An Overview of Wearable and Implantable Medical Sensors

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Summary

Objectives: To give a brief, introductory overview of current developments and trends in miniaturized medical sensors which will be informative to non-specialists in the field.

Methods: Summary of the different types of wearable and implantable sensors with examples of current state-of-the-art devices and systems used in medical applications.

Results: After more than a decade of intensive research and development around the world, miniaturized medical sensors are becoming commercially available, allowing increasingly rapid collection of large-scale medical data and its wireless transmission to health care centers. However, most sensor systems are not yet in routine use and still restricted to specialized sites, undergoing validation trials, mostly within research laboratories.

Conclusions: Challenges to routine adoption of medical sensor systems often arise from a combination of lack of awareness of the technology among many medical practitioners, technological limitations of the device systems (artifacts and noise resulting from problems in garment fit or device implantation), and open issues of evaluation and validation for the very broad scope of conditions in home-care and ambient environments over which medical sensors need to operate for routine, reliable, practical use.

Keywords

Medical sensor systems, miniaturized wearable and implantable sensors, preprocessing and filtering for medical sensors, wireless body area systems (BANs), evaluation and validation of sensor systems

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Wearable and Implantable Medical Sensors

The main reasons for the development and deployment of wearable medical sensors are to allow better follow-up and eventually better diagnosis outside the hospital, while allowing the patient to follow a normal life, engaging in everyday activities. There are two methods widespread today for outpatient medical follow up. The first is the traditional home-care environment, where equipment is installed in the patient's home, allowing the patient to take regular measurements and transmit them to a medical center. The second involves specialized wearable sensors able to record vital signs and upload them to the medical center at the end of the day or other interval via standard telephone lines.

The trend today is towards the second alternative, where the goal is to provide interactive advice appropriate to changes in the transmitted vital signs and inferred medical clinical condition of the patient. This requires increasing miniaturization of sensors and related hardware, incorporation of wireless transmission technologies, and development of new algorithms allowing on-patient processing of the measured signals. The sensors are best if wearable, in the full meaning of the word, incorporated in the patient's clothes, or, implanted under the skin, or stuck onto the skin.

With wearable or implantable sensors, the patient can be (or will be) eventually monitored round the clock every day of the week (24-7). This, however, changes the way the measurements are taken. If the patient is able move freely, the measurements will be distorted by noise, movement artifacts, communication interruptions, or other disruptions or artifacts. As result, sophisticated algorithms for preprocessing or filtering the measurements need to be used, so the signals reflect the underlying medical condition of the patient. Most available systems do provide some type of filtering and claim valid results. However, independent studies validating the effectiveness of filtering under comprehensive noise and artifactual conditions are difficult and expensive to carry out, and hard to come by since they are often undisclosed for competitive business reasons, so in this paper we will refrain from commenting on them. Widely available "open source" filtering, then, presents a major challenge for validation and standarization of sensor technologies, especially important for routine, long-term acceptance and use.

Miniaturized medical sensors, whether wearable or implantable, require the medical sensor (such as an ECG or glucose sensor) to be linked to a storage and control device, which can be integrated with the sensor or be a separate device or a software program loaded onto a commercially available mobile device, like a PDA or smart-phone. Wearable sensors can be either woven into the fabric of clothes, being an inseparable part of a garment supported with by a control and communication device, or be independent devices with wired or wireless communication and transmission capabilities. Implantable sensors, in contrast, almost always incorporate a wireless communication module for the transmission of measurements to an external storage or communication device.

In this paper we present a few typical examples of wearable sensor technologies that demonstrate current trends and issues they raise. This is by no means a comprehensive survey of the state of the art. The chosen examples are representative, but should not be construed as necessarily the best and most exemplary cases of the technology. Other systems and services exist, with possibly better performance and characteristics. Technologies are evolving very rapidly, with new systems and new versions appearing on the market and within the research community every few months.

Wearable Medical Sensors and Actuators

Among the two types of wearable medical sensors (those woven into the fabric of clothes and those worn as independent or interconnected devices), woven sensors have the advantage of being simple to use - the patient just wears the garment and starts the device. However, they can present problems, like requiring the correct garment size and a good fit for the patient, so that the sensors are well-placed, especially if dry sensors yield a lower quality signal (like in the case of ECGs). On the other hand, systems that allow aggregating sensor signals from different vendors require more effort in being worn, and need specialized software to manage the sensors and their incoming signals. But potentially they allow for a larger and more customized set of sensors, depending on patient requirements and needs.

The *LifeShirt* System [1] by VivoMetrics is a representative example of an intelligent medical garment. It is based on a miniaturized, ambulatory version of inductive plethysmography. The LifeShirt System consists of the LifeShirt garment itself, a machine washable shirt with embedded sensors, the LifeShirt Recorder, an integrated PDA, and the VivoLogic analysis and reporting software. The system continuously measures more than 30 parameters of cardiopulmonary function as a patient goes about their daily activities. After processing the data, the system integrates subjective patient input from an on-board digital diary. Results can be viewed as full-disclosure, high-resolution waveforms or as summarized reports.

To measure respiratory function, sensors are woven into the shirt around the patient's chest and abdomen. A single channel ECG measures heart rate, and a three-axis accelerometer records patient posture and activity level. Optional peripheral devices measure blood pressure, blood oxygen saturation, EEG, EOG, periodic leg movement, core body temperature, skin temperature, and end tidal CO2 and cough.

A second example is the ***Cardiac Vest*** from Signalife [2], featuring dry (e.g., quarter-dollar size, metal) ECG electrodes embedded in the cloth fabric. Wireless transmission of the measured ECG signals to the CPU and the incorporation of sophisticated artifact elimination algorithms allow capturing of data in very harsh environments, such as might be found during strenuous outdoors training.

The Cardiac Vest provides ambulatory 12-lead ECG monitoring and is driven by the Fidelity100 system that compresses and reduces noise prior to amplifying the ECG signal, eliminating the need to filter the signal after amplification. Signalife claims that 100% of the signal is preserved, allowing physicians to detect shifts in the ST segment as small as 5 μ V. According to Singalife's brochures, the improved quality of the data means that physicians can record full ECG signals from a patient during exercise or everyday activities. The system requires a laptop where the data are transmitted and be visualized.

A third example is LifeCore's ***LifeVest*** [3], advertised as the first wearable cardioverter defibrillator, providing a new treatment option for sudden cardiac arrest, offering patient protection and monitoring as well as improved quality of life. LifeVest incorporates a sensor and an actuator, the defibrillator, providing an example of active automatic response to measured signals. Unlike implantable cardioverter defibrillators (ICD), the LifeVest is worn outside the body rather than implanted in the chest. This device continuously monitors the patient's heart with dry, non-adhesive sensing electrodes to detect life-threatening abnormal heart rhythms. If a life-threatening rhythm is detected, the device alerts the patient prior to delivering a shock, and thus allows a conscious patient to disarm the shock. If the patient is unconscious, the device releases a gel over the therapy electrodes and delivers an electrical shock to restore normal rhythm.

The above systems provide examples of integrated, closed systems. The sensor farm is predefined, and new sensors cannot be added without major changes to the system. A different approach is taken by other companies, with the development of an open system, based on wireless Body Area Networks (BANs). A BAN is defined as a network of communicating devices worn on, around or in the body, providing mobile services to the user (patient) and optionally communicating with remote users (like healthcare centers) using public wireless networks. The wireless connection of the BAN can use radio signals or even acoustic signals. There are several systems of these type that are starting to appear as prototypes or commercial systems.

A representative example of a system based on a BAN is the **Ericsson Mobile Health** [4] solution. Users are equipped with sensors interconnected under a BAN, and managed by a PDA or mobile telephone. The collected data are transmitted continuously via a wireless UMTS or GPRS service to a medical centre or directly to medical professionals, where they can be monitored. Content-management functions enable immediate analysis of individual body data and personalised patient feedback in real time using alarms and reminders. The system monitors vital signs such as ECG, EMG (electromyography), oxygen saturation, respiration, activity and temperature. In the case of patients whose medical condition is deteriorating rapidly, the data centre can send an SMS alarm or provide the patient with first-level medical support.

The EMH system also provides a patient diary for remote entry of questionnaire responses and diary entries (entered by the patient on a computer or a smartphone), and patient Messaging, a dialogue made simple between the caregiver and the caretaker. Content-management functions enable immediate analysis of individual body data and personalised patient feedback in real time using alarms and reminders. The system monitors vital signs such as ECG, EMG (electromyography), oxygen saturation, respiration, activity and temperature. The sensors themselves are standard sensors available on the market, with EMH offering the interconnection, aggregation and transport means.

Sensor Miniaturization Directions

The systems described above provide examples of the currently available wearable systems. One of the main problems they present are concerns over the size of the sensor aggregator and control devices, which can be relatively large. Some of the above systems require a PDA, while others, like EMH, incorporates the control device within a belt. A new generation of sensors is currently under development, on a single chip, integrating sensor control, signal processing and wireless transmission, at an extremely low cost, possibly allowing it to be a disposable sensor system. Two examples of this technology are Telzuit's STATPATCH, and Toumaz's Sensium platform.

The **STATPATCH** System [5] is a mobile cardiac monitoring technology offering an entirely wireless 12-lead EKG with 24-hour near real-time monitoring. It is an 1-piece, easy-to-attach, and wear patch utilizing Bluetooth technology to transmit cardiac data to a Treo smartphone. The smartphone transmits this data to a central independent diagnostic testing facility where it is processed and read by trained technicians. Medical practices can almost instantly retrieve patients' reports from a dedicated HIPAA (Health Insurance Portability and Accountability Act)-compliant Web site.

The **Sensium** [6] platform is designed to work with a range of body-worn physical and bio-chemical sensors. Sensium is an ultra low power sensor interface and transceiver platform for a wide range of applications in healthcare and lifestyle management. The device includes a reconfigurable sensor interface, digital block with 8051 processor and an RF transceiver block. An on-chip program and data memory permits local processing of signals. This capability can significantly reduce the amount of transmitted data. Together with an external sensor, the Sensium provides ultra low power monitoring of ECG, temperature, blood glucose and oxygen levels. It can also interface to 3 axis accelerometers, pressure sensors and includes a temperature sensor on a chip. One or more Sensium enabled digital plasters continuously monitor key physiological parameters on the body and report to a base station Sensium plugged into a PDA or Smartphone, from where they can be further filtered, processed or transmitted live to the medical center. Sensium is designed for purely Body Area Networking (BAN), that is, transmitting to a distance of no more than 1.5 to 2 meters.

Implantable Medical Sensors

All the above systems implement non-intrusive medical monitoring. However, slowly gaining ground are implantable in vivo monitoring devices. Implantable sensors can be either placed under the skin, or at special locations in the body, like the mouth in place of a tooth, or in the knee. Direct physical contact with the body allows the sensors to measure with higher accuracy physiological values, like blood flow, glucose level and even detect infections. However implantable sensors are still at the research or prototype level, with the first simple commercial products expected in late 2007.

A first example is **IntelliDrug** from Saliwell [7]. Intellidrug is a tiny drug-dispensing system that goes into a person's mouth - with the ultimate goal of getting the parts small enough to fit into a replacement tooth placed in the back of the mouth, like a molar. The device can release a specific amount of medicine at certain intervals, ensuring that the patient gets the proper dosage at the right time. By placing the device in the mouth, the drug can be delivered directly into the bloodstream through the lining of the cheek and around the mouth, a surface that is porous enough to absorb the medicine. Saliva, meanwhile, mixes with the drug and carries it to the lining more consistently than just swallowing a pill every few hours.

Intellidrug consists of a stainless steel housing, a pump and custom valves to regulate the drug flow, a microprocessor, batteries and a reservoir for the drug pill. It is a block the size of two teeth that is strapped to the side of teeth so it hugs the inside of the cheek. Developers hope to ultimately turn it into a replacement tooth. The unit can be removed from the mouth, where a technician can refill the drug reservoir, clean the system and replace the battery if needed. IntelliDrug also has a communication port that enables the user to control the device via remote control with the hope of eventually linking it with a cellular phone or to a nearby hospital or care center. Intellidrug is currently under animal model testing, with human prototype testing expected by the end of 2007.

A more general approach is the Lab-on-a-Chip (LOC) concept. LOC is a term for devices that integrate (multiple) laboratory functions on a single chip of only a few millimeters to a few square centimeters in size that are capable of handling extremely small fluid volumes (down to less than pico-liters). LOC applications and other current sensor research directions are many, ranging from environmental pollution monitoring, food quality and finally medical analysis. LOC for medical tests are mainly used today for laboratory analysis. However the miniaturization and integration of communication circuits on LOCs, is preparing the ground for fully implantable and autonomous LOCs. The possibilities offered by implantable LOC devices are many, ranging from real-time bacteria detection to virus and cancer detection, to blood sample preparation and DNA extraction. Current research concentrates on mastering the different sensing materials that range from optical to bio-electrical and micro-needle devices, investigating their long term effects when implanted in the body, their calibration, and many other considerations..

Conclusions

In the next few years several systems allowing mobile monitoring of vital parameters will be appearing on the market. Although the possibilities they offer for follow-up and possibly diagnosis are many, their adoption by the public will depend on many side-issues, which are not yet studied or resolved.

A first such issue is the creation of a concise end-to-end service that will allow large scale deployment of the technologies. Today, most of the proposed technologies are able to measure signals and place them on a server where medical personnel can consult them. However when hundreds of thousands of patients come to be monitored in parallel, it will no longer be possible to manually follow-up each patient. Automatic analysis tools will be needed at the healthcare center, able to detect anomalous patterns and alert medical personnel, or even provide automatic replies.

A second issue that hinders deployment on a commercial scale is the reluctance of insurance companies to reimburse the costs. Although the potential for savings is clearly there, it has not been proven to the satisfaction of insurance companies (at least in Europe).

Other issues that will hinder the deployment of these services in Europe include the fragmentation of the European health market and the different laws applicable in each country, the security requirements and liability regulations as well as simple technical issues like the short battery life-time of the systems when they transmit the data live to the medical center.

Nevertheless, we expect that the pressure from the patients and their need to better control their health will encourage the invention and development of new mobile and continuous monitoring technologies within the next few years, which will be adopted in medical practice, and reimbursed by the insurance companies.

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