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An ambulatory electrocardiograph with a high-resolution signal recording function

N. V. Turushev[1] · D. K. Avdeeva[1] · S. I. Yenshin[1] · M. L. Ivanov[2] · I. V. Maksimov[3] · G. S. Evtushenko[4,5]

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Abstract
A new hardware/software system for recording high-resolution electrocardiograms is presented. This system is capable of continuous recording of the electrocardiogram throughout the day with a sampling frequency of 16 kHz in a frequency range of up to 3.5 kHz. Analysis of recordings showed that the resulting electrocardiograms have a clearer wave morphology and contain information about cardiac micropotentials.

Introduction

Electrocardiographs are the main tool for the diagnosis of human cardiac activity. Two types of cardiograph are used in medical practice: static and ambulatory.

The main difference between ambulatory and static electrocardiographs is the ability to study cardiac activity over long periods of time (a day or more), which supports detection of non-obvious signs such as arrhythmias which are not detected by examination by a physician, along with monitoring of the effects of antiarrhythmic drug therapy [1, 2].

Ambulatory electrocardiographs (AECG) can be divided into different types depending on the method of recording information: classical, loop, and post-event [3, 4]. Classical ambulatory electrocardiographs—Holter monitors—make continuous ECG recordings, in contrast to loop and post-event electrocardiographs. Post-event electrocardiographs make recordings after the patient presses a button or are driven automatically by an arrhythmia recognition function. Loops continuously record a small fragment of the ECG, overwriting old unneeded fragments and saving fragments containing target events. The latter two types allow more episodes of rhythm disturbances to be recorded, as they have longer recording durations than standard Holter monitors [5, 6].

Design trends in the development of modern ambulatory electrocardiographs are aimed at reducing size, increasing recording duration, improving automation, and increasing the number of recording channels, as well as providing the opportunity for integration into more complex scalable measurement systems [2, 7], though at the same time their own diagnostic functionality remains at the previous level despite existing research potential.

Ambulatory electrocardiographs can be used for investigation of cardiac micropotentials. A high-resolution ECG study was conducted to identify total cardiac micropotentials energy patterns to assess the risk of sudden cardiac death [8]. This study was carried out using a static electrocardiograph and the time window for observing patients was small, limiting the opportunity to investigate the phenomenon of micropotentials in more detail with analysis of their composition depending on the time of day, physical activity, or during exacerbations of pathological conditions. This requires long-term and continuous monitoring of patients.

The aim of the present work was to develop an ambulatory electrocardiograph using technical solutions used in modern AECG. The device developed here is designed to

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✉ N. V. Turushev
nvtur90@mail.ru

1 Scientific-Industrial Laboratory for Medical Engineering, National Research Tomsk Polytechnical University, Tomsk, Russian Federation

2 Department of Electronic and Automatic Physical Systems, Northern Technology Institute, National Research Nuclear University MIFI, Seversk, Russian Federation

3 Emergency Cardiology Department, Science Research Institute of Cardiology, a branch of Tomsk National Research Medical Centre, Russian Academy of Sciences, Tomsk, Russian Federation

4 Department of Electronic Engineering, National Research Tomsk Polytechnical University, Tomsk, Russian Federation

5 Science Research Institute Republican Research Science and Expert Consulting Center, Ministry of Education and Science, Moscow, Russian Federation

expand the capabilities of this area of research by improving the quality of ECG recording and expanding the frequency range as required for recording cardiac micropotentials.

Materials and methods

The electrocardiograph developed here is a hardware-software system (HSS), which includes a set of nanosensors, groups of cables with alligator clips for leads, a measuring unit, a battery pack, and a smartphone.

Nanosensors are a new type of cutaneous silver chloride electrode where the sensory element is a porous ceramic body embedded with silver nanoparticles. This design gives high noise immunity and practically neutralizes the effect of electrode polarization during operation.

The design of the nanosensors was developed based on results obtained by testing 12 nanosensor prototypes on a verified metrology system The study selected the sensory elements of nanosensors and grouped them according to the shape of the silver particles: spherical, cubic, and prismatic.

Testing was with a UPE-2 system of our own construction for testing silver/chloride electrodes (measuring instrument type approval certificate RU.E.31.113.A No. 33700, State Register of Measuring Instruments No. 39325–08).

The measuring unit is the main part of the system and which records the electrocardiogram as detected by the nanosensors. The power supply of the unit is separated from the measuring part and is built into a separate housing.

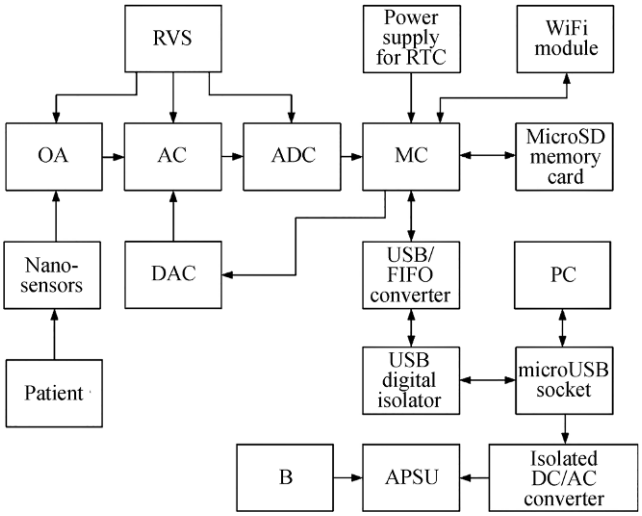

Fig. 1 Block diagram of the measuring unit: *OA* operational amplifier, *AC* amplification cascade, *ADC* analog-to-digital converter, *MC* microcontroller, *DAC* digital-to-analog converter, RVS reference voltage source, *PC* electronic computer, *B* battery, *APSU* auxiliary power supply unit, *RTC* real time clock

The measuring unit was separated from its power supply because of the weight of the HSS and size considerations. The block diagram of the measuring unit is shown in Fig. 1.

The operating principle of the measuring unit is described below. Biopotentials from the nanosensors are amplified in the amplification cascade (OA and AC), converted into digital code using a 24-bit ADC with a sampling frequency of 16 kHz, and the measurement cycle is controlled using a 32-bit microcontroller (MC). Detection of biopotentials from the patient can form a constant component alongside the useful signal; the circuit includes a DAC to compensate for this. After the measurement cycle, the microcontroller records the ECG into the non-volatile memory of the microSD card or transmits the data to the computer via a USB/FIFO buffer and a USB digital isolator. A real-time clock (RTC) is used to generate time markers for recordings and to allow subsequent comparison with the patient's diary. The necessary internal voltages are formed and distributed by an auxiliary power supply unit (APSU). Energy for power comes from a battery or via cable from the computer.

A distinctive feature of the measuring unit is that it has multiple communication channels, i.e., wired and wireless. The wired channel communicates with a personal computer via a Type C USB port. The wireless channel transmits data to a smartphone with a specially installed app via Wi-Fi. The mobile app is written in Delphi. Interaction between the measuring unit and smartphone is controlled using the microcontroller of the Wi-Fi module.

The functions of the electrocardiograph developed here were assessed by recruiting groups of patients and running studies at the Science Research Institute of Cardiology, Tomsk National Research Medical Center: patients with coronary heart disease (group 1), patients with heart rhythm disturbances (group 2), and healthy volunteers (group 3).

The total number of volunteers was nine (three in each group): two ECG recordings were made using the HSS in volunteers of the first two groups, while single recordings were made in volunteers of group 3. All volunteers additionally underwent studies using a MEKG-NS-02 Holter monitor (DMS Advanced Technologies LLC, Russia); potentials were monitored using three pairs of electrodes from the chest. Monitoring was recorded at a sampling rate of 250 Hz over a voltage range from 0.05 to 10 mV.

Investigations of cardiac micropotentials started after research using software tools on computer. The algorithm for the micropotentials detection program operates as follows: after initialization of the program, the processed ECG file is loaded, the program sets parameters characterizing the elements of the ECG of a particular record: for example, the maximum heights of waves, the boundary points for the start of the rise phase and the end of the decay phase of waves, and the interval of wave durations. Signal process-

ing is then started, and includes the sequential removal of ECG waves; after removal of waves, only micropotentials are left on the ECG. After pre-processing, micropotentials are determined using three extreme points. After finding a specific micropotential, data on it are recorded and the recorded fragment is replaced with a straight line. The algorithm continues to search, analyze, and remove micropotentials until the signal fluctuation drops to 5%. Method errors are minimized by carrying out the search in several stages, starting with the smallest fluctuations. Before searching for micropotentials, the signal is processed using low-pass Butterworth filters with different cutoff frequencies. As the algorithm searches first for small and then for larger micropotentials, the cutoff frequency of the filter decreases from stage to stage: 3500, 1500, and 500 Hz. A report is generated based on the data obtained and histograms of the distribution of micropotentials are plotted.

Results

Metrological testing of the sensory elements of nanosensors using the UPE-2 system produced the following results:

1. the mean polarization voltage of the first group was no greater than 194 μV, that of the second group was no greater than 36 μV, and that of the third group was no greater than 105 μV;
2. the impedance of the nanosensor (at a frequency of 0.1 Hz) of the first group was no greater than 2.16 kΩ, that of the second group was no greater than 1.52 kΩ, and that of the third group was no greater than 1.03 kΩ;
3. the mean difference in electrode potentials in the first group was no greater than 3.2 mV, that in the second group was no greater than 160 μV, and that in the third group was no greater than 121 μV.

The data obtained indicate that the third group of sensory elements has the best characteristics. Nanosensors were developed on the basis of this group. Despite the current trend of using sensors grouped on a single patch or integrated into one device [9, 10], the nanosensor design was implemented in a classical version as individual attached electrodes. This approach was selected because it does of the impose any restrictions on the configuration of the electrodes applied to the patient and provides the opportunity to use electrodes both with conventional patches and with special wearable electrode fixation systems.

The work reported here led to the development of a measuring unit with the following technical characteristics:

– sampling frequency of the recorded signal: 16,000 Hz;
– range of signal frequencies measured: from 0 to 3500 Hz;

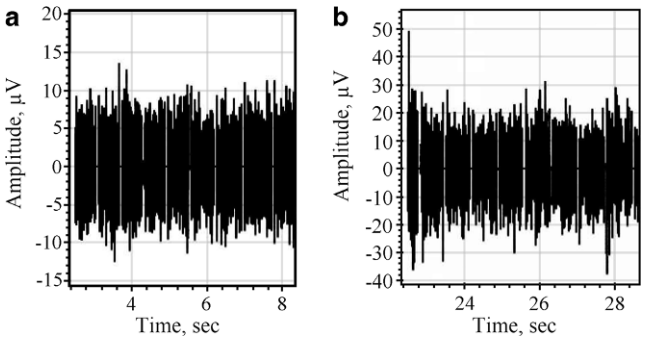

Fig. 2 Comparison of ECG micropotentials recorded from volunteers of the group 3 (**a**) and group 1 (**b**) after excluding the ECG curve

– amplitude of the input recorded signal: from 1 μV to 10 mV;
– uneven amplitude/frequency response in the operating range of the HSS: from ± 20 to ± 10%;
– input current in the patient circuit: no more than 0.05 μA.

The device developed here supports wireless communication with a smartphone via Wi-Fi. An app is used on the smartphone to interact with the measuring module. The app is able to synchronize time with the module, download, view, save, and analyze data on a smartphone. Use of a smartphone makes it easier to place the electrodes in the required position because of the rapid feedback received from the measuring unit.

The high-resolution ECG measured by the device, as compared with results obtained using the MEKG-NS-02 Holter monitor, looks clearer, allowing for a better assessment of signal morphology and its elements. After processing and analysis as described above, micropotentials were detected in the high-resolution ECG. Assessment of the composition of micropotentials on segments of the high-resolution ECG from a volunteer from the control group (Fig. 2a) showed that the amplitude of micropotentials varied from –14 to 14 μV and that the maximum was 14 μV, while the amplitude range in a volunteer from group 1 (Fig. 2b) was from –38 to 49 μV and the maximum was 49 μV.

Conclusions

An ambulatory electrocardiograph based on sensitive, noise-resistant nanosensors able to record ECG traces in the frequency range 0–3.5 kHz with a sampling frequency of 16 kHz was developed. The quality of the resulting signal is sufficient for isolating and analyzing cardiac micropotentials. The amplitudes of micropotentials in these ECG recordings were significantly greater in volunteers with confirmed coronary heart disease than in the control group

studied using this device, which s consistent with data reported in [8] and confirms the notion that micropotentials are present in the ECG rather than random noise. Future plans are to study the relationship between the numbers of micropotentials in cardiac activity at different times of the day and at moments of pathological heart function.

Use of a wireless communication channel in the device simplifies electrode mounting, such that ECG noise and electrode locations can be adjusted to obtain the required signal morphology. In addition, this method allows monitor traces to be produced, viewed, downloaded, and transferred for analysis of micropotentials in minimal time periods. Future studies will implement a medical telemetry system based on the device developed here and will include detailed long-term medical studies of the relationship between of the number of micropotentials and the condition of the heart.

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