New ready-to-wear sensor devices: the new vogue for disease management

Management, coordination and medicines management in the public health systems are currently undergoing tremendous changes. Everything, from first aid to inpatient hospitalisation, is due to transform. The focus is on prevention, early risk detection, general wellbeing, patient education and new ways of empowering individuals to influence their own health

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Changes in healthcare are driven by society and extraordinary research and technology improvements. Social factors include an ageing society, increasing numbers of chronic diseases and the rise in public healthcare costs. When talking about technology, the main contenders include, micro and nano technologies mobile communication, information and biomedical technologies. Combining cost-effective telemedicine platforms with intelligent, wearable systems that provide personal and early feedback to the patient through continuous measurement of vital functions can significantly reduce sickness and increase early detection, diagnosis, treatment and therapy of diseases, as well as rehabilitation at home. Future interdisciplinary research is important in developing powerful, user-friendly, cost-effective, wearable and implantable health systems. Such electronic devices play a crucial role in collecting patients' physiological parameters or supporting vital functions.

Miniaturisation of medical devices

Thanks to microelectronics miniaturisation, new sensor concepts, more powerful signal processing and compact communication capabilities, many new medical devices have emerged. These include devices such as mobile phones with integrated electrocardiogram (ECGor GPS). However, when planning new groundbreaking wearable devices, a developer has to take into account more user requirements than those needed to create stationary equipment. The considerations and challenges should include the following.

Small and lightweight The device should be unobtrusive in order to be worn as a daily accessory and not necessarily look like a medical device. Meeting these restrictions requires mechanical and electrical codesign throughout the entire development phase.

Low power A stand-alone power supply of at least one working day without recharging is mandatory. Apart from low-power electronic components, the duty cycle should also be minimised in order to optimise the power consumption of permanently operated equipment. Biological parameters do not necessarily have to be measured continuously. Instead, a "quasi-continuous" measurement can be employed, depending on the measured parameters (eg, blood oxygen saturation can be measured every two minutes and skin temperature every five minutes).

Life cycle High reliability and a minimum of four years of field life will make devices eligible for possible reimbursement by health insurances.

Housing The device should be shockproof, at least IP65 (dust tight, protected against water jets), complying with the IEC529 standard, and must be biocompatible in areas exposed to the user.

Input/output interconnection If a plug/socket option is selected, this adds mechanical issues and (comparably) large, expensive hardware. In comparison, wireless connections such as Bluetooth, ZigBee, GSM or infrared require a larger power budget.

Sensors Novel applications demand new sensor concepts, which are often not easily integrated into standard electronics or housing. Also, when direct physical contact to the patient/user is required, biocompatibility issues may influence the sensor principles and signal post-processing.

Well-established wearable medical devices that use sensors include pacemakers, implantable defibrillators, pulse measurement devices and data logger for continuous ECG monitoring. Currently, companies worldwide are developing new sensors and systems for better and easier surveillance, as well as improved patient support.

Sensors

Sensors make up the basic parts of wearable measurement devices. They measure a person's vital parameters using physical parameters such as temperature and pressure (for pulse), electronic potentials (ECG) or gyro sensors (movement). The following subsections provide an overview of the approaches and sensors on the market or under development for measuring vital parameters.

Pulse – state-of-the-art pulse measure methods

- ECG-type sensors that measure heart activity continuously are usually built into a belt worn around the chest or integrated into a shirt. They send information to a control-and-display unit through a wrist-worn device.
- Transmissive photoplethysmography (PPG), worn on the ear or finger, is commercially available, and reflective PPG worn on the forehead is also available. Wrist PPG devices are still at the research stage. Commercialy available devices require either optical measurement at the ear, a finger clip or a finger ring.
- Devices for pulse detection during oscillometric blood pressure measurement. These devices are intended for periodic use, not continuous use. A lot of battery power is required to pump up the cuff for blood pressure measurement.

In order to integrate a pulse measurement into a wrist device using minimum power, the most promising approaches include:

- Piezoelectric pressure sensors.
- Capacitive pulse sensors similar to pressure sensors.

Skin temperature Temperature sensors are available with accuracies of up to fractions of 1˚C and can be used for skin temperature measurement. But skin temperature is different from body core temperature. Thus, this value is not really useful unless for recognition if, for example, a device is worn. An algorithm can only be applied when first calibrated on the patient.

Skin humidity A galvanic skin response value can be used in metabolic disorders or for the calibration of other sensors.

Blood pressure It is mostly measured using cuffs with air pump. New approaches deal with pulse wave velocity (PWV). The pressure pulse travels much faster than the blood itself. PWV describes how quickly a blood pressure pulse travels from one point to another in the human body. The time difference between these two locations is known as the pulse transit time (PTT). PWV is typically measured between the carotid and the femoral artery. Atherosclerosis causes the arterial wall to thicken and harden, and narrows the arterial lumen. The increased inflexibility of the arterial wall serves to increase PWV, because the energy of the blood pressure pulse cannot be stored in an inflexible wall. PWV can be used as an index of arterial distensibility. In terms of medical diagnosis, PWV is a highly interesting subject, because it estimates the extent of the cardiovascular condition based on a large area of the human body.

Furthermore, as blood pressure is essentially dependent on the pulse wave velocity, the velocity pulse and the arterial diameter, it can be calculated from PWV after an individual initial calibration by means of a standard blood pressure meter.

In principle, three methods can determine PTT:

- ECG pulse to laser doppler flow pulse on arm or leg.
- ECG pulse to PPG pulse on arm or leg.
- Time between two PPG pulses or laser Doppler flow measured at least 100 mm apart on arm or leg.

Blood oxygen saturation The technology is well known but not easy to implement. For reliable measurements a transmissive measurement device shall be used as described in Pulse/PPG. Commercial devices are available.

ECG For reliable and medical useful measurements, glued electrodes are generally required. Other approaches use a belt to support the electrodes. New systems deal with intelligent clothing shirts with woven electrodes and electronic connections.

Philips Research and others have developed wearable, wireless monitoring systems that can warn patients with underlying health problems. However, for constant supervision of people with cardiovascular

Resources

EC 6th Framework Research Projects CAALYX
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MyHeart
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problems, for example, the key technology required consists of dryelectrodes that can be integrated into common items of clothing such as bras, shorts or waist belts. These systems are currently at the research stage.

Thoracic impedance Impedance cardiography is used to measure and calculate haemodynamic parameters. Haemodynamics are the forces affecting the flow of blood throughout the body. Four dual sensors on the neck and chest are used to transmit and detect electrical and impedance changes in the thorax. The sensors consist of glued electrodes that are not intended for continuous supervision and are not ideal for mobile applications.

Posture Posture supervision uses textile sensors. An application is posture training to improve a patient's body posture in daily life and for orthopedic patients who should avoid certain postures and body movements. Movement training can also be supported. Various sensors as well as computational and communication abilities in a textile is used. Different approaches are currently at the research stage, such as a mesh of measurement nodes distributed over the body and woven electronic wires in the textile that act as a changing capacity.

Movement/fall Fall detection is provided by several commercial devices through the use of movement sensors. The only device currently available was developed at ETH Zurich. However, fall detection cannot be 100% warranted by the use of this device, as it causes too many false alarms (eg, hits of the arm on a table). Another approach to detect dangerous situations, especially for elderly people, is to detect a person falling and not standing up again. This is only a summary of some of the most important and promising sensor principles. Biochemical measurements have not been covered as, to the best of our knowledge, most of the principles are still in at very basic research stages.

Devices

The following devices are only a very small selection of wearable medical devices in order to illustrate the possibilities.

AMON The "advanced care & alert portable telemedical monitor" AMON was a EU-funded research project under the fifth EC framework programme. The target of the project was to develop a multiparameter sensor device that can be worn like a watch. The device measures a three-lead ECG, skin temperature, blood pressure, pulse frequency and blood oxygen saturation. The sensor data are analysed on the device and transmitted via GSM to a medical care centre periodically and upon detection of abnormal values. Data are further analysed by medical experts at the medical centre and stored to provide a history. This provide the patient with real-time care, while preventing unneeded hospitalisation.

Auricall The Auricall Home Monitoring System is an ideal solution for short-, medium-, and long-term monitoring of patients at home. Miniaturised sensors for ECG and SpO_2 continuously monitor the patient's state and enable a proactive management of the patient's health in combination with a mobile phone. The system can be used for recognition of arrhythmias, optimising medication, monitoring patients with congestive heart failure, screening for sleep apnoea, monitoring patients with pneumonia and monitoring patients during ambulatory rehabilitation or within disease management programmes (DMPs).

QBIC The cubic belt integrated computer QBIC can support various applications where computational power, low power, mobile data storage and wireless communication capabilities are the main requirements. Examples include mobile ECG recording and processing and polysomnographic monitoring.

Conclusion

There are already a lot of sensors, sensor principles and even medical measurement devices available on the market for surveillance of vital parameters, especially for elderly or chronically ill patiens. To allow unobtrousive surveillance of healthy people or people at risk for accidents or sickness, further investigations have to be undertaken within the next 10 to 20 years. Measurement of biochemical parameters and the handling of artifacts in particular are the focus of further inverstigations and, with the help of the sixth and seventh EC framework programmes, we can expect completely new approaches of security enhancement tools to become available.

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