

## REVIEW ARTICLE

# TOWARDS THE DEVELOPMENT OF A PATIENT MONITORING SYSTEM: REVIEW OF AVAILABLE SOLUTIONS AND ASSUMPTIONS FOR BUILDING A FUNCTIONALLY OPTIMAL SYSTEM

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**Abstract:** The article reviews the technical solutions of devices that enable the patient to monitor selected medical parameters in time. The authors referred to solutions that record data in internal memory as well as solutions enabling direct transmission of medical data, including information on the current location of the patient in the open space and inside buildings. The latest technical solutions of subassemblies allowing us to design a functionally optimized patient monitoring system in the field of sensor and telecommunications technology were also reviewed. Finally, the authors proposed preliminary assumptions for a functionally optimized patient monitoring system.

**Keywords:** continuous patient monitoring, life monitors, patches, vital signs recorders, wearable sensors, wrist band, indoor and outdoor positioning, locating systems

## INTRODUCTION

As a result of the analysis of the problem of patient monitoring over time, it can be concluded that the earliest appeared the design of personal recorders of medical parameters recording data in internal memory, with the possibility of reading it only offline. This group includes the Agat [4] and Ventus [30,42] recorders developed by WIML.

With the development of wireless data transmission (GSM, Bluetooth, Wi-Fi, etc.), devices have begun to emerge that offer online patient monitoring and visualization of medical data. In this scope, a series of SMP recorders (SMP-100, SMP-200, SMP-300) [32,33,34], developed under research and development projects carried out by WIML can be used as an example. The development of the GPS system and miniaturization of the receiver modules have made it possible to equip personal medical recorders with the function of tracking the location of people in open space (outdoors) [11,21]. Examples include the SMP-300 recorder or the FT (FlagTag) victim tagging micro-modules of the system that supports the evacuation of victims in mass casualty events [12]. Nowadays, there is a clear trend of research groups to search for solutions to monitor physiological parameters and track the location of people inside buildings [45].

Recorders to date have taken a variety of forms, such as electronic and optoelectronic devices with sensors embedded in the mattress of a bed, the seat of a chair, or a wheelchair [6]. The disadvantage of this type of solution is the limited ability to monitor the patient – only while they are on the bed/chair/wheelchair. Embedded devices may be considered for necessary but only temporary monitoring of the patient, such as during sleep or MRI [14].

Attempts have been made to embed sensors in elastic belts worn over the chest or in undergarments such as T-shirts [19,27,38], but the need for a relatively wide range of shirt sizes to achieve satisfactory contact of a sensor with the patient's skin surface and the relatively rapid wear and tear of textile sensors result in a fact that research groups quite rarely develop this type of device. An example of a commercially available system of this type is the Equivital EQ02 Lifemonitor, which is available at WIML [23]. Experience with the use of this system indicates a rather poor quality of recording of the measured signals, even with average physical activity of a patient.

A separate group of recorders is the so-called patch recorders glued on the skin of a patient, which can record selected parameters for up to several days [9]. Despite initial power problems, frequent instances of dampness of electronic circuits, and limited data transmission capabilities, this type of recorder continues to be used in telemedicine. At least a dozen different solutions are known [23,7], the most well-known of which are listed in Table 1 [8,17,31,43,48].

Tab. 1. List of skin-adhesive recorders.

<b>Patches – non-invasive recorders</b>						
Model	Recorded parameters		Connectivity	Working time [h]	Data recording time [h]	Manufacturer
	medical	other				
Biosensor BX100 [8]	HR, respiration	Body position detection	BLE 4.2	120	115	PHILIPS
FreeStyle Libre [17]	blood glucose level	-	13.56 MHz	336	8	ABBOTT
Sensium Vitals [31]	HR, respiration, body temp	-	Wi-Fi 802.11 b/g	120	3	Sensium
VitalPatch [43]	HR, HRV, respiration, body temp	Body position detection	BLE	168	10	VitalConnect
Zephyr BioPatch [48]	HR, respiration	Body position detection, device temp, location (GPS)	BLE	28	500	Medtronic

Previous work suggests that airtight bands, the form of which resembles a wristwatch, worn on the wrist or arm are the optimal solution [36]. Recorders of this type are currently most intensively developed by designers because of their convenience of use. Batteries of bands can be recharged multiple times, bands can be retrofitted with additional functionality, and can be used interchangeably for continuous recording. The limitations of such recorders are primarily related to the small number of parameters that can be extracted from a small area of the patient's skin and the artifacts created by the movements of the band on the subject's arm. The available devices are shown in Table 2 [20,42,46].

Tab. 2. List of non-invasive recorders made in the form of bands.

Model	Recorded parameters		Connectivity	Working time [h]	Data recording time [h]	Manufacturer
	medical	other				
IntelliVue Cableless Measurement Solution [20]	blood pressure, SpO <sub>2</sub>	-	Wi-Fi	no data	no data	PHILIPS
ViSi Mobile [42]	ECG, HR, respiration, SpO <sub>2</sub> , blood pressure, body temp	body position detection	Wi-Fi 802.11	14 hours	no data	Soltera
Wireless Vital Signs	ECG, HR, SpO <sub>2</sub> , blood	-	BLE, Wi-Fi	4.5	no data	Athena GTX

Monitor (WVSM) [45]	pressure		802.11g	hours		
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There are also recorders where the sensor is placed shallowly under the surface of the skin (invasively). The sensor transmits data via radio to a receiver stuck to the skin. Such recorders are mainly used to measure blood glucose levels. Available solutions are listed in Table 3 [16,13].

Tab. 3. List of recorders with implanted sensors (invasive).

Model	Recorded parameters		Connectivity	Working time [h]	Data recording time [h]	Manufacturer
	medical	other				
Eversense XL [16]	blood glucose level	-	sensor no data transmitter BLE	sensor 2160 hours, transmitter 24 hours	no data	Ascensia Diabetes Care
DEXCOM G6 [13]	blood glucose level	-	sensor BLE transmitter BLE	sensor 240 hours, transmitter no data	no data	DEXCOM

Monitoring basic vital signs such as heart rate (HR) and transmitting these data for online analysis can provide very valuable information about the condition of the monitored person and, if necessary, refer such a person for outpatient testing, extended diagnostics [5,39], and, in life-threatening situations, send medical assistance to the patient. Telemedicine systems are increasingly being used to identify patient health risks 24 hours a day, 7 days a week [35]. The devices listed above communicate with a smartphone, which is used to transmit data to the medical provider responsible for monitoring the patient. Most are equipped with an alert system that informs both the patient and the medical provider of the type of threat. Also increasingly popular smartwatches, offered by smartphone manufacturers, allow for monitoring heart rate and physical activity (e.g. number of steps). An available option for these solutions is to monitor patient location, but only outdoors, based on the smartphone's built-in GPS receiver. None of the systems mentioned above allow for patient location inside buildings and none allow the patient to send an alarm by pressing a button.

The patient location tracking option only allows for identification of the location of, for example, residents of care and rehabilitation centers, hospitalized patients, as well as other people in public buildings such as offices, airports or railway stations. In the context of the current global epidemic situation, telemedicine systems can be successfully used to monitor

both patients infected or suspected of being infected with pathogens, such as SARS-CoV-2, as well as medical personnel exposed to infected patients. Monitoring of medical personnel working with infected patients is advisable because of the optimization of the organization of medical supplies in terms of staff workload, stressful situations and cumulative psychological stress [18]. It is also possible to detect unsafe gathering of patients, which is related to the failure to maintain the required distance.

An essential element of a comprehensive monitoring system should be a paging functionality (e.g., an emergency button) that allows a monitored person to send an alarm to a medical provider, with information about their location, in order to enable the activation of the procedure of immediate assistance. While there are various paging button solutions, including personal ones, there is only one solution offered on the market that comes close to the comprehensive monitoring system outlined above. Chinese manufacturer – Shenzhen Xexun Technology Co. Ltd. offers wrist bands and band tracking modules. The U01 (UWB tracking watch) wrist band allows monitoring of heart rate, number of steps walked, and patient location indoors where U20 (UWB indoor anchor) tracking modules are installed or outdoors where U21 (UWB outdoor anchor) outdoor modules are installed [41]. According to the manufacturer, the wrist band has a touch button that can be used as an alarm button. The wristband's battery is inductively charged and allows for 14 hours of wristband use. Documentation of the system is only available in Chinese, and no scientific paper using this monitoring system has been published to date.

The experience in designing and constructing medical recorders was used by WIML engineers to develop and patent a warning device in the form of a wrist band that warns an aircraft crew member of the threat of hypoxia. Details of the design solution of the warning device are described in the invention patent, confirmed in the Polish Patent Office, registered under PL.238338(B1), “Hypoxia warning device” [29].

This warning device comes in the form of a wrist band. Among other features, the device is equipped with an oximetry sensor, indicator LEDs, a wireless inductive charging module, and a vibrating module that notifies the person wearing the wrist band of the risk of hypoxia.

The above-mentioned FT (FlagTag) victim tagging micro-modules of the system supporting the process of evacuation of victims in mass events, developed at the WIML, were made within the framework of the project titled “The system for evacuation and rescue of victims of natural disasters – EvaCopNet” (original title “System ewakuacji i ratowania

poszkodowanych podczas klęsk żywiołowych – EvaCopNet”), contract with the National Centre for Research and Development (NCBiR) No. BS3/B9/37/2015 [10,12]. The FT (FlagTag) victim tagging micro-modules were made in the form of bands used to determine, by the rescuer, the victim's health status (triage), their location and to determine parameters such as geographical location, blood oxygen saturation (SpO<sub>2</sub>), heart rate (HR) value and ambient temperature. The bands have radio modules with which they form a Mesh radio network. This network, expanded by radio modules placed on drones, enables the transmission of information about the injured person's condition to the rescue command center.

The above review of technical solutions of monitoring systems was based on own materials and using PubMed, Scopus and Web of Science databases. Literature from the last 5 years was included. The following keywords and their combinations were used for the search: “continuous patient monitoring”, “indoor positioning”, “life monitors”, “patch monitors”, “real-time locating systems”, “ultra-wideband”, “vital monitor devices”, “vital monitoring indoor”, “vital signs recorders”, “vital signs recording”, “wearable sensors”, “wrist band”, “wrist monitoring”.

## **DIRECTIONAL ASSUMPTIONS FOR CREATING A REMOTE PATIENT MONITORING SYSTEM**

The assumptions will incorporate the results of an analysis of the data processing, sensor, localization, and signal transmission technologies available in the global electronics equipment market. Ready-made, commercial solutions of recorders are also available for use in one's own remote patient monitoring system designs. One such solution is a project by the US chipmaker Maxim Integrated Products. The cited project is a demonstration design platform [46] for making a recorder in the form of a wrist band. The manufacturer declares the ability to measure medical parameters SPO<sub>2</sub>, HR, HRV (heart rate variability) and acceleration in a three-axis coordinate system. A MAX86141 sensor using photoplethysmography (PPG) technology is used for medical measurements. The BLE system, PAN1326B, is responsible for wireless connectivity to the platform. The manufacturer also declares the ability to calculate a sleep quality algorithm. A schematic diagram of the platform is shown in Fig. 1. Depending on the needs of potential users of the remote patient monitoring system, it is possible to extend the presented platform with additional sensors or design another solution based on available technologies.

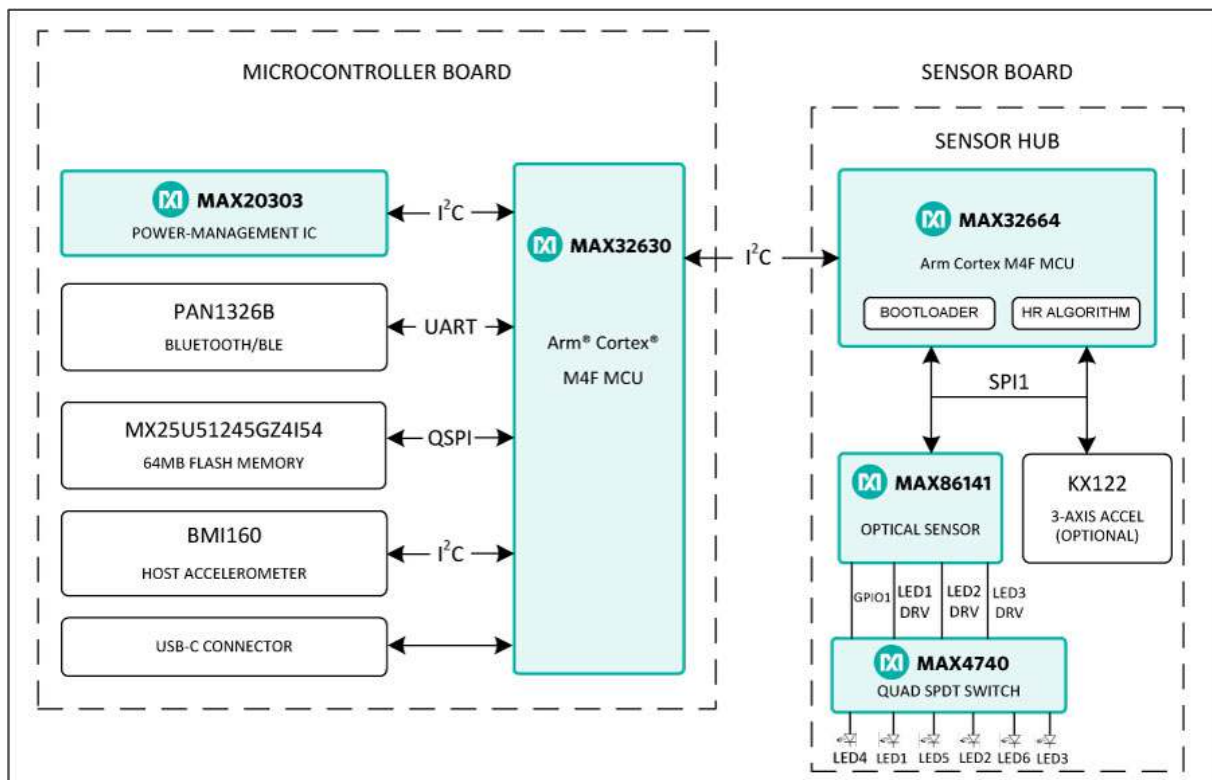


Fig. 1. Schematic diagram of the recorder platform from Maxim Integrated Products [47].

## DATA PROCESSING

Currently, there are two leading microcontroller architecture solutions the use of which allows for making a personal recorder for a remote patient monitoring system. These solutions are implemented in ARM (by Advanced RISC Machines) and PIC (by Microchip) integrated circuits [7,26]. The two companies' architecture solutions enable energy-efficient operation of the microcontroller and its integration with BLE (Bluetooth Low Energy), GPS and eSim (embedded-SIM) modules. Although the solutions of both companies provide energy-efficient operation of devices based on the use of their microcontroller architecture, the size of the recorder will be directly affected by the number of sensors used and, consequently, the size of the power source (battery).

## MEDICAL SENSORS

Photoplethysmography (PPG) sensors can be used to measure HR and SPO<sub>2</sub>. Sensors using this measurement technology have already been used by designers at WIML, in the EvaCopNet project. The sensors were located in a band worn on the wrist of the hand. The results of testing wrist bands with sensors of this type in experiments conducted under field

conditions were very good for SPO<sub>2</sub> measurement and promising for HR measurement. Given the advances in the design of these sensors, it seems reasonable to use them to measure SPO<sub>2</sub>. Table 4 shows examples of commercially available PPG sensors that can be used in the recorder design [28,2,25].

Tab. 4. List of PPG sensors.

Mark	Measurement capability	Dimensions	Manufacturer
OB1203 [28]	SPO <sub>2</sub> , HR	4.2mm×2mm×1.2mm	RENESANS
ADPD144RI [2]	SPO <sub>2</sub> , HR	5.1mm×2.9mm×1.45mm	Analog Devices
MAX86150 [25]	SPO <sub>2</sub> , HR	5.6mm×3.3mm×1.3mm	Maxim Integrated Products

The designers' long experience shows that the best HR measurement results can be achieved by using electrodes placed on the chest. For this purpose, an elastic band with electrodes embedded in it that adjusts its shape to the chest surface is used, with a HR measurement module connected to it. The table below shows examples of commercially available HR measurement systems that can be used to make an HR measurement module attached to a band with their marks shown in Table 5 [42,43].

Tab. 5. List of HR measurement systems.

Mark	Measurement capability	Dimensions	Manufacturer
AD8233 [1]	HR, ECG	2mm×1.74mm×0.15mm	Analog Devices
MAX3003 [24]	HR, ECG	5mm×5mm	Maxim Integrated Products
TIPD116 [37]	HR, ECG	no data	Texas Instruments

To assess body position, MEMS (microelectromechanical system) sensors, for example accelerometers, are used (Table 6).

Tab. 6. List of MEMS sensors.

Mark	Measurement capability	Dimensions	Manufacturer
ADXL372 [3]	3-axis accelerometer	3.3mm×3.1mm×1.14mm	Analog Devices
KX122-1037 [22]	3-axis accelerometer	2mm×2mm×0.9mm	KINONIX



## **PATIENT LOCATION**

Currently, useful technologies that can be used in patient location recorders are BLE and GPS technologies.

GPS-assisted localization technology [11] will perform well outside of buildings, but a significant energy expenditure for its operation must be expected. This expenditure can be reduced by making software changes to its mode of operation at the expense of accuracy. The technology requires no additional investment in its application other than the cost of the GPS module itself.

Technology of localizing with the help of BLE beacons. Beacons are miniature transmitters that generate a unique code of information to be transmitted to mobile receivers. The technology allows the network to be extended to determine patient location inside buildings. The energy expenditure for its operation is small. However, the technology requires additional costs to install beacons in the rooms of a given facility.

A sort of sister technology to BLE beacons is ZigBee beacons, which can be successfully used interchangeably for indoor location. ZigBee is a communication technology that uses a different radio frequency than BLE, but is also characterized by low power consumption.

A monitoring system based on available sensors and telecommunication technologies can be realized in two versions: basic and extended.

## **BASIC VERSION OF THE SYSTEM**

In its basic version, the system consists of two main components: a recorder in the form of a wrist band and a remote computerized data acquisition system. The basic version of a recorder can be equipped with:

- **PPG optical sensor** – used to measure heart rate and blood oxygenation,
- **gyroscopic sensor** – used to determine body position,
- **BLE module** – used for wireless communication with a computer equipped with a local information system,
- **GPS module** – used to determine the location,
- **eSim module** – used for wireless GSM communication with a remote information system,
- **LCD touch screen** – used to control the device,
- **physical control buttons** – used to control the device,

- **battery with inductive charging loop** – used to power the device.

## EXTENDED VERSION OF THE SYSTEM

In the extended version, the system consists of five main components: a wrist band, a chest band, an arm patch, a smartphone, and a remote computerized data acquisition system.

The wrist band can be equipped with:

- **PPG optical sensor** – used to measure blood oxygenation,
- **gyroscopic sensor** – used to determine the position of the body,
- **BLE module** – used for wireless communication with: a patch (mounted on the arm) and a band (mounted on the chest), beacons and a smartphone,
- **LEDs** – used to indicate the operating mode of the device,
- **button** – used to call for help in emergency mode,
- **battery with inductive charging loop** – used to power the device.

Chest band:

- **temperature measurement sensor** – used to measure the temperature of the body surface under the band,
- **electrical signal converter** – used to measure the frequency of heart contractions,
- **BLE module** – used for wireless communication with the band,
- **power module** – replaceable battery.

Module in the form of an arm patch:

- **sensor** – used to measure blood glucose level,
- **BLE module** – used for wireless communication with the band,
- **power module** – replaceable battery.

The use of additional modules in the extended version of the recorder allows to achieve many advantages over the basic version:

- 1) Relieving the energy burden of the wrist band module by moving HR measurement to a separate module, abandoning communication using eSim in favor of connecting to a smartphone using BLE.
- 2) Possibility to use additional modules equipped with sensors and own power supply: blood glucose level and HR measurement.

## IT SECURITY OF PATIENT MONITORING SYSTEM

When designing the architecture of a patient monitoring system, special attention must be paid to security issues.

In the case of the basic version recorder, security issues are related to the stage of authentication and data transfer from the recorder to a remote information system. An eSim card operating on a 5G GSM network with IPv6-based addressing should be used to enhance security. This combination of applied telecommunication technologies and communication protocol, when properly implemented, can partially protect against, among others, the following types of attacks: spoofing (impersonation), man-in-the-middle (information interception), DDoS (distributed denial of service) [15].

For the extended version of a recorder, security issues are related to the vulnerability of the Bluetooth technology to hacking attacks and external interference. When using Bluetooth or Zigbee wireless communication technologies, one has to take into account increased financial expenditures incurred for constant updating of internal software, to which security improvements will be introduced, along with disclosure of further vulnerabilities reducing the security level [38]. The BLE communication protocol between system components should be encrypted (using, for example, RSA or AES protocol) and the data format should be protected (classified) [40].

An equally important consideration is the security aspects of the remote information system used to acquire data from the recorders.

## AUTHORS' DECLARATION

**Study Design:** Marcin Piotrowski, Mirosław Dereń. **Data Collection:** Marcin Piotrowski, Mirosław Dereń. **Manuscript Preparation:** Marcin Piotrowski, Mirosław Dereń. The Authors declare that there is no conflict of interest.

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