Wearable nanosensor-based hardware and software complex for dynamic cardiac monitoring

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Abstract. To date, continuous dynamic monitoring of the cardiovascular system is relevant for improvement of the quality of diagnosis of cardiac diseases. The equipment available for continuous cardiac monitoring operates in the standard frequency range, has a low resolution, and contains filters that limit signals in low and high frequencies. The development of wearable devices and high-resolution methods for dynamic cardiac monitoring to record signals in the range from 0 to 3500 Hz without filtering and averaging is of high priority. In addition, this will allow us to obtain new data on the atria and ventricles of the heart and to detect cardiovascular diseases at an early stage. A wearable hardware and software complex based on nanosensors was developed, and preliminary technical tests of the complex were carried out. An algorithm and a program were developed to detect micropotentials over the entire duration of the ECG signal except for the waves of cardiac pulses and sharp peaks in signal processing. Histograms were built for quantitative evaluation of micropotentials, and the total energy of micropotentials was calculated. Preliminary medical studies were carried out on volunteers.

1. Introduction

Human health is the main resource essential for activities that affect the work of any enterprise, organization and society. Health maintenance is a guarantee for successful existence and development of the country as a whole. For this reason, improvement of the quality of medical care, the work of medical personnel, the quality of life and awareness of patient’s health, and optimization of health care costs are relevant for the developed society.

Maintenance of the health of the cardiovascular system is one of the most urgent tasks. According to statistical studies conducted by the World Health Organization, the annual mortality rate from cardiovascular diseases is 31 percent of all global deaths; people with low and middle incomes are subjects at risk [1]. In 2018, the American Society of Cardiologists reported that cardiac abnormalities is the leading cause of death for both men and women. According to their forecasts, by 2035 more than 45% of the total population in the US will die from cardiovascular diseases [2]. The analysis conducted by Rosstat also shows a significant share of deaths from cardiovascular diseases and accounted for 65.1% of women and 50.1% of men in 2017 [3].
Studies conducted by the American Society of Cardiologists show that one of the common causes of cardiac death is the patient’s lack of awareness of the abnormal state of health. Due to this, the patient does not take measures to correct his lifestyle and to take necessary medical procedures or precautions [2]. Another common cause is the lack of awareness of medical personnel about the problem, which is primarily due to the fact that the patient is examined either with insufficient periodicity or with a short duration of the observation period during which the pathology may not manifest. These pathologies include arrhythmias that significantly affect human health and cause sudden cardiac arrest, which results in death if not timely treated [4, 5]. Also, arrhythmias can cause thrombi that are critically dangerous as they can lead to a stroke.

According to studies [6], one of the types of arrhythmia known as atrial fibrillation (AF) leads to a stroke in one of three cases and is often ignored by physicians and patients as it is mostly asymptomatic [7]. At the same time, strokes caused by AF are characterized by a greater brain damage than ischemic ones. The detection of AF often depends on the diagnostic strategy applied to the patient. According to the results of some studies, the number of detectable episodes of AF increases with observation time [8]. For example, when analyzing 122815 recordings of a long-term ECG, it was found that on the 1st day of monitoring, 45% of episodes of AF were detected, on the 2d day – 61%, on the 7th day – 91%, and on the 12th day – 100% [9]. In another study, the first manifestation of AF was observed on average 18 hours after the start of recording, and 14.3% of all first cases after 48 hours of recording, which exceeds the recording of both a conventional ECG and a daily Holter ECG [10].

Thus, the development, improvement and application of methods and technical means for long-term and periodic monitoring of the cardiovascular system are relevant for one or several month monitoring. In addition, this enables making a complete map of changes in the state of the human heart to carefully analyze and detect abnormalities that may be precursory symptoms of life-threatening events such as heart attacks, strokes and sudden cardiac arrest.

2. Hardware and software complex

Electrocardiography is most widely used for cardiac diagnostics. Electrocardiography is the technique that is used to monitor the state of human heart by recording and analyzing cardiac bioelectric potentials from the surface of the patient's body [11, 12]. Within the framework of this problem, devices for electrocardiography can be divided into two types: stationary and portable.

Applied methods of stationary electrocardiography are mainly designed for short-term monitoring in the cardiologist's office or hospital ward. However, most cardiac episodes occur outside the hospital, including dangerous arrhythmic episodes that lead to sudden cardiac death (SCD) [13]. Thus, it is necessary to use wearable devices to monitor the state of the heart outside the hospital.

The development of communication and computing technologies contributes to new technical solutions in electrocardiography for mobile devices. Among mobile devices for ECG recording, the most relevant are ambulatory electrocardiographs (AE) and activity trackers.

Ambulatory electrocardiographs are wearable devices that record ECG during daily activities [14]. Ambulatory electrocardiographs can be divided into Holter cardiographs [14] and ECG event recorders [15, 16].

According to monitoring duration, Holter monitors can be divided into two groups: monitors for a short-term and long-term monitoring [17]. During a short-term monitoring, monitoring duration is from 24 to 72 hours, and during a long-term monitoring, it varies from 1 to 2 weeks.

Other outpatient cardiographs are ECG event recorders. These devices are used for a long-term monitoring of a patient’s heart rhythm from one to several months [15, 17, 18]. Unlike Holter monitors, an ECG event recorder performs recording when the device is activated, that is data on the state of the heart are not stored permanently.

Activity trackers are a separate class of instruments designed to track biological parameters of the human body in real time. Modern trackers are designed in the form of wristwatches with a sensor module that records the parameters and transmits them to the user's smartphone. The technology of
activity trackers continues to evolve together with the development of mobile smart platforms suitable for mobile medicine, which makes this industry very promising for personal medicine. A personal medical device that helps raise awareness of a person’s health, including the state of the heart, enables combating causes of coronary heart disease, atherosclerosis and stroke at early stages, which can significantly reduce the number of cardiovascular diseases and improve the quality of life [19-21]. It should be noted that the use of activity trackers cannot replace a full-fledged electrocardiographic monitoring and can be used only to increase a person’s awareness of his health.

The equipment available for continuous cardiac monitoring operates in the standard frequency range, exhibits a low resolution, and contains filters that limit signals in the low and high frequencies. The development of wearable devices and high-resolution methods for dynamic cardiac monitoring and recording signals in the range from 0 to 3500 Hz without filtering and averaging is an urgent task. In addition, this will allow us to obtain new data on the atria and ventricles of the heart and to detect cardiovascular diseases at an early stage.

The block diagram of a wearable hardware and software complex based on nanosensors, hereinafter referred to as HSC, is presented in Figure 1.

![Figure 1. Block diagram of a wearable HSC based on nanosensors.](image)

As can be seen in Figure 1, the HSC consists of: IA - instrumental amplifier, AS - amplification stage, ADC - analog-to-digital converter, MC - microcontroller, DAC - digital-to-analog converter, RVS - reference voltage source, APU - auxiliary power unit, RB - rechargeable battery, C - computer, RTC - real time clock, and DC/DC - dc-to-dc converter.

Nanosensors are porous ceramic structures, which contain silver nanoparticles and exhibit good metrological parameters: DC electrode potential difference is no more than 2.0 mV; DC voltage drift does not exceed 0.005 μV/s; self-noise voltage does not exceed ± 200 nV in the frequency range from 0 to 10 kHz. In addition, the electrodes are not polarized under the DC impact and are characterized by high noise immunity that enables implementation of a hardware part of the measuring unit without filters in the input circuit [22].

Technical characteristics of the developed hardware and software complex are presented in Table 1.
Table 1. Technical parameters of the HSC.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSC mass</td>
<td>not more than 0.15 kg</td>
</tr>
<tr>
<td>Number of nanosensors</td>
<td>3 pcs.</td>
</tr>
<tr>
<td>Input voltage range for ECG recording</td>
<td>from ±1 μV to ±10 mV</td>
</tr>
<tr>
<td>Input impedance</td>
<td>not less than 10 MΩ</td>
</tr>
<tr>
<td>Common mode attenuation</td>
<td>not more than 120 dB</td>
</tr>
<tr>
<td>Absolute error of measuring the heart rate:</td>
<td></td>
</tr>
<tr>
<td>- in the range of 30–90 1/min</td>
<td>not more than ±1 min⁻¹</td>
</tr>
<tr>
<td>- in the range of 90–180 1/min</td>
<td>not more than ±4 min⁻¹</td>
</tr>
<tr>
<td>Relative deviation in the range from 0.3 μV to 5.0 μV</td>
<td>±15 %</td>
</tr>
<tr>
<td>Relative deviation from 5 μV to 10,000 μV</td>
<td>±10 %</td>
</tr>
<tr>
<td>Frequency range</td>
<td>from 0 to 3500 Hz</td>
</tr>
<tr>
<td>Channel sensitivity, μV/s</td>
<td>0.1; 0.2; 0.5; 1; 5; 10; 15; 20; 30; 50; 70; 100; 150; 200; 300; 500; 700; 1000</td>
</tr>
<tr>
<td>Relative sensitivity deviation</td>
<td>±5.0 %</td>
</tr>
</tbody>
</table>

The study of a dynamic electrocardiogram recorded using a wearable hardware and software complex based on nanosensors was conducted on volunteers in the Laboratory for Medical Engineering.

Unlike known wearable devices, a wearable HSC based on nanosensors has a high sensitivity of 1 μV, a wide frequency range, and a sampling frequency of 16000 Hz. The HSC accurately controls the dynamics of the heart rhythm, the potentials of the atria and ventricles, the spontaneous activity of myocardial cells and respiration. Figure 2 illustrates that nanosensors are placed on the diaphragm. Data processing is carried out using the algorithm and the program for micropotential detection (Figure 3).

![Figure 2. Attachment of nanosensors.](image)

![Figure 3. Micropotential detection algorithm.](image)
The direct detection of micropotentials is performed in three stages, each of which employs different low-pass filters (3500, 1500 and 500 Hz) to reduce side extremum. A single micropotential is detected by three extremum points (beginning, middle and end of micropotentials), where the derivative is close or equal to zero. Once the micropotentials are detected, histograms are plotted according to data stored in the arrays (amplitude and duration of micropotentials).

3. Results of the preliminary studies
The study was conducted on 9 volunteers, including: 6 volunteers - norm, 2 volunteers - atrial fibrillation, and 1 volunteer - after a heart attack. Before the experiment, the volunteers were informed about the examination methodology. Figure 4a, b, c, d presents the results of examination of volunteer 1 with atrial fibrillation conducted on February 15, 2019.

Figure 4. Results of examination of the volunteer with atrial fibrillation: (a) fragment of recording, sensitivity of 20 μV/div, (b) heart rate, (c) cardiac micropotentials.
Figure 5a, b, c, d shows the results of examination of volunteer 2 with atrial fibrillation conducted on April 26, 2019.

Figure 5. Results of examination of volunteer 2 with atrial fibrillation: (a) fragment of recording, sensitivity of 20 µV/div, (b) heart rate, (c) cardiac micropotentials.
Analysis of the results of examination of volunteers with arrhythmia showed:

1. A wearable HSC allows simultaneous monitoring of heart and respiratory rate.

2. Unlike Simson’s method used to detect late ventricular and atrial potentials, which is based on averaging of cardiac cycles, real-time investigation of spontaneous activity of myocardial cells based on the results of micropotential recordings can be carried out with any deviations in the ECG form as compared to the conventional one and with arrhythmia and instability of the ECG form during the observation period.

4. Conclusion
A single-channel wearable hardware and software complex based on nanosensors was designed for real-time ECG recording in a wide frequency range from 0 to 3500 Hz, with a level of more than 1 μV, and a sampling frequency of 16 kHz without filtering units in the measuring circuit for dynamic cardiac monitoring.

An algorithm and a program were developed to detect micropotentials over the entire duration of the ECG signal except for the waves of cardiac pulses and sharp peaks during signal processing. Histograms were built for quantitative evaluation, and the total energy of the analyzed micropotentials was calculated.

Preliminary studies of the developed HSC were carried out on volunteers.

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