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SMALL SENSORS ARE WATCHING YOU

Biosignal sensors in Wearables

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Figures: HUAWEI Consumer Business Group

Small Sensors are watching you

Biosignal sensors in Wearables

Wearables are computer-based devices that are worn on the body and also record various biosignals through integrated sensors. These are forwarded wirelessly and evaluated by algorithms and analysis tools. Wearables are used on the one hand to observe and increase fitness and wellness. On the other hand, they can be used in the medical field. Here, however, standards and high safety requirements must be met.

The DKE (German Commission for Electrical, Electronic and Information Technologies, German standardisation organisation) deals with standardisation for wearables. In two committees, they work on corresponding standardisations in parallel, both nationally and internationally. A clear distinction is made between fitness and medical wearables.

Leisure Wearables

- DKE National Working Committee: DKE/K 802
- DKE cooperation internationally: IEC/TC 124

The international body IEC/TC 124 deals with the following topics:

- Terminology
- Development of measuring and testing methods for textile materials, devices and systems with electrotechnical functionality
- Measurement and evaluation methods for equipment and packaging
- Enclosures
- Test methods for measuring contact surface temperature
- Reliability of fitness wearables for heart rate measurement and step counting
- Other services

The national group DKE/K 802 deals with legal and technical requirements for leisure wearables as well as the adaptation of international guidelines. They concern, among other things, wearable electronic devices, implantable components, electronic textiles and interfaces. Table 1 shows the existing draft standards.

Standard draft	Content
E DIN EN IEC 63203-201-3 (VDE 0750-36)	Electronic textiles – Determination of electrical resistance of conductive textiles under simulated microclimate (IC 124/62/CD:2019)
E DIN EN IC 63203-402-1 (VDE 0750-35-1)	Devices and Systems – Accessory – Test and evaluation methods of glove-type motion sensors for measuring finger movements (IC 124/60/CD:2019)
E DIN IC 63203-401-1 (VDE 0750-33-1)	Devices and Systems – Functional elements – Evaluation method of the stretchable resistive strain sensor (IEC124/39/CD:2018)
E DIN IC/TR 63203-250-1 (VDE 0750-32-1)	Electronic textiles – Snap fastener connectors between e-textiles and detachable electronic devices (IEC124/42/CD:2018)

Table 1: Draft standards for leisure wearables (data source: DKE)

Medical Wearables

Medical wearables should be used according to a doctor's prescription and are not intended for free personal use. Accordingly, appropriate certifications are required for this type of equipment. Internationally, the European Medical Devices Regulation applies to this, nationally it is implemented as the Medical Devices Act.

- DKE National Working Committee: DKE/UK 812.1
- DKE cooperation internationally: IEC/TC 62

The international panel deals with the following topics:

- Electrical appliances
- Electrical systems
- Healthcare Software
- Effects on patients
- Impact on operators
- Effects on other people and the environment
- Data integrity
- Privacy

The national working group DKE/UK 812.1 deals with the legal and technical requirements for diagnosis with medical wearables. Table 2 shows standards and draft standards for this segment.

International standards and drafts	Content
DIN EN IC 80601-2-59 (VDE 0750-2-59)	Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IC 80601-2-59:2017); German version EN IC 80601-2-59:2019
DIN EN IC 80601-2-30 (VDE 0750-2-30)	Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers (IC 80601-2-30:2018); German version EN IC 80601-2-30:2019
DIN EN ISO 80601-2-61	Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, amended version 2018-02); German version EN ISO 80601-2-61:2019
DIN EN 60601-2-40 (VDE 0750-2-40)	Particular requirements for the basic safety and essential Performance of electromyographs and evoked response equipment (IC 60601-2-40:2016): German version EN 60601-2-40:2019
E DIN EN ISO 80601-2-85 (draft)	Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (ISO/DIS 80601-2-85:2020): German and English version prE ISO 80601-2-85:2020
E DIN EN IC 80601-2-86 (VDE 0750-2-86) (draft)	Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires (IEC [62D/1628/CD:2018)
E DIN EN IC 60601-2-23 (VDE 0750-2-23) (draft)	Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (IEC62D/1627/CD:2018)
E DIN EN 60601-2-4/A1 (VDE 0750-2-4/A1) (draft)	Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 62D/1344/CDV:2016); German version EN 60601-2-4:2011/FprA1:2016

Table 2: Standards and designs for medical wearables (data source: DKE)

Medical wearables can be used as part of medical diagnosis, treatment or medication dosage. Only if they comply with the Medical Devices Act, recognition by the health insurance companies is possible at all. Examples of applications that could be considered for future certified use as a medical wearable are: ECG devices, blood pressure and blood oxygen measurement, textiles for heart flow measurement, patches for temperature measurement, recording of respiratory parameters, control of patient positioning and monitoring of Diabetes patients. This could support medical home monitoring and telemedicine.

Sugar alarm

Medical wearables include, for example, systems for continuous glucose monitoring (CGM). They measure the sugar level in the subcutaneous fatty tissue and can be used as real-time CGM (rtCGM) or as Intermittent Scanning Continuous Glucose Monitoring (iscCGM).

An rtCGM system includes sensor, transmitter and receiver. The sensor is glued to the body and contains a measuring thread that is fed into the subcutaneous fatty tissue. This measures continuously. In other systems, the transmitter is located directly on the sensor. An app displays the measured values via a smartphone, smartwatch or tablet.

The iscCGM requires a sensor, reader or app. The difference is that the values are read out manually with a reader or smartphone by the person placing them over the sensor. The measurement methods are intended for different applications and circumstances.

In addition, plasters and pumps are used in the field of glucose measurement and drug delivery. These are techniques that are used only on medical advice and prescription.

For example, the company Diabeloop has developed the DBLG1 system, a medical device for automated insulin delivery (AID). It is an integrated personalised hybrid closed-loop system. The CE-certified DBLG1 system reproduces the functions of the pancreas and implements automated blood glucose control.

The self-learning algorithm is hosted on a protected handset and connected via Bluetooth to a continuous glucose monitor (CGM) and a patch insulin pump. In real time, the glucose values of the patient can be analysed and the necessary insulin dose can be calculated.

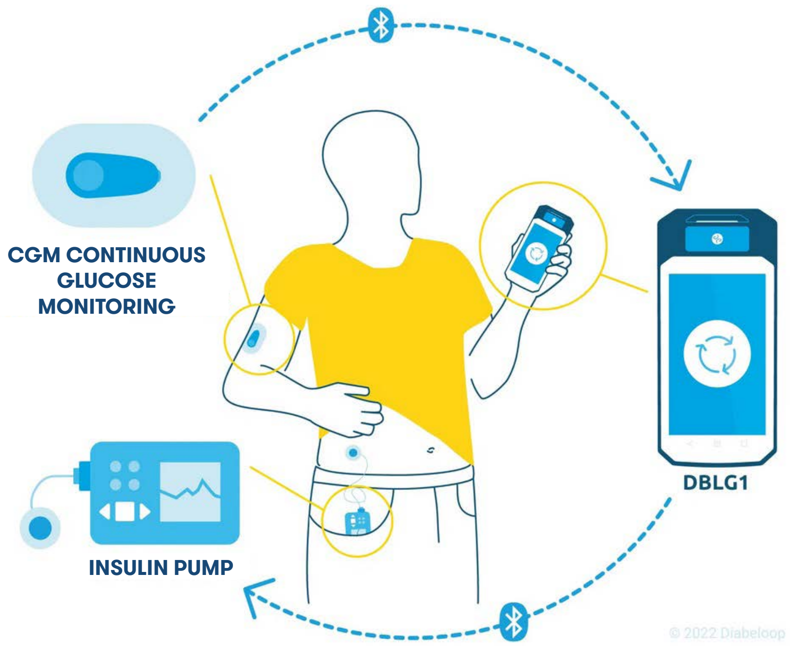

Fig. 1. The DBLG1 system adjusts the insulin delivery by means of an algorithm. (Image: Press image Diabeloop)

How am I doing - Leisure wearables

There are leisure wearables for many applications, but they are intended for healthy people and do not provide medically accurate parameters. However, they are well suited to support a healthy lifestyle or for sports motivation. On the one hand, it is important that the devices do not disturb the user and do their work as unnoticed as possible. In addition, there must be broad acceptance and operation must be simple and comfortable.

With leisure wearables, vital signs of the body can be recorded and monitored. Among other things, the following devices are used for this purpose:

- Smartwatches
- Intelligent clothing (e.g. T-shirts, soles, caps)
- Smart accessories (e.g. diaper sensors)
- Non-contact sensors (e.g. bed sensors)
- Electronic measuring belts
- Sensor patches (Patches)
- Smart glasses
- Tattoos (nanoinks)
- Hearing aids
- Glasses

The evaluations can be carried out in the wearable, on the smartphone or similar, in the cloud or on other devices. They provide information about vital signs (e.g. heart rate, oxygen saturation of the blood), well-being (activity, stress level) and physical status (analyses, trends).

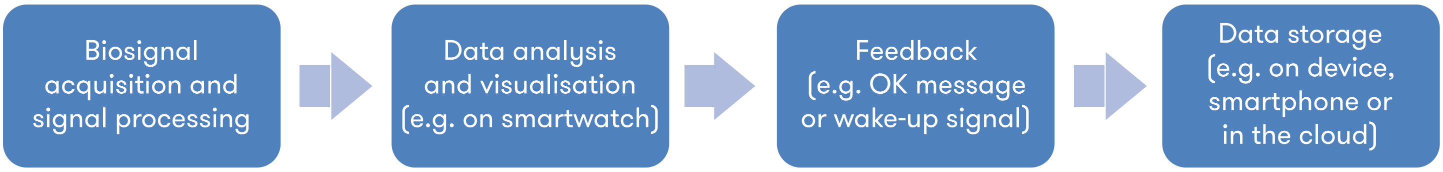

Fig.2. Overview of functions of leisure wearables

In its latest research report "Wearable Technology Market", the market research institute Facts and Factors estimates the global market for wearable technologies at around USD 115.8 billion in 2021. By 2028, analysts are forecasting growth to approximately $380.5 billion. However, this also includes wearables outside the health sector - e.g. AR and VR headsets in the gaming sector.

A lot of different approaches are being taken for the development of leisure wearables and many start-ups have been founded in recent years to develop products for this area. Not all ideas have been or are successfully implemented, for some the metrological solution proves to be not optimal or there is a lack of acceptance among potential users and end customers. In any case, a lot is tried.

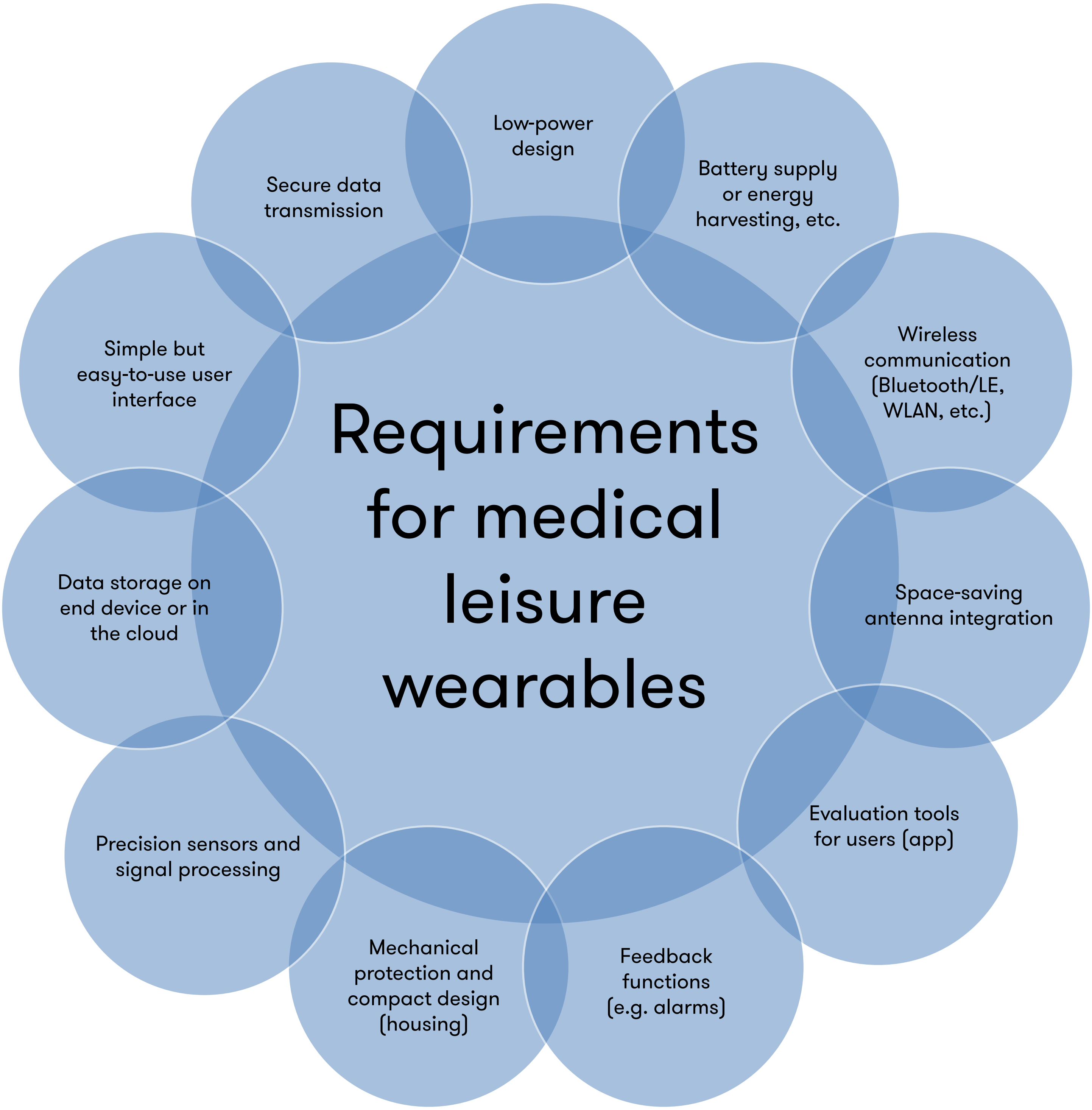

Fig. 3. General functionalities of medical leisure wearables

The watch for all occasions

A category of wearables are smartwatches that, in addition to communication and watch functions, can also perform pulse measurement, ECG, measure blood pressure, work as a pedometer or determine the calorie consumption during exercise.

The pulse measurement is done optically by a smartwatch with infrared light (photoplethysmography, PPG). Infrared light is sent into the skin and measures how much light the skin reflects from it. This value depends on how much blood flows through the superficial capillaries. With each pulse beat, the amount of blood in the capillaries becomes larger and more light is then absorbed and less reflected. The watch converts the amount of reflected light into a pulse wave. This pulse wave analysis can be used to determine the heart rate and, for example, to detect a rhythm disturbance.

If the wrist and sensor are clean and the watch is close to the skin, a reliability of over 90% can be assumed in this measurement, according to experts from the German Heart Foundation.

The ECG measures the electrical impulse that triggers each heartbeat. In a single-channel ECG, a 30-second measurement process is started. Cardiac arrhythmias can thus be detected better than with a pure pulse measurement. Smartwatches that also measure blood pressure generally have to be calibrated regularly with a blood pressure monitor.

Fig. 4. A stand-alone miniature V-sensor device from Leman Micro Devices sends the measurement results via Bluetooth to a smartphone. There, the e-Checkup app shows the results of the blood pressure measurement. (Image: Press image Leman Micro Devices)

The V-sensor used by Leman Micro Devices (LMD) can measure the five vital parameters blood pressure, blood oxygen content (SpO2), respiratory rate, pulse rate and body temperature. The results are displayed within less than a minute by the associated e-Checkup app.

The V-sensor is a module with a fingertip-shaped recess on the surface and a MEMs pressure sensor embedded in flexible plastic. It also includes an optical sensor, a temperature sensor and an ASIC that processes and digitises the signals from the sensors and controls the LEDs and communication.

Fig. 5. The Huawei Watch GT 3 Pro is compatible with smartphones from Android 6.0, Harmony OS 2 or iOS 9.0 and can be connected to the devices via the current Bluetooth 5.2 standard. (Image: Press image HUAWEI Consumer Business Group)

The HUAWEI Watch GT 3 Pro also offers health features. Step count and calorie consumption, heart rate, blood oxygen saturation (SpO2), stress level and sleep quality can be measured. In addition, an ECG analysis via app including atherosclerosis risk screening is in preparation. Currently, the ECG app is still going through the CE marking procedure for medical devices. It shall be made available when all legal requirements for placing on the market and putting into service in accordance with Regulation (EU) 2017/745 are met.

Smart patches

Patch sensors (smart patches) are also wearables that can be used for diagnosis in the health sector. Together with its partner accensors, Covestro, for example, has developed an intelligent patch that consists of two elements. One is a disposable single-use patch. On it are the sensors. The other is a reusable patch that contains the electronics.

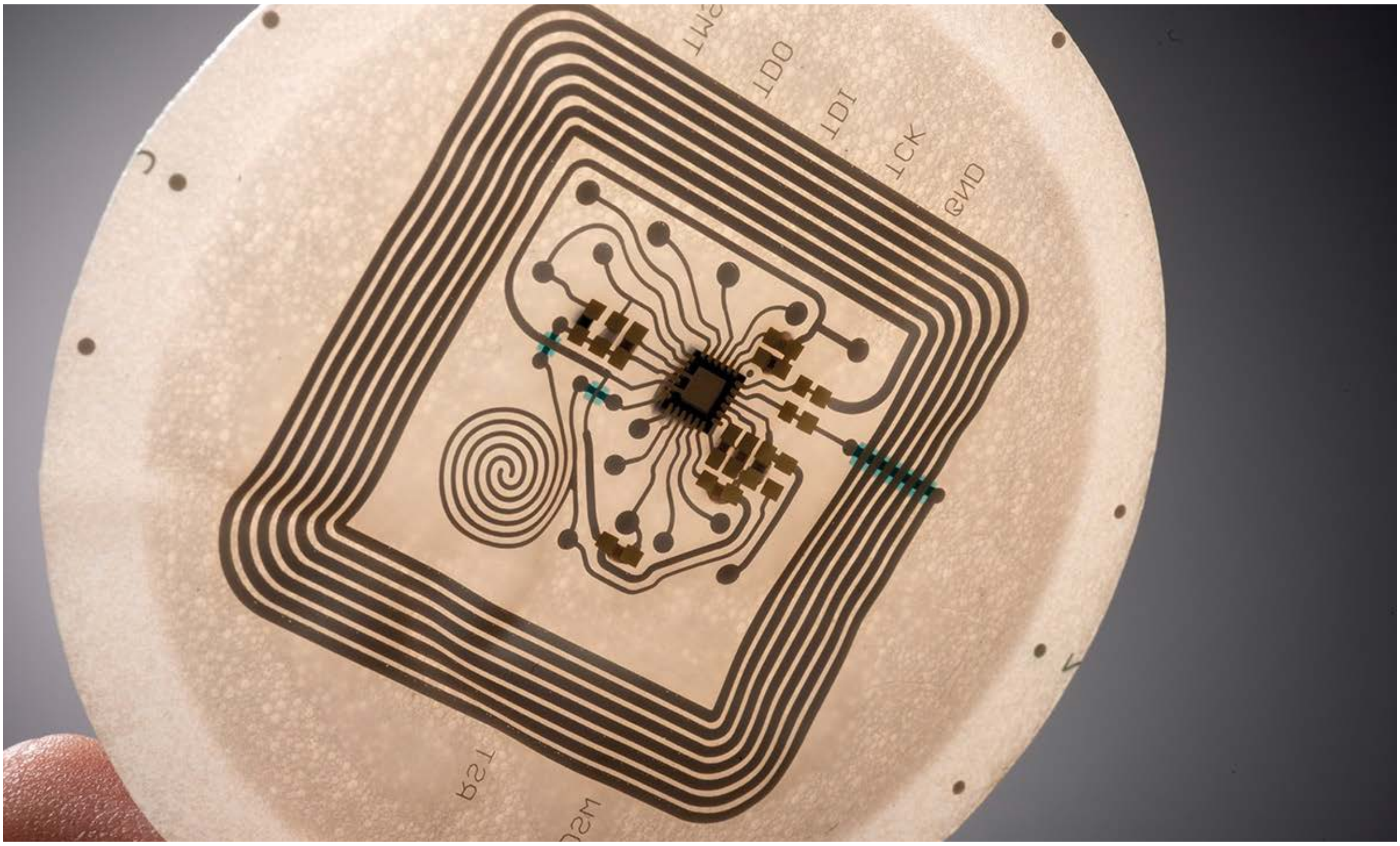

Fig. 6. The smart patches from Covestro contain electronic circuits (Image: Press image Covestro)

Flexible temperature sensors, strain gauges and chemical analysis technologies can also be manufactured from nanoinks. If compatibility is achieved, individual medical applications can be realised with these printed sensors.

Smart soles

A so-called textile wearable is the intelligent sole. There are various technologies that, for example, perform a gait analysis for Parkinson's patients, record pressure and temperature in diabetics, evaluate running training or trigger an alarm in the event of an emergency.

An example of sensor soles that communicate wirelessly are Moticon's ReGo soles. This allows loads and movements on the foot to be automatically analysed by pattern recognition. Trainers or therapists thus receive information about the performance level of the person and about the peculiarities of his or her musculoskeletal system.

The sole records the plantar pressure distribution at the foot, foot position, jump distances or ground contact times. For this purpose, 16 plantar pressure sensors and a 6-axis inertial measuring unit are used. A USB-C charger is integrated in the sole and the data is transmitted via Bluetooth Low Energy. The smartphone or tablet works as an edge computing system for data processing and synchronisation with the ReGo Cloud.

Fig. 7. The data acquisition is triggered by integrated motion detection (Image: Press image Moticon ReGo AG)

Curious

Co-drivers Fraunhofer IIS and Daimler AG are working together on the validation of a "mobilisation seat" with integrated capacitive sensor technology. The seat contains 36 textile sensors that are incorporated into the backrest and seat. By changing the electric field, the capacitive motion sensors record the weight shifts of the seated persons with precise position and in real time. The aim of the project is to improve the living and working conditions of people who have to sit in vehicle for a long time in everyday life.

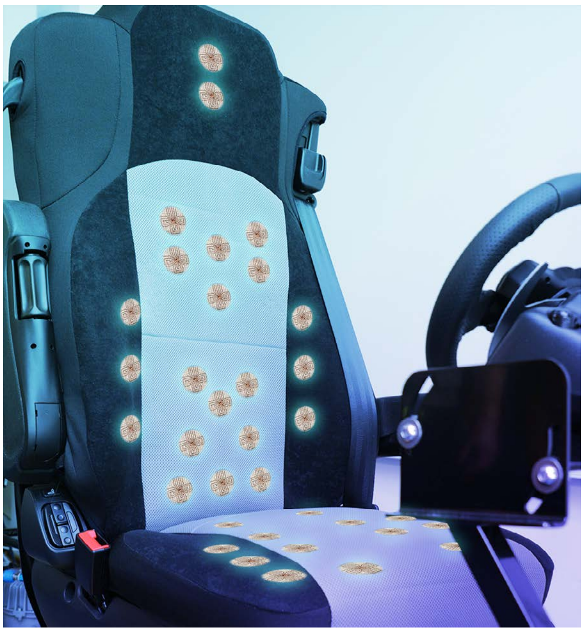

Fig. 8. Truck drivers could benefit from the electronic seat. (Photo: Press photo Fraunhofer IIS/Jakob Wagenbrenner)

A ring for all occasions

The Finnish company ŌURA has developed a smart finger ring. The Ring Gen3 offers 24/7 health tracking with daytime heart rate monitoring, temperature system, period prediction and exercise heart rate monitoring. A new sleep stage algorithm and blood oxygen detection (SpO2) are in preparation.

In the ring there are infrared, red and green LEDs for monitoring heart rate, seven temperature sensors (research level). NTC sensors (NTC = negative temperature coefficient) and a calibrated sensor can detect fluctuations in skin temperature. An IR sensor helps with optimal alignment and a built-in charger displays the charging status indicator via LEDs. 16 MB of flash memory is available. There is a smartphone app for data analysis and evaluation.

Fig. 9. The rings can be used, among other things, for sleep monitoring. (Image: Press picture ŌURA)

A sensor with three LEDs

The Biofy® Eco1 sensor from Intelligent LED Solutions contains a Biofy® SFH7070 sensor. SFH7070 consists of a photodiode and three green LEDs with a wavelength of 530nm and can be used to monitor heart rate. It measures the amount of blood that flows through the blood vessels by illuminating the skin surface with light. The light is absorbed differently by the blood and the surrounding tissues. Unabsorbed light is returned to the detector. The green emission spectrum allows the measurement of the pulse rate on the wrist. The Eco1 components are LED light sources on FR4 printed circuit boards with thermal through connections for thermal management.

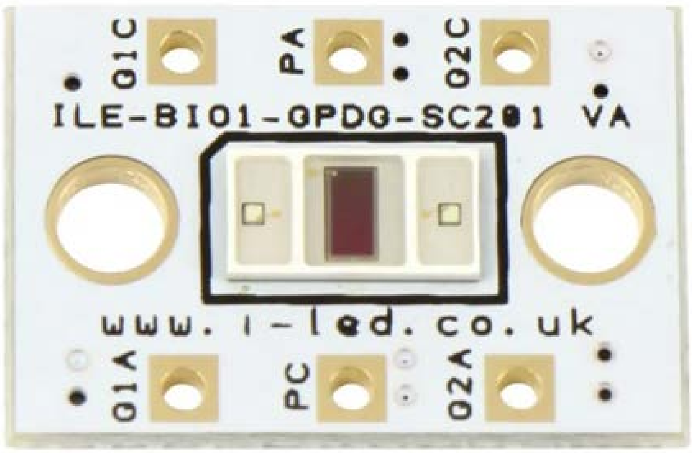

Fig. 10. The SFH7070 contains two green LEDs with 530nm and a detector with a spectral sensitivity in the range of 402 to 694 nm. (Image: RS Components)

The kit

If you want to try programming a simple smartwatch for yourself, you can do so with the BitWearable Kit from the micro-bit system from Shenzhen Chaihuo Maker Education. This can be used, among other things, to create a pedometer or to trigger an alarm if you fall asleep unintentionally. The kit includes a BitWear that serves as a Micro:Bit expansion board, on board are a vibration motor, a buzzer and an addressable RGB LED.

Fig. 11. The kit the basis for various wearable applications (Image: RS Components)

Nimble platform

The STEVAL-MKSBOX1V1 kit from STMicroelectronics is available for wearable sensor platforms (e.g. Pedometer for belt mounting). This allows motion and environment sensor data to be recorded and transmitted via Bluetooth via the ST BLE sensor app on the smartphone. The board includes a digital temperature sensor (STTS751), a 6-axis inertial measurement unit (LSM6DSOX), a 3-axis accelerometer (LIS2DW12 and LIS3DHH), a 3-axis magnetometer (LIS2MDL), an altimeter/pressure sensor (LPS22HH), a microphone/audio sensor (MP23ABS1), a humidity sensor (HTS221), an ARM Cortex-M4 microcontroller with DSP and FPU (STM32L4R9), Bluetooth Smart connectivity v4.2 (SPBTLE-1S) and a programming and debugging interface.

Fig. 12. In addition to many other functions, the STEVAL-MKSBOX1V1 from STMicroelectronics can be used to implement a pedometer (Image: RS Components)

Wrist kit and heart wearable

Silicon Labs' Si117× optical biometric sensors can implement advanced heart rate measurement (HFM) in conjunction with ECG capabilities in wearable products in the fitness and wellness sector.

They are suitable for smart watches, bracelets, patches or other wearables. A complete solution includes the Si117× sensor module, the HFM algorithm, wireless gecko SoCs for Bluetooth connectivity and a wrist development kit with sample code and sample projects.

The sensors have a power consumption of less than 50μA (sensor and LED together) with continuous HFM operation. Buffer and accelerometer synchronisation provides system-level energy savings. The sensors offer a signal-to-noise ratio (SNR) of >100 dB and are able to block out ambient noise and erroneous data.

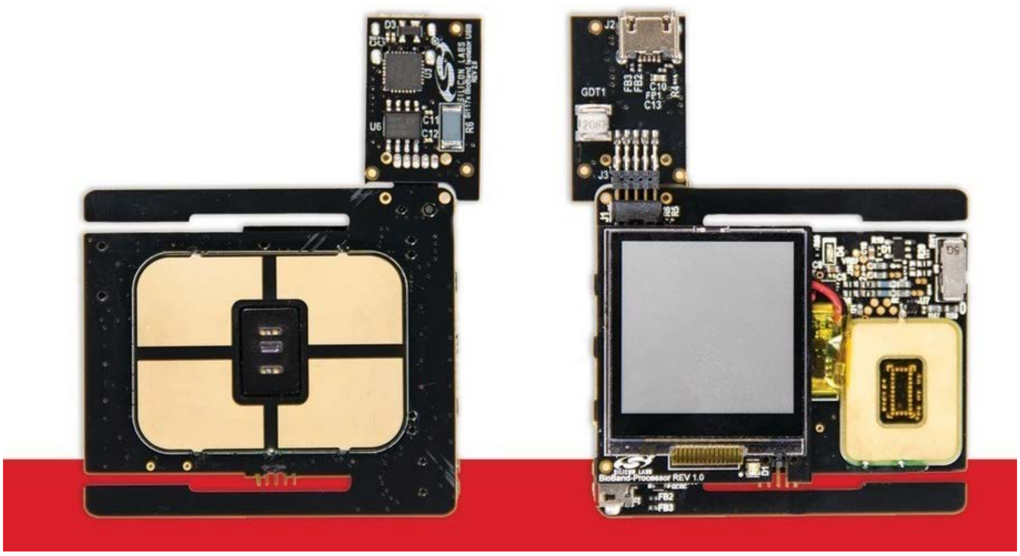

Fig. 13. Silicon Labs' Si117× biometric sensors are located in a 28-pin LGA module with 3.7mm x 7mm. There are also ECG and PPF development kits for the wrist. (Image: Press image Silicon Labs)

A more accurate analysis of the heart rate waveform enables biometric analysis, including heart rate variability (HRV), stress analysis, and pulse volume. In addition, biometrics can be combined with optical photoplethysmogram (PPG) measurements and physiological parameters can be derived from them. One module supports up to four LEDs (which can be controlled simultaneously). The four LED drivers are independently programmable (from 1.7 to 310mA). Other features include a photodetector, a 24-bit ADC with a dynamic range >100dB, digital I2C and SPI interfaces, a programmable event interrupt processor, a host communication processor, and inputs for two external photodiodes.

Fig. 14. The evaluation kit [Si1145/46/47-M01](Si1145/46/47-M01) (USB tool stick) also from Silicon Labs is supplied with programming software. This allows access to functions of the optical sensors (Si1145-M01, Si1146-M01 and Si1147-M01). The kit can also be used to implement heart rate and pulse oximetry applications. (Image: RS Components)

Sources:

www.dke.de

www.diabinfo.de

www.herzstiftung.de/smartwatches-herzpatienten