Development of Wireless Medical Systems for Recording Biomedical Parameters, Created at ITAM in Recent Years, in Light of Global Achievements in the Field

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***Abstract*—Progress in technology and the demand for systems used for psychophysiological measurements, which record several synchronous parameter / signal types at a time, have a significant impact on the increasing number of innovative solutions available in the market. This article focuses on the design and engineering path of the created systems with special emphasis on the latest solutions, developed at the Institute of Medical Technology and Equipment (ITAM) in Zabrze. Competitive systems and other systems are also referred to by way of a comparative analysis, both in terms of their benefits and drawbacks. The overview shows that the new system may become a competitive solution for the already existing options and that it is characterized by a number of properties that make it unique.**

***Index Terms*—body sensor networks, wireless medicine, Hexoskin, Equivital, Zyphyr, Quariocor, BioSip, WBAN, wirless body area network, BioSip, Monitel**

I. INTRODUCTION

PROGRESS in technology contributes to the improvement of the quality of human life at all levels. The incessant search for more and more applications has resulted in the development of several innovative systems in many branches of industry. One of the branches is the measurement of a person's psychophysiological parameters. The measurements can be divided in the context of the group of people that they are dedicated to. The systems that are being developed make it possible to measure the parameters in various people, starting from the youngest ones, i.e. newborns, infants, through children, youth, mature adults, and ending with elderly persons. The parameters may be recorded and analyzed in persons representing the so-called higher risk group, in sick persons, and in those who care about prevention. The systems may also be classified from the vantage point of their application. They contribute to the improvement of the quality of life of elderly persons, let them live normal lives, as well as make it easier for the parents to look after young children. The devices are capable of supporting medical diagnostic systems or may by used by professional athletes, and all those who are willing to maintain a healthy and active lifestyle. They may also be used for special purposes, such as testing the predisposition of people exercising demanding professions, e.g. pilots, privileged vehicle drivers or soldiers [1, 2, 3, 8].

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The popularity and sales volume of individual devices depend on several factors. Apart from functionality, application, appearance, simple service, ease of use, and price, the factors also include an aspect of primary importance for medical products: conformity with all medical standards and medical certification [4]. When it comes to the ease of use, intensive works have been in progress since 2005 to develop the so-called smart clothes or underwear. Such clothes, apart from traditional applications (protection of the body, maintenance of body temperature, visual aspects), are equipped with dedicated measurement sensors for biomedical measurements such as ECG (used for the determination of HR, i.e. the heart rate, heart dysfunction, breath (depth, respiratory rate), the electromyographic signal (EMG), body temperature. A small electronic device, attached to the clothing, is responsible for the acquisition of these signals, and their transmission to mobile devices. Next, the signals are uploaded to the server and they additionally record the GPS signal, movement speed and the number of steps per minute.

The paper aims at presenting the latest solutions applied in monitoring systems, the market demand, and at carrying out a comparative analysis of the existing systems and those created at the Institute of Medical Technology and Equipment (ITAM). The article also demonstrates the difficulty in creating and introducing to the medical market the systems building on measurement modules which operate in WBAN (Wireless Body Area Network) networks.

From the constructor point of view, it is quite important to use the dedicated electronics that are used to manufacture as many measurement functions as possible.

In this case the SoC (System on Chip) devices are very helpful, as they contain analogue, digital and mixed circuits. They are quite popular in many branches of industry, ia. in medicine.

Polish constructors have engineered a BioSoC (Bio System on Chip). It can integrate measurements of such psycho-physiological parameters as ECG, EMG, body temperature, stress level, breath count.

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The main advantages of such system are high energy efficiency and reliability. Those chips have a great potential and are eagerly used in many wireless and wearable technologies. [26, 27].

II. Systems Developed at ITAM

In response to market challenges, ITAM in Zabrze has been designing systems for the measurement of psychophysiological parameters for various applications for a long time now [2, 5]. The first such systems making it possible to monitor the pilots and drivers are SMP 200 and SMP 300. The systems enable the measurement of such parameters as ECG, respiration, blood saturation, plethysmographic curve, EMG signal, skin resistance and blood pressure. Apart from biomedical parameters, the modules permit the monitoring of the subject's movement, as well as environmental parameters, such as the temperature and atmospheric pressure [3]. This was a measurement system concept where all the sensors and electrodes placed on the patient's body are wired to one measurement module which at the same time functions as an integrator. The integrator was connected to the patient's monitoring station in a wireless mode.

The presented idea was changed in order to develop another SkpBio system, among other things because additional parameters had to be measured, such as EEG (a record of the brain's activity) or GSR (galvanic skin response). The new solution provides for additional parameter measurement modules whose sensors are placed at a distance from the integrator (e.g. a GSR module placed on the forearm and an EEG module placed on the head). The separation of the integrator's function into smaller modules enables easier placement of electrodes on the patient's body and prevents connections with long cables which generate artefacts and restrict movement. GSR and EEG modules were connected to the integrator in a wireless mode; one of the integrator's functions is to gather data from the measurement modules. Additionally, the integrator records biomedical parameters whose sensors are placed nearby (on the chest), e.g. for the ECG signal or respiration [4]. Just like for SMP, the integrator enables monitoring of the subject's movements, as well as environmental parameters (temperature and humidity).

However, the scientific and construction research did not come to an end at this point. In the next BioSip project a decision was made to miniaturize the existing measurement modules and to introduce their new division owing to the necessary functionalities and development of new ones. A different method of charging the batteries in the modules was also proposed. Additionally, particular attention was paid to the comfort of attaching the measurement electrodes and their optimal placement. All introduced innovations are aimed at monitoring the biomedical and psychophysiological parameters by means of BioSip in various environmental conditions in such subjects as soldiers, drivers and pilots performing their professional duties [3, 4, 5].

Attempts were also made to use conductor materials for the construction of smart clothing integrated with the created systems. A shirt was developed that could be used interchangeably with ECG leads attached in a traditional way. Design and engineering research indicated a problem with obtaining the ECG signal of the quality that would be good enough for detailed medical analysis. A large number of muscle artefacts distorting the signal during movement is an issue. The developed solution requires to be further improved [5].

Further works consisted in solving the problem of synchronizing the network of measurement sensors placed all over the patient's body and handled by secondary measurement modules. The works mattered for the creation of systems for the measurement of parameters determined from the dependence of several varying signal types. The signals include e.g. PTT (*pulse transit time)* or PWV (*pulse wave velocity*). Their measurement requires two signal types to be recorded: the synchronous ECG and SpO_2 signals.

III. Systems Used for Monitoring Biomedical Parameters in the Global Market – Design and Engineering Issues

The idea behind all systems is based on a similar operating mode in which the main module receives data from peripheral sensors and modules. The systems vary with functionality, appearance, and software (both for mobile devices and web applications, there is a different method of data storage and data representation). The primary and key evaluation criterion before a device is selected is its functionality and the possibility to synchronize it with as many other devices as possible. The subsequent criterion is the design, ease of use, software and price. More professional medical usage requires the product to be certified, and in conformity with specific standards.

The systems available in the market make it possible to measure the psychophysiological parameters, such as the activity level, the number of steps made, the frequency of steps (*Hz*), and the amount of calories burnt (*kCal*). In most systems, this is achieved with accelerometric, magnetometric and gyroscopic sensors installed in the device. The device is usually placed on the subject's body. It may be installed e.g. on a dedicated belt fastened around the patient's hips (*BioSip, Monitel*). In systems based on smart clothing, the device is attached directly to the clothing (*OMsignal, AIQ Smart Clothing*) or inserted into special pockets on the clothing (*Equivital, Hexoskin*). The device may also be connected to electrodes, and thus attached directly to the body (*Zephyr, QARDIOCOR*).

Apart from the measurement of the subject's activity level, the device is also capable of wireless communication (e.g. via a Bluetooth) with the patient's workstation, e.g. a mobile device or a PC. The patient's workstation makes it possible to upload the data to a server where it is stored. The data is analyzed, and provides a basis for reports. In professional medical systems data is additionally sent to a medical facility in charge of overseeing the patients. The device also records medical signals and carries out their basic analysis. The available systems usually permit the measurement of the ECG signal used for determining the following parameters: the heart rate (HR), detection of the QRS complex, measurements of the R-R interval and the HRV (Heart Rate Variability) analysis. The analysis of the signal related to breathing allows for the determination of such parameters as the breathing rate, breathing volume, respiratory minute volume, detection of gas inhaled and exhaled. It is also possible to record the electromyographic signal (EMG) on the basis of which the tension of specific muscle groups is determined, as well as the electroencephalographic signal (EEG), the plethysmographic pulse curve used for determining HR, and blood saturation levels [8, 9, 10, 11, 12]. The diagram of such a system is shown in the figure below.

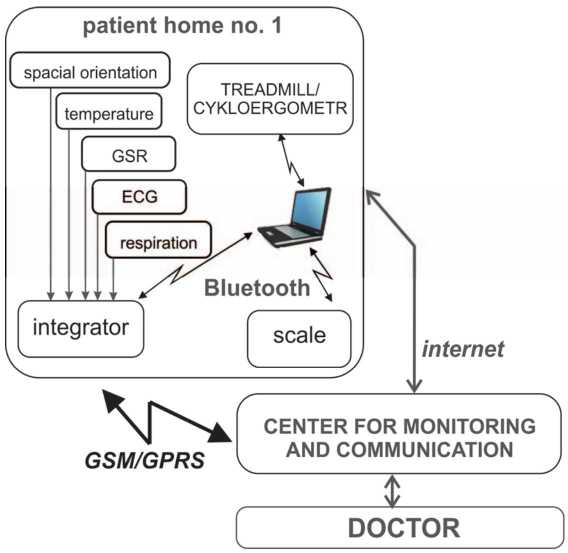

Fig. 1. Diagram of a system used for monitoring psychophysiological parameters.

Equivital is an example of such a system; this is an integrated, smart belt with sensors, capsules for the measurement of deep temperature of the body, devices for blood pressure, SpO_2 and GSR measurements [10]. Another system, *QRADIO*, provides both a device for the measurement of biomedical parameters, movement (*quardiocore*), and a *quardiobase* platform for the measurement of body weight [22]. At ITAM, one of the first systems of this type was dedicated to cardiac rehabilitation of patients at home. The system was responsible for integration of the cycloergometer with the scales, the blood pressure measurement device and the ECG device [3, 4, 5].

Depending on the manufacturer, the recording devices vary with shape, they may be round (*Zephyr*) [11] or streamlined like an arrow (*cardio leaf*)[24]; however, the main module is usually rectangular (*Hexoskin, Equivital, module integrators manufactured by ITAM*) [5, 9, 10].

The size depends mainly on the capacity of the battery required to supply power. The dependence is directly proportional: the heavier the battery, the longer the operating time of the device. The operating time matters for long-term monitoring, such as Holter monitoring. The modules *Hexoskin* 85x55x25 [9], *Equivital* 78x55x11 [10], *Qardiocore* 185x87x9 [22] (where the parameters denote, respectively: length[mm], width[mm], thickness[mm]), module *Zephyr* 28x7; the former parameter denotes the diameter, whereas the latter – thickness) [11]. For the sake of comparison, the latest integrator designed by ITAM has the following sizes: 120x75x25, while the ECG measurement module has been reduced to the sizes of 75x45x10, and the temperature module to 100x35x13. As was mentioned before, the weight depends on the battery's capacity, as well as on the materials used for the enclosure; the modules described above have the following weights: *Hexoskin* 90g, *Equivital* 38g, *Zephyr* 33g, *Quardiocore* 130g, *ITAM* integrator module 163g, ECG and/or respiration module after miniaturization 75g [9, 10, 11, 22].

Examples of modules (Hexoskin, Equivital, the ECG measurement module, as well as the integrator made by ITAM) are demonstrated in Fig. 2. The top left-hand corner depicts the ITAM integrator module, and the bottom left-hand corner shows the ECG and/or respiration module made by ITAM. The Hexoskin module is in the top right-hand corner, and the Equivital module is shown underneath.

Fig. 2. Modules for the measurements of psychophysiological parameters.

As regards the degree of protection provided against intrusion, the casings and enclosures of the devices usually have a rating of IP67. The first digit, 6, indicates the level of protection that the enclosure provides against access to hazardous parts and dust-tightness, and the second digit, 7, the level of protection against short immersion in water (30min at a depth of 0.15m above the top of the enclosure or 1m above the bottom for enclosures lower than 0.85m).

Each device has a user interface which consists of buttons and a lighted display module. The devices usually have one button used for initiating various events (e.g. by pressing the button quickly, by holding the button down for a while ((1s, 3s, 5s) or double-pressing it etc.). Additionally, the status of the device, e.g. recording, data upload, is indicated by a LED diode. The devices vary largely in this respect. Some devices are equipped with one diode which indicates all the necessary information, some other have separate LEDs installed for each functionality, e.g. one for the battery level, another one for the communication or operation mode. As regards ITAM devices, smaller modules are equipped with one button and LED diodes, while the integrator has four additional buttons, one for switching the module on and off, and the remaining three for handling the menu shown on a dedicated graphic display.

The modules are usually charged through wire and a special socket in the device. The socket may be a microUSB or a dedicated socket designed by the manufacturer and connected directly to a USB socket or to the mains socket via an adapter. There are solutions with dedicated charging stations for a large number of modules. At ITAM, inductive charging has been chosen for smaller modules, e.g. for the measurement of body temperature. The module is charged when placed on a dedicated charging plate connected to a USB socket. This solution has a positive impact on the tightness of the enclosure; the tightness depends on the number of sockets (openings in the enclosure).

All devices have built-in memories to save the recorded examination. The examination is uploaded from the memory after the device is connected to a mobile device, a patient's workstation etc. This is designed in different ways in the available devices. The poorest solution seems to be the one where the data is irretrievably lost in case of unsuccessful data transmission to the mobile device or the patient's workstation [10]. The best solutions permit the management of the memory of each examination by the user. It is the user who decides which recordings should be uploaded to the server or database, and which of them should be deleted [9]. Most available systems are equipped with software for mobile devices. Versions which are compatible with iOS, Android or Windows Phone, as well as those which do not require advanced mobile devices [5, 9, 10, 11, 22, 24] are an asset. The designed software must be simple and intuitive because it may be used by persons at different ages. When it comes to presentation methods, the systems compete with one another in terms of the ways of displaying the parameters. The best visual solution encountered so far is one where the ECG curve appears against a backdrop of the lungs gradually changing to white depending on whether the patient is inhaling or exhaling; the next tab presents the intensity level of the physical strain, and all measured parameters. The system *Zephyr* is characterized by variable software for mobile devices, suited to the user's current needs. The applications for mobile devices also make use of various functionalities such as reception of the GPS signal and/or verification of the received signal with that measured by the device [11]. For *Hexoskin* the data is uploaded to a PC with the use of dedicated software [9]. The application detects the device and sends the data to a web server automatically after login. Additionally, it shows the battery levels, charging control, software update, device memory management and monitors data upload to a web server.

Due to an extensive network application, the user may browse through the recorded data on the web server, as well as analyse statistics and browse through reports. The application enables data download in various formats [6]. Developing an application to browse through and collect data on PC computers is an alternative solution. Sometimes the manufacturers create software versions to be used in our leisure time and when practising sports; they are designed for everyone. Besides, other software versions are intended for professional and qualified medical personnel for diagnostic purposes. Each version must comply with certain requirements [10]. Significant restrictions are imposed on applications for medical purposes because the data that they deliver is used for diagnostics and subsequent treatment, and ultimately people's health and life depend on it. Medical applications are also secured against forgery and potential interception.

IV. Description of the BioSip System

The BioSip system was developed in order to miniaturize the measurement modules and increase their number so that they can be matched with their usage in the best possible way [5]. This solution offers more comfort during the test for the subject, and an optimal selection of the required monitoring modules. A flexible arrangement of a personalized system, adjusted to a specific disease, offers a positive quality/price ratio [8].

The basic system consists of seven modules, and a workstation for data collection and presentation; this may be a PC, tablet or smartphone. The measurement modules may be divided by the recorded parameters and their function. The modules can be divided by functionality into those which only record the biomedical signal and/or environmental parameters, and a module which additionally acquires data from other modules, collects the data and transmits it to the monitoring station (the so-called integrator) [6, 7, 8]. The developed modules and their proposed placement on the human body are shown in Fig. 3.

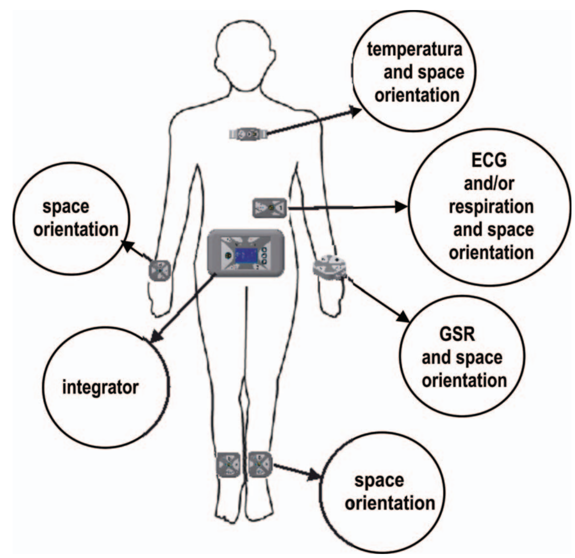

Fig. 3. Measurement modules placed on the human body.

The described system uses one integrator module. The integrator is capable of measuring the environmental parameters, such as humidity, temperature or pressure. The integrator also measures biomedical parameters by recording the ECG, EMG, respiration and SpO_2 signals.

The integrator communicates with other modules in a wireless mode via radio transmission in band 2.4GHz (Nordic), whereas transmission to the operator/host is handled via a Bluetooth interface. The integrator has a real-time clock and GPS. The user interface is convenient because of a graphic display and a few buttons.

The system also consists of a module which allows GSR and spatial orientation measurements to be made. Skin impedance can be measured within a range of 10kΩ - 10MΩ.

The module, in the form of a watch, is fastened to the subject's forearm. It is also capable of measuring and monitoring the position of the wrist with the accelerometric sensors [5, 8].

The next measurement module has functionalities enabling the measurement of the patient's body temperature (with two independent temperature sensors) and environmental parameters, i.e. temperature and humidity. The module has an accelerometer.

The subsequent measurement modules are equipped with accelerometric sensors, gyroscopes and magnetometers. One of them is capable of simultaneous recording of a dual-channel ECG curve and respiration, the other one can optionally record the two channels of the ECG curve or respiration [8].

The spatial orientation module is another element of the system. This is a small-sized electronic system enabling the measurement of spatial orientation with the use of the accelerometer, gyroscope and magnetometer. The position of the patient's parts of the body and the patient's movement can be monitored with a network of modules placed all over the body. A system consisting of such a network of sensors connected in a wireless mode with relevant software responsible for visualization is likely to be competitive with other systems in the future, dedicated to the analysis of biomechanics of the body or the performed activities or movements (e.g. walking, running, sitting) [8].

It is worth mentioning that the listed system elements may be duplicated freely (e.g. the system may additionally consist of several other modules for temperature measurement and spatial orientation). The modules may be selected freely. It is also possible to create a system without an integrator. In such a case the sensors, placed on the patient's body, will transmit the data directly to the central unit (a mobile device, a PC). For instance a system dedicated exclusively to ECG measurements can be created. It is possible to create a network of temperature sensors (the temperature is then recorded from various parts of the body) or a network consisting of orientation sensors which records the subject's movements. If the above configurations are used, the integrator and other measurement modules may be omitted [8].

Subsequent modifications included the adaptation of the system to the measurement of parameters depending on the recording of several biomedical signals. PWV, i.e. pulse wave velocity, is one of such parameters [18]. It is critical for the evaluation of arterial stiffness. PWV is determined by means of the recorded ECG signal and pulse. The ECG signal is used as a source of the reference signal; the pulse transit time runs from the moment when the R wave appears. The moment when the pulse wave appears is determined in different ways in scientific literature. It is assumed for instance that this is the beginning of the wave defined as the intersection point of the tangents to the base and slope of the rising pulse wave [14], the moment of maximum speed of the rising process of the pressure wave [14] or the moment of achieving 30% [15] or 50% of the wave's maximum [16]. First of all, recording of the pulse signal from the finger was adjusted to be made via the integrator in such a way so as to achieve high frequency sampling (1000Hz) of the same frequency as the ECG signal. Appropriate software was developed, implemented and tested in a microcontroller, with added algorithms for the analysis of both signals, and with the option to compute significant parameters. As a result of further development of the system, the measurement was made in a dispersed manner, and a seventh module was added to monitor the pulse wave on the subject's hand. The module is also capable of measuring the temperature and GSR, thus replacing the aforementioned modules, but, as a matter of fact, it has been designed to measure, in line with the integrator module, the PTT, i.e. the pulse transit time, and to compute the PWV, i.e. the pulse wave velocity. To this end, the measurements must be made synchronously. The data exchange protocol enables synchronization of their clocks.

V. System Comparison

During the works on the design of the BioSip system, it was compared with the most popular and successful systems for the measurement of psychophysiological parameters, and with those that might be compared with systems created at ITAM in terms of their functionality. Gaining insight into the technology and solutions was one of the objectives of the project in question. A decision was made to compare *Hexoskin, Equvital, Zephyr, QArdio* systems in terms of the price/quality ratio, the recording method and ease of use. Each system element was evaluated (the recording device, biosensors and software). Table I reveals system comparison in terms of their interesting functionalities.

TABLE I.
System comparison table

Parameter	*Hexoskin*	*Equivital*	*BioSip*	*Zephyr*	*QArdio*
heart rate	x	x	x	x	x
heart rate variability	x	x	x	x	x
physical activity	x	x	x	x	x
perspiration		x	x		x
arterial oxygen saturation		x	x	x	
long-term measurement temperature of the skin surface of the sternum		x	x		x
short-term measurement temperature of the skin surface of the sternum				x	x
“deep” temperature of the body		x			
electromyography			x		
position of the body at night	x	x	x	x	x

It can be concluded from the presented data that *Equivital, QArdio and BioSip* systems offer the highest functionality. A large number of functions is as important as their optional selection in the system. As a result, they buyers select only those modules that are necessary in the system, which leads to significant cost reduction. Systems created at ITAM are more flexible in this respect than other systems. Moreover, the *BioSip* system may be adapted in such a way that it becomes a system for recording motion or for biomechanical analysis (motion capture techniques) provided that appropriate software is added. The modules may be duplicated freely in the system, e.g. the number of modules for the measurement of orientation or temperature. None of the other presented systems is equipped with such a functionality.

Yet, a close dependence between comfort and quality of the obtained signal may pose a problem with the design of various clothing items with sensors. Shirts with electrodes made from conductor materials woven into them are much more comfortable to wear. Unfortunately, they are rather difficult to put on. On the other hand, measurement straps are easy to fasten and unfasten although very uncomfortable in long-term use (they tend to chafe the body while lying down and rub the skin at the fastenings). However, the quality of the signal from the straps is much better than from the shirts. It is a good idea, like in the case of Zephyr, to have a choice between a shirt and a strap, hence either the quality of the signal or comfort of use will prevail as necessary.

The design and parameters of the device recording the data also play a role in the evaluation. Hexoskin, Equivital and Zephyr have one device connected directly to the electrodes. The device is equipped with a similar interface (one button and light electrodes). Those with LED electrode indications (e.g. Equivital or Zephyr) are more convenient. A single button is convenient, although the device may be switched off accidentally during use. Another evaluation criterion is the battery capacity, the charging method and charging time. Equivital has the best parameters in this respect; the charging time is one hour which is equivalent to 35 recording hours without an active Bluetooth transmission [10]. Zephyr is the smallest in terms of size and weight. The module of this system is connected to the sensors by screwing in, the other systems have sockets. The sockets make it possible to charge the device via USB. Zephyr must be charged with the use of an additional base [11].

The presented systems also differ by software. The problem is solved best in Hexoskin where a PC application makes it possible to upload data to a server. Data from a mobile application are also uploaded to a server. The recorded training sessions and the course of the activity may be browsed with network applications. Practical solutions have been provided for memory management and data upload. Data in various formats may be downloaded directly from a web server. A device manager accompanies the Equivital product to upload the data to a file and save it in a different format. Unfortunately, the data are difficult to browse because browsing requires extra paid software. Zephyr has diversified software for the mobile device. The software interface is very simple and intuitive. The applications contain advanced help for the user. They are adjusted to the needs of individual patients by monitoring them at home or during a stay in specialist facilities. The quality of the application is a key criterion for system selection by the patients [9, 10, 11, 22, 24].

VI. Summary

The available devices measuring the psychophysiological parameters may be integrated in a cloud, within the Internet of Things (IoT) which is gaining popularity in the 21st century, or within the Internet of Everything (IoE) in broad terms [20, 21]. The idea behind the cloud is to create a network of as many devices as possible, and connect them in a smart and easy to manage manner, based on secure infrastructure.

Additionally, owing to IoT, the systems measuring biomedical parameters may also acquire information from devices and appliances for everyday use, e.g. the scales for weighing the body or kitchen scales used to determine the calorific values of the meals. This solution allows for maintaining the balance between the consumed and burnt calories, and helps the user get rid of excessive weight and keep in shape. The systems are also capable of reminding the users of the need to take exercise or to relax. They provide monitoring during sleep, and warn against dysfunctions such as sleep apnoea. The systems may also be used by patients suffering from diabetes, chronic kidney diseases, hypertension or cardiovascular diseases [17, 18, 19]. They permit all-day blood pressure and oxygen saturation (SpO_2) measurements. In the future, the presented ITAM systems will be adapted for use within the Internet of Everything (IoE).

BioSip is a system developed, among other things, on the basis of experience gained in the process of developing previous versions of systems dedicated to monitoring biomedical parameters at ITAM. In light of the existing market trends for this type of products, a decision has been made to use the best and optimal solutions in the system. Not only basic solutions have been applied; a different, more comprehensive concept has also been proposed. Since a more varied integrator interface was created, it was possible to improve its ease of use (e.g. parameters can be changed now without the need to use external software). As mentioned before, the system may be adapted without any problems to the recording of detailed spatial orientation of the patient's body, as well as its biomechanics. The system's measurement modules may be selected and duplicated freely as necessary. The modules are capable of communicating directly with the monitoring workstation or via an integrator.

It is also worth mentioning that the created systems have CE and FCC labels and are not certified as medical products. The ITAM systems are being prepared to be submitted for medical certification, which distinguishes them from the other systems. Presumably, subsequent systems created at *ITAM* may become tools supporting practical medicine after market launch. It is worth noting that the potential and the future of medical solutions are systems using on-chip systems such as BioSoC.

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