

► Wearable devices for telemedicine applications

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Summary

Wearable medical devices (WMDs) can provide both continuous monitoring and ubiquitous treatment. Challenges in this area include the need for a low-power/power-saving design to extend battery life and to reduce the size of the battery itself. This is followed by size and weight restrictions to meet patient expectations of being 'wearable', the biocompatibility of all outer housings and the final assembly concept. Two WMD examples are described: a wrist-wearable telemedicine monitor for heart patients (AMON) and a generic belt-integrated computing platform for home and hospital use (QBIC). The electrocardiogram (ECG), the blood oxygen saturation (SpO₂) sensor and the blood pressure meter of the AMON device were tested with 29 subjects. The sensors were found to be functional, but as expected the data processing algorithms will need some fine-tuning. The prototype QBIC demonstrates a size reduction of 30–50% in relation to comparable devices.

Introduction

Life expectancy is increasing in many countries. More chronic diseases are surfacing, which need to be addressed as early as possible, in order to ensure optimum treatment. (The difference in cost between well-monitored and badly monitored diabetic patients is reported to be 2000 per year¹). Medical advice is sought more often, since people become more health conscious, but do not want to spend more time at health centres or hospitals. The overall cost is thus ever increasing.

The only possible solution is to set up health and patient management systems that provide continuous monitoring, allow ubiquitous medical treatment and can advise patients at minimum cost. Continuous monitoring is required to obtain a better understanding of the key medical variables by increasing the measuring frequency. Thus, trends and history data allow for a more accurate analysis of abnormal values. Telemedicine enables permanent access to medical knowledge and reduces cost due to improved efficiency. It also increases patients' quality of life since people feel safer and their lives become more independent from stationary treatment.

Wearable medical devices (WMDs) can provide both continuous monitoring and ubiquitous treatment. They are omnipresent due to their portable nature, and can offer 24-hour direct access to a telemedicine centre, when equipped with mobile phone capabilities. By continuously monitoring patient health data, they enable doctors to identify possible diseases earlier and so that less costly treatment is required.

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For some time, medical device manufacturers have provided mainly laboratory/hospital equipment and implants. Only a few products were truly wearable. Recently, due to microelectronics miniaturization, new sensor concepts have emerged, with more powerful signal processing and compact communication capabilities. WMDs such as digital hearing aids, and mobile phones with integrated electrocardiogram (ECG) and GPS, further improve patient comfort and security.

Q1

Design guidelines and challenges of WMDs

The developer of wearable devices has to take additional user requirements into account, when compared to stationary equipment. Also, instead of first designing a functional prototype and then making it wearable, both tasks need to be tackled concurrently, in order to avoid costly redesigns:

- *Small and lightweight:* To suit the size of a forearm, for example, typical dimensions would be about $60 \times 50 \times 15 \text{ mm}^3$. Therefore, the inner dimensions are fixed and volume/weight restrictions apply. These restrictions require mechanical and electrical co-design throughout development. The WMD needs to be unobtrusive in order to be worn as a daily accessory and not necessarily to look like a medical device.
- *Low power:* Power is required for at least one working day without recharging. If the application has only low power consumption, a primary battery is suitable. Otherwise, a secondary/rechargeable accumulator is needed.
- *Life cycle:* High reliability and a minimum four-year field life is necessary in order to be eligible for possible reimbursement by health insurance schemes.

- **Housing:** The device needs to be shockproof and must be biocompatible where exposed to the user.
- **Input-output connection:** If a plug and socket is chosen for input-output, then there are mechanical issues and relatively large and expensive hardware is required. If wireless connections (Bluetooth, GSM or IR) are used, they will require much more power.
- **Sensors:** Novel applications depend on new sensor concepts, which cannot easily be integrated into standard electronics or housings. Also, when direct physical contact with the user is required, biocompatibility issues may influence the sensor principles and signal post-processing.

Q2

Two WMD examples are described below: a wrist-wearable telemedicine monitor for heart patients (AMON) and a generic belt-integrated computing platform for home and hospital use (QBIC). A wrist-wearable non-invasive continuous glucose monitoring device (Pendra) has been described elsewhere.^{2,3}

Heart monitor

The 'Advanced care and alert portable telemedical MONitor' AMON is an European Union-funded research project under the 5th framework, with partners from three European countries and Israel.⁴ The aim of the project was to develop a multi-variable sensor device that can be worn like a wristwatch. The sensor data are transmitted via GSM to a medical care centre for analysis (see Figure 1). The patient receives real-time care at the point of need and unnecessary hospitalization can be prevented.

Due to the design decision to use off-the-shelf modules with no miniaturization potential, the first prototype was rather bulky, at $68 \times 60 \times 30 \text{ mm}^3$ in size (see Figure 2a). It consisted of 10 sub-modules, folded together in order to embrace the wrist. Electronics and sensors are mounted in

a plastic enclosure containing a blood pressure cuff. The enclosure was built with a rapid prototyping, laser sintering method to avoid an injection moulding tool or

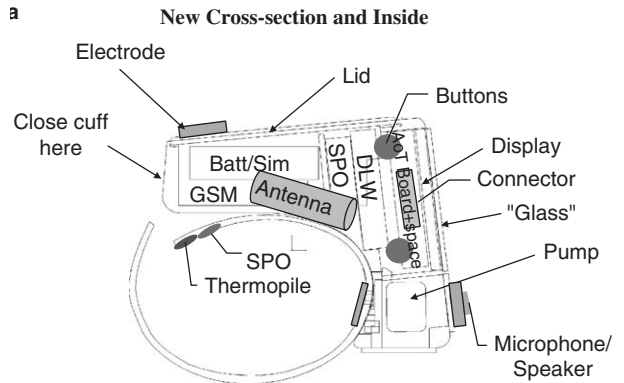


Figure 2 AMON prototype, mounted on the wrist, positions of sensors are shown. An SpO₂ sensor and thermopile are integrated into the cuff. (a) Cross-section of the first prototype and (b) picture of the second prototype.

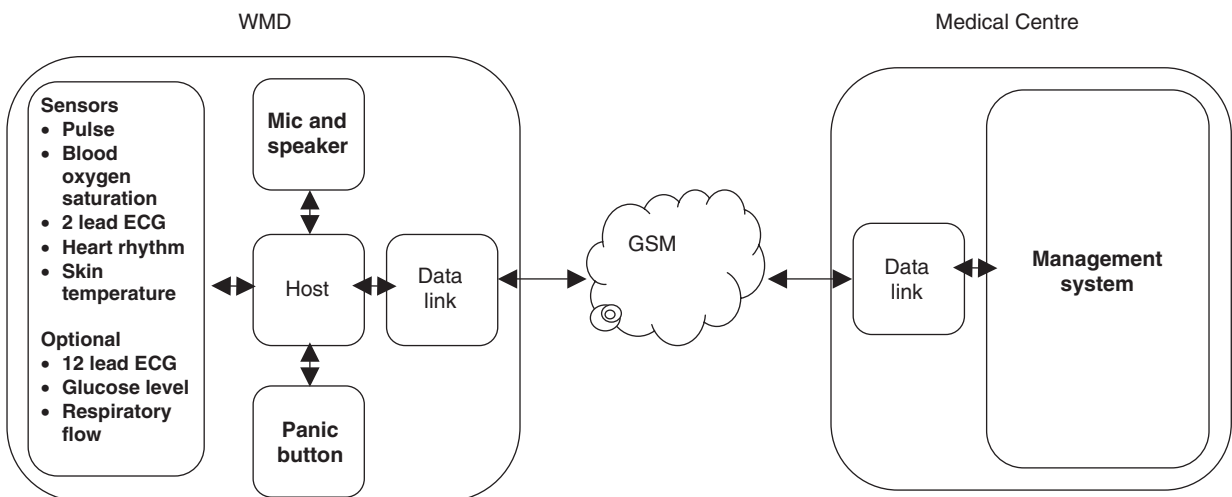


Figure 1 AMON architecture: data are collected and pre-processed on the WMD and first information is displayed to the patient. After data transmission to the MMC and analysis there, the patient is notified of the findings.

complicated milling processes. The second enclosure version (see Figure 2b) was an improved design.

Comparable systems do not exist. In principle, four measuring devices plus a mobile phone can be miniaturized to meet the form factor of a conventional off-the-shelf blood pressure monitor.

Sensors and clinical results

The blood oxygen saturation (SpO₂) sensor is a prototype for wrist measurements, based on a reflective sensor principle (standard sensors transmit light through the finger tip). The ECG sensor and the blood pressure measurements are standard but adapted to the WMD requirements. A thermopile was chosen for temperature measurement. This should provide better results than a simple thermistor, but the relationship between the measurement, skin temperature and body temperature is still a topic for research. Therefore, this sensor has not yet been validated.

The ECG, the SpO₂ sensor and the blood pressure meter were tested with 29 subjects, using two AMON devices. The sensors were found to be functional, but as expected the data processing algorithms will need some fine-tuning.

Generic computing device

The cubic belt-integrated computer QBIC, developed by Art of Technology for the Wearable Computing Lab of ETH Zurich, 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 apnoea surveillance. The system collects and processes data, for example, from respiratory sensors or ECG electrodes, stores them in an extractable memory card or transmits the processed data wirelessly. Thus, patients can be monitored constantly without needing to be connected by wires to their beds or any fixed positions. Adding a receiver station with a connection to the telephone network makes QBIC suitable for home care applications.

The QBIC incorporates an XScale processor (Intel PXA263B1C400) using 32 MByte internal flash memory, 256 MByte 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 also more battery units could be placed (Figure 3).

QBIC consists of two microvia boards. 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 cm², eight layers) and mounted as chip scale packages. Application-specific interfaces reside in the rigid-flex extension board

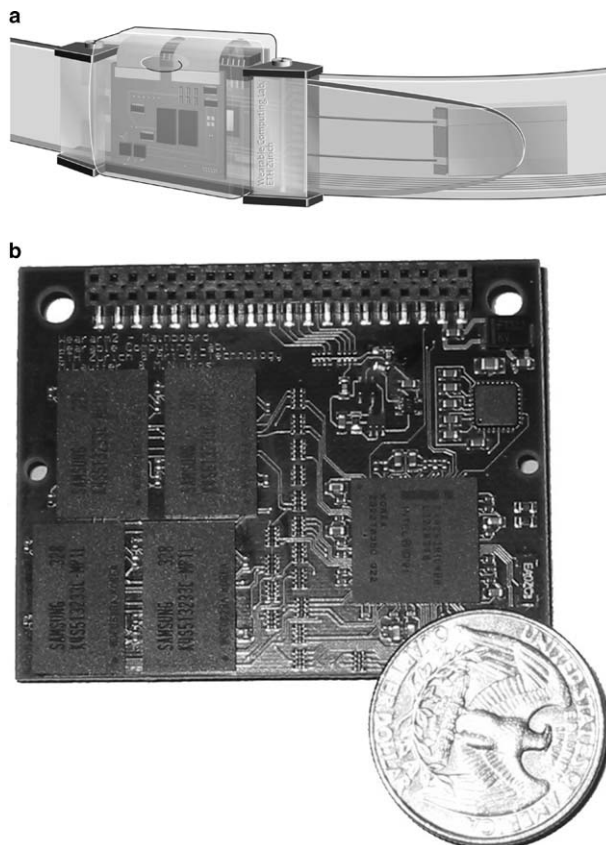


Figure 3 The QBIC. (a) The transparent drawing shows the main board and the flex connectors of the extension board in the belt buckle. The belt itself hosts the battery. A touch pad (not visible) could be added on the buckle front. (b) Main board to scale to a US quarter coin.

(15 cm², four layers), which connects via the flex cables to the main board (see Figure 3). Comparable systems require an area of 56–80 cm², which corresponds to a size reduction from 30% to 50%.

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