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Development Of Hardware-Software System For Remote Wireless Diagnostics of Functional Status of Human Cardiovascular System Based on Photoplethysmography Method.

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ABSTRACT

Worldwide, cardiovascular diseases are the main causes of morbidity and mortality in the older age groups. For timely medical aid to patients with cardiovascular pathology it is necessary to develop portable devices for individual long-term outpatient monitoring. The aim of this work was the development and construction of experimental prototype of the hardware-software system based on photoplethysmography method. The developed device consists of an optical transducer that receives the information on the hemodynamic condition of the patient, and the software that performs comprehensive analysis of the pulse wave. This device allows carrying out qualitative analysis of the status of the cardiovascular system and the timely identification of pathological conditions through remote monitoring of basic physiological parameters.
Keywords: non-invasive system, remote diagnostics, photoplethysmography, cardiac monitoring, cardiovascular disease, pulse wave, heart rate, hemodynamics, outpatient examination.

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INTRODUCTION

Currently, there is a tendency of transition from a conventional diagnostics and treatment system at the clinic to the individual monitoring systems of various nature diseases. This is contributed by scientific and technical progress in this field along with the global aging of the population and changing morbidity patterns. Thus, different technical solutions in the field of remote diagnostics of a human body status become very relevant. The ease and simplicity of use of the developed hardware systems is of great importance for reallocating and reducing the existing load on the public health system and promoting popularity of periodic self-check of health status among population.

Worldwide, cardiovascular diseases (CVD) occupy a leading position among the causes of morbidity and mortality. In the general population, the mortality associated with pathology of the cardiovascular system, is more than 6000 per 100,000 population aged over 70 years per year [1]. In Russia, cardiovascular disease also ranks first among causes of death and disability of seniors [2, 3, 4, 5]. When solving problems of timely medical care for patients with CVD, the portable devices for individual ambulatory monitoring can be highly effective. Currently, the standard procedure for the diagnostics of CVD is based on monitoring using electrocardiography, which is a rather labor-intensive process that requires involvement of specially trained medical personnel.

Contemporary stationary systems for the CVD diagnostics, produced by domestic and foreign manufacturers of medical equipment and available on the market, usually are very expensive and difficult to operate. A survey by means of these devices requires the presence of a patient in a health care institution and takes a long time. Operating this equipment requires not only special medical education, but also extensive training. Thus, existing diagnostic technologies are unavailable to most people.

Summarizing the results of studies conducted by many scientific groups, it is shown that the method of photoplethysmography (PPG) can be an acceptable compromise for an individual daily monitoring of the cardiovascular system (CVS). The advantages of the PPG method are: easy to study vascular responses in the flat areas of the body; the ability to work in the conditions of high humidity and strong electromagnetic fields; the lack of electrode contacts with human flash and electrical effects on the studied biological object; ease sterilization and transducers attachment, which have a small effect on blood circulation that is important for long-term monitoring of physiological and hemodynamic factors of a person. This is one of the non-invasive methods to measure changes in blood volume in a vein, which can be used to assess the state of cardiac activity by measurement of heart rate variability. In the general case, the recording unit for a long-term PPG-based monitoring should be ease of attachment and tracking of multiple physiological parameters of a person such as heart rate, pulse wave characteristics, the level of oxygen in the blood, etc.

The objective of our work was to develop and construct experimental prototype of hardware-software system (HSS), which will operate based on the photoplethysmography method. It was supposed that the device would consist of optical transducer receiving information about the hemodynamic status of the patient, and the software performing a comprehensive analysis of the pulse wave. The design of this device will allow for a qualitative analysis of CVS status, early detection and relief of CVS disease by remote monitoring of basic physiological parameters of a person.

METHODS

In the course of research work we have constructed the research prototype of the device for diagnostics of the functional status of a human cardiovascular system. It was decided that the verification of the experimental sample would be easier to start with the design of the case of the device for CVS monitoring to carry out its further refinement in order to make it convenient for use.

Initially, the dimensions of the device with the case thickness of 2 mm did not exceed 50x45x15 mm. Though, prolong testing of the case (during one month) has shown that in the first place it was necessary to decrease the height of the device, since it is the height of the device that mainly assures the comfort and invisibility to the user. The height of the device was reduced through replacing bolted connections by the latch for fastening the printed circuit board, using hot melt adhesive for fixation, reducing the thickness of printed circuit boards, using open-frame rechargeable battery with a minimum thickness and low-profile electronic components (both active and passive).

In the final version of the case of the device for the diagnostics of the CVS status, window size was determined by the size of the DCM03 transducer, namely 9.8x4.3 mm (taking into account manufacturing tolerances). For the manufacture of the case we employed the technology of hot extrusion of plastic (3D printing) by fused deposition modeling.

The ABS-plastic was selected as a material for case fabrication of the CVS diagnostic device, because this kind of plastic was suitable for both hot extrusion in case of prototype production and injection casting technology in case of serial and mass production.

To protect printed circuit boards of the device against the aggressive effects of the environment, we used the conformal coatings that preserve the shape and dimensions of the original boards. These coatings allow obtaining required level of protection against moisture and corrosion properties of human physiological fluids without changing characteristics of electronic device and increasing its dimensions. Several types of compositions including those based on acryl, urethane, parylene, and silicone are used for printed-circuit board coating. The durability and reliability of the designed circuit boards can be extended using any coating method; however, a silicone immersion coating has shown the highest biocompatibility that determined the final choice of the coating material [6].

Since the case is designed for a standard watch bracelets, and, respectively, standard watch shackles, we chose store-bought silicone bracelet. Width of the bracelet is 22 mm, while the width of the shackle is 24 mm. After verification of the proto model, the case was produced by an industrial method.

The Bluetooth transceiver was implemented as a system-on-board and has dimensions of 18x18.5 mm with a lead spacing of 1.5 mm. However, while producing and debugging this module, it was found that a lead spacing of 1.5 mm was excessive: reducing the lead spacing did not cause problems during assembly, as evidenced by common practice [7]. Thus, the lead spacing of 1.2 mm was taken as a basis that allowed reducing the system-on-board size to 13.2x14.4 mm. Besides, the resonator with the standard size of 3225 (3.2x2.5 mm) was replaced by the resonator with the standard size of 2016 (2.0x1.6 mm) with similar characteristics that did not affect the consistency of operation of the transceiver.

The PPG transducer, as a part of the device, consists of a light source and the detector, wherein the infrared LED is used as a light source. The transducer monitors changes in light intensity reflected from the human flesh [8, 9].

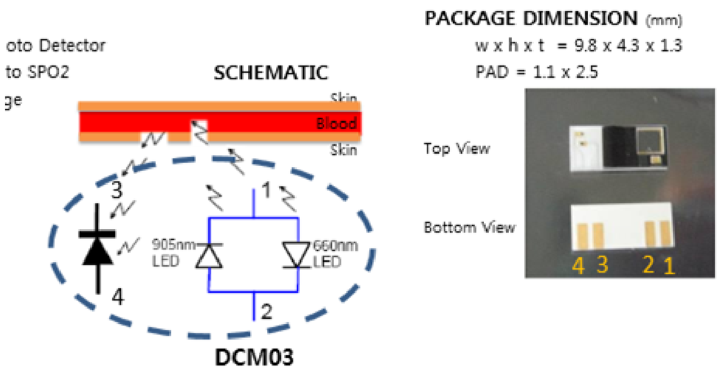


Figure 1. The design of the DCM03 transducer produced by APMKorea company [10]; the transducer must be perpendicular to the blood vessels.

In consequence of the experimental testing it was revealed that the position of the PPG module (in particular, the transducer for photoplethysmography) with respect to the center of the device is the most optimal one, given that the location of the narrow side of the DCM03 transducer, used in this project, is perpendicular to the blood vessels on the wrist. This condition follows from the design features of the transducer: the LEDs are placed on the same line with receiving photodiode (Fig. 1), and in order to cover the greatest area of large blood vessels, it is necessary to place the transducer perpendicularly to them.

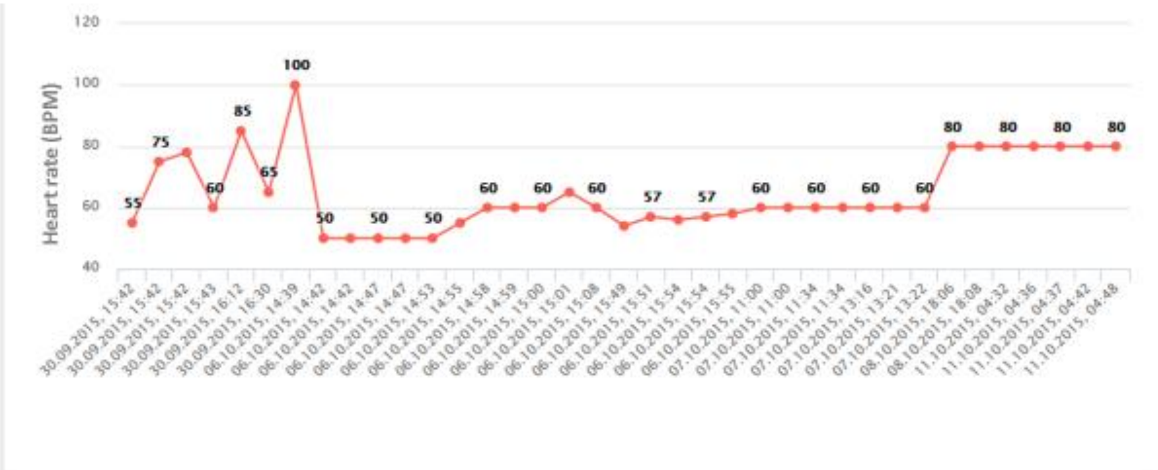
For the CVS status diagnostic device we used purchased lithium-polymer battery in die form. The battery has the dimensions of 30x30x5 mm.

The hardware-software system to diagnose the CVS status includes smartphone and computer workstation of a physician. The smartphone is an intermediate link, playing the role of a distributed unit for receiving and transmitting information from patient to physician's workstation, as well as data gateway. Thus, we achieve a high degree of awareness of the user even in the case of lack of communication.

Data communication from the smartphone to the physician's workstation server is carried out by means of GET and POST requests as per RFC 2616 [11], thus forming a REST-interface; the communication occurs over the HTTP Protocol [11].

In the framework of the project implementation, we have developed special applications for both the Android platform and the Windows Phone platform 8.1.

Data about the patient's CVS status received from the device is displayed on the physician's workstation (Fig. 2), which displays data of the patient and the physician, including the graphs showing heart rate and pulse wave characteristics as well as tables indicating date and time of data receipt.



№	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

Figure 2. Data received from the patient's CVS status diagnostic device and displayed on the physician's workstation.

DISCUSSION AND RESULTS

The PPG method to monitor physiological parameters of the body, such as heart rate and arterial oxygen saturation, is used for a quite long time for CVS diagnostics and treatment. The current stage of the CVS diagnostic technology development is presented by devices based on transducers, which contact the skin surface to analyze the physical characteristics of the pulse wave. The parameters of the pulse wave reflect the current status of CVS. At the moment, stationary complexes located at specialized cardiology centers are used to register pulse wave and heart rate. This procedure requires presence of a patient in a hospital or a specialized centre that complicates the use of such complexes. Thus, challenges related to the mobility of patients remain still unsolved, because the only analysis of the current characteristics of the cardiac rhythm facilitates timely actions to prevent severe CVD symptoms. Also, none of the existing methods on indirect periodic monitoring of heart rate and pulse wave characteristics through periodic and routine observations in clinical and outpatient settings allow clear tracking of changes in the characteristics of the patient's CVS functioning during the day. Daily monitoring method is not only the most effective in terms of detecting hidden disorders of cardiac rhythm, but also one of the most standardized and widely used in primary diagnostics, monitoring the results of therapy, identifying the disease development dynamics, and so on. In our work for the first time, the PPG method is used for outpatient daily monitoring. Thus, we have developed the device to monitor human physiological signals providing the record of all obtained data in nonvolatile memory for subsequent transmission to a physician using the USB interface or the Internet.

The use of daily monitoring in the outpatient setting, similar to a "Holter" monitoring, may be medically necessary in the following cases:

Diagnostics of previously identified arrhythmias:

- complaints of patient on unconscious and semiconscious states as well as dizziness of unknown cause;
- the heart beats and interruptions in cardiac work;
- the heart beats in patients with an established WPW syndrome.

Diagnostics of myocardial ischemia:

- vague chest pains, which do not allow neither confirming nor excluding angor pectoris.

Assessment of the medical treatment effectiveness:

- assessment of antiarrhythmic treatment;
- the choice of treatment at atrial fibrillation when diagnosing adrenergic or cholinergic types of flicker;
- assessment of proarrhythmic action of drugs with a high risk of its development;
- assessment of efficacy of radiofrequency (or other) ablation of pathways in patients with the WPW syndrome, ventricular tachycardia and other arrhythmias;
- assessment of antianginal therapy;
- assessment of surgical treatment of coronary insufficiency;
- assessment of an artificial pacemaker performance.

Preventive monitoring of patients with possible threatening arrhythmias:

In diseases with impaired contractile function of the myocardium:

- postinfarction patients with left ventricular dysfunction;
- patients with cardiac malformations.

With disturbances of water and electrolyte balance:

- chronic circulatory failure of stage 2-3;
- end-stage kidney failure.

With arterial hypertension:

- arterial hypertension with left ventricular hypertrophy;
- arterial pulmnary hypertension with signs of pulmonary-cardiac insufficiency.

Before surgery:

- on the heart;

- on the other organs.

Carrying out monitoring to predict disease:

Assessment of autonomic regulation of heart rate based on time and spectral analysis of heart rate variability:

- in diabetic patients with neuropathy;
- in patients with nocturnal apnea;
- in patients with impaired function of the sinus node for the assessment of
- chronotropic function of the cardiac;
- in patients with cerebrovascular crises.

The PPG method is based on characterization of the pulse wave, which carries information about the status of the physiological parameters of the patient, in particular, about the CVS status. The pulse wave data largely correlate with the electrocardiogram (ECG) data. However, the pulse wave contains more information about the CVS status as compared to ECG. It allows better reflect parameters such as arterial stiffness and vascular tone to assess indirectly the obliteration of peripheral arteries that is difficult to do when using the data of ECG and arterial tension.

The mechanism of the pulse wave occurrence is relatively simple. The ejection of blood from the left ventricle at the moment of systole causes a high pressure wave, which propagates along the blood vessels. The pressure wave is accompanied by a stretching of the vascular wall and is defined as the pulse wave. Extending from the aorta to the capillaries, the pulse wave attenuates.

The pulse wave propagation velocity (PWPV) in the aorta (the classic marker of vascular stiffness) reflects the status of arterial stiffness and the magnitude of the muscle tone of blood vessels. This parameter is important in the diagnostics of atherosclerosis of the aorta, hypertension, symptomatic hypertensions, aortic insufficiency, and diabetes mellitus. It reveals also obliteration of peripheral arteries, their stenosis, and the decrease in stroke volume. Studies of recent years show that the increase in aortic stiffness, which can be assessed by the increase in PWPV in it, is an independent predictor of risk of cardiovascular complications; it allows detecting the onset of severe violations of the CVS and to choose the right individual therapy. This applies not only to the aorta but also to all blood vessels of elastic and muscular-elastic type.

Researchers on this subject have reveled variety of factors, disorders and diseases associated with increased arterial stiffness [12]. For people of young and middle age, PWPV in the aorta is 5.5-8.0 m/s. Elasticity of the arteries decreases with the age, and consequently, pulse wave propagation velocity increases.

Also, pulse wave carries sufficient data to assess the following parameters:

- heart rate;
- the degree of blood oxygenation (arterial oxygen saturation);
- blood pressure (using mathematical apparatus);
- derived data (considering the shape of the pulse wave).

Heart rate (HR) is the most studied parameter among all determined parameters. Heart rate can be used to determine critical conditions listed in Table 1, which require an immediate response. In turn, blood pressure obtained on the basis of PPG method is inaccurate and may carry basically just the indicator function.

Today, the very shape of the pulse wave and its informativeness are understudied and require further statistical research, which in future will allow revealing the onset of other critical states by means of proper software tools to improve early remote diagnostics based on the use of the pre-existing device for diagnosing the CVS status.

Table 1. Pathological conditions determined by heart rate and requiring immediate response.

No.	Critical states	Threshold values
1	Tachycardia	HR is more than 180 heart beats per second
2	Bradycardia	HR is less than 40 heart beats per second
3	Asystole symptoms	Interval between two heart beats is more than 3 seconds

Critical changes in heart rate and other monitored parameters are symptoms indicating disorders of the CVS. Thus, the occurrence of these situations must be notified not only to the physician but also to the patient as well and in the shortest possible time. To this end, in this work we have developed an algorithm for processing data on heart rate, which has been implemented in the CVS status diagnostic device. This algorithm provides the notification of the user about the occurrence of critical conditions by means of sound, light and visual indication (via a smartphone), as well as transmits the data to the physician's workstation for initialization of further logic response to pathological conditions of CVS.

To provide sound notification, the CVS status diagnostics device is provided with embedded magnetic sound-emitting device, which generates sound with a frequency of 4 kHz and a volume of approximately 80 dB that is a sufficient signal to notify the user. At that, the notification to the user about a pathological state does not depend on the connection with the physician's workstation or a smartphone, because the analysis of possible pathological conditions is performed by the PPG module.

Since heart rate depends, among other things, on the age of the patient [12], individual heart rates and threshold levels to trigger the alert in case of the pathological conditions requiring an immediate response are calculated for each patient.

The developed algorithm makes it possible to alert a user about the occurrence of the critical state without connecting with the smartphone and physician's workstation server that allows the patient to independently respond to this alert and to take appropriate measures even in case of the absence of any kind of communication.

This algorithm requires the preliminary verification of the fact that the PPG module is correctly attached to the patient's body and receives the data. The data obtained during the adjustment time (from several seconds to tens of minutes) is analyzed in terms of the following parameters:

- average heart rate for a certain period;
- the distance between neighboring peaks.

Based on the data obtained, the pathological conditions such as tachycardia, bradycardia and asystolia can be determined according to the threshold values. In case of occurrence of pathological condition the user gets an alert through all available means.

Further extension of the list of the detected critical states and immediate notification of the patient needs sampling the data on the patients in order to confirm or refute the hypotheses associated with other abnormalities in the indicators. A statistical sample is required, which would include both healthy patients and patients with cardiovascular disease to determine additional criteria for the onset of critical conditions. This will be possible only in case of availability of a large number of observations of the patients in real-time mode.

The development of the CVS status diagnostic device required the solution of some of the challenging technical problems associated with the registration and analysis of pulse wave. Pulse wave is rarely standardized in terms of its shape and proportion. The shape of the curve is exposed to a large number of factors. Analysis of the pulse wave depends largely on the transducer, condition and age of the patient, the surrounding environment conditions, motion artifacts and interference. The following stages of data collection and analysis were established: check the parameters of instantaneous blood pressure, calibration of the device, generation of the resulting curve, highlighting the peaks and subsequent analysis with report generation [13]. Automated analysis of pulse wave curve is hampered by the fact that the shape and nature of the resulting curve strongly depend on the patient's age, physical fitness, gender, current activity, and even level of glucose and insulin in the blood.

Another important factor distorting the pulse wave curve is hypertension. It is widely accepted that the main factor influencing hypertension is the destructive effects of abnormally high blood pressure on the walls of the arteries, and primarily, the aorta, causing distortion of the pulse wave curve, similar to age-related changes. This primarily affects the pulse wave propagation velocity together with the increase in the amplitude of the secondary systolic pulse wave. Shape of the pulse wave curve is significantly distorted in a variety of diseases that destroy the walls of blood vessels, such as atherosclerosis, diabetes, etc.

In addition to permanent distorting factors, the shape of the curve is affected by a number of temporary factors, such as emotional stress, physical activity, pain, sleep state or wakefulness, as well as prescribed medicines.

Thus, the original signal of the pulse wave is quite complex in terms of its processing. It is sensitive to the effects of various factors and in some cases is non contrast to highlight targeted features. Therefore, in designed hemodynamics assessing automated system it is necessary to use several different signal processing algorithms in parallel. Some features of the signal are caused by the photoplethysmography technology used in the proposed device, which is sensitive to carrier drift, the individual characteristics of the patient, position and pressing force of the transducer, motion artifacts, etc. However, a comparison of different approaches to signal processing would be possible after accumulating sufficient experimental data base, including the expert consensus document of physicians along with the measurements of hemodynamic parameters of the patients.

CONCLUSION

The proposed system opens up the ample opportunities of collecting data on the physiological parameters of the patients in the form of the pulse wave characteristics and heart rates, obtained using the medical software tool providing automated formation of a standard report reflecting the instantaneous values of the pulse wave amplitude and heart rate. Such simplified form allows conducting quick analysis of the clinical situation and hand down an opinion. Architecture of the existing system provides scalability, integration with other health information systems, arbitrary treatment of the records stored in database and their analysis. The possibility of using several types of on-line data processing algorithms and plug-ins for offline methods allow implementing different solutions of predictive and recommender systems.

Thus, the developed device, fixed on the human's wrist, provides recording of all data into a nonvolatile memory and transmits these data to the physician's personal computer (PC) in a standalone mode. It can replace the traditional monitoring systems, while demonstrating similar or even better resolution. These transducers allow solving a wide range of tasks - from simple cardiac monitoring to more complex clinical and diagnostic examinations.

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