chapter six

Sensors and wearable technologies for pervasive healthcare

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6.1 *Introduction*

"Health is wealth" goes the age-old saying. It is as true today as it was when it was first coined. In fact, the economic vitality of a nation can be severely limited by the poorer health, premature deaths, and long-term disabilities of individuals without proper access to healthcare.[1] Consider the following facts pertaining to healthcare in the United States:

- Healthcare spending was $1.8 trillion in 2004. It is projected to reach $3.6 trillion in 2014, growing at an average annual rate of 7.1 percent from 2003 to 2014.[2]
- As a share of gross domestic product (GDP), health spending is projected to reach 18.7 percent by 2014, up from its 2003 level of 15.3 percent.[2]
- In the first half of 2005, 14.4 percent of the population was uninsured, which was not significantly lower than the 2004 estimate of 14.6 percent.[3]
- As of mid-year 2005, 5.7 percent of the population was unable to obtain needed medical care because of cost at some time during the past twelve months. The estimate is slightly higher than, but not significantly different from, the 2004 estimate of 5.5 percent.[3]
- In early 2005, 25.1 percent of adults twenty years and over were obese, which was similar to the 2004 estimate of 24.5 percent. Obesity is defined as having a body mass index (BMI) of 30 kg/m^2 or more.[3]
- 7.2 percent of adults over eighteen years old had never been diagnosed as having diabetes.[3]
- More than 1.7 million Americans die of a chronic disease each year, accounting for about 70 percent of all deaths in the United States.[4]

- Cardiovascular disease (including heart disease and stroke) alone is the leading cause of death in the United States, affecting over sixty million Americans and costing the nation more than $351 billion in direct and indirect healthcare costs per year.[4]
- Medical care for people with chronic diseases such as arthritis, asthma, cancer, diabetes, and heart disease accounts for more than 75 percent of the money spent as a nation on medical care.[4]
- The prolonged course of illness and disability from diseases such as arthritis, cancer, diabetes, heart disease, and stroke result in pain and suffering, poor quality of life, and disability for millions of Americans.[4]

Taken together, these facts represent a *silent* crisis that is dramatically affecting the quality of life for individuals—*silent*, because it doesn't have the violent and sudden devastation of a natural disaster or a military attack. Although seemingly less dramatic, the long-term social implications of lack of quality healthcare are as significant.

6.2 The healthcare challenge

In a landmark study, the Institute of Medicine concluded that "the U.S. healthcare delivery system does not provide consistent, high-quality medical care to all people."[5] Moreover, with universal access to information (e.g., through the Web), today's healthcare consumer is demanding more options and is taking more control in determining the course of healthcare. Therefore, the healthcare industry faces the following critical challenges:[6]

- Reducing healthcare costs while maintaining a high quality of care
- Providing access to care for as many people as possible
- Providing easy access to specialized professionals anywhere and anytime
- Shifting the focus of healthcare expenditures from *treatment* to *prevention* through wellness programs
- Controlling lengths of hospital stays and *decentralizing* the provision of healthcare
- Addressing the increase in the aging population and caring for chronically ill patients

The healthcare industry is facing a set of significant challenges on several fronts, namely, availability (or access), quality, and cost.

6.2.1 Meeting the challenge: The pervasive healthcare paradigm

According to Musich et al., seven major diseases accounted for 80 percent of deaths in the United States in 1990: heart disease, cancer, diabetes, arthritis, chronic bronchitis, influenza, and asthma.[7] For many of these health conditions, *early, systematic intervention* would be highly beneficial.

6.2.1.1 *Continuous monitoring—the patient view*

Let's take the example of an individual with Type 1 diabetes. Self-monitoring of glucose levels up to four times per day or more is important for preventing and detecting hypoglycemia (low sugar) and avoidance of hyperglycemia (high sugar). Moreover, regular monitoring of the sugar level enables the individual to adapt and respond appropriately by modifying the diet, treatment, or exercise regimen to maintain desired glucose levels and comply with the physician's recommendation. Thus, *continuous* monitoring of individuals, especially those with chronic conditions, is essential for the major facets of *prevention, detection, avoidance* and *compliance* associated with such a disease.

During the course of a typical day, an individual is likely to engage in a wide range of activities (e.g., working, shopping, exercising, etc.) in different physically and geographically distributed locations as shown in Figure 6.1, such as a hospital, gymnasium, theater, or restaurant. Regardless of the location or the activity, the individual must monitor the glucose level and respond appropriately and in a timely manner to prevent a potential fatality. This means the *point* of care represented traditionally by the hospital is now the *continuum* of care, spanning a wide range of locations as shown in the figure. Therefore, continuous monitoring is critical to achieve responsive care anytime, anywhere. Moreover, the individual (or the typical caregiver) is not necessarily a trained medical professional but an ordinary citizen. So the solution or technology for providing care anytime, anywhere, should be readily accessible to and usable by anyone.

Let us consider another scenario where a patient is recovering at home after heart surgery and is being monitored remotely by the hospital or a monitoring service. Such monitoring will help the patient feel more "secure" and will facilitate recuperation while simultaneously reducing the cost and time associated with recovery. For example, at the Montefiore Medical Center in New York with 140 heart-failure patients on its "Telescales" remote-monitoring program, the hospital has seen overall medical expenses decline by 18 percent compared with a group of patients who aren't being monitored.[8] A patient whose vital signs have been monitored continuously in the hospital feels that the "umbilical cord" is cut off when discharged from the hospital because typically there is no more real-time monitoring of the individual; this

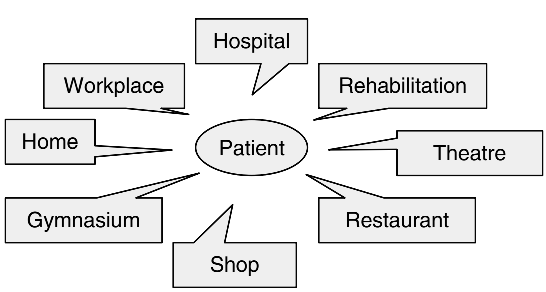

Figure 6.1 A typical day in the life of a patient.

causes a state of uncertainty in the patient's mind and the ensuing anxiety impedes the patient's recovery and recuperation. Because the daily cost of a hospital stay is typically greater than the daily cost of staying at home, the overall costs will also come down when the individual can go home sooner and be monitored remotely in real time. Moreover, in the event of an emergency, the doctor can be notified instantaneously. Thus, with *continuous* monitoring, the physician can administer the *right* treatment at the *right* time at the *right* cost, and indeed could save a life.[9]

6.2.1.2 *Continuous monitoring—the healthcare professional view*

The healthcare industry must meet the challenge of balancing cost containment with maintenance of desired patient outcomes. Consequently, healthcare professionals are trying to provide patient care more efficiently, and whenever possible, in the least expensive setting—be that an ICU (intensive care unit), a hospital general care unit, a skilled nursing facility, or an outpatient clinic. Even a patient's home is becoming the site of many types of care or monitoring that were once provided only by hospitals.[10] This has created a demand for portable, versatile medical devices that can be moved easily from the ICU all the way to a homecare setting.

The demand for high-tech medical devices is pushing the need for technologies that enable physicians to interact effectively and efficiently with *any* patient *anywhere* in the continuum of care *anytime*. In such an environment, the physical boundaries and distances that limit a doctor's healing area could potentially disappear and patients would have access to *any* doctor they desire. In fact, taken one step further, this approach could potentially lead to a network of specialty centers around the world, where each hospital could focus on a particular area of medicine rather than attempt to excel in *all* the specialties.

6.2.1.3 *Continuous monitoring—the pharmaceutical industry view*

Pharmaceutical companies developing new medicines and cures need to test them on subjects in as "natural" an environment as possible. Therefore, there is a need for *continuous* monitoring of test subjects as they go about their daily activities (see Figure 6.1) so that pharmaceutical companies can gain a better idea of the benefits and limitations of proposed treatment regimes.

6.2.2 *Continuous monitoring—a way of life*

In fact, *continuous* monitoring is quickly becoming a way of life. For instance, the OnStar Vehicle Diagnostics service from General Motors (GM) automatically performs hundreds of diagnostic checks on four key GM vehicle operating systems: the engine/transmission, antilock brakes, airbags, and OnStar communications system. Vehicles automatically send the results via electronic mail to owners each month. The report also provides maintenance reminders based on the vehicle's current odometer reading, remaining engine oil life, and other relevant vehicle ownership and OnStar subscription information.[11] If automobiles with finite price tags can be monitored for their "health" on a continuous basis, it is only appropriate that humans, whose lives are priceless, be continuously monitored for their care and well-being. Thus, the need for continuous monitoring in the continuum of care leads to the paradigm of pervasive healthcare: healthcare that is available to anyone, anytime, and anywhere with the potential to successfully enhance quality of life while reducing healthcare costs.

The remainder of this chapter is organized as follows: The principal modules constituting a patient-centric pervasive healthcare system are presented in Section 6.3 along with the main enabling technologies. Sensors, a key component of a pervasive healthcare system, are discussed in Section 6.4 with specific examples of wearable sensor systems for biomedical monitoring. In Section 6.5, the need for multiparameter sensing is established and a textile-based personalized health monitoring system (the Smart Shirt) is discussed. The challenges and opportunities for research in pervasive healthcare are presented in Section 6.6.

6.3 Pervasive healthcare system: A patient-centric approach

6.3.1 The life cycle of unit operations

Figure 6.2 shows the typical life cycle of unit operations associated with providing pervasive healthcare for an individual such as the diabetes patient discussed earlier. The first step is to *sense or observe* the patient's condition. The next unit operation is to *process* the sensory information to estimate the individual's vital signs such as heart rate, electrocardiogram (ECG), body temperature, pulse oximetry (SpO_2), and glucose level, among others. The next step is to *transmit* these vital signs to a doctor's office or a hospital. There the domain expert (e.g., physician) must *interpret* the signals and *diagnose* the condition of the patient. As shown in the figure, the next unit operation is to *respond* to the diagnosis by developing and administering a treatment. The final step is to *learn* from the experience so that future responses can build on the knowledge gained. Thus, a pervasive healthcare system must be designed to facilitate these unit operations in a cost- and time-effective manner.

6.3.2 The enabling technologies

A careful analysis of the unit operations identifies the key *enabling* technologies required for carrying them out to facilitate pervasive healthcare; as shown in Figure 6.3, these are:

- Sensors
- Signal processing system
- Communications system
- Decision support system

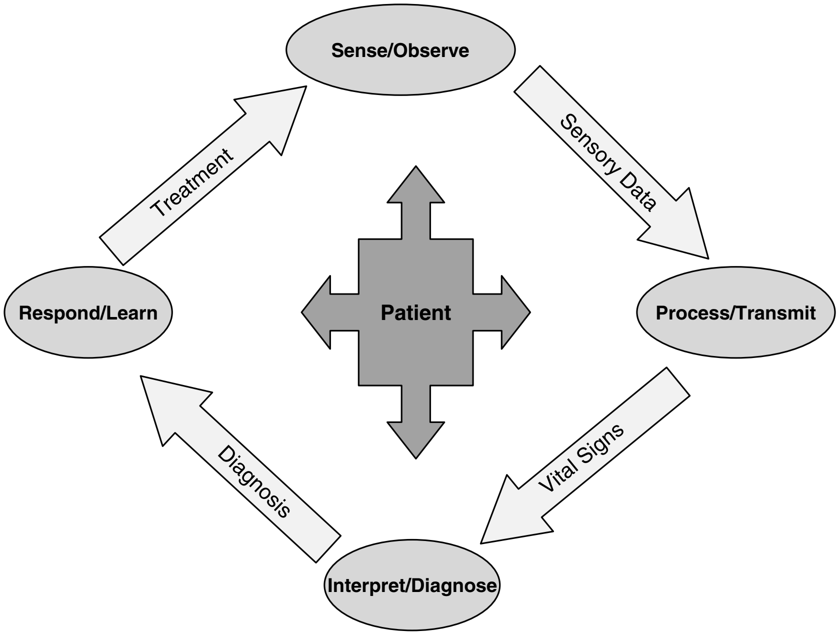

Figure 6.2 Life cycle of unit operations in pervasive healthcare.

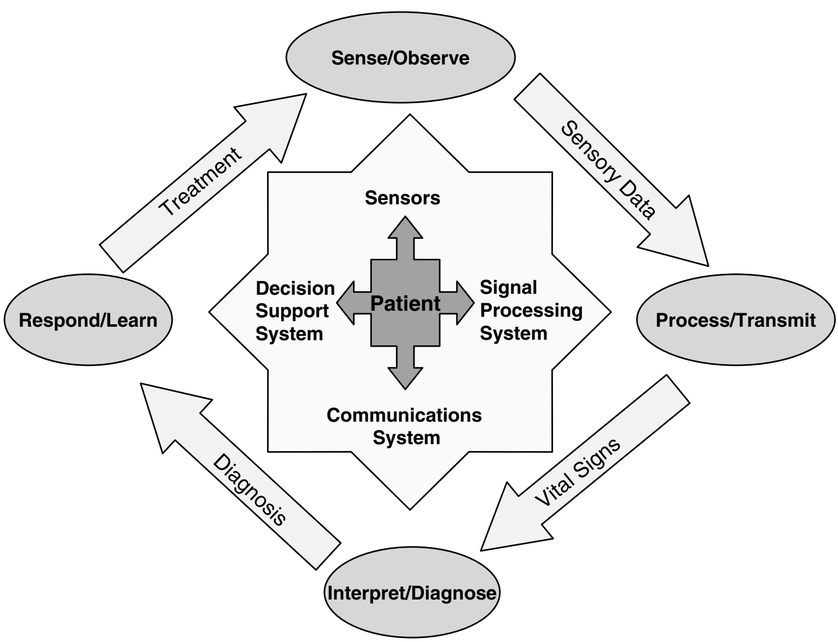

Figure 6.3 Key enabling technologies for pervasive healthcare.

The *sensors* will be responsible for gathering information from the individual and the environment (if appropriate) to provide contextual awareness. The *signal processing system* must then process the signals—biometric, video, environmental, etc.—and compute the appropriate parameters, including vital signs in terms of heart rate, body temperature, and ECG. The *communications system* must then transmit the computed data to the hospital or doctor's office (or a remote monitoring station) for storage and analysis. There, a knowledge-based *decision support system* can help the healthcare professionals interpret the information, diagnose the individual's condition, and develop an appropriate treatment to be administered in a timely manner thus completing the cycle. The treatment can be initiated by the individual based on the real-time recommendation from the healthcare professional or, if necessary, triggered automatically by the monitoring site (assuming the user is incapacitated or has previously authorized such automatic intervention). The specifics of each of these technologies and their relevant communications protocols, such as 802.11, Bluetooth, and ZigBee, are beyond the scope of this chapter and are not covered here.

Thus, these technologies—by enabling pervasive healthcare—can rapidly transform healthcare and the practice of medicine by improving the quality and safety of patient care as well as increasing the efficiency of healthcare providers.

6.3.3 Requirements of a pervasive healthcare system

First and foremost, the pervasive healthcare system must be *patient-centric*, meaning that it must be designed from the viewpoint of the patient, the ultimate beneficiary. Moreover, the resulting system must be *safe*, *effective*, and provide *timely*, *efficient*, and *equitable* care that does not vary in quality across the nation—aspects defined as key attributes by the Institute of Medicine in its "national statement of purpose" for a healthcare system.[5]

Figure 6.4 shows the key requirements from the patient's viewpoint. For example, *functionality* defines the functions to be carried out by the system or its intended purpose; in this case, it is the monitoring of a set of vital signs associated with the patient. *Usability* of the system is another critical requirement

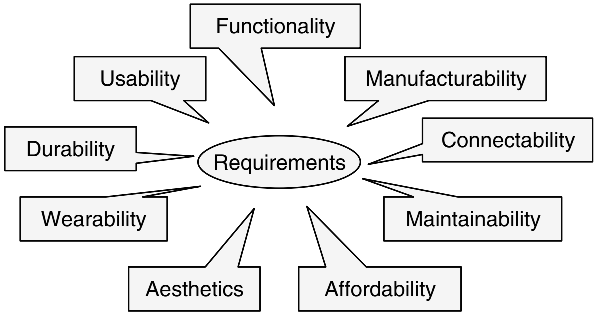

Figure 6.4 Key requirements: Patient view.

that significantly influences compliance, namely, whether the resulting system will indeed be used by the patient. If the system is not easy to use, the likelihood of its use will be greatly diminished thereby affecting compliance. The ability to integrate various sensors, devices, and processors—represented by *connectability* in the figure—determines the versatility and capability of the system. The other requirements shown in the figure include *wearability*, *maintainability*, *aesthetics*, *durability*, and *manufacturability*. Together, these requirements (and others that may be defined depending on the specific end-use application) must be considered in the design of a pervasive healthcare system. System performance- and information-related requirements are discussed in the following section.

6.3.4 Technology trends and pervasive information processing

Today, healthcare is at the threshold of a radical transformation as a result of the following technology trends:

- The significant advancements in computing and communications technologies are fundamentally changing when, where, and how individuals work and live. No longer confined to a workplace or chained to a static computing infrastructure *anyone* can process information *anytime* and *anywhere*, giving birth to the paradigm of *pervasive information processing* or "computing on the go."
- The advancements in, and convergence of, microelectronics, materials, optics, and biotechnologies, coupled with miniaturization, have led to the development of small, cost-effective intelligent sensors for a wide variety of applications.
- The transparency of the user interface coupled with the invisibility of "embedded" technology in the various devices and systems have contributed to the proliferation of sensors and sensor networks—from homes to outer space—and everywhere in between.

By effectively harnessing the benefits of these technological advancements, it is possible to create a pervasive healthcare system that will provide affordable healthcare to *anyone anywhere* at *anytime* and enhance the quality of life for everyone in the continuum of life from newborns to senior citizens. The challenge, however, lies in the development and realization of such a system.

In proposing the paradigm of pervasive or ubiquitous computing, Mark Weiser said, "The most profound technologies are those that disappear. They weave themselves into the fabric of everyday life until they are indistinguishable from it."[12] In Weiser's vision, computing and communications systems are totally integrated with the user. In a similar manner, the components or modules of the pervasive healthcare system must be tightly integrated with and unobtrusive to the patient so as to indeed "disappear." In short, the system must be *personalized*, be *mobile*, and facilitate *health information processing*, leading to the concept of personalized mobile health information processing, or PM-HIP for short.

6.3.4.1 System- and information-related performance requirements

The successful realization of a patient-centric pervasive healthcare system depends on rigorously meeting another set of performance requirements, namely parameters related to the system and information facets. While pervasive healthcare enables the healthcare professional to access patient records from anywhere at anytime, it also poses a set of significant challenges related to ensuring the *security*, *privacy*, and *confidentiality* of patient information (see Figure 6.5). Thus, in designing the pervasive healthcare system there is a critical need to balance easy access to patient information with the

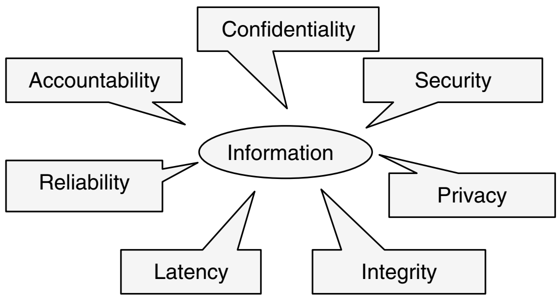

Figure 6.5 System- and information-related performance requirements.

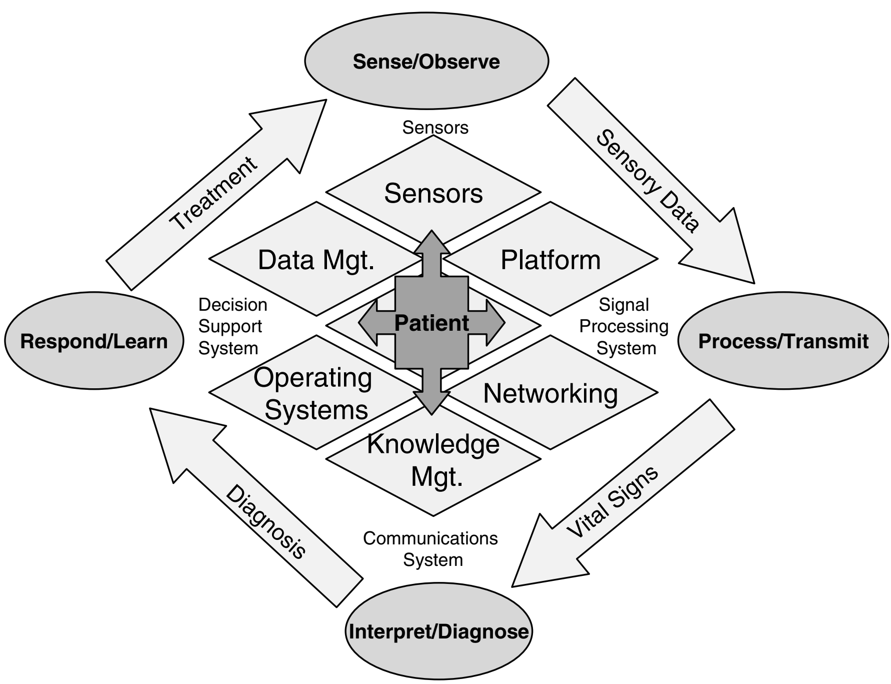

Figure 6.6 A patient-centric pervasive healthcare system with *building blocks*.

legal and ethical complications of inappropriate disclosures of such information. In this sensitive, information-rich domain, *accountability* becomes another important requirement as do data *latency* and data *integrity*. Any unnecessary delay in accessing or responding to the signals or erroneous data could mean the difference between life and death for the patient.

Thus, an overall vision of a patient-centric pervasive healthcare system emerges as shown in Figure 6.6. The underlying *building blocks* for realizing the system, such as sensors, platform, networking, operating systems, data management, and knowledge management, are also shown in the figure. For a pervasive healthcare system to succeed, all these factors must operate robustly and seamlessly.

We now discuss wearable biomedical monitoring systems for pervasive healthcare that address chronic diseases such as hypertension, heart disease, and diabetes.

6.4 Wearable biomedical systems for chronic care

A sensor is defined as "a device used to detect, locate, or quantify energy or matter, giving a signal for the detection of a physical or chemical property to which the device responds."[13] A biosensor has been defined "as an analytical device that incorporates a biologically active material in intimate contact with an appropriate transduction element for the purpose of detecting—reversible and selectively—the concentration or activity of chemical species in any type of sample."[14] Sensors transduce between the electrical, optical, thermal magnetic, mechanical, and chemical signal domains. For example, the glucose biosensor transduces from the chemical to the electrical domain. Thus, the sensor is at the heart of the wearable biomedical system because it is the component that captures data about the patient's condition (see also Figure 6.3).

6.4.1 Classification of sensors

At the top level, sensors can be classified as implantable, minimally invasive, or noninvasive. Implantable sensors require a hospital procedure to be put into place inside the body. Minimally invasive sensors penetrate the skin (subcutaneous) to obtain the signals. Noninvasive sensors are worn on the body. Sensors can also be classified as active or passive. Active sensors require power to operate, such as pulse oximetry sensors, while a temperature probe is an example of a passive sensor, which does not require a power source. Yet another way to view sensors is the mode in which the signals are transmitted for processing, as wired or wireless. In the former, the signals are transmitted over a physical conducting line to a processor. In wireless sensors, communication capabilities are built into the sensor, which transmits the signals wirelessly to a monitoring unit. Noninvasive sensors are typically used in systems for continuous monitoring because their use does not require extensive intervention from a healthcare professional. This is the type of sensor most commonly found in pervasive healthcare.

6.4.2 Ambulatory blood pressure monitoring (ABPM)

Hypertension, or high blood pressure, is a chronic condition affecting approximately fifty million people in the United States. However, there are different types of hypertension. For instance, 20 to 35 percent of patients may experience "white-coat hypertension," where they are hypertensive in the physician's office but normotensive at home.[15,16] Therefore, continuous monitoring of a patient's blood pressure is extremely important for the physician to determine which drug therapy regime will work best with each individual. According to the new Joint National Committee VII Guidelines,[17] ambulatory blood pressure monitoring (ABPM) is "warranted" for patients with white-coat hypertension. Additional studies have shown the following advantages of ABPM:[18–20]

- End-organ damage is more closely correlated with ambulatory blood pressure (ABP) than with clinic blood pressure (CBP) readings.
- ABP may be a better predictor of cardiovascular events and mortality than clinic blood pressure readings.
- Patients with hypertension whose nocturnal (sleep) blood pressure remains high (< 10 percent lower than daytime average) may have a worse prognosis.
- ABP provides a twenty-four-hour profile, allowing assessment of clinic effects, drug effects, work influence, etc.

6.4.2.1 Commercial ABPM systems

In an ABPM system, automatic measurements of blood pressure are obtained throughout a twenty-four- to forty-eight-hour period at specific intervals (say, every thirty minutes) or when triggered by the patient. The resulting stored data enables the physician to assess the blood pressure profile during the patient's typical day of activities. These systems indirectly measure blood pressure through auscultation (of Korotkoff's sounds) either with piezoelectric microphones, through oscillometric measurement of the vibratory signals associated with blood flow in the brachial artery, or through the combined use of both technologies.[16] Auscultatory devices record both systolic and diastolic pressures, whereas the oscillatory units record systolic and mean pressure and then calculate diastolic pressure through a variety of algorithms. Validation testing against mercury sphygmomanometry and intra-arterial measurement has confirmed the accuracy of these technologies.

In the typical ABPM machine, the blood pressure cuff is fitted around the upper arm and is fastened with Velcro. Figure 6.7 shows representative commercial ABPM systems from WelchAllyn and SunTech Medical, respectively. The monitor—typically worn on the belt and weighing around 250 to 300 grams—records the blood pressure at set intervals. The data are

Figure 6.7 Ambulatory blood pressure monitoring systems: (left) WelchAllyn ABPM 6100 (www.welchallyn.com); (right) SunTech Medical Oscar2 (http://www.suntechmed.com).

downloaded in the physician's office and the software provides a complete analysis of the data over the study period. The physician can then provide the appropriate treatment to the patient.

Commercially available ABPM systems already provide pervasive healthcare and enhance the quality of life for individuals suffering from hypertension. In a study evaluating the potential value of ABPM for patients with established hypertension, a group of forty patients (thirty-three to sixty years old) that was being treated for hypertension was randomly selected from a general practice list and subjected to a single twenty-four-hour ABPM evaluation.[21] ABPM values were compared with CBP values obtained on the day of monitoring together with previous readings taken by the general practitioner. The study concluded that ABPM provided information over and above that obtained by CBP in a substantial proportion of patients, thus demonstrating the value of ABPM.

In another study, the objective was to describe patient satisfaction with ABPM performed in a primary care office in the United States, using modern ABPM technology.[22] There were 235 eligible respondents in the study. Three-fourths of the patients believed that undergoing the test was worthwhile considering the time and money involved, while most (90 percent) reported they thought the information provided by the test would be helpful to their physician in making treatment decisions, despite probable lack of insurance coverage, and appeared willing to experience some discomfort for the overall gain of the results obtained from undergoing the session. Patients reporting that their physician had clearly explained the benefit of undergoing the testing were more likely to report that they thought the results of the test would be more helpful in making treatment decisions. Few patients (20 percent) found that wearing the monitor was uncomfortable. Thus, ABPM has the potential to be valuable in pervasive healthcare.

6.4.3 Ambulatory cardiac monitoring: Holter monitors

As mentioned previously, cardiovascular disease is the leading cause of death in the United States. Holter monitoring provides a continuous recording of the heart's electrical activity (the heart rhythm) during the patient's typical day. The battery-operated monitor is usually worn for twenty-four hours to obtain the recording. Electrodes are placed on the patient's chest and attached to a small recording monitor that is carried in a pocket. Simultaneously, the patient keeps track of activities during the day. The stored data can be sent to the physician's office for analysis and treatment. Any irregular heart activity is correlated with the patient's activity at that time.

The Zymed DigiTrak Plus from Philips Medical Systems is a digital Holter monitor that is the size of a pager and weighs around 90 grams (Figure 6.8). It is typically worn on the belt or, in the case of young children, around the neck using a lanyard. The patient places five electrodes at designated locations on the body as shown in the figure. From the five EASI electrodes, three channels of ECG recording are made and stored in the recorder.

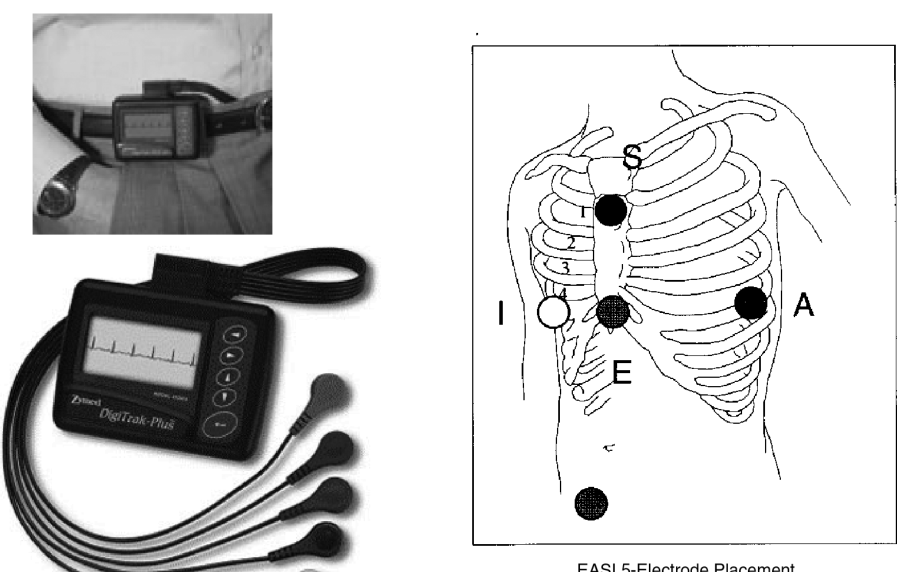

Figure 6.8 The Zymed Holter monitor from Philips Medical Systems showing electrode placements (from http://www.medical.philips.com/us/products/cardiography/products/holter/digitrak/).

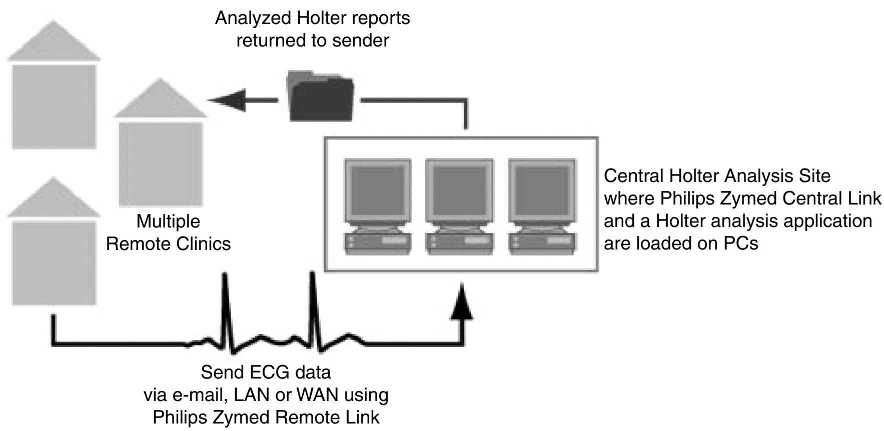

Figure 6.9 Pervasive monitoring using Zymed's Central Holter Analysis System (from http://www.medical.philips.com/us/products/cardiography/products/holter/central/).

The recorded data can be electronically sent to a central location (e.g., hospital or doctor's office) for analysis as shown in Figure 6.9. The results of the analysis can then be communicated back to the physician or patient for suitable intervention, thus facilitating pervasive healthcare for cardiac patients.

6.4.4 Continuous glucose monitoring

Diabetes mellitus is another chronic disease affecting nearly 7 percent of the population in the United States.[23] As stated earlier, proper disease management requires self-monitoring of the blood glucose level several times a day and taking necessary action—in terms of diet, exercise, and medication—based on the measured values. The typical procedure for glucose monitoring is invasive and it involves drawing a drop of blood from the patient (using a lancet), placing it on a test strip, and reading the glucose levels in the monitor. The process can be painful and prone to infection, especially because tests need to be repeated several times each day. This in turn affects compliance with glucose monitoring by patients. The traditional "finger-stick" measurement reveals the blood glucose value at a single moment or "snapshot" in time. An A1C test, which measures blood glucose control over a two- to three-month period, gives an average glucose value. Both can miss highs and lows in the user's blood glucose present at various times during the day—highs and lows that may lead to diabetes-related complications.[24]

Therefore, for successful continuous blood glucose monitoring of a diabetic patient, there is a need for less invasive procedures. Several techniques are under development. Noninvasive blood glucose monitoring generally involves either radiation or fluid extraction.[25] Nearly noninvasive blood glucose monitoring involves transcutaneous harvesting and measurement of interstitial fluid, which is the fluid surrounding every cell of the body.[26] We will now look at two systems that facilitate continuous monitoring of diabetic patients.

6.4.4.1 *Continuous noninvasive glucose monitoring by fluid extraction*

The GlucoWatch Biographer uses reverse iontophoresis (using an electric current to move a substance across body tissue) to monitor glycemia in diabetes patients.[27] The device is worn like a watch and the glucose readings are taken noninvasively by the AutoSensor (left in Figure 6.10). Induced by a low electric current, glucose is pulled through the skin and accumulated in two gel collection discs in the AutoSensor, which is a single-use component that snaps into the back of the watch and lasts for up to thirteen hours. The glucose reading is displayed on the screen as frequently as every ten minutes. A built-in alarm system alerts the patient when the reading exceeds the user-defined threshold level (for low or high glucose levels) or if there is a clear declining trend and the lower limit is likely to be reached in the next twenty minutes. However, the traditional finger-stick method must be used to calibrate the AutoSensor each time it is changed.

The GlucoWatch Analyzer software can be used to perform trend analysis by downloading the monitored data to a personal computer. This enables the patient to track patterns in glucose concentrations and to evaluate the effects of meals, exercise, insulin, and medication. Using this information, a healthcare professional can suitably fine-tune the diabetes treatment and thereby reduce the risk of long-term health complications from diabetes such as eye, nerve, kidney, and heart disease.

6.4.4.2 *Continuous, nearly noninvasive glucose monitoring by interstitial fluid harvesting*

The Guardian RT System from Medtronic provides real-time continuous monitoring of glucose values in subcutaneous interstitial fluid. A tiny sensor is inserted under the skin and is connected to a transmitter that is taped to

Figure 6.10 Continuous blood glucose monitoring systems: (left) G2 Biographer from GlucoWatch (www.glucowatch.com); (right) Guardian RT from Medtronic (www.medtronic.com).

the skin with a soft adhesive. The sensor can be worn for up to seventy-two hours. The transmitter uses RF (radio frequency) technology to wirelessly send glucose values automatically to the monitor (right in Figure 6.10). The monitor displays updated glucose readings every five minutes and alarms when values fall outside the user-defined threshold levels, for when the patient is hyperglycemic or hypoglycemic, respectively. The monitor stores up to twenty-one days of data; this data can be downloaded to the computer for detailed trend analysis. The Guardian Solutions software is similar to the GlucoWatch Analyzer software and enables the patient to better manage the disease in consultation with the healthcare professional.

We will now discuss cutting-edge technologies that enable *multiparameter* biomedical monitoring of mobile patients for personalized pervasive healthcare.

6.5 *Integrated multiparameter biomedical monitoring system*

While the systems described in Section 6.4 certainly facilitate continuous monitoring of patients, they are typically stand-alone systems for single parameters, such as for ABP, blood glucose, or cardiac monitoring. They are also distinct units and tend to be conspicuous on the individuals using them. If multiple parameters need to be monitored, the patient must wear multiple systems, which will be cumbersome and pose a whole host of challenges. Also, in the desired scenario of healthcare discussed in Section 6.3, these devices must *disappear* into the patient's lifestyle. Moreover, the patient, in essence, is an *information node* or *sensor* furnishing valuable real-time data and providing enhanced situational awareness to the healthcare professional at the remote site. This data must be transformed into "knowledge" for diagnosis and treatment. A structured analysis of the sensing requirements for monitoring the individual leads to the following conclusions:[28]

1. Different *types* of sensors are needed to *simultaneously* monitor the various vital signs (e.g., heart rate, body temperature, pulse oximetry, blood glucose level).
2. Different *numbers* of sensors may be needed to obtain the signals to compute a single parameter (e.g., at least three sensors are required to compute the ECG).
3. The sensors need to be positioned in *different* locations on the body to acquire the proper signals (e.g., sensors for ECG).
4. Different *subsets* of sensors may be used at different times necessitating their easy attachment and removal, or *plug and play*.

In short, what is needed is the design and implementation of a "sensor network" on the individual to achieve the desired functionality of vital signs monitoring for pervasive healthcare. Moreover, attributes such as functionality, modularity, and flexibility (such as plug-and-play capabilities) that are required of the sensor network (Figure 6.4) suggest the choice of the motherboard paradigm. Just as special-purpose chips and processors can be plugged into a computer motherboard to obtain the desired information processing capability (e.g., high-end graphics), the motherboard paradigm can provide an extremely versatile framework for the incorporation of sensing, monitoring, and information-processing devices.[10] However, because the sensor network—in the form of the motherboard—needs to be on the patient's body, it must be *wearable*. This leads to the paradigm of a "wearable motherboard." The rest of this section presents an example of how a versatile, networked pervasive healthcare system, including a wearable motherboard, can be achieved.

6.5.1 Textiles: The information infrastructure for pervasive healthcare

Textiles are pervasive, can be personalized, and present a "universal" interface that is natural and easy to use.[10] They provide the ultimate flexibility in system design by virtue of the broad range of fibers, yarns, fabrics, and manufacturing techniques that can be deployed to create products for desired end-use applications. Moreover, fabrics provide "variable" surface areas (very small to very large) that may be needed for "hosting" varying numbers of sensors and processors needed for creating sensor networks. These sensor networks may be deployed on the individual or in the environment to enable pervasive healthcare. It is also possible to build in redundancies for enhanced fault tolerance in the structure. Thus, textiles can serve as an effective mobile information infrastructure that can be tailored to the patient's specific requirements, making textiles an ideal platform for creating a wearable motherboard.

6.5.2 The Georgia Tech Wearable Motherboard (Smart Shirt)

Research at Georgia Tech led to the realization of the world's first wearable motherboard or "intelligent" garment.[29] Initially funded by the Defense Advanced Research Projects Agency (DARPA) through the U.S. Navy, the Georgia Tech Wearable Motherboard (GTWM), or Smart Shirt, uses optical fibers to detect bullet wounds and uses special interconnected sensors to monitor vital signs during combat conditions. The principal advantage of the Smart Shirt is that it provides, for the first time, a very systematic and personalized way of monitoring the vital signs of humans in an *unobtrusive* manner.[30] A set of user requirements similar to those in Figures 6.4 and 6.5 was developed and used in the design of the Smart Shirt (the details of the design methodology can be found in reference 31). Several versions of the Smart Shirt have been produced; with each succeeding version, the garment has been continually enhanced from all perspectives—functionality, capabilities, comfort, ease of use, and aesthetics.

6.5.2.1 The wearable motherboard architecture

Figure 6.11 shows the architecture of the wearable motherboard intended for medical applications. The comfort or base fabric (woven, knitted, nonwoven, etc.) provides the necessary physical infrastructure for the wearable motherboard. The base fabric is made from typical textile fibers (e.g., cotton, polyester, blends) where the choice of fibers is dictated by the intended application. The developed interconnection technology has been used to create a flexible and wearable framework to plug in sensors for monitoring a variety of vital signs including heart rate, respiration rate, ECG, body temperature, and SpO_2. In addition, voice can be recorded by plugging a microphone into the Smart Shirt.

These sensors can be positioned in desired locations on the body and will plug into the Smart Shirt. The motherboard or "plug-and-play" concept

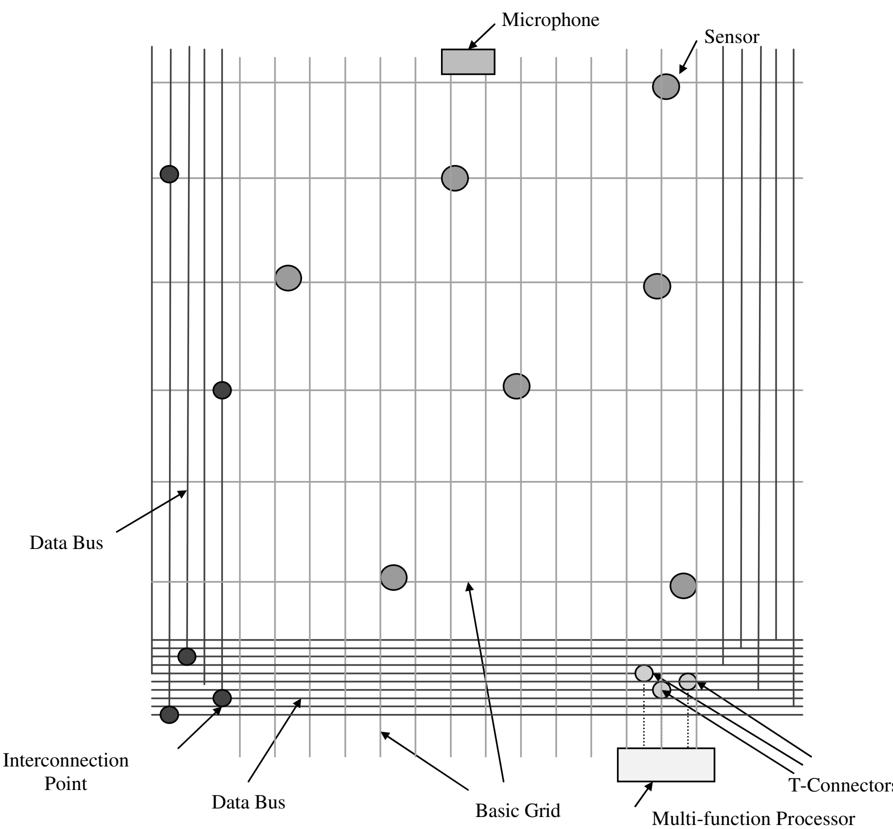

Figure 6.11 The wearable motherboard (Smart Shirt) architecture.

means other sensors (e.g., accelerometers to detect falls, carbon monoxide detection sensors) can be easily used with the structure. The flexible data bus integrated into the structure transmits the information from the suite of sensors to the multifunction processor known as the Smart Shirt Controller. This controller, in turn, processes the signals and transmits them wirelessly (using an appropriate communication protocol such as Bluetooth, 802.11b) to desired locations (e.g., doctor's office, hospital). The bus also carries information *to* the sensors (hence, the wearer) from external sources, thus making the Smart Shirt a valuable information infrastructure.[32]

6.5.2.2 Testing of the Smart Shirt

The vital signs monitoring capability of the Smart Shirt has been successfully tested in a variety of applications. The heart rate, respiration rate, ECG, and body temperature of individuals were measured using commercial off-the-shelf sensors that plugged into the Smart Shirt. Initial testing was done at Crawford Long Hospital in Atlanta, followed by another set of tests in the Department of Physiology at Emory University. An infant version of the Smart Shirt was subsequently tested in collaboration with the Egleston Hospital of Emory University School of Medicine.

The vital signs data were wirelessly transmitted to a personal computer or a medical ECG monitor (e.g., Nihon-Kohden hospital monitor). Figure 6.12 shows the display of key vital signs, including the ECG waveform. The garment is also comfortable and easy to wear and take off, similar to a typical undershirt. All these tests conclusively demonstrated the ability of the Smart Shirt to unobtrusively monitor the vital signs of individuals (from infants to

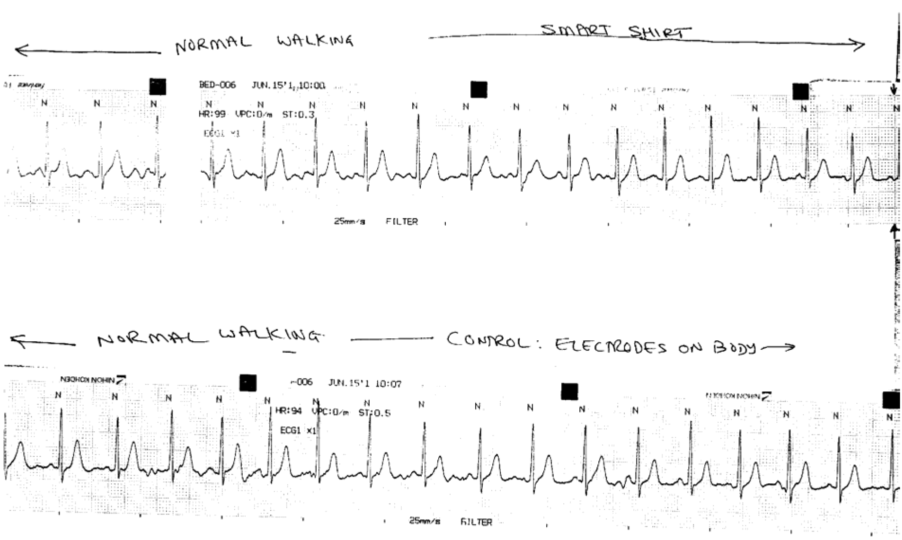

Figure 6.12 Wireless transmission of vital signs from the Smart Shirt. Top trace: from the Smart Shirt. Bottom trace: directly from the user.

adults) engaged in normal activities in an easy-to-use form with the convenience and familiarity associated with a garment.

6.5.2.3 Launderability of the Smart Shirt

The Smart Shirt successfully withstood a series of industry-standard launderability tests (washing and drying) typically carried out on textiles and apparel. In one such test, it was subjected to twenty wash/dry cycles; it functioned effectively after every wash/dry cycle, thus demonstrating the robustness of the wearable motherboard paradigm and embodying the principle of plug and play (the sensors and key electronic components are "unplugged" from the Smart Shirt prior to it being laundered).

The Smart Shirt facilitates multiparameter biomedical monitoring for mobile patients and enables personalized pervasive healthcare.

6.5.3 The next generation: Fabric as a sensor

Many sensors are not practical for long-term use and patient observation. For instance, the conventional ECG electrode has a conductive gel (silver-silver chloride) and an adhesive backing to affix the conductive lead to the patient's skin. Because the electrode sticks to the body, it is difficult to remove and can cause skin irritation when used continuously for extended periods of time. Therefore, for pervasive healthcare to realize its full potential, it is important to deploy sensors that do not have these shortcomings. The need to replace conventional ECG electrodes and eliminate the associated discomfort has led to the design and development of a fabric-based sensor and garment for obtaining the signals in monitoring vital signs.[33]

Figure 6.13 shows three different types of fabric-based sensor garments. In the first one, conductive materials (fibers/yarns) have been used to create a sensor (in the form of a stand-alone *patch*) that will replace the conventional ECG electrode for cardiac monitoring. This patch can be plugged into the lead wires of a Holter monitor (e.g., Zymed) or into the Smart Shirt discussed in Section 6.5.2. In another version, the conductive sensor has been integrated into the garment itself during manufacturing. The figure shows a knitted version of this next-generation sensing garment with integrated sensors in desired locations for obtaining ECG signals. It is important to have excellent electrical connectivity between the sensor and the body to ensure high fidelity signals. Therefore, to keep the sensors in place on the patient's body and ensure connectivity, spandex fiber is used as a form-fitting component in the sensing garment.

An infant version of the fabric-based Smart Shirt used for monitoring babies prone to SIDS (sudden infant death syndrome) is also shown in the figure. In fact, with this type of fabric-based sensing garment, it is possible to use the monitored vital signs to "close the loop" and provide a suitable response to the patient. For example, when the built-in sensor detects that a baby has stopped breathing, a small electrical pulse (shock) can be sent from a monitoring source to the child to stimulate breathing. By having

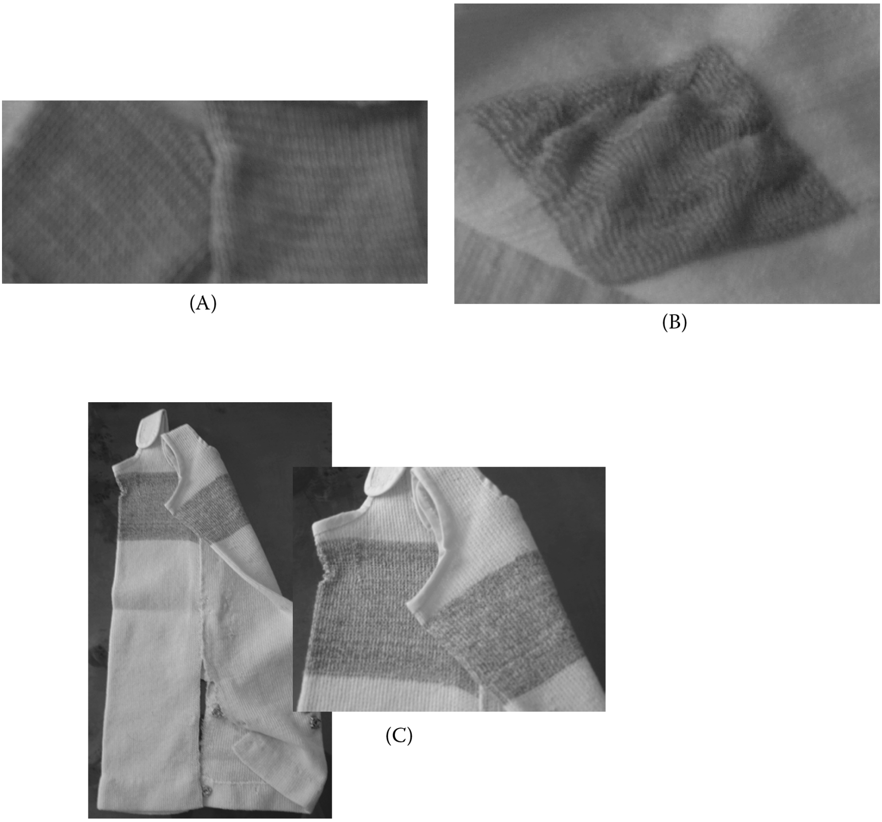

Figure 6.13 Fabric as a sensor for pervasive healthcare. (A) A pluggable stand-alone fabric-based sensor; (B) Smart Shirt with integrated intarsia knitted fabric-based sensor; (C) Infant Smart Shirt with fabric-based integrated sensors: multiple views.

a technology that is not only ubiquitous but also has the ability and intelligence to respond to the changes in the needs of the wearer, the quality of preventive care can be significantly enhanced, further reinforcing the paradigm that "investment in prevention is significantly less than the cost of treatment."

Thus, with the development of this new generation of fabric-based sensors (garments) such as the Smart Shirt, the textile-based pervasive healthcare system is a step closer to becoming a reality.

6.6 *Looking ahead: Challenges and opportunities*

Significant progress has been made in medical and information technologies over the last decade, resulting in the enhancement of the quality of life for everyone through better and increasingly pervasive healthcare. Change is the *only* constant today and the significant advancements in computing, communication, and biological systems offer exciting convergence opportunities that can be harnessed to meet the challenge of making pervasive healthcare a reality.

The pervasive healthcare system depicted in Figure 6.6 can be used as the basis for identifying these challenges and opportunities in each of the six *building blocks*: namely, sensors, data management, platform, operating systems, knowledge management, and networking. For pervasive healthcare to be truly successful, technology employing smart sensors with multifunction capability, integrated wireless communications capability, and low power consumption must be developed. The challenge is to balance functionality with the requirements of size and power consumption. Integration of these sensors into fabric-based networks that can be worn by patients or deployed in the environment points to the need for a standard or universal interface for these sensors.

In the typical pervasive healthcare scenario, multiple parameters (e.g., vital signs) will be continuously monitored. The challenge, and the opportunity, in the area of signal processing is to develop algorithms for multisensor data fusion that require minimal hardware so that the cost of the system can be minimized while keeping them "power-aware." Newer communications technologies (e.g., ZigBee) and their integration with smart sensors provide another active area of research. The success of pervasive healthcare depends on "closing the loop," that is, providing the right treatment at the right time to the patient without compromising the patient's other needs, such as privacy. The development of knowledge-based decision support systems that can facilitate such diagnosis and treatment presents ample opportunities for research. Of course, the challenge is to be able to "understand" and codify the physician's decision-making process. With the increasing use of computer-based physician order entry (CPOE) systems in hospitals, avenues are opening up for understanding the decision-making process and for documenting and assessing the impact of such decisions (treatments) on patients through electronic medical records (EMR). At a system level, issues related to the integration of the various enabling technologies shown in Figure 6.3 along with the requirements defined in Figure 6.4 and Figure 6.5 present interesting challenges and opportunities for research and development. Such a pervasive healthcare system will give rise to an integrated view of the patient as an information node. However, with it come significant amounts of data in various formats including text, graphics, audio, and video. For example, the medical record of an asthma patient intended for review by a specialist in a different location could, in addition to an x-ray image and quantitative data, contain an audio recording of the patient's breathing pattern. Tools and technologies for handling these multiple types and streams of data—while preserving the integrated view of the patient—must be developed to ensure their timely and effective utilization.

The ease with which personal data can be collected in real time using the various technologies described in this chapter will result in the creation of "knowledge banks" of human performance. This knowledge base can be used in clinical and pharmaceutical research and potentially lead to new treatments, drugs, and drug delivery systems. These benefits should be weighed in the context of potential invasion of personal privacy. Therefore, there is a critical need for a major initiative that brings together experts from the medical, insurance, and legal communities to address this important facet of advanced technologies so that society can harness the benefits from technological advancements and enhance the quality of life without sacrificing an individual's most prized possession: privacy.[9]

This chapter has shown how technology in general, and sensor technology in particular, is the catalyst that enables the transformation of today's healthcare to tomorrow's personalized pervasive healthcare.

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