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A Modular System for Rapid Development of Telemedical Devices

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Abstract: Remote patient monitoring is gradually attracting more attention as the population in developed countries ages, and as chronic diseases appear more frequently in the population. Miniaturization in electronics and mobile technologies has led to rapid development of various wearable systems for remote monitoring of vital signs, supervision systems in home care, assistive technologies and similar systems. There is a significant demand for developing the necessary devices very rapidly, especially for shortening the way from an idea to a first function sample. This paper presents a solution for rapidly developing devices for telemedical applications, remote monitoring and assistive technologies. The approach used here is to design and realize a modular system consisting of input modules for signal acquisition, a control unit for signal pre-processing, handshaking of data communication, controlling the system and providing the user interface and communication modules for data transmission to a superordinate system. A description of specific applications developed on the basis of the system is also presented in the paper.
Key Words: telemedicine, telemonitoring, assistive technologies, heart rate, electrocardiography, plethysmography
Category: B.4, I.5.4

1 Introduction

Information and communication technologies have become integral and almost inseparable parts of our lives. They have also penetrated many application areas, including medicine. In connection with this, the new term *eHealth* has appeared. It refers to activities in healthcare practice that are supported by electronic processes and communication. The term encompasses a rather wide range of systems on the border between healthcare and information technology. The systems include electronic health records; telemedicine; consumer health informatics; health knowledge management; medical decision support systems; and *mHealth* (the use of mobile devices for various applications in healthcare).

One of the fast developing areas is remote patient monitoring, which uses devices to collect data remotely and send it to a monitoring station for interpretation. These *home telehealth* applications may include a specific vital sign, such as blood glucose or heart ECG, or a variety of indicators for homebound patients. These services can be used to supplement the services provided by visiting nurses. This area has been attracting more and more attention as the population in developed countries ages. Especially in this area we can find a lot of mobile applications based on wearable sensing systems (wearable sensors, body area networks, etc.) These systems enable vast amounts of data on individuals to be measured and collected. This multiparametric data may include physiological measurements, medical images, biochemical data, and other measurements related to a person's activity, lifestyle and surrounding environment. There will be increased demand for processing and interpreting this data for accurate alerting and signalling of risks, for supporting healthcare professionals in their decision making, for informing family members, and for informing the person himself/herself.

Although many issues have been successfully introduced and solved, both in applied research and in the development of prototypes and final products, there are still many problems on the waiting list. Nowadays we can measure many physiological parameters on a human body relatively unobtrusively: electrocardiogram (ECG), heart rate, breathing rate, body temperature, blood pressure, energy output, etc. [Xiao-Fei et al. 2008]. Many clinical trials have been performed e.g. [Martín-Lesende et al. 2011, Kraai et al. 2011], assessing the usefulness and efficiency of telemonitoring systems. However the task of processing data and especially evaluating and interpreting it remains challenging. There are many reasons for this, especially if the signals are recorded while the persons are performing their daily activities in a standard environment, and not in a noise-free laboratory. The data contains noise and artefacts, both from the body itself (movements, poor contact of sensors to body) and from the environment. The task of noise and artefact removal has not yet been fully solved, and remains open for future research and development. Another challenging and open issue is standardization of the data formats – ECG, electroencephalography, and other medical devices for measuring biological signals generate proprietary data formats which are usually not publicly accessible. It is impossible to integrate these devices into larger systems, because the signals can be processed only by software delivered by the device producer. Data transfer protocols, security and data privacy are further issues. Many papers analysing these problems have been published recently, comparing existing standards and recommending future standardization activities, e.g. [van Broeck 2009]. Standards have been defined for wired and wireless communication between electronic devices [IEEE 2005, IEEE 2006, IEEE 2007]. However, these standards define communication protocols only, and do not solve the problem of the semantic content of the transmitted data. In recent years, several projects have focused on semantically correct exchange of data between devices and information systems. One example is the iCARDEA project [SRDC 2012], in which the interface Medical Device Modelling Tool has been designed and developed. Another example is presented in [Lee and Gatton 2010], where a scheme for data exchange between HL7 and IEEE 1451 standards is proposed. [Lhotská et al. 2011] propose a general architecture for systems of this type respecting existing standards

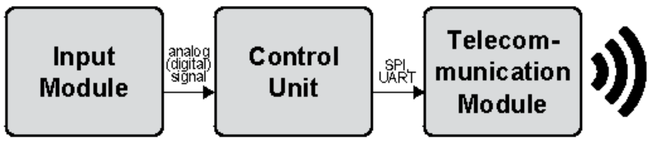

Figure 1: General concept of the system

in communication between individual modules. It covers the whole chain from data acquisition/measurement, via data collection, identification and transformation, to evaluation and storage in an EHR system. To enable the plug-and-play approach, the interfaces must be based on well-defined standards. We have in mind especially the following categories: ISO units for measurement of physical quantities, ISO IEEE standards in communication, standard file formats in the software area, and HL7 standards on the information systems side.

Another very important problem is the ability to develop a first function sample. Generally, there are many ideas and many opportunities for using telemedical devices in the field of assistive technologies and monitoring of vital signs, but it is often not easy to verify whether the idea can be realized and used in a wider range. Before a new idea is tested and evaluated, there must be a function sample of the intended device, and a set of tests needs to be carried out. The crucial problem is how to develop the function samples rapidly and inexpensively. It seems that developing function samples rapidly is the critical element in the development process, and has a decisive influence on the success of the project.

This paper presents a modular system for rapid development of telemedical devices. The next section describes the design and development of the system. The solution presented here allows synchronized measurement of physiological parameters, data processing and broadband communication. The subsequent section focuses on the tested applications. The conclusions summarize the results, discuss issues closely linked with these applications, and suggest topics that should be considered when developing future systems.

2 Hardware Design and Realization

The general concept of the modular system presented here is based on several requirements. The most important of these are:

- system modularity

  One of the most important requirements is to have a modular system. This concept provides the opportunity to make quick and easy changes to the design of a device that is under development.

– and an easy-to-use system.

  Another requirement is to have an easy-to-use telemedical kit. This is very important, because it enables the system to be rebuilt for new applications with minimum effort.

The system presented here is modular, and can be divided into three main parts: input modules, the control unit, and the telecommunication modules (see Fig. 1). The main task of the system is to sense several vital signs, e.g. electrocardiograph (ECG), blood pressure (NIBP) and oxygen saturation (pulse oxymetry, SpO2), to process acquired signals, and to communicate them to a PC-based system (a desktop PC, a laptop or a computer network access point) using some type of standardized wireless technology, such as Bluetooth, WiFi or GSM. The choice of the vital sign that is monitored by the system and the choice of the wireless technology used for data transfer depend on the intended application of the system.

The input modules transduce measured biosignals to an electrical value, especially analog voltage (though any type of digital data can be used as an input value). The output of these modules can be a one or more dimensional signal. This means that the control unit behind the input module has to be able to process several signals at the same time, for example leads I to III for ECG signal processing, or red and infrared signals for pulse oxymetry measurements.

The control unit is the core of the whole system, and has to perform several tasks simultaneously. The most important of these are:

– to acquire input analog signals and to convert them to digital data,

– to process these signals and/or to parameterize them,

– to prepare data packets according to a defined communication protocol,

– to control the communication line (handshaking the line) and to send the data,

– and to provide the user interface of the whole system.

Communication modules are the last part of the system. The main task of these modules is to support signal transmission between the control unit and the PC based system on the level of the physical layer. The handshaking of the line is controlled by the control unit and/or by the PC based part of system.

The communication interfaces between the modules are strictly defined, the modules are reciprocally interchangeable. This means it is possible to choose the measured signal (for example ECG, NIBP, SpO2) and the type of connection (Bluetooth, WiFi, GSM), choose appropriate modules and set the user-defined system up quickly and easily. The data format is well defined, and satisfies the basic requirements on interoperability [Lhotská et al. 2011].

2.1 Input Modules

A set of input modules has been prepared for general use. The modules allow monitoring of commonly required signals. This ensures that the system can be used as the basis for a wide range of applications.

All modules originate from our own circuit design, and they are realized using standard components mixed on surface mount (SMT) and through-hole technologies. The PCBs are designed as four layer boards, with two signal layers and two layers for power supply and shielding. The size of one module is approximately 5×5 cm (depending on the type).

2.1.1 Electrocardiography

Electrocardiography (ECG) is a widely used method for heart diagnostics. An ECG signal, an electrocardiogram, is an electrical signal reflecting heart activity. A three-lead system (leads I, II and III) is usually used for monitoring vital signs. Leads I, II and III are defined as the difference between the potential (voltage) of the electrodes placed on upper extremities and the left leg. The three electrode system is sometimes supplemented by a fourth electrode, placed on the right leg. This electrode is used as a feedback electrode for decreasing noise.

In our design, the ECG input module has 4 inputs (three signal electrodes and one feedback electrode) and 3 analog voltage outputs (leads I, II and III). This means that the ECG circuit design consists of amplifiers, differentiators and antialiasing and supply voltage noise reduction filters.

2.1.2 Plethysmography

Plethysmography is a standard measuring method for obtaining the volume changes caused by pulse wave propagation. Plethysmography is based on illuminating the skin and measuring the changes in light absorption. Standard plethysmographs use monochromatic light to measure tissue light transmission. The skin is illuminated by an infrared LED, and a phototransistor is usually used for light detection. The LED and the photodetector are most often placed on the inner sides of a finger peg.

In our design, the plethysmography module has combined input/output on the patient side (driver signal for LED and signal from the photodetector) and two analog voltage outputs (raw infrared signals – AC and DC components separately). This means that the circuit design of the photoplethysmography module consists of the LED driver, the input amplifier, the ambient light zeroing circuit, the filters for noise reduction and for separating the AC and DC component, and the antialiasing filters [Havlík and Dvořák 2010].

2.1.3 Non-Invasive Blood Pressure

Non-invasive blood pressure (NIBP) is the most frequently measured hemodynamic parameter. The basic measurement uses an electronic tonometer with a cuff on the left arm. In the standard approach, the systolic and diastolic pressure values are evaluated using the oscillometry method. In fact, the values are not directly measured, but are only computed from the oscillometry curve. This is crucial, because it has been argued that the oscillometry signal (curve) is more important than the systolic and diastolic pressure values [Mancia at al. 2007].

In our design, the NIBP module has one input/output on the patient side (air pressure in the cuff), and one analog voltage output represents the pressure in the cuff. This means the circuit design of NIBP module consists of the driver for the air pump, the air pump for increasing the air pressure in the cuff, the electronic valve controller for decreasing the pressure in the cuff, the pressure sensor with the voltage output, and the signal amplifier [Dvořák and Havlík 2010].

2.1.4 Phonocardiography

A record of the sounds produced by the contracting heart, the heart valves and the great vessels – a phonocardiogram (FCG) – is the standard signal in cardiology. It is a vital sign that includes a lot of information about heart function, including its mechanical function. The signal is usually sensed manually by a physician using a phonendoscope, but without any recording. A record of the FCG can be acquired using an appropriate microphone and a simple acoustic amplifier.

In our design, the FCG module has the input fitted with the head, with the pipe from the phonendoscope, and with a high sensitivity microphone. The output value of the FCG module is the voltage corresponding to the acoustic pressure in the pipe. The circuit design of the FCG module consists of the input amplifier and the filters for reducing the noise.

2.2 Control Unit

The main function of the control unit is to acquire signals from the input module, to filter and/or parameterize them, to pack them to appropriate data packets, and to send them via the communication module. The STMicroelectronics STM32 Primer2 module has been chosen [STM32 Primer2 2011] as the control unit. The Primer module is versatile and mechanically robust, with sufficient computational performance. The module includes an ARM Cortex-M3 processor, a 512 kB flash memory, a Li-Ion battery (which provides power supply autonomy, and is important for the safety of the patient), a touch screen display, an on-board 3D MEMs accelerometer, analog and digital inputs, SPI, I2C, mini USB and USART busses, and a MicroSD card connector.

The control unit is supplemented by the extension board. The extension board provides the possibility to connect the external modules with the control unit, and/or to connect the external power supply to the control unit.

2.3 Communication Modules

Communication modules serve to transfer data from the control unit to the PC based system using standard wireless communication technologies. The BT, GSM and WiFi modules have been developed for this application. This provides many opportunities for utilization, from local transmission (BT or WiFi connection) to long distance data transmission (GSM). The design and realization of the communication modules are very similar as in the case of input modules – four layer boards with their own circuit design, which are similar in size. The communication modules are based on small commercial sockets, such as KC Wirefree KC21 (BT) [KC WireFree 2011], ConnectOne Nano Socket iWiFi (WiFi) [ConnectOne 2011] and Cinterion TC65i (GSM) [Cinterion 2011]. These types of modules provide fully embedded wireless communication port systems.

2.4 Software Libraries

The hardware realization of the telemedical system is supplemented by software libraries in our design. The software libraries that are implemented include code libraries for the control unit, pre-prepared firmware setups for the communication modules, and the software application for the desktop PC. This application serves as a basic gateway from the system to the PC-based platform, and provides an easy way to set up the parameters for the transfer and initial visualization of the data that is received. The role of the software libraries is to support users in developing their own project without detailed knowledge of the registry implementations in each module and assembler coding, and also without additional requirements on time and effort.

2.5 Hardware Realization

All modules are realized using standard components mixed on surface mount and through-hole technologies. The PCBs are designed as four layer boards, with two signal layers and two layers for power supply and shielding.

3 Applications

The designed and realized modular system for rapid development of telemedical devices can be used as a basic platform for many applications in the field of

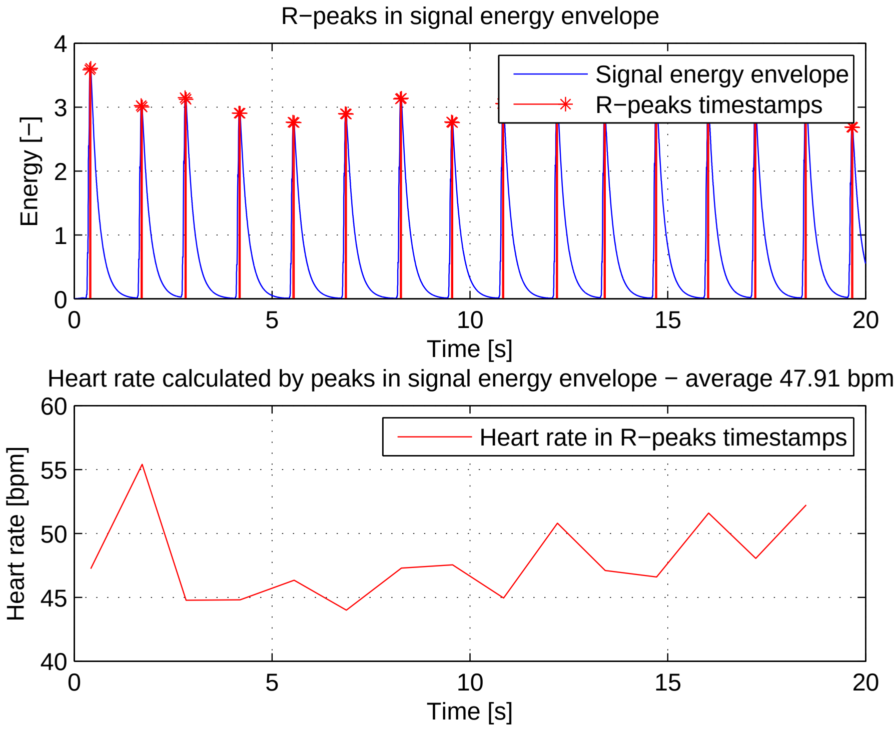

Figure 2: The smoothed ECG signal, localized R-peaks and the computed heart rate

assistive technologies, telemonitoring of vital signs, or as a supervision system at home and in institutional care for sick, disordered or elderly people, etc.

The system is also able to transfer both raw data and aggregated data. The communication protocol and the data processing method can be chosen according to the application demands.

The evaluation of the system has been based on its successful utilization in developing two telemedical devices – a system for long term heart-rate measurements, and the Intelligent Primer Nurse project.

3.1 Long Term Measurement of Heart Rate

Long-term measurement of the heart rate (HR) is the most common vital signs monitoring method. Many cardiac abnormalities can be diagnosed from a long-term record of heart activity. For these reasons, long-term recording of heart activity is used not only for medical purposes, but also during psychical and

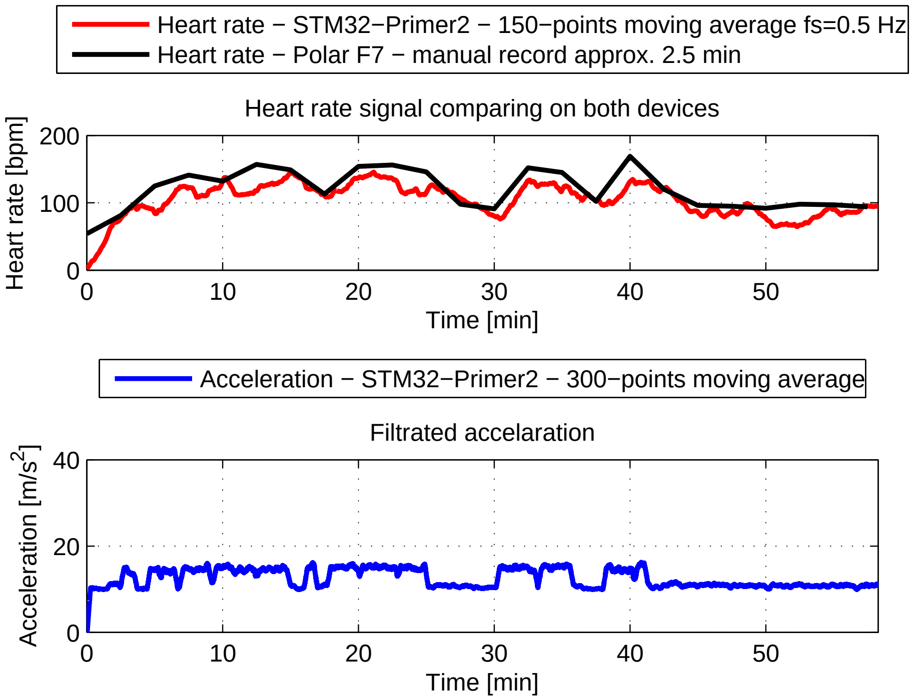

Figure 3: Comparison of the signals from our device based on STM32-Primer2 with the signal from Polar F7 during running, walking and standing at ease

physical stress testing. Recordings of acceleration and heart rate are frequently performed in physical stress tests.

A portable device for long-term HR measurements has been developed, using the modular system described above. The device consists of a control unit and an ECG input module. The measured ECG signal is processed in the control unit, and the extracted HR is stored to an SD card. Storing to an SD card is fully implemented directly in the control unit. The device does not use communication modules.

The device is supplied by the internal battery from the control unit. It significantly decreases the number of necessary cables only to cables for connecting electrodes. Thus the device is fully autonomous.

There are many methods for obtaining and processing the ECG signal, and for computing the HR from the signal. Unfortunately, only a few of these methods can be implemented in small portable devices, due to the lack of computational performance in these devices. A method for processing ECG signals with very small computational demands was therefore designed and implemented in our project. The raw ECG signal is first normalized and the mean value is removed. After normalization, 50 Hz filtering is applied using a bi-quad band stop, and filtering of breathing activity artefacts is also applied, using the 0,5 Hz Butterworth high pass filter. Finally, the signal pre-processing is completed by R-peak filtering using a Butterworth band pass filter with pass band 15 Hz to 20 Hz. The filter parameters are determined and a complete description of the signal processing methods is presented in [Parák 2010].

After signal pre-processing, the energy of the ECG is computed. This operation enhances the R peaks in the signal. Finally, the integrator filter is applied to the signal. The filter smooths the signal and highlights the R-peaks. After this operation, the R-peaks are localized by the thresholding and the HR is computed from the R-R intervals. The signal smoothed by the integrator, the localized R-peaks and the computed HR are shown in Fig. 2.

The realized device was evaluated during a stress test consisting of running, walking and standing at ease in a park. The Polar F7 professional HR meter [Polar USA 2012] was used as a reference device for the evaluation. A comparison of results from the device that we developed and from the Polar F7 device is shown in Fig. 3. The upper part of the image shows a comparison between the heart rate computed by our device and by the Polar F7 device, and the bottom part shows the signal from the accelerometer. This signal corresponds with the sensed activity – running, walking and standing at ease. It can be seen that the heart rate increases during running and decreases during walking and standing at ease.

The results from the device are fully sufficient. The main advantage of the device is the possibility to store signals for future processing on an SD card or to transfer them to a superordinate system.

3.2 Intelligent Primer Nurse

This application focuses on the design and development of a device for monitoring vital activity. The device is able to monitor vital signs continuously and to activate an alarm if the signs are not within the specified range. This means that the device is a kind of personal, portable vital signs monitor, similar to the monitors in intensive care units. Chronically diseased, elderly and other threatened persons are the target group of users.

The device is based on the EvoPrimer [STM32 EvoPrimer 2012] development kit, which is the new version of the STM32 Primer2 kit. The electrocardiography (ECG) and photoplethysmography (PPG) signals are acquired by the device described above, and then they are sampled and processed by the software in the

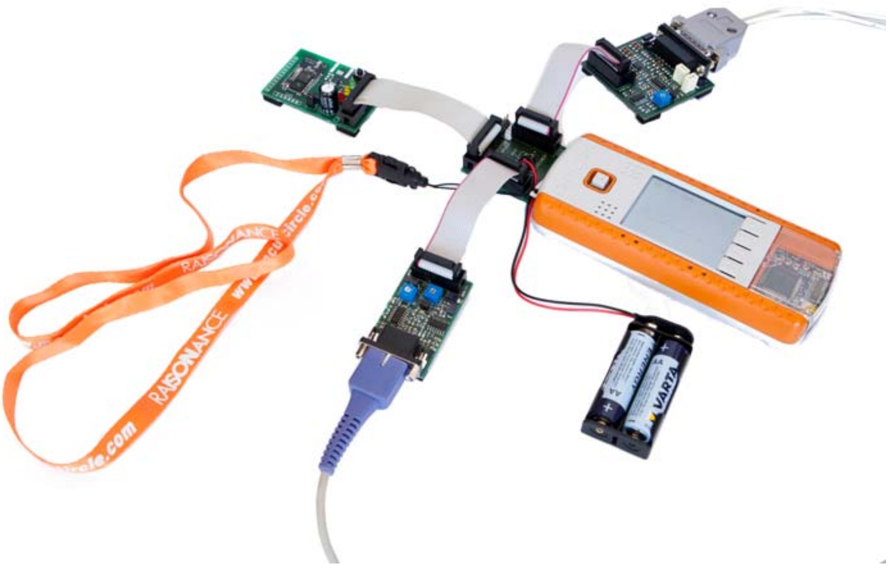

Figure 4: Intelligent Primer Nurse

control unit. The signals are displayed on the screen in real time. The behaviour of the signals is supplemented by the current heart rate value.

A heart rate alarm, which detects low and high heart rates, is implemented in the device. The thresholds that activate the alarm are 50 bpm (beats per minute) and 100 bpm. The alarm informs the user about any probable heart rate problem that may cause a life-threatening situation.

Another alarm that is implemented is the activity alarm. The alarm starts when the user shows no activity for a long period of time. This alarm works like the vigilance button in a locomotive. The user has to move, or to click the primer button, every 30 seconds in order to deactivate the alarm. Movements are detected by the built-in accelerometer.

Information about the heart rate, with time marks, is logged on a flash card every 4 seconds. If the device is connected to a computer via Bluetooth, the heart rate, the selected signal and alarm flags are visualized by special software on the PC in real time.

Figure 4 shows a photograph of the whole Intelligent Primer Nurse device (IPN). It is a good example of the capabilities of the system presented here. As was described above, the IPN project consists of an ECG module (upper right module), a PPG module (bottom), a BlueTooth telecommunication module (upper left) and a control unit (in this case, the EvoPrimer development kit was used). The development of an IPN device based on this system requires only that the modules be connected and that the firmware be implemented. This greatly decreases the demands on developing hardware parts, and reduces the whole development process to minimum operations. It greatly shortens the way from an idea to a function sample. This is the most significant contribution of our modular system.

3.3 General features and future applications

The applications that have been presented are not the only possible applications. There are many more of them in the field of assistive technologies, telemonitoring of vital signs and telemedicine. For example, the system is easily applicable for monitoring vital signs and classifying urgent states, for fall detection and alarms, and also as a surveillance system in the home and in institutional care, in smart homes, etc. The main advantages of the system in these applications are its mobility, portability, robustness and modularity. The processing currently performed on a PC can be relatively easily implemented on an iPad, a tablet or a smart phone. An optimized version of the algorithms can also be implemented in embedded systems.

In addition, there is an easy way to design and realize new input modules. Due to the modular design, the interface between the input modules and the control unit is precisely defined. This means that only a small number of requirements have to be observed, e.g. voltage range, output resistance, pinout, etc. before adding a new user-defined input module to the current system.

One of the most important questions is how messages (or data generally) from the telemedical system can be transmitted, for example in the case of alarm messages. There are many possible ways to do this. BT and WiFi communication can be used in the local area. This type of communication is fully appropriate both for transmitting full data, e.g. signal behaviour, and for sending alarm messages. A fully appropriate way to transmit data over large distances is by using a WiFi connection as a gate to the Ethernet, or, alternatively, by using the GSM communication module.

The communication module should be chosen on the basis of a detailed specification. The selection depends mainly on the type of data (and/or messages) that will be transmitted, on the area where the device will be used (inside a single building, within a city, without limits) and also on the type of data processing. For example, the WiFi/Ethernet or GSM/GPRS network could be used for transmitting the signal behaviour from a patient inside a hospital. The GSM/SMS service might be better for transmitting alarm messages from a person being monitored (with an unlimited area of operation) to other family members.

The system as it is designed has great potential for dramatically shortening the time between the formation of the idea for a device and the production of a functional example of that device. It is very difficult to compare the system described in this paper directly with other similar systems, because of the lack of directly comparable criteria. There is no standard that could be used for a direct comparison. However, based on existing experience, it is evident that developing a new device using the prepared modular system is approximately ten times faster than developing it from scratch.

It is possible both to process data directly in the control unit and to store or to transmit aggregated information, and to transmit raw data to subordinate system like PC, data-server etc. and process them there. The choice depends mainly on the objective of the solved project and also on the computational demands.

4 Discussion and Conclusion

In this paper, we have focused on describing the hardware solution of a modular mobile system for rapid development of telemedical devices such as systems for remote monitoring of vital signs. The data communication and storage in a PC satisfy the requirements laid on medical data privacy [Gibert et al. 2010]. We have not discussed the mobile processing application in detail. However, the processing that is basically performed on a PC can be performed in the same way on a mobile platform, either a smart phone or a tablet. Based on a literature review and practical experience, we have designed and implemented standard communication from the sensing part up to the processing modules. Modularity and a strict definition of the interfaces is the basic requirement for implementing new input modules into the system. An example of planned modules is a module for transthorasic bioimpedance measurements. For practical use, the system must satisfy additional requirements, namely low power consumption, small size, light weight, and long battery life. As far as software development is concerned, it is necessary to design new, more efficient signal processing methods, filtration and classification techniques that will be implementable in embedded systems. The measured data is in bit format, accompanied by information about type of the data (ECG, blood pressure, FCG, etc.), sampling frequency, and other information, if required. The software libraries support the development of applications. The interfaces of the software modules are also standardized. Thus the output of the processing module can easily be sent to an information system or to an EHR system. We have in mind that correct mapping of acquired data onto a data model that describes the electronic patient record is a very important issue, especially with respect to future development and the possibility of sensing and storing far more volumes of heterogeneous physiological parameters for a single patient. Interoperability may significantly influence the effectiveness both of the design and of the development of an integrated system and of its routine operation. This will become increasingly important with the development of telemedicine, home care and the possibility of monitoring the state of a patient remotely.

As the technology is developing very quickly, we have to assume that new types of sensors and devices will appear. The newly designed and developed systems must necessarily be created as open modular systems, allowing direct connection of the new sensors and devices without any need to modify the communication and data input, so that new data processing modules may be added. Integrating information acquired from different sources and implementing it with knowledge discovery techniques allows medical and social actions to be appropriately performed with reliable information, in order to improve the quality of life of patients and carers.

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