WEARABLE MEDICAL DEVICES

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1. INTRODUCTION

A wearable medical device can be defined as a device that is autonomous, that is noninvasive, and that performs a specific medical function such as monitoring or support over a prolonged period of time. The term “wearable” implies that the support environment is either the human body or a piece of clothing. Handheld and portable devices are therefore not strictly speaking wearable, but this distinction is not always clear as it also depends on the conditions of their use. Personal digital assistants (PDAs), for example, are handheld devices by design, but they have been used as components of wearable personal medical monitoring systems. In a broader sense, commonly used medical equipment such as splints, bandages, eyeglasses, and contact lenses can be referred to as wearable medical devices, because they are wearable and provide a medical function. In this context, however, we deal more with sophisticated devices that integrate mechanical functions with microelectronics, computing capabilities, and in some cases, a degree of intelligence. The medical functions that are currently performed by such devices cover applications of medical monitoring, rehabilitation assistance, and long-term medical aid.

Wearable monitoring devices assist in managing the treatment of chronic diseases such as heart diseases, asthma, and diabetes and the monitoring of vital signs such as heart rate, blood oxygen level, respiration, and body fat. They normally provide noninvasive sensing, local processing, user feedback, and communication capabilities. However, most of the current devices usually rely on user intervention to record data that are processed later offline. The most established wearable monitoring device is the heart holter monitor that records the cardiac activity of patients during normal activities, usually for a time period of 24 hours. Electrodes are placed on the patient’s chest and are attached to a small recording monitor that is worn by the patient and is battery operated. Patients are required to keep a diary of their activities used by their therapist along with a tape of the recordings. Any irregular heart activity can then be correlated with the patient’s activity at that time.

The next generation of wearable monitoring devices goes beyond recording and aims to provide intelligent patient monitoring with real-time feedback, in the form of alerts and clinical decision support (1). Such devices collect, process, display, and often transmit information related to the user’s health condition, which involves the use of noninvasive electronic, mechanical, or biochemical sensors for monitoring physiological and kinesiological parameters, depending on the application. A processing unit deals with the incoming information and provides the necessary feedback. Devices with wireless connection capabilities can instantly send alerts to the health care provider, which provide ambulatory health monitoring within the health-care environment. Sleep apnea monitors are examples of medical monitoring and warning devices available at home or at the hospital (2). They monitor patients in periods of high risk, such as infants susceptible to sudden infant death syndrome. The infant wears a respiratory effort belt while sleeping, and an alert is provided to the parents or doctors when the breathing patterns cause reasons for concern.

The miniaturization of wearable devices enables the provision of clinical monitoring beyond the hospital area, in the home or during outdoor daily activities. The evolving applications of multisignal monitoring, real-time monitoring, and the incorporation of varying degrees of intelligence improve their capabilities. Feedback and assessment is provided to the wearers in real time. Devices incorporating wireless data transmission capabilities can also immediately communicate with remote sources or destinations of information providing a telemedicine service. Products with such capabilities are already available, and they target the health market, researchers, health-conscious individuals, and athletes. Patients can constantly monitor several vital signs such as electrocardiography (ECG), respiration, skin temperature, pulse, blood pressure or blood oxygen saturation, body kinematics, as well as sensorial, emotional, and cognitive reactivity. The analysis of the received information provides feedback in the form of alerts or medical decision support directly to the patient and the medical supervisors. Devices intended for athletes measure parameters such as heart rate, pace, speed, and calorie burn, with the information constantly accessible during exercise. They also enable the long-term monitoring of progress and planning of workouts. It is important that these advancements provide an improved service to the users while minimizing the risk of becoming overwhelming.

Wearable medical aid devices are designed to provide long-term assistance to patients with temporary or permanent disabilities. Conventional medical aid devices include contact lenses and hearing aids, both of which provide specific medical functions. More advanced systems include information processing capabilities such as speech recognition, contextual awareness enhancement, alerts, or feedback. Examples of such devices include a range of global positioning system (GPS)-based navigation devices designed for the visually impaired to assist in wayfinding, obstacle avoidance, and navigation (3).

Wearable rehabilitation assistance devices can combine functions of monitoring and medical aid devices for patients in rehabilitation. A monitoring device may assist in rehabilitation through the prevention or diagnosis of potentially dangerous situations for patients in periods of high risk, such as after surgery or a heart attack.
The design of wearable medical devices poses a range of considerations and technical challenges, because they are used under varying and often demanding conditions. Several devices are used in specific environments, such as the hospital, home, or sports field. Others can be used during specific periods of time, as while sleeping, in periods of high risk, or during exercise. Technical issues that need to be addressed include (4)

- **Biomedical sensors**: For measuring physiological and kinesiological parameters. They need to be noninvasive, reliable, compact, wearable, and capable of integration with the device.
- **Data Handling**: It involves decisions on the type and amount of data to be recorded, stored, and transmitted.
- **Decision support**: It refers to custom-developed algorithms combining and analyzing medical data to provide decision support. These are usually based on fuzzy logic or neural network models.
- **Feedback**: Deals with decisions involving the nature, frequency, and quality of the feedback provided to the patients.
- **Telecommunications**: This involves the link between the sensors and the device and the link between the device and the health provider. It also deals with standardization and interoperability issues such as the ability of the devices to communicate between them and with existing hospital information systems.
- **Physical Design**: It refers to issues dealing with the physical shape, size, and weight of a wearable and its ergonomics. For some devices, this process also involves the distribution of wearable components around the body, as well as their attachment to the human body.
- **Autonomy**: Deals with the power requirements of the device, which have to be met for specified periods of use.

In addition, several other issues must be considered. These include

- **User acceptability**: The acceptability of the device depends on the conditions of its use, its user friendliness both during setup and operation, its comfort and wearability, the quality of the feedback, and its functional value as perceived by the user.
- **Legal and ethical issues**: This addresses patient confidentiality and the protection of sensitive personal medical data.
- **Safety and reliability**: Potential physical and operational risks are examined through the operation of the device in its intended use conditions and use environment.
- **Validation plan**: A set of validation trials dealing with possible clinical scenarios must be carried out against diagnostic or screening tests.
- **Risk analysis**: It deals with security problems for each specific application and helps in determining contingency plans to ensure a level of security corresponding to the level of risks.

The impact of wearable medical devices on personal health care is currently limited. As far as individuals are concerned, this is expected to change, as people become more health conscious and increasingly behave as health consumers. Health-care providers must offset the direct and indirect cost of the devices by increasing the number of patients moving from hospitals to their homes during rehabilitation, by avoiding unnecessary hospitalizations, by enabling prompt hospitalization reducing the likelihood of long-term treatment, and by freeing up dedicated beds with heavy equipment. The indirect costs include the availability of a physician for receiving and assessing telemedicine information and for providing a point of contact in case of an emergency, the cost of training the patients to setup and use the device, and maintenance costs. An exception to the financial line of thinking is made when the device significantly improves the patient's quality of life, particularly when considering patients with chronic diseases or disabilities.

The market for medical devices that are either wearable or used at home has seen a dramatic increase in recent years. Its size in 1992 was $1.6 billion (2). In 2001, the market for medical devices with microsystems and nanotechnology alone reached $5.2 billion (5) and is expected to grow. However, the growth in miniaturized medical technology has not been accompanied by a corresponding decrease in hospital utilization. This lag can be partially explained by issues normally associated with the development of new medical products, such as the requirements for clinical testing, the strict legislation rules for manufacturing and testing clinical products, and the potential threat of litigation. These reasons may have contributed to wearable medical devices acting mainly as complementary rather than as alternatives to hospital equipment. However, their ever increasing capabilities combined with their practical benefits in providing unconfined medical monitoring, medical assistance, improvement in the living conditions of chronically ill patients, and point-of-care service in remote locations should make them cost effective in the not-so-distant future.

2. **HISTORICAL OVERVIEW**

The ongoing development and increase in wearable medical devices follows the greater health trend to move from hospital care to home care, and subsequently to personal health care. As a consequence, developers are shifting their focus from fully fixed medical systems to portable ones and more recently to wearable ones. Wearable devices provide a miniaturized and versatile means for medical monitoring and support, but their core medical functions are based on existing technologies. Their
development has been made possible by parallel advance-
ments in microsensor technology, wearable computing
technology, and wireless communications and their inte-
gration with textile technologies that enable wearability.

The first wearable medical application was the holter
monitor, which was used for the acquisition of data that
were stored in a wearable device and evaluated at a later
stage. In the 1990s, telemedicine was a new concept and
was used by health-care providers mainly for obtaining a
second opinion and for patient consultation regardless of
time and location. The requirement for real-time accessi-
bility to the monitored individual has led to the develop-
ment of wearable devices that combine clinical data
recording and handling functions with telemedicine in
the form of real-time wireless telemetry. The first devices
of this nature were initially developed for high-profile ap-
lications such as the U.S. space program, where NASA
continuously monitored the physiological responses of
astronauts in space. This was followed by the U.S. army,
which developed wearable battlefield computers through the
Land Warrior program (6). These computers have a
range of operational capabilities, part of which is moni-
toring the soldier’s health and his ability to fight. Apart
from knowing whether the soldier is alive, the analysis of
vital signs such as heart rate and breath rate can serve as
indicators of the current level of fatigue, stress, and anxi-
ety. The next stage of improvement is to provide the mon-
itoring personnel with decision support. A medical status
monitor reading blood pressure, pulse, respiration, and
blood oxygen level can use an expert system to determine
the soldier’s condition. When appropriate, an alarm is
transmitted along with the soldier’s GPS location and pos-
sibly injury severity. The incorporation of telemedicine fa-
cilities within the wearable computer can assist the
soldier to cope with his or her condition (7). Wearable
medical devices with such capabilities are currently be-
coming commercially available. They are predominantly
used for monitoring the vital signs of patients in high-risk
periods, for the remote monitoring of patients when direct
medical support is not available, for monitoring athletes,
and for research purposes.

3. TECHNOLOGIES

The development of wearable medical devices requires
components that are small, light, durable, and comfort-
able, and that provide the necessary functions reliably and
safely at low cost. These requirements have been made
possible by recent advancements in wearable technology,
particularly through the miniaturization of sensor tech-
nologies, computer and wireless communications technol-
gies, and through the novel concept of computational
clothing.

3.1. Sensors

There are specific requirements in selecting and using
sensors for wearable devices. Wearability implies that
they must be noninvasive, having the added advantage
of offering painless measurement, comfort, and preven-
tion from infections and contamination. The sensor must
provide an electrical output so that its measurements can
be digitally processed. Both requirements limit the range
of sensors that can be used. Once these conditions have
been met, sensor selection is based on the functional re-
quirements of the device and there is usually a tradeoff
among size, cost, power consumption, durability, and its
reliability in the intended operating environment. The se-
lection may also be influenced by the operating conditions.
Piezoelectric sensors, for instance, are of limited use when
the subject is moving.

The sensors are attached to the human body and moni-
tor physiological or kinesiological conditions such as
the heart and muscle activities, respiration, skin temper-
ature, blood pressure, posture, movement, and accelera-
tion. A wearable device may also include a wide range of
peripheral sensors monitoring or receiving information
from the outer environment. These sensors include cam-
eras, microphones, contact sensors, environmental sen-
sors, GPS, and geographic information system (GIS)
inputs (8). Noninvasive medical sensors commonly used
in wearable devices include

- Skin surface electrodes—used for detecting surface
  potentials in bioelectric signal monitoring such as for
  ECG, electroencephalography (EEG), and electro-
  myography (EMG).
- Temperature thermistors—for detecting skin surface
  temperature.
- Piezoelectric sensors—often used for monitoring
  heart rate and respiratory effort.
- Photoplethysmography (PPG) (9)—for the detection
  of blood volume changes of a selected skin area. In-
  frared light is emitted into the skin and is absorbed
  according to the blood volume in the skin. The back-
  scattered light corresponds to the variation of the
  blood volume. Blood volume changes can be deter-
  mined by measuring the reflected light and using
  the optical properties of tissue and blood. PPG
  techniques have provided indirect measures of blood
  pressure.
- Pulse oximetry—a technique for detecting blood oxy-
  gen saturation and heart rate from a PPG signal. An
  infrared emitter/receiver is worn on parts of the body
  where the blood vessels are close to the skin (finger,
  ear lobe), monitoring the percentage of hemoglobin
  saturated with oxygen. Light is transmitted through
  the skin, and some amount is absorbed by the blood.
  The detector reads out continuously the varying con-
  centrations of oxygen in the blood. The heart rate can
  be indirectly deduced from the variation in concen-
  tration over time.
- Galvanic skin response—detecting skin conductance
  in relation to skin hydration.

In addition, many types of sensors take advantage of mi-
croelectronics technology. These include some applications
of micro electromechanical systems (MEMS) and micro-
electronic biosensors.

MEMS have been used in the medical industry since
1980 for a variety of applications, and they are small,
reliable, and inexpensive. The most commonly used MEMS in medical sensing applications are based on the Wheatstone bridge piezoresistive silicon pressure sensor, which is used in various forms to measure blood pressure, respiration, and acceleration (10).

Microelectronic biosensors monitor biological processes and are either calorimetric or electrochemical (11). Calorimetric biosensors are based on the detection of the heat of biological reactions, by using conventional thermistors, thermopile sensors (an array of thermocouples), silicon, or thermopiles integrated on thin micromachined silicon membranes. They are used for monitoring enzymatic reactions. Electrochemical biosensors are subdivided into (1) conductometric biosensors measuring the impedance between planar electrodes that have found limited applications; (2) potentiometric transducers determining the electrical potential between two electrodes at zero current flow (e.g., the pH electrode and related ion-selective electrodes); and (3) amperometric biosensors measuring the current derived from a redox reaction at an electrode. They detect and monitor enzymes such as glucose, lactate, and urea.

The development of sensors for wearable medical applications is a research field of high interest. Ongoing research efforts aim to produce multi-biosensor elements, integrating amperometric and potentiometric sensors on one substrate forming an integrated laboratory on a chip (11). Research into wearable ethanol-vapor skin surface sensors (12), or for the development of wireless biomedical applications is a research field of high interest. Ongoing research efforts aim to produce multi-biosensor elements, integrating amperometric and potentiometric sensors on one substrate forming an integrated laboratory on a chip (11). Research into wearable ethanol-vapor skin surface sensors (12), or for the development of wireless biomedical applications, improves the potential capabilities of wearable medical devices and increases their design flexibility.

3.2. Clothing

The term computational clothing refers to pieces of clothing that have the ability to process, store, retrieve, and send information (13), which is achieved either by attaching or embedding electronic systems into conventional clothing and clothing accessories, or through the merging of textile and electronic technologies.

Clothing with embedded sensors and computing components is particularly relevant for wearable medical devices as clothing provides an ideal supporting structure for simple sensors, particularly for the upper part of the body. Multisensor clothing has been used in applications of context awareness and medical monitoring, which allow for multisensor data fusion of distributed or centralized sensors (14). Prototype applications include the development of networked clothing such as Internet-connected shoes, which allow one to run with a jogging partner located elsewhere. The prototype detects the runner’s pace by monitoring the impact of the shoe on the ground, informs the partner through the Internet connection, and thereby enables both runners to run at the same pace. Another prototype example is the ProComp system, which incorporates ECG, EEG, respiration, and sweat sensors built in a bathing suit for monitoring individuals during sleep. The measurements assess discomfort for adjusting room heating (15). Computing hardware and sensing components have also been integrated into fashion accessories, such as belts, jewelry, gloves, eyeglasses, and wrist watches. Eyeglass-based head-mounted displays and eyeglass-based complete multimedia computer systems that include cameras, microphones, and earphones are already commercially available.

A different approach is to integrate circuits into clothing during the manufacturing process and produce electronic textiles (e-textiles). The objective is to create fabrics that can be crushed and washed and to retain their properties unaffected. Post et al. (16) described the fabrication of computing textiles as e-broidery. They created textiles incorporating conductive fibers of metallic silk organza, a finely woven silk fabric with a thin gold, silver, or copper foil wrapped around each thread. A strip of this fabric can function as a ribbon cable. They created a row and column fabric keyboard that can be rolled up, crushed, or washed and operated with direct electrical connections. They also developed a musical jacket with an embroidered keypad. This jacket allowed the wearer to play notes, chords, and rhythms using the keypad and through any instrument with MIDI facilities. The keypad used capacitance change as a sign of pressing a key. Park and Jayaraman (17) presented a wearable motherboard (Smart Shirt) consisting of sensing devices containing a processor and a transmitter. It was formed by a mesh of electronically and optically conductive fibers integrated into the normal structure of the fibers and yarns that created the garment (Fig. 1). The research into e-textiles is ongoing and seeks materials with electric properties. Lorussi et al. (18) developed a wearable sensing garment for detecting posture by identifying the position of joints, and for enabling the remote description of posture through telemedicine for

Figure 1. The Georgia Tech Wearable Motherboard (courtesy of the Georgia Institute of Technology, Atlanta). (This figure is available in full color at http://www.mrw.interscience.wiley.com/ebe.)
monitoring and rehabilitation applications. The authors fabricated a sensing glove detecting the posture of the hand with lycra-based textiles, treated with polypyrrole and carbon-filled rubber materials for creating strain-sensing fabrics. Piezoelectric materials may also offer many benefits to wearable applications as they have low power consumption and can potentially generate power, detect motion, create sound, and respond to sound (they have already served as microphones in basic sound detection devices). Edmison et al. (19) developed a prototype glove based on piezoelectric materials to detect typing motions that allowed the glove to replace a keyboard.

Fabrics developed primarily for the sport industry are now finding use in everyday clothing and have the potential to assist in wearable computing applications (13). These include electroconductive fabrics for protecting digital circuits and the safety of the wearer and intelligent fabrics responding to their environment. Phase-change materials such as polyethylene glycol and zirconium carbide can trap and release heat responding to inverse temperature changes of their environment. Sweat-absorbent fabrics are made of polyester and are formed with a hollow center and with many micropores on the surface. Sweat is absorbed through the pores and diffused in the hollow center leaving the fiber surface dry.

3.3. Computing Hardware

Computer technology provides the means for handling and communicating digital information and is the backbone of any wearable device. The ongoing miniaturization of computing hardware and of the supporting accessories has led to the development of components that enable wearability (13,20). Common components in wearable prototypes include

- Processing Unit: Custom-developed wearable research prototypes are often based on the PC 104 motherboard, which allows design flexibility and the inclusion of components that may not be jointly available in commercial products. Industrial and research products are commonly based on PDA platforms, which provide all required processing and interaction facilities in a single box. More advanced prototypes make use of user-programmable integrated circuits, such as field programmable gate arrays, electronically programmable logic devices, and complex programmable logic devices. The functions of these circuits are identified by a user program and are not set by the manufacturer. The integration of hardware and software components maximizes the overall processing speed of the system while minimizing the CPU’s requirements. Wearable medical devices particularly benefit from digital signal processing microchips.
- Data storage: The current trend is to use Compact Flash memory cards, which are light and small, making them ideal for use in PDAs and wearable applications. They are also robust and reliable and do not require a battery to retain data indefinitely. The available capacities currently range from 8 MB to 3 GB.
- Input/output devices: Developers have used technologies that facilitate human–computer interaction while trying to avoid hindering other activities. For input devices, these technologies include microphones in conjunction with voice recognition software, body-mounted keyboards, miniaturized pointing devices, touch screens, or handheld keyboards (21). Common output devices include miniature liquid crystal displays, clip-on monitors or embedded monitors in glass frames, and speakers.
- Wireless medical telemetry/communications: Wireless communications are required for transferring information between sensors and the device, between the device and the telemedicine server, and for providing Internet access. The available medical telemetry frequency bands are (22) (a) The VHF band at 174–216 MHz; (b) The UHF band at 450–470 MHz; (c) The industrial, scientific and medical (ISM) bands at 902–923 MHz and 2.4–2.483 GHz, and (d) the wireless medical telemetry service bands at 608–614 MHz, 1395–1400 MHz, and 427–1432 MHz. Many telemetry systems are also based on wireless infrared data association (IrDA) serial data links. The data transfer volume, speed, and range requirements often dictate the wireless protocol, and are particularly important in real-time applications. Communications between the device and the sensors, or generally between the wearable components of a device, is achieved through wireless personal area networks, also referred to as body area networks (23). They are increasingly based on the Bluetooth protocol (incorporated in IEEE Std 802.15.1 = 2002, and IEEE Std 802.15.2 = 2003) operating in the 2.4-GHz ISM band. Communication between the wearable device and the telemedicine server is achieved through a wireless local area network, based on the IEEE 802.11 standard (ANSI/IEEE Std 802.11 = 1999 and subsequent supplements and amendments), which is essentially a wireless extension of the ethernet and often referred to as wireless fidelity. It also operates in the 2.4-GHz ISM band. Cellular mobile phone technology, such as global system for mobile communications (GSM) and the third-generation universal mobile telecommunications system (UMTS) protocols, provide the means for mobile communication and Internet access. These are also described as wireless mobile area networks.

4. APPLICATIONS

This section presents a range of wearable medical devices and applications that are either subjects of research or are already commercially available. They provide solutions for both personal (patient) and user (physician or health-care provider) applications (1). They are subdivided into wearable monitoring devices primarily for monitoring and feedback, rehabilitation devices for assisting in the
The main components of a wearable medical device are shown in Fig. 2. The sensors refer to all components for monitoring a person or the surrounding environment and involve the information that is automatically collected by the device. The input devices are the hardware components used by the user to enter information into the system. The wearable computer is the heart of the system providing all data processing, data storage, and the means for wireless communication. The remote server is any distant communication link between the wearable and the outer world. It involves connections with local area networks, connections to the Internet, and with telemedicine facilities. The output devices are either the components that provide a display/feedback or the means of taking an action as a result of data processing (e.g., functional stimulation, drug delivery).

4.1. Wearable Monitoring Devices

The primary function of medical monitoring devices is to provide dedicated monitoring of specific medical conditions. Apart from the previously described Holter and sleep apnea monitors, dedicated wearable monitoring devices have been in clinical practice for the monitoring of myocardial ischemia, the long-term monitoring of heart rate variability, the detection of epileptic seizures, the detection of drowsiness, and the provision of physical therapy feedback during rehabilitation. A recent commercial application is the noninvasive blood glucose monitoring for patients with diabetes (24). It is achieved through a wrist-worn device extracting glucose through intact skin via reverse iontophoresis, and with glucose being detected by an amperometric biosensor. The device provides readings every 20 min for 12 hours along with alerts indicating when abnormal measurements are encountered.

Multisignal monitoring devices are multipurpose devices that are predominant in medical research as long-term health pattern recorders. Many promising ideas remain on the drawing board and have not yet reached the development stage. However, some devices have been successfully commercialized, the main application fields being the monitoring of athletes during exercise, and the monitoring of patients within the health-care environment.

Examples of commercially available products include the Bodymedia SenseWear Pro Armband (Pittsburgh, Pennsylvania, USA) (25), a wireless wearable body monitor collecting physiological and lifestyle data such as movement, heat flow, skin temperature, ambient temperature, and galvanic skin response (Fig. 3). Vivometrics LifeShirt (Ventura, California, USA) shown in Fig. 4 is a noninvasive ambulatory monitoring system in a single garment unit with embedded sensors, which monitors 40 physiological signs, including heart rate, breathing, and lung capacity (26). The AME wearable polysomnograph is a wearable 16-data channel recorder with ECG, EMG, electrooculography, EEG, chest effort, pulse oxymetry, body position, airflow, and snore sensors. It provides local recording and an optional wireless digital radio connection for data transmission, and it is designed for a clinical environment (27).

![Image](http://www.mrw.interscience.wiley.com/ebe.)

Figure 2. Components of wearable medical devices. (This figure is available in full color at http://www.mrw.interscience.wiley.com/ebe.)

![Image](http://www.mrw.interscience.wiley.com/ebe.)

Figure 3. The LifeShirt (courtesy of Vivometrics, Inc.). (This figure is available in full color at http://www.mrw.interscience.wiley.com/ebe.)
More complex approaches and applications are continuously investigated and have shown a great potential. One application is a wearable monitoring device for monitoring psychological states such as driver stress (28), which is performed by measuring skin conductance, respiration, muscle activity and heart activity, and supplemented by an attached digital camera capturing the driver’s facial expressions. Each feature is ranked individually, and an intelligent algorithm identifies the optimal set of features for recognizing the patterns of driver stress. Much effort has also been put on the development of monitoring aids for athletes. FitSense (Southborough, Massachusetts, USA) and Nike (Beaverton, Oregon, USA) are among the manufacturers having developed wearable monitoring and motivational aids for improving the performance of athletes. Promising research efforts have focused on monitoring athletes during rehabilitation, for assessing the recovery of physical fitness and for providing medical decision support aiming to prevent injury relapses (29). This particular system (Fig. 5) is composed of a wearable platform monitoring athlete motion, respiratory effort, heart condition, temperature, blood pressure, and injury pain in real time. Measurements are wirelessly transmitted to a central monitoring unit and can be accessed by trainers and medical professionals. Real-time feedback is provided to the athlete and the monitoring personnel through a virtual reality interface. A portal stores long-term information for research purposes.

4.2. Wearable Rehabilitation Devices

Wearable rehabilitation devices actively assist in the rehabilitation process. The most recognizable devices are those associated with mechanical orthosis and can range from a simple splint to a wearable tremor assessment and suppression orthosis, which applies mechanical damping to suppress tremor (30).

A technology with significant prospects in wearable rehabilitation devices involves external electrical nerve stimulation for controlling pain and for providing functional stimulation. Small electrical impulses applied by transcutaneous electrical nerve stimulation block pain (31), whereas functional electrical stimulation (FES) exploits the same principles for controlling weak or paralyzed muscles, assisting in the restoration of gait and movement in persons with paraplegia, cerebral palsy, or when recovering from heart strokes (32). The principle of FES is already commercially available in some wearable forms of sporting equipment for exercising several muscle groups.

The wearable accelerometric motion analysis system prototype (33) is designed to monitor people with balance disorders, acting as a diagnostic tool to quantify hitherto qualitative measures of balance, as a biofeedback device during therapy and as a fall-prevention aid for institutionalized and community-living fall-prone elderly. It consists of two small triaxial digital accelerometers attached on eyeglass frames for measuring head motion, and two more accelerometers attached on a belt at the waist. A handheld control is used to control the wearable unit. The system interacts wirelessly with the accelerometers and provides real-time visual, speech, and/or nonverbal feedback to trainers, medical professionals, and researchers.
auditory feedback to the user, which communicates the patient status to a remote clinician and recognizes if the system is unused or used incorrectly.

A wearable sensing garment for detecting posture was developed in a research effort to identify the position of joints, and to enable the remote description of posture through telemedicine for monitoring and rehabilitation applications (18). The authors fabricated a sensing glove detecting the posture of the hand with lycra-based textiles treated with different materials and incorporating strain-sensing fabrics.

Another example of a wearable rehabilitation device is the wearable ultrasound platform for the remote monitoring and acceleration of the healing process of long bones (34). This prototype system incorporates a pair of miniature ultrasound transducers implanted into the affected region, an ultrasound wearable device, and a centralized unit located in a clinical environment. The system is designed for patients with open fractures treated with external fixation devices. The wearable device is mounted onto the frame of the external fixator and is responsible for the initiation of low-intensity pulsed ultrasound therapy sessions, for carrying out ultrasound measurements and for wirelessly communicating the data with the centralized unit.

### 4.3. Wearable Medical Aids

We describe as wearable medical aids the wearable devices that improve the user’s quality of life, but that do not necessarily help in rehabilitation. They have also been described as assistive technology devices allowing their users to experience higher levels of independence and social and vocational participation (35). These devices include the long-term functional aids for the cognitive and physically disabled and the chronically ill. Basic applications include devices such as hearing aids and glasses, whereas more advanced applications can provide communication assistance, memory assistance, and context awareness.

Augmented reality involves a head-mounted display that serves as a means for projecting computer-derived information in the physical environment for augmenting real objects (7). Prototype applications of augmented reality have not particularly focused on medical applications, but the potential is there to develop applications for assisting doctors and surgeons while performing their clinical duties, or to function as memory aids for the elderly suffering from memory loss and Alzheimer’s disease.

The PARREHA project (36) has developed a prototype wearable computing platform for assisting patients suffering from Parkinson’s disease. Clinical research indicates that certain types of visual information, when combined with human sensory data, can greatly enhance patients’ coordination while walking. The patients wear a head-mounted display on one eye superimposing computer-generated geometric shapes giving them visual cues with sensory data to help navigation. They found that the system greatly enhanced patients’ awareness, motor skills, and coordination specifically related to walking.

There have also been considerable efforts to develop GPS-based navigation and guidance aids for the visually impaired (3). Prototype systems make use of a GPS receiver for locating the traveler with respect to his surrounding environment, and who is represented in a spatial database forming part of the GIS within the computer. Systems also integrate differential correction for GPS localization, a compass for determining the traveler’s orientation, and a mobile phone for communicating with a central server to retrieve information. A synthetic speech display then provides information about locations of nearby streets, points of interest, and instructions for traveling to desired destinations.

The applications of assistive technology devices can be increased significantly with the inclusion of implantable components in the system. For example, phrenic nerve stimulation is currently the only available alternative to mechanical ventilation for patients suffering from respiratory muscle paralysis. Emerging alternative techniques such as intramuscular diaphragm pacing, combined intercostals muscle, and unilateral phrenic nerve stimulation are also based on the principle of electrical stimulation (37). Therefore, the combination of a wearable control unit and a set of implanted electrodes can potentially provide a portable respirator.

### 5. DESIGN CHALLENGES

Wearable medical devices have two important characteristics differentiating them from other medical devices. The first is that they are wearable, which implies that they are likely to be used in varied environmental conditions and should be comfortable, nonobtrusive, autonomous, and compact, while raising several technical considerations. The second is that the patient plays a predominant role in their proper use, which has important design implications on their ease of setup and use, and on the nature and means of providing the patient with medical support during their use. Finally, as with any commercial product, a range of financial issues will influence their acceptance and use.

#### 5.1. Ergonomics and Wearability

The ergonomics and wearability of wearable devices play a decisive role in meeting the functional needs and for their acceptance by their prospective users. Wearability is defined as the interaction between the human body and the wearable object, and dynamic wearability extends this definition to include the human body in motion (38). Ergonomics and wearability deal with a wide range of design issues including the physical shape of wearables, their active relationship with the human anatomy in motion, their acceptability as a function of comfort, fashion, and purpose, the relationship between the wearable device and the work environment, the physical factors that affect their use, and the human–device interaction (39). A list of general design guidelines for wearability developed at Carnegie Mellon University is presented below, which outline the considerations and principles that need to be taken into account during the design of wearable products (38):

- **Placement:** It involves the selection of the location for placing the wearable on the body, so that it is unobtrusive.
Form Language: The shape of the wearable must ensure a comfortable and stable fit, while protecting it from accidental bumps and nags.

Human Movement: The wearable should allow freedom for the movement of joints, the shifting of flesh, and the flexion and extension of muscles by designing around the more active areas of the joints or by creating moving spaces on the wearable form.

Proxemics: Proxemics refer to the aura around the body that the brain will perceive as part of the body. Intimate space can be between 0 and 5 in (0–13 cm) off the body. The rule of thumb is to minimize thickness as much as possible.

Sizing: The wearable must be designed to fit as many types of users as possible, taking into account both the shape of a body and the ways in which weight and muscle is gained and lost.

Attachment: It deals with the form of the wearable for its attachment to the body, while allowing for size variations. Attachment is particularly important for sensors as dislocations and movements may cause significant interference on the received inputs.

Containment: The containment of the required components will often dictate the overall shape and nature of the device, which particularly affects multisignal medical monitoring devices having sensors spread out in various locations of the body.

Weight: The overall weight of a wearable should be kept as low as possible. Weight distribution is also important as heavier loads can be carried closer to the center of gravity of the body around the stomach, waist, and hip than the extremities. Loads should also be balanced to avoid altering the body's natural movement and balance.

Accessibility: Refers to the location of the wearable on the body to make it usable, which depends on the need for visual, tactile, auditory, or kinesthetic access on the human body.

Sensory Interaction: This involves the way the user interacts with the wearable, passively or actively, and should be kept simple and intuitive.

Thermal aspects: There are functional, biological and perceptual thermal aspects of designing objects for the body, as it needs to breathe and is very sensitive to products that create, focus, or trap heat.

Aesthetics: The culture and context of use will dictate the shapes, materials, textures, and colors of the wearable.

Long-term effects: The long-term effects of the use of wearable devices on the human body are currently unknown, and if any, they could be dependent on their nature and their use conditions.

These guidelines cover a significant range of issues concerning the design of wearables, and they address issues that enhance user acceptability. It is accepted that trade-offs exist between them, and that some can be overlooked in applications of static wearability. Medical devices will often have additional design restrictions, as many components will need to be located at a specific part of the body to provide their medical function. From an ergonomics point of view, Knight et al. (40) clustered a list of 92 terms describing how wearing a device may affect the wearer and how the wearer feels (physically and mentally) about the device, and they proposed a list of six comfort descriptors and corresponding rating scales for assessing the comfort of wearable computers. These descriptors are:

1. Emotion—dealing with concerns about appearance and relaxation: I worry how I look when I wear this device or I feel tense or on an edge because I’m wearing the device;
2. Attachment—covering the physical feel of the device on the body: I can feel the device on my body or I can feel it moving;
3. Harm—describing the physical effect or damage to the body: The device is causing harm or is painful to wear;
4. Perceived change—Wearing the device makes me feel strange, physically different, upset;
5. Movement—The device physically affects movement or inhibits or restricts movement; and
6. Anxiety—Worry about the device, safety, and reliability.

5.2. Technical Considerations

5.2.1. Safety. No device should cause harm to patients, irrespective of its clinical duties. The noninvasive nature of wearable devices reduces the likelihood of causing direct harm, but there are also known circumstances where they may cause nuisances and inconvenience to their users, such as skin rashes caused by the prolonged use of some sensors. Apart from the general risk factors associated with any medical device, wearables can be easily misused, as they are intended for use by nonexperienced users with no medical training, with diverse educational backgrounds, and a varying degree of familiarization with technological equipment.

5.2.2. Reliability. Reliability is an essential parameter for the acceptance of any medical device. Continuous false alarms or breakdowns will diminish their functional utility and result in frustration and reduced usage. Apart from any functional implications, the underachievement of a monitoring, alerting, or supporting device may also have medical implications. Reliability is therefore particularly important for medical devices designed for monitoring and dealing with potentially life-threatening situations and for devices designed for long-term use without expert intervention, such as hearing aids.

The reliability of wearable devices is particularly affected by factors related to the conditions of their use. Wearable devices are often designed to operate in noncontrolled environments with varying humidity and ambient temperature. Furthermore, physical factors such as sweating, vibration, or movement may affect the operation of the hardware components, such as causing dislocation or loss of contact of surface sensors. Backup systems to enhance reliability are avoided when not essential, as they would normally increase the size and complexity of the system. The reliability of a wearable medical device can be improved by simplifying its design and, hence, reduce the number of hardware or software components that can fail. This approach also fits in with the
crucial ergonomics requirement of keeping the total size and weight of the system as low as possible. For devices monitoring vital signs or other medical parameters, reliability can be improved through redundant sensors providing backup inputs.

5.2.3. Information Handling. Wearable medical devices may collect, process, display, and possibly transmit information, all of which have their particular requirements. The data-handling considerations listed as follows are relevant to most types of wearable devices and are particularly relevant to wearable monitoring devices.

5.2.3.1. Data Acquisition. Data may be acquired by a wearable system though various means. It may be the result of the direct input by the user, the connection to a sensor, or through a wireless connection. User input is usually achieved through a range of input keys, a touch screen, or even speech recognition software and is supported by a user interface. Sensors require their rooting and connection, often through multichannel input hardware, that will also convert analog inputs to a digital form. Wireless data transfer requires the incorporation of a transceiver within the wearable’s processing unit. It is important to note that the reliability of the acquired data may be affected significantly by environmental factors. A high level of noise will affect the recognition utility, whereas ambient temperature and humidity may affect sensor readings. Wireless transmission will also have its distance and transfer rate limitations.

Wearable medical sensors provide design challenges, and their selection is influenced by their intended conditions of use. Piezoelectric sensors, for example, are of limited use if the subject is expected to be on the move. Another major requirement is that they are noninvasive. In practice, this characteristic means that they may be embedded into textiles and pieces of clothing, or they are attached to the body through direct skin contact. In any event, their attachment to the body must be secure, as their movement or dislocation may provide false readings. Skin contact sensors, in particular, may be influenced by physiological responses such as vibration and sweating, and their prolonged use may cause skin irritations. Furthermore, the contact resistance between an electrode and the skin may alter over time as when gels in ECG and thermore, the contact resistance between an electrode and their prolonged use may cause skin irritations. Furthermore, the contact resistance between an electrode and their movement or dislocation may provide false readings. Skin contact sensors, in particular, may be influenced by physiological responses such as vibration and sweating, and their prolonged use may cause skin irritations.

5.2.3.2. Signal Processing. Many wearable medical devices need to incorporate signal processing capabilities in varying degrees. A holter monitor may only collect patient data over a specified time period, and processing can be performed in a later stage. However, autonomous systems and particularly those providing real-time monitoring will have high signal processing demands that need to be performed in situ. These demands will normally involve A/D conversion, noise filtering, and signal distortion correction. Particular problems in wearable systems are the presence of noise from motion and body fat movements, the possible power line interference from components and subcomponents of the wearable device, and the uncontrolled conditions of the measuring environment.

5.2.3.3. Storage. Wearable devices will require several functional data buffers for signal acquisition, storage, processing, and transmission. For applications involving long-term monitoring or acquisition of large volumes of data, there may be a need for data compression. This process, however, consumes considerable CPU energy and needs to be balanced with the energy capacity of the system for the duration of its intended use.

5.2.3.4. Information Processing. The processing of information in wearable systems should be kept as simple as possible to minimize the computing requirements, which is particularly relevant in cases where a real-time response or feedback is required. The processing may initially involve simple conversions or more sophisticated feature extractions, which on their own provide medical feedback. The incorporation of alerting and decision support mechanisms will increase the processing requirements, as the extracted features will need to be compared, correlated, or classified through additional algorithms. The most demanding algorithms will be those incorporating intelligent functions for real-time multisensor assessments. These algorithms are prone to the curse of dimensionality, whereby increases in the number of sensors will slow the learning process exponentially.

5.2.3.5. Privacy and Security. Devices that store and transmit personal medical information are subject to regulations dealing with patient confidentiality. These devices are normally handled by restricting the access to the system to authorized users and through encryption techniques. However, the need for encryption needs to be balanced with the power capacity of the system.

5.2.3.6. Feedback. Feedback can be provided by visual, tactile, or auditory means. Real-time feedback is particularly relevant in medical monitoring applications. The feedback should be informative and provide access to the monitored parameters and any visual or audio alerts. It must be provided in a way that is comprehensible and relevant to the person viewing it.

5.2.3.7. Data Transmission. The data transmission design deals with concerns about data transfer rates, power consumption, transmission range, and possible interference or compatibility problems between different telecommunication protocols and between devices.

5.2.4. Power Consumption. Power consumption is an important consideration, especially in power-demanding applications, as batteries have a significant contribution to the total size and weight of the wearables. Power requirements are controlled by the application, and there is a tradeoff between system performance and battery life for the expected use period of the device. Designers must also decide on whether the power supply should be centralized or distributed to the subcomponents of the device. Fortunately, rechargeable battery cells have become smaller and with higher capacities through the developments in mobile phones, camcoders, and PDA markets. However, it is still important that wearable medical
devices provide online power monitoring functions, as their failure to operate may have health implications (44). Alternative means for covering or at least supplementing the wearable’s power supply requirements are continuously investigated. Efforts have been made to use solar cells woven on clothing to supplement lost power. Research into human-powered wearable computing has investigated the possibilities of generating sufficient power with body heat, breath, or motion to power a wearable computer (45). It was concluded that power generation through walking seems best suited for general-purpose computing, calculating that 5–8 W may be recovered while walking at a brisk pace. For lower power requirements, piezoelectric inserts in shoes could also be used.

5.3. Standards and Litigation

Wearable medical devices must comply with the relevant medical device standards, codes, and regulations, which ensure their safety and reliability. The ANSI Medical Device Standards Board and the Association for the Advancement of Medical Instrumentation (AAMI) have issued a report (ANSI/AAMI/ISO TIR 16142) providing guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices. Wearable devices with communication capabilities must also comply with the CEN/IEEE/ISO Health informatics—point-of-care medical device communication standards. These standards are expressed through ISO 11073 and IEEE Std 1073 for medical device communications. The European Union standards counterpart is the CEN Technical Committee 251/Working Group IV. The devices must be reviewed by the U.S. Food and Drug Administration’s Center for Devices and Radiological Health in the United States or obtain the CE marking in the European Union before they can reach the market.

Compliance to standards and regulatory approval is a legal prerequisite for any medical device. Manufacturers of wearable devices will also be keen to disclaim responsibility for the outcome of medical conditions, as they will want to minimize the chance of being sued if the device does not correctly predict a medical event.

6. DISCUSSION

The commercial development of wearable medical devices is still at its early stages. Their design often involves tradeoffs between meeting the intended functional requirements and the requirement for wearability. A major challenge, therefore, involves the development of sensors and other hardware components that help improve their functionality, wearability, reliability, and security. The other main challenge involves the management and use of the provided information, which includes the information stored in the patient’s medical record, information collected by the device (ideally in real time), information that could help predict future events, and provision of medical decision support through intelligent functions.

Current trends indicate that wearables of the future are likely to store complete electronic medical records. They are also likely to be integrated with and form part of digital accessories such as cellular phones, pagers, and mobile e-mail devices (mobile personal communication systems) and incorporate GPS and GIS functions and applications such as speech recognition, audio, video, and virtual reality. Furthermore, all items may come assembled into clothing, in the form of a vest, shirt, or jacket.

From a clinical point of view, the trend is to go beyond monitoring, which is currently the predominant clinical task, and develop devices that will actively assist in the treatment of a health condition. In many cases, this process is likely to involve the combination and integration of wearable and implantable devices for applications such as the provision of drug delivery, the functional stimulation of the nervous system, or heart management (in conjunction with pacemakers). Taking the example of noninvasive monitoring of insulin and glucose, a step further, the system can send a signal to an implantable infusion pump to automatically infuse insulin if blood sugar levels are too high. Microsystems technology and MEMS applications are already serving as micropumps in drug delivery systems, DNA diagnostics implants, artificial retinas, components in pacemakers for nerve stimulation, and disposable sensors for monitoring glucose, urea, sodium, and calcium (46).

Other issues related wearable medical devices go beyond any technological trends. These issues concern their potential social impact as a result of their operating characteristics, or through influencing the public perception toward health. Wearable medical devices are designed to be worn and to operate for prolonged monitoring periods and, as a consequence, have operational modes that have not been associated with previous computing experiences. Mann (15) has identified three operational modes that represent the interaction between the human and the computer in relation to computational clothing, which are equally valid for wearable medical monitoring. These modes are as follows:

1. Constancy: The device runs continuously and is always ready to interact with the user.
2. Augmentation: Computing is not the primary task. The assumption behind wearable devices is that the user will be doing something else while doing the computing. The device serves to augment the user’s sense of control in a medical situation and to provide health information.
3. Mediation: Computational clothing will encapsulate us and act as an incoming information filter, and it will provide privacy as an outgoing information filter, far more than handheld devices and laptop computers.

Nonprescribed wearable medical devices will depend greatly on their public acceptance. Designers will need to focus their attention on fashion and human–device interaction as much as they do on functionality. Pervasive computing and ubiquitous health monitoring will be embedded in ordinary clothing and fashion accessories such as watches, belts, hats, and jewelry. The widespread use of wearable medical devices can significantly influence the public perception of health care, as people become
accustomed to the concepts of remote health management, health care at home, unconfined health monitoring, and telemedicine.

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