VII. CONCLUSION

Although advances in wearable medical systems can potentially address most of the challenges currently facing the development of a comprehensive and innovative healthcare system

and the transformation to p-Health, several major problems to widen the scope of application of wearable medical systems still exist

To further understand the physiological mechanism is the foundation to develop innovative measurement principles and methods for the design of future wearable medical devices. Besides, low power consumption is especially crucial [145]. Due to the slow varying nature of most physiological signals (from 0.5 to 4 beats per second), designing integrated circuits with very low cutoff frequency is necessary, though unfortunately it is very challenging to meet the design specifications for these systems. Several endeavors have been made in this research area [146], [147]. For wearable medical devices to provide continuous monitoring and health information to doctors or clinician, seamless transmission of data must be available. Despite the low-power mode of some wireless communication standard, power consumption and complexity of the protocol are still limiting factors [97]. To increase the acceptance of wearable medical systems, advances must be also made in interoperability standards that promote information exchange, plug-and-play device interactions, and reconfigurability [148].

With the transformation of healthcare from a system based on addressing general symptoms in large patient populations to a system focused on p-Health, it is hoped that health services will be accessible and affordable to everyone, whenever and wherever they need them. We believe that it is reasonable to anticipate that many types of medical tests that currently require a person to visit a hospital or doctor's office will be performed eventually using wearable medical devices in the home setting.

ACKNOWLEDGMENT

The authors would like to thank the reviewers for their constructive comments and suggestions, which have improved the manuscript substantially.

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