



Ready-to-wear devices: the new vogue for disease management?

Many health systems face cost problems due to increasing life expectancy and extending chronic diseases. Continuous monitoring using wearable medical devices can improve both the treatment quality and the cost problem

HIGHLIGHTS

- More chronic diseases are surfacing, which need to be addressed as early as possible, in order to ensure optimal treatment
- The WeMeD should be unobtrusive in order to be worn as a daily accessory and not necessarily be looking like a medical device
- Market research shows that there are already wearable applications/services on the market

The situation in many national health systems is complex, but can be described as follows:

- Life expectancy is increasing.
- More chronic diseases are surfacing, which need to be addressed as early as possible, in order to ensure optimal treatment. (The difference in the annual disease cost between well monitored and badly monitored diabetics patients is claimed to be €2000 per year).¹
- Medical advice is sought more often, as people become more health-conscious, but do not want to spend more time in hospitals.
- The overall cost is ever increasing.

The only possible answer to these problems is to set up health and patient management systems that support continuous monitoring, allow ubiquitous medical treatment and can advise patients at minimal cost. Continuous monitoring is required in order to have a much better understanding of a person's key medical parameters. Thus, trends and history data allow for a more accurate analysis of "deviated" values. Telemedicine is key for "ubiquitous treatment", enabling permanent access to medical knowledge, while also minimising cost due to improved efficiency. In addition, the patients' quality of life increases as people feel safer and their lives are becoming more independent from stationary treatment.

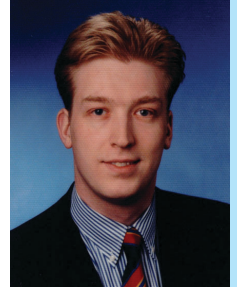
Wearable medical devices (WeMeDs) can provide both continuous monitoring and ubiqui-

tous treatment, and do it already in several applications. They are omnipresent due to their portable nature, and can offer – if required – 24 hour direct access to a telemedicine centre, when equipped with mobile phone capabilities. While continuously monitoring patient health data, they enable doctors to identify possible diseases earlier and to provide less cost intensive treatment. Even within buildings or restricted areas, WeMeDs can help reducing nursing effort providing wireless monitoring solutions that offer advanced wandering prevention with resident and nurse call solutions.

Miniaturisation of medical devices

Medical device manufacturers have provided mainly lab/hospital equipment and implants, with only a few products that were truly wearable. Thanks to microelectronics miniaturisation, new sensor concepts, more powerful signal processing, and compact communication capabilities, many more WeMeDs have emerged, such as mobile phones with integrated ECG and GPS, further improving the patients' comfort and security.

A wearable devices developer has to take into account an extended set of user requirements, when compared to stationary equipment. Also, instead of first designing a functional prototype and then making it wearable, both tasks should be tackled concurrently, in order to avoid costly and lengthy redesigns. The considerations and challenges should include the following.



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Events

Medetel 2005
The International Trade
Event and Conference for
eHealth, Telemedicine and
Health ICT
6-8 April 2005
Luxexpo, Luxembourg,
W:www.medetel.lu

ISWC 2005
The 9th annual IEEE
International Symposium
on Wearable Computers,
18-21 October
Osaka, Japan,
W:[www.cc.gatech.edu/ccg/](http://www.cc.gatech.edu/ccg/iswc05)
iswc05



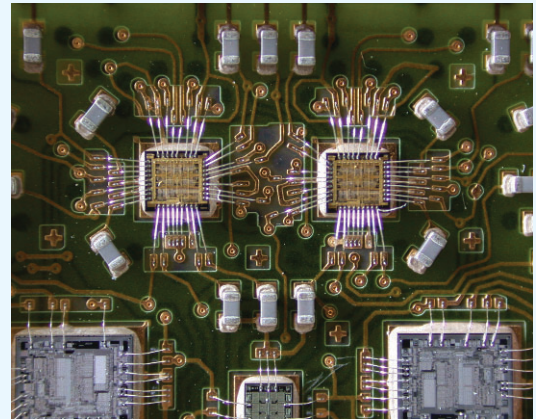
IT & COMMUNICATIONS

WEARABLE DEVICES

Box 1. High-density packaging (HDP) explained

Usually, packaged integrated circuits (ICs) are soldered on printed circuit boards (PCBs). In this soldering process, known as surface mount device (SMD) fabrication, the ICs are all placed sequentially on the PCB, then soldered/connected in parallel. Each package bridges the fine pitches of the IC connection pads (down to 75 microns) to the rather coarse pitches on the PCB, where there are several hundred microns between interconnect lines. These packages increase the size and weight of a system.

HDP now uses unpackaged ICs (so-called bare dies) to reduce size and weight. The bare dies are placed onto substrates that have a smaller lines pitch (20–80 microns) than standard PCBs. Also, the ICs are not soldered, but connected in a different way. With wire bonding, small wires are used to connect every single connection pad from the IC to the substrate. By using flip-chip, the IC is turned over, thus the connection pads are pointing towards the substrate. Either small solder balls or conductive gluing make the connection.



Mixed wire bonding of an SMD

Small and lightweight The WeMeD should be unobtrusive in order to be worn as a daily accessory and not necessarily be looking like a medical device. So, if it is being worn like a watch, typical device dimensions should not exceed the range of 60mm x 50mm x 15mm. This dimension guideline leads to a fixed maximum inner space, so volume/weight restrictions apply. Meeting these restrictions requires mechanical/electrical codesign throughout the entire development phase.

Low power A stand-alone power supply of at least one working day without recharging is mandatory. If the application has only low power consumption a primary battery meets the requirement. Otherwise, a secondary/rechargeable accumulator is needed, which in turn demands a holistic charging concept (connection, auxiliary equipment, etc). Apart from low-power electronic components, the duty cycle should also be used 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 what is measured, eg, blood oxygen saturation could be taken every 2min, skin temperature every 5min.

Life cycle High reliability and a minimum four years of field life should be targeted in order to be 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 where exposed to the user.

I/O interconnection If a plug/socket option is selected, this option adds mechanical issues and (comparably) large, expensive hardware. Wireless connections, such as Bluetooth, ZigBee, GSM, or infrared, require a much larger power budget.

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

AMON

AMON, the “advanced care & alert portable telemedical monitor” is an EU funded research project under the fifth framework, with partners from three European countries and Israel.² The project won one of the Information Society Technology prizes in 2003.

The target of the project was to develop a multi-parameter sensor device that can be worn like a watch. The sensor data are transmitted via GSM to a medical care centre, where experts and expert systems analyse it. The patient gets real-time care at the point and time of need, while preventing unneeded hospitalisation.

References

1. Konstantas D, Jones V, Bults R and Herzog R. MobiHealth – wireless mobile services and applications for healthcare. 7th International Conference on Telemedicine – Integration of Health Telematics into Medical Practice; 2002 Sep 22–25; Regensburg, Germany.
2. Lukowicz P, Anliker U, Ward J, Tröster G, Hirt E. AMON: A wearable medical computer for high risk patients. In: Proceedings of the 6th Symposium of Wearable Computers ISWC, 2002. Los Alamitos CA, USA: IEEE Press (IEEE Computer Society); 2002.



Due to the decision to use off-the-shelf supplied modules with no miniaturisation potential, the first prototype (68mm x 60mm x 30mm) was still rather bulky. It consisted of ten sub-modules, folded together in order to embrace the wrist. The modules developed inside AMON are realised in surface mount device technology to meet time and cost constraints. Electronics and sensors are mounted into a plastic enclosure containing a blood pressure cuff. The enclosure is built with a rapid prototyping laser sintering to avoid an injection molding tool or complicated expensive milling processes. The second enclosure version improved design and wearability.

The ECG, the SPO2 sensor and the blood pressure meter have been tested with 29 subjects, on two AMON devices using the engineering enclosure. The sensors have been found to be functional and the acquisition of raw data is working; however, as expected the algorithms processing them need some fine-tuning.

Comparable systems do not exist – in principle four measuring devices plus a mobile phone are miniaturised to meet the form factor of a conventional off-the-shelf blood pressure monitor. Future device integration is expected to yield a further volume reduction of 30–50%.

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 are mobile ECG recording and processing, and polysomnographic monitoring (comparable to the ALICE 4). The system collects and processes data, such as from respiratory sensors or ECG electrodes, stores them in an extractable memory card, or transmits the processed data wirelessly. Thus, patients can be constantly monitored without being “hard-wired” to their beds or any fixed positions. When a

receiver station connected to the phone network is added, it is even suitable for homecare applications. The QBIC incorporates an XScale processor (Intel PXA263B1C400) using 32MB internal flash memory, 256MB external SDRAM, a VGA connector, a low-power RF transceiver, RS-232/USB serial ports, a Bluetooth module, as well as a slot for an external miniSD card.

All external connectors as well as the single rechargeable battery cell are located in the belt, where more battery units could also be placed. QBIC consists of two microvia boards (“main” and “extension”). In order to provide high modularity for other not yet known applications, the large basic components such as processor and memory are grouped on the main board (24.2cm², 8 layers) and mounted as chip scale packages. Application specific interfaces reside in the rigid-flex extension board (14.9cm², 4 layers), which connects via the flex cables to the main board (Figure 1). Comparable systems require 56–80cm², which corresponds to a size reduction from 30 to 50%.

Conclusion and outlook

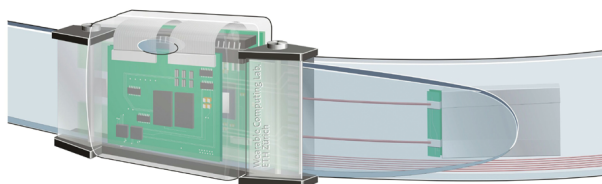
In this article we have demonstrated that the technology for wearable devices has proven to be feasible and ready to use. Wearable devices:

- Empower patients to actively participate in their well-being, especially when suffering from a chronic disease.
- Empower medical personnel and nursing staff to extend their efficiency without compromising the quality of care.

Market research has shown that wearable applications/services are already available. Wearable devices are the field of activity for new business units of already established companies or start-up companies, and notable evolution has been seen during the recent 2–3 years. Since telecom companies, trying to generate new traffic for their communication channels, support developments (the “tele” aspect, next to private care centres and hospitals wanting to offer a better or new service to their patients), further growth is expected in the next 5–10 years.

From a clinical point of view, WeMeDs can foster also clinical research and biological understanding by making “quasi-continuous” raw measurement data available. But one has to keep in mind that the special circumstances of uncontrolled trial conditions by freely moving patients require a very conservative and precise analysis of such data before announcing new findings. ■

Figure 1. The QBIC – the transparent drawing shows the main board and the flex connectors of the extension board in the belt buckle. The belt itself hosts the battery. A touch pad (not visible) could be added on the buckle front



Acknowledgement

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