Biomedical & Pharmacology Journal Vol. **9**(2), 483-489 (2016)

The Hardware-software Package for Long-term Wireless Remote Monitoring of A Cardiovascular System

EVGENY ANATOLYEVICH BOGDANOV[1], DANIL ALEKSANDROVICH BORCHEVKIN[1], EKATERINA VLADIMIROVNA SILINA[2], NATALIA NIKOLAEVNA SHUSHARINA[1] and MAKSIM VLADIMIROVICH PATRUSHEV[1]

[1]Immanuel Kant Baltic Federal University (IKBFU), Nevskogo Str., 14, Kaliningrad, 236041, Russia.
[2]I.M. Sechenov First Moscow State Medical University (First MSMU), Trubetskaya str, 8, Moscow, 119991, Russia.

http://dx.doi.org/10.13005/bpj/962

(Received: April 24, 2016; accepted: June 20, 2016)

ABSTRACT

The work aims to produce a scientific and technological potential in the field of telemedicine for the timely detection and abortion of the cardiovascular system (CVS) diseases through the remote monitoring of the major physiological measures in a human. For this purpose, an experimental model of the hardware-software package was designed and developed for a non-invasive remote wireless diagnosis of the CVS functional status in humans based on the photoplethysmography method consisting of an optical sensor and software that performs a comprehensive analysis of a pulse wave, showing the heart rate values along with the real-time assessment of physical activity. The developed method of remote wireless data transmission to a doctor's workplace as well as to the ambulance service, to which the signal on the critical life-threatening situations may be transmitted in on-line mode, solves a wide range of medical and social problems, such as constant cardiac monitoring, clinical and diagnostic tests, and emergency response. The experimental research on the device was carried out. Within a month, the device was measuring the physiological CVS parameters and the physical activity in 10 healthy volunteers. The results showed that the analysis and processing of data allows doctors to conduct remotely a qualitative analysis of the hemodynamics status. It is assumed that the widespread introduction of the developed hardware-software package will improve the results of treatment in patients with CVS pathology as well as increase the length and quality of life among the population.

Key words: cardiovascular diseases, pulse wave, heart rate, non-invasive monitoring, cardiac monitoring, photoplethysmography, remote diagnostics, hemodynamics.

INTRODUCTION

Due to the advances in health care services, including preventive medicine, there is an increase in life expectancy of the world's population. However, the problem of the cardiovascular system (CVS) diseases concurrently emerges full-blown. Each year, more than 17 million people die of the CVS diseases, including 7.6 million deaths caused by myocardial infarction and 5.7 million — due to blood stroke[1-2]. According to a comprehensive analysis of 188 countries, the mortality from cardiovascular diseases (CVD) worldwide has increased since 1990 by 41%, while the most significant contribution to the overall mortality falls on the elderly people[3]. This issue is of especial urgency in the middle- and low-income countries[4]. In Russia, the proportion of deaths from cardiovascular diseases (CVD) is 57% within the structure of total mortality in population. This is over 1 million deaths per year[5]. At the same time, according to the state report on the health status of the population and health care implementation, following the activity results of the executive authorities of the Russian Federation in 2014 as compared to 2008, the proportion of cardiovascular diseases increased by 3.6% and amounted to 22,842 cases per 100 thousand people. The CVD epidemiology is indicative of the necessity to study more profoundly their pathogenesis and introduce the new and effective means of the timely adequate diagnosis and treatment of CVS diseases.

It is known that the relationship between the level of blood pressure, heart rate (HR) and CVD risk is continuous and constant. Therefore, active steps are taken to diagnose early the hypertension and tachycardia, reduce the risk factors for their development, develop new methods of treatment, study the mechanisms of drugs action, and improve the diagnosis and tactics of patient treatment. All these activities are ultimately aimed at preventing development of cardiovascular accidents, mainly of myocardial infarction and blood stroke, and increasing the life expectancy of population. In spite of the numerous activities, the prevalence of the CVS diseases still remains on the high level. This suggests the impossibility to solve the CVD problem with the means available.

A manufacturable way of solving this problem is to design and develop a device for the long-term, remote, safe, and reliable monitoring of the main CVS parameters, including the HR.

Similar developments have been actively conducted worldwide [6-8]. Such devices can provide constant monitoring of patients, belonging to the groups of high risk related to the development of dangerous socially significant cardiovascular diseases. The invasive means allow for maximum accuracy, but the high price, the complexity of operation and the need for surgery with a permanent security control within a health institution impede the widespread adoption of such systems on the market. Therefore, these technologies are not available to the majority of people. Thus, the urgency of this problem consists in the non-invasive continuous monitoring of CVS, which should be simple to operate, its safety and lows cost.

One solution is to provide a simple device, such as a bracelet based on the photoplethysmography method. The photoplethysmography (PPG) for monitoring physiological parameters of an organism, such as heart rate and blood oxygenation, have been used for a considerably long time within the process of CVD diagnosis and treatment [9]. The advantage of the PPG method as compared to the electrocardiography (ECG) is the lack of necessity to visit a medical institution, the ease of use, any possible sensor location, and no need for electrodes with gel. This is one of the non-invasive methods for measuring the change in blood volume in a blood vessel, through which the state of cardiac activity can be estimated by measuring the heart rate variability, which is primarily convertible into a HR indication[10]. In addition, the relation between the pulse wave parameters and indicators of blood pressure was proven[11-12]. Thus, the PPG-based device for a long-term monitoring of multiple CVS physiological parameters can be simple, easy, cheap, and have great potential for large-scale implementation into the outpatient practice.

In this regard, the objective of our work is to produce a scientific and technological potential in the field of telemedicine for the timely detection and abortion of the cardiovascular system diseases through the remote monitoring of the major physiological measures in a human.

Methods

To achieve this goal, first an experimental model of the device for diagnosing the CVS functional state was manufactured, and its technical tests were conducted. Then, an experimental model of the hardware-software package for remote wireless diagnostics of the functional CVS state of a human was designed and developed based on the photoplethysmography method. Concurrently, an algorithm of intellectual real-time processing of the pulse wave and HR data has been developed to detect pathological conditions that require an immediate response according to the existing standards in the field of medical signal processing and cardiology.

The developed device is designed for attachment to a person's wrist as a watch. Under standalone operation, it records all data to the volatile memory and features a function of the CVS processed status data transmission to the attending doctor's personal computer. The pulse wave, which carries information about the state of a patient's physiological performance, in particular about the CVS state, serves as the characteristic under study. The PPG sensor, as part of the device structure, consists of a light source and sensor, wherein an infrared LED is used as the light source. The sensor monitors the light intensity changes because of reflection from the living tissue.

The developed device is based on the TCRT1000 optical sensor designed for periodic recording of a physiological signal from the human body. In addition, the dimensions and design of the sensor allow to use it in the form-factor of a pin fixable on the human body, or using a vacuum or silicone suction cup. Since the sensor outputs an attenuated signal with different interferences, it is necessary to use an operational amplifier. The LM324 series chip with low input offset current was selected as an operational amplifier. The chip has a direct differential input, intra-frequency compensation at unity gain, and short-circuit protection. The PCB design and production as well as the assembly of printed circuit assemblies were held in accordance with the IPC standards. Meanwhile, the focus was set to the acceptance criteria for printed circuit assemblies in accordance with the second class of electronics, according to IPC A610.

To display the HR values, a character mapped display was chosen due to the ease of its usage and compatibility possible with a microcontroller Arduino UNO.

The electrical capacitors, as part of the device model, are used to build a high-pass filter. The main function is the filtering of the periodic physiological signal interferences. They were used in the two stages of signal amplification and filtering. The selection of electrolytic capacitors is caused by their commercial availability, low cost, and a sufficient stability.

The ceramic capacitors are implemented into the device model for building an OS-based low-pass filter. They were used in the two stages of signal amplification and filtering. The ceramic capacitors are cheap, commercially available and sufficiently stable during operation.

To verify and test the analog part of the circuit, an output signal was displayed on a digital oscilloscope screen, and then transmitted to the Arduino UNO platform, where the HR was calculated and the parameter values were displayed.

An optically recorded photoplethysmogram features the following characteristics: (1) the amplitude characteristics corresponding to the anacrotic and dicrotic period (despite the fact that these parameters are relative, their study in dynamics provides valuable information about the strength of the vascular reaction during the short-acting factor's influence on the body). (2) The temporary characteristics providing information about the cardiac cycle duration and heart rate, the ratio and duration of systole and diastole, and the phases that form them (these parameters are of absolute values and can be compared with the existing regulatory parameters – the duration of an anacrotic and dicrotic phase of a pulse wave, the duration of a pulse wave, the rising wave index, the filling time during systole, the duration of the systolic and diastolic phases within a cardiac cycle, the heart rate). (3) The statistical characteristics that determine the variability of amplitude and heart rhythm on a large period of time (minutes). (4) The calculated parameters using the values of the previous groups. This group includes the dicrotic wave index that reflects the position of dicrotic wave peak with respect to the anacrotic wave – the duration ratio of the anacrotic and dicrotic phases.

Thus, the developed device allows to solve a wide range of tasks – from simple cardiac monitoring to more complicated clinical diagnostic studies. Calculating the foregoing parameters contribute to diagnosing the same as at estimating the instantaneous reaction of an organism to the external physical factors effect, such as at providing intensive care and registering hemodynamic changes over a long period of time, which makes it generally possible to judge on the CVS state.

Monitoring the CVS state was conducted as follows. The PPG sensor was attached to the soft tissues, in this case to the wrist. The signal from a sensor photodiode passed through the soft tissues and reflected from them. Depending on the blood saturation of soft tissues, the intensity of waved varied within the infrared range. The reflected signal was sent to a phototransistor. Depending on the reflected wave, the current changed inside the phototransistor, which was a part of the PPG sensor. Since the current value changed in real time, a time to voltage dependence function was built, the schedule of which represented a pulse wave. To remove interference and smooth the curve, the voltage data were filtered by hardware using a low pass filter. The mathematical processing of the pulse wave chart was conducted using the moving average method for smoothing and subsequent visualization convenience, taking the square of the time function. As a result, the PPG graph was obtained, which had the same form as the ECG graph, which is more common for doctors. The processing and conversion of the PPG signal essentially passes the stage of squaring and the stage of differentiation. As a result, the reference ECG signal is obtained.

Thus, the interpulse interval of the PPG signal closely correlates with the ECG signal peak interval (with the R-R interval). This indicates the possibility of using the PPG signal to analyze the CVS parameters as effectively as with the ECG signal.

The next stage of work was to develop the algorithms for comparing the physical activity of a patient with the medical data of the pulse wave and heart rate measuring to increase the diagnostic accuracy. To compare the physical activity of the patient with the medical data of the pulse wave and heart rate measurements, the data transmitted to the processer from the accelerometer for numerical reference axes data processing made it possible to determine a person's position in space and his velocity. At the same time, the numerical data from the PPG sensor were received in real time and further compared with the accelerometer data. The data comparison resulted in the real-time automated evaluation of the person's physiological state. In the event of a critical change in the CVS state, the alarming data can be automatically sent to a doctor or to an ambulance station. To this end, the methods were developed for automated formation of the advisory system reports on the compilation of medical comment projects for further processing thereof by medical workers.

To test the device the experimental studies were carried out, and the data on CVS status and physical activity were obtained from 10 people for 1 month. After processing the information obtained, the data were averaged by key issues. The final sample consisted of 500 measurements for each subject.

RESULTS AND DISCUSSION

A device for remote wireless diagnosis of the CVS functional status based on the photoplethysmography method was developed, comprising an optical sensor, which picks up information about the state of the patient's hemodynamics. This device is designed in a form of a wireless bracelet wearable on the patient's body, which further comprises a non-volatile memory for data storage, a battery for the wireless device usage, a Bluetooth module for communication with a cell phone, an emergency button for alerting about the patient's emergency state, an accelerometer for comparing the physical activity of the patient with the medical data of the pulse wave and heart rate measurements. By using a Bluetooth module and a cell phone as an Internet transmitting device, the transmission of information on the patient's CVS status to a doctor occurs in real time. Besides, it is possible to receive a doctor's feedback.

A method of wireless remote diagnoses of a person's cardiovascular system functional status based on the method of photoplethysmography, in which a comprehensive analysis of the pulse wave and heart rate is carried out by processing the obtained data from the PPG sensors. The intelligent processing of the pulse wave and heart rate data to identify critical (pre-stroke, pre-infarction, etc.) conditions requiring immediate medical response takes place in real time. Moreover, to improve the accuracy of diagnosing critical CVS conditions, the pulse wave and heart rate data measurements are compared to the patient's physical activity.

Figure 1 shows an operational diagram of the device for remote wireless diagnosis of the cardiovascular system functional status.

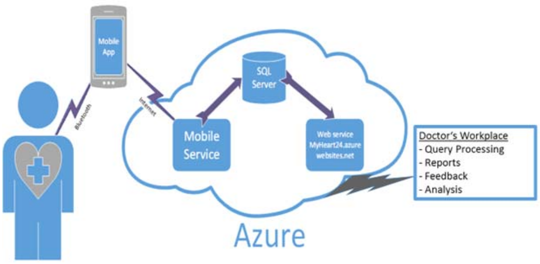


Fig. 1: A scheme of data transmission and information exchange of the MyHeart24 service

In practice, a patient wears a light device in the form of a bracelet, comprising a PPG sensor, a signal filtering system, a battery, a Bluetooth module to communicate with a cell phone in order to transmit in real time the patient's state data, an emergency button, an accelerometer, a non-volatile memory for storing the CVS status data.

The device operates as follows. The PPG module in housing in the form of a bracelet is fixed on the patient's body. In the ON mode, it transmits the data on HR, pulse wave and physical activity to a cell phone. Then, the data are transmitted to the server or, in the event of a critical state, directly to the doctor through the cell phone.

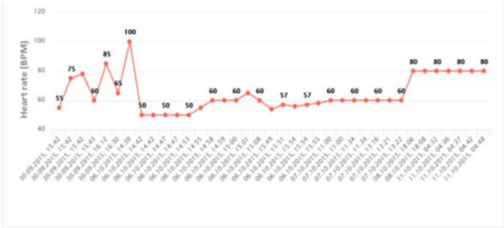
By applying this device, it is possible to diagnose the cardiovascular system status, and transmit in real time the obtained data to a doctor via the Internet connection.

The developed device has a number of advantages. Firstly, it enables immediate medical response to the critical conditions of a patient. Secondly, it allows for a long and safe ambulatory monitoring of the SVC status, without requiring additional financial, human and time resources.

Given the ubiquity of smartphones and iPhones, an additional transmitter is not required. Figure 2 shows a photo of a smartphone with the device connected thereto, transmitting data to an automated doctor workplace.

Fig. 2: The device for diagnosing the CVS status, which is connected to the Microsoft Lumia 730 smartphone via the Bluetooth protocol and transmits the data to the doctor's workplace (the smartphone is running a BTLE Explorer application designed to analyze devices developed using the Bluetooth Smart services and features)

Figure 3 shows the total picture of the HR dynamics. These data can be presented in different ways: per-minute, averaged per hours, days, etc. with simultaneous indication of the physical activity level.



№	Date	Value (heart rate)
1	30.09.2015, 15:42	55
2	30.09.2015, 15:42	75
3	30.09.2015, 15:42	78

Fig. 3: The data obtained from the CVS status diagnostic device

It also allows to eliminate the need for logging, in which a patient should record the forms of its daily activities within the course of data recording by the device.

CONCLUSION

The CVD epidemiology causes an interest in developing devices for continuous remote monitoring of the CVS parameters, especially in people belonging to the high-risk groups. The relevance of this project is justified by the need for exploratory research in the field of biomedical signal transducers development to produce new devices for the ambulatory wireless remote diagnostics of the human state with a sufficient condition for its mobility.

To achieve this goal the following tasks were accomplished: (1) an experimental sample of the device for diagnosing the CVS status was developed. (2) An experimental model of the hardware-software package for remote wireless diagnosis of the CVS functional status based on the photoplethysmography method was designed and developed. (3) The algorithms for the real-time intellectual processing of the pulse wave and heart rate data were developed to detect pathological conditions that require an immediate response according to the existing standards in the field of medical signal processing and cardiology. (4) The algorithms for comparing a patient's physical activity with the medical data on the pulse wave and heart rate measurements were developed to improve the accuracy of diagnosing. (5) The methods for automated formation of the advisory system reports on the compilation of medical comment projects for further processing thereof by medical workers were developed. (6) The instructions on the use of an automated doctor's workplace for working with the medical data on the pulse wave and heart rate measurements were developed. (7) The experimental studies were carried out.

Thus, the CVD signs were determined within the data stream, recorded by the device for the real-time monitoring of the physiological parameters of a human. At the same time, first the signal was obtained recorded by an optical sensor, and then the software was developed that can carry out a comprehensive analysis of the pulse wave, show a patient's HR parameters during the device operation, and perform a qualitative real-time analysis of the hemodynamic status with an estimation of its physical activity based on the received data.

The conducted experimental work has shown that the designed device exhibits a similar, and in some respects even better resolution ability, so it can replace the traditional systems. Such device will ensure the constant monitoring of patients with the high risk of CVD occurrence, with a heart rhythm disorder, chronic cardiac insufficiency, and other cardiovascular comorbid conditions. In the event of critical, hazardous and life-threatening conditions, the device is able to inform the emergency ambulance service, which as a result will increase the length and quality of life among the population.
At further work stages, it is planned to improve the method, to further miniaturize and intellectualize the device, as well as to conduct cohort studies on determining the efficacy and safety of the device.

ACKNOWLEDGEMENTS

This work was supported by the Ministry of Education and Science of the Russian Federation Grant No. RFMEFI57814X0053.

REFERENCES

1. Young, J., The Global Epidemiology of Heart Failure. Medical Clinics of North America, 2004; **88**: 1135-1143.
2. Tsao, C.W. and R.S. Vasan, Cohort Profile: The Framingham Heart Study (FHS): Overview of Milestones in Cardiovascular Epidemiology. *International Journal of Epidemiology*, 2015; **44**(6): 1800-1813.
3. Roth, G.A. *et al.,* Demographic and Epidemiologic Drivers of Global Cardiovascular Mortality. *The New England Journal of Medicine*, 2015; **372**(14): 1333-1341.
4. Bowry, A.D., J. Lewey, S.B. Dugani and N.K. Choudhry, The Burden of Cardiovascular Disease in Low- and Middle-Income

Countries: *Epidemiology and Management. Canadian Journal of Cardiology*, 2015; **31**(9): 1511-1519.

5. Oganov, R.G. and Y.N. Belenkov, Cardiology. National Leadership. Moscow: GEOTAR-Media, 2010.
6. Park, J.H. *et al.,* Wearable Sensing of In-Ear Pressure for Heart Rate Monitoring with a Piezoelectric Sensor. *Sensors,* 2015; **15**(9): 23402-23417.
7. Rumyantseva, S.A., V.A. Stupin, R.G. Oganov, E.V. Silina, V.A. Petrov, V.A. Kasimov et al., The Ways of Long-Term Blood Pressure Control Systems Development. *Cardiovascular Therapy and Prevention,* 2015; **1**: 78-82.
8. Stupin, V.A., E.V. Silina, R.G. Oganov, Y.A. Bogdanov and N.N. Shusharina, Development of an Invasive Device for Long-term Remote Monitoring of Cardiovascular System Parameters, Including Blood Pressure, in Patients with Comorbid Conditions. *Biosciences Biotechnology Research Asia*, 2015; **12(**2): 1255-1263.
9. Lee, D.E. and R.S. Cooper, Recommendations for Global Hypertension Monitoring and Prevention. *Current Hypertension Reports*, 2009; **11**(6): 444-449.
10. Allen, J., Photoplethysmography and Its Application in Clinical Physiological Measurement. *Physiological Measurement*, 2007; **28**(3): R1-39.
11. Lee S.S., M.C. An and S.H. Ahn, A New Measurement Method of a Radial Pulse Wave Using Multiple Hall Array Devices. *Journal of Magnetics*, 2009; **14**(3): 132-136.
12. Nam, D.H. *et al.,* Measurement of Spatial Pulse Wave Velocity by Using a Clip–Type Pulsimeter Equipped with a Hall Sensor and Photoplethysmography. *Sensors,* 2013; **13**(4): 4714-4723.