Implantable Biotelemetry System with Extended Functional Capabilities

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Abstract—**Biotelemetry, or medical telemetry is being developed more and more recently. Biotelemetry has enormous opportunities to make health care more efficient and safe while reducing costs. However, the currently existing implantable devices must be periodically removed from the body of the object of observation to replace the source of energy, and then re-install into the body. Power sources have become the main limiting factor for increasing the life of the implant. They are an obstacle to the further miniaturization of implantable devices. The development and further application of this work will lead to a significant improvement in the use of implantable medical devices, thanks to the improvement of a number of indicators, including those associated with charging an implantable device. Analysis results of similar works and predictive research in the field of energy supply of implanted devices, the most efficient and safe method to reduce the battery recharge time suggests the use of pulsed current or pulsed voltage.**

I. Introduction

The relevance of the problem is evidenced by the data from the Federal Institute of Industrial Property (Russia), the Federal Service for Intellectual Property, Patents and Trademarks (Russia), US patent databases and the European Patent Organization. Preliminary findings on a thematic search indicate the continued interest in biotelemetric monitoring of physiological parameters, and the search for technical solutions has shifted towards non-contact charging of batteries. For a detailed study of existing technical solutions, the authors turned to articles published in journals under the publication of the world's largest association of experts in the field of technology - the Institute of Electrical and Electronics Engineers (IEEE).

In our opinion, all existing directions and development of modern biotelemetry are most fully reflected in the works of such companies as: Data Science International, Millar, Integrated Telemetry Systems, Telemetry Researcher Ltd., Mini Mitter Company, Inc. Bend, Indus Instrument, while in Russia there are no domestic counterparts.

However, as the use of implants around the world expands, for example, for remote monitoring of human health (telemedicine), it is possible to predict a further increase in interest to this problem.

The purpose of research is the development of the scheme and the manufacture of a prototype of an implantable biotelemetric system (hereinafter referred to as the "System") with additional capabilities, comparing to traditional ones [1]. These include the following:

1) Ability to operate on disposable lithium batteries for short-term (3-14 days) experiments;

2) Ability to operate on contactless charging battery. This ensures long-term System’s operation (up to 1 year);

3) The ability to determine the motion activity and orientation in the Earth's gravitational field of a biological object by implanted System. In gravitation-free conditions, it is possible to determine the acceleration of motion and angular velocities along the 3 axes;

4) The ability to apply a pulse power to device modules allows to increase the System’s functionality without significant increase of the power consumption from the power source and without reducing the equipment’s wear rate.

5) The ability to remotely change the transmitted parameters during long-term experiments will increase the possibilities of experimental research.

Thus, it becomes possible, with the help of one System, to provide experimental research with technical equipment for solving a wide range of problems (pharmacology, efficiency, influence of environmental factors, etc.). It provides the transmission of both electrophysiological signals (ECG, EMG, EEG, etc.), and others - blood pressure signals, signals from a three-axis accelerometer and gyroscope, a magnetometer. In addition, signals are transmitted that carry information about the technical parameters of the System - charging current and battery voltage, current consumption. This allows you to make a decision about the appropriate modes of operation of the System and take them into account in further developments. Such an approach will allow to pay attention to the development of both individual modules of the System and its structure as a whole. Considering the absence in Russia of biotelemetric implantable systems of local production, the article’s goal is relevant.

This paper presents the structure of the system, which defines the main functional parts of the product, their purpose and the relationship between them. It also describes how to solve the above problems and shows the developed prototype of the system with the contactless charging circuit. The results described in this article will serve as a basis for further research, development and testing of the implantable system prototype.

II. Structure of the System

To gain an understanding of the System's operation, as well as to determine the sequence of interaction of individual functional parts, the structure of the System is shown in Fig. 1.

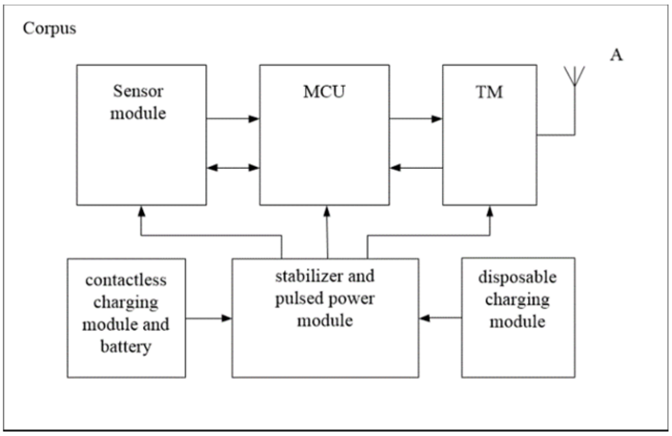

Fig. 1. Structure of the System

The task of the sensor module is the conversion (amplification) of electrical and other signals, which characterize the state of a biological object, into an electrical signal sufficient to convert by analog-to-digital converter (ADC) of the microcontroller (MCU) into a code that is transmitted via the transceiver module (TM) to the receiving module of the System via the antenna A. The contactless charging module, combined with the battery, provides a contactless charge of the battery and a non-stabilized voltage to the stabilizer and pulsed power module. It is possible to use a disposable charging module instead of a battery, if there is ~~a~~ need of short-term operation. This will also minimize the size of the System, since the contactless charging module and battery will not be required. Also it is important to solve a packaging task. The corpus ensures the tightness of the implant and protects electronic modules from the aggressive environment of the body. In this case, the body material must be biocompatible, do not cause a rejection reaction by the body and do not cause inflammation at the implantation area.

III. Methods of Implementing the Additional Capabilities of an Implantable Biotelemetric System

A. Short-term disposable lithium batteries-based operation

To solve problem 1, i.e. to ensure the System operation on the disposable lithium cell with a voltage of 3.0-3.2 V, it is necessary to provide possibility of stabilizing the power supply voltage of the System at the level of 2.8-2.9 V. This will allow the System to operate on the battery consuming 80-85 % of its energy. Depending on the duration of the data transfer sessions and their quantity, the duration of ~~the~~ work can vary from 3 to 7 days.

B. Long-term battery-based operation

To solve the problem 2, it is necessary to use the contactless charging device of a Li-Ion battery. Since it does not have a memory effect, it can be charged (recharged) at any time, when it is free from the experiment. Experience shows that a battery with a capacity of 95-250 mA/h provides at least 20 hours of continuous operation of the System while transmitting no more than 10 parameters of a technical and physiological nature. Modern batteries provide 500-1000 cycles of charge-discharge, which allows to ensure a long period of operation of the implanted System. Given the existence of prototypes of the contactless battery charging device, it is possible to implement them in the System being developed.

C. Determination of the motion activity and orientation

To solve the problem3, it is relevant to use modern accelerometers produced by many firms. A wide application in devices powered by batteries, find accelerometers produced by STM [2]. As an example, we can cite a 3-axis accelerometer LIS2DS12 [3]. Having dimensions of 2x2x0.86 mm and consuming a current of 0.15 mA at a voltage of 1.16-1.8 V, it is ideally suited for estimating the motion activity of an experimental object, since the band of recorded frequencies reaches 6 KHz. If it is necessary to determine the position of the object, then it is possible to reduce the power consumption (current) to 10 μA, by switching it to the economy mode and reducing the frequency of recorded movements. There are also accelerometers for medical applications with digital output with similar characteristics, for example MIS2DH, having dimensions 2x2x1 mm [4], and also directly connected to a microcontroller with a standard interface such as SPI and I²C. With multiple functional capabilities, consumption current is 0.18 mA, and the supply voltage is 1.7-3.6 V, which is an advantage for implantable systems.

D. Pulsed power supply of the System modules

When solving the task of pulsed power supply of the System modules we encountered the problem of data lackage on the operation of sensors (sensors) in pulsed mode. For amplifying elements the parameters of the output signal setting are given when supplying voltages, but it is not always possible to predict the time of setting the output signal for specific sensors. Fig. 2 shows oscillogram of a blood pressure sensor with a signal of amplifier INA333 type [5].

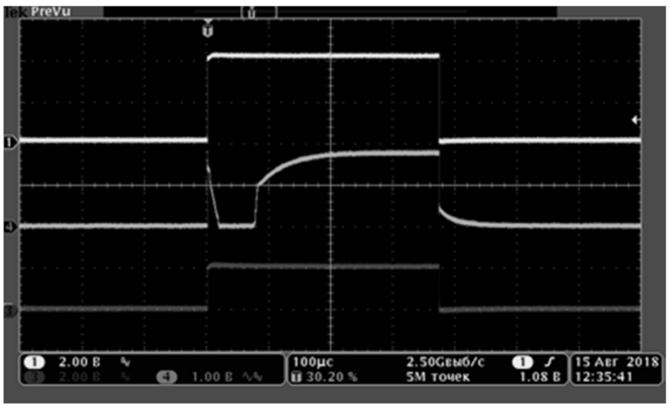

Fig. 2. Oscillograms of blood pressure sensor in pulsed power mode

On the screen there is the oscillogram when the sweep is 100 mks/div. The upper trace displays the voltage pulse applied to the pressure sensor module. The middle trace is the output signal of the instrument amplifier when the pressure is applied to a sensor of 150 mm Hg. The lower trace displays the output signal from one diagonal of the bridge type sensor.

These traces shows that the current consumption from the power source occurs only at the moment of power supply, at the rest of the time the energy is not consumed. The signal at the output of the amplifier can be considered to be fixed at 300 µs, and it can be fed to the A/D of MCU for conversion to the code and subsequent transmission to the communication line.

It can also be seen that the main delay is made by instrumental amplifier type INA333, consuming current 50 µA. To reduce the delay, you either need to power the instrument amplifier constantly (Fig. 3), or use a high-speed instrumentation amplifier (IA) with pulsed power. The gain on the consumed energy will be obtained due to a significant reduction in the time of the setting the output voltage of the amplifier.

The gain in the power consumption for a pulsed power supply can be calculated from the pulse duty cycle, defined as the ratio of the repetition period to the power pulses duration. With a supply voltage of 4 V, a current consumption, the pressure sensor and the amplifier of 4.05 mA, a power pulse duration of 380 µs, a pulse repetition period of 5 ms (a frequency of 200 Hz), we obtain an average power consumption of 1.2 mW at a peak of 16, 2 mW. With a constant power supply of the IA, the pulse power duration can be 200 µs (Fig. 3), which is almost two times less than with a general pulsed power supply. The amplifier consumes 0.2 mW power in the constant power mode. The pressure sensor will consume an average power of 0.64 mW. The total power consumption of the channel for measuring blood pressure will be 0.84 mW, which shows the advisability of a constant supply of IA and pulse supply of the pressure sensor. A further decrease of the average power is possible due to a decrease in the repetition frequency of these pulses (if possible).

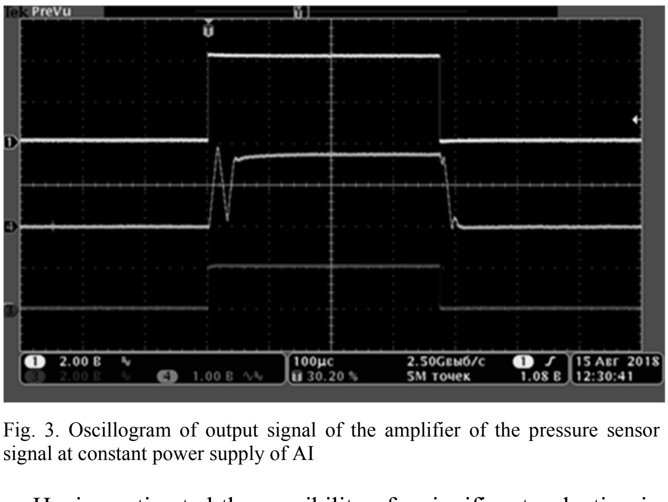

Fig. 3. Oscillogram of output signal of the amplifier of the pressure sensor signal at constant power supply of AI

Having estimated the possibility of a significant reduction in power consumption by modules of the implantable biotelemetric System due to pulsed power supply, we come to the conclusion that in the presence of a modern element base, it is possible to introduce hardware redundancy into the System's structure without significantly increasing the power consumption and without increasing the dimensions and weight of the latter. This will allow us quickly change the protocol of scientific research in the course of chronic experiments.

IV. Prototype of the System

Fig. 4 shows the prototype of the biotelemetric System with the contactless charging circuit. Currently, the contactless charging circuit is made in the form of a coil made of a multi-layer printed circuit boards and is located at the bottom of the circuit. At the top in the middle, there is the microcontroller CC430F5137 [6], which includes a 16-bit computational core, a multichannel 12-bit ADC, and a transceiver at 430-460 MHz. On the right there are the biopotential amplifiers and the signal amplifier of the pressure sensor described above. In the lower left corner of the microcontroller there is a three-axis accelerometer. At the bottom there is the memory chip that allows to accumulate information from active channels within 1 hour in case of radio channel failure (with subsequent data transmission upon request). On the left there is a place for the ceramic antenna for receiving and transmitting data. The remaining elements provide the necessary operating modes for analog and digital modules of the System.

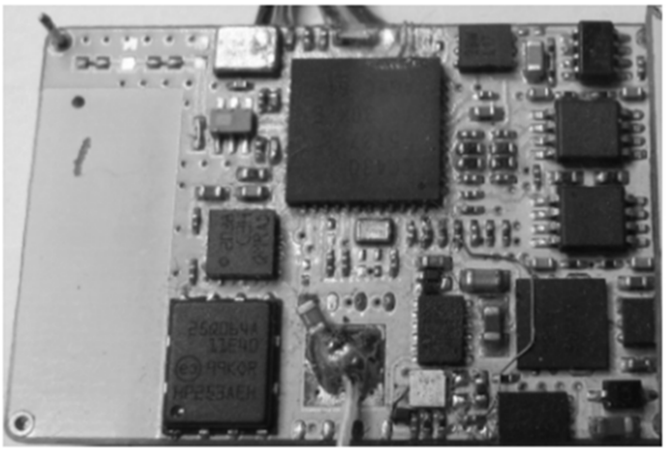

Fig. 4. The Prototype of the implantable biotelemetric system board with extended functional capabilities

Fig. 5. The prototype of the implantable biotelemetric system in the corpus from the battery's side (left) and the receiving contour's side (right)

Fig. 5 shows the prototype of the implantable biotelemetric System in a corpus made of biocompatible material. Elements of telemetry, shown in Fig. 4, are under the battery, so they are not visible. The battery has the parameters clearly visible in the photo. The operating voltage is 3.7 V. When the battery is fully charged, it is 4.2 V, at the end of the discharge cycle, the operating voltage drops to 3.5 V, which corresponds to 90 % of the energy stored by the battery. To ensure normal thermal conditions, the charging current is 20-30 % of the battery capacity, i.e. 45-80 mA. Accordingly, the time of full charge of the battery is from 5 to 3 hours.

Fig. 5 also shows the model of the implantable biotelemetric System from the side of receiving contour of the contactless battery charge module. The receiving antenna of the module is made using the technology of multi-layer printed circuit boards, which has made it possible to reduce the antenna's dimensions and improve the manufacturability and reproducibility of the parameters for future mass production. It should be noted that the receiving contour must be on the other side of the battery to eliminate the shielding effect of the metallized corpus.

As it was mentioned before, hardware redundancy allows creating a multifunctional biotelemetric complex. Biotelemetry necessarily includes biopotential amplifiers.

Their number can vary from 1 to several dozen. Therefore, an important task is to reduce the dimensions of the latter, and this is possible by reducing the number of components in their composition. "Table 1" shows the main parameters of instrumental amplifiers of leading manufacturers.

"Table I" shows that it is preferable for devices with autonomous power supply (including biotelemetric systems) on a single Li-Pol battery, to use an IA of the type INA333, which provides the necessary amplification characteristics of electrophysiological and physical signals with a minimum power consumption and min current consumption).

TABLE I. INSTRUMENTAL AMPLIFIERS' MAIN PARAMETERS OF LEADING COMPANIES

Name of instrumentation amplifier	AD620	INA118	INA333
Gain range	1-10000	1-1000	1-1000
Common-mode rejection ratio, dB	100	110	100
The maximum input bias current, nA	1	5	0,2
Frequency range (bandwidth) (at G = 100), kHz	120	70	3,5
Input Voltage Noise, nV/√Hz	9	10	50
The minimum supply voltage, V	4,6	2,7	1,8
Maximum supply voltage, V	36	36	5,5
Own current consumption, mA	1,3	0,35	0,050

Fig. 6 shows three typical schemes of biopotential amplifiers (preamplifiers). These data are based on the documentation for the instrument amplifiers listed in Table I, referred to the websites of the manufacturers.

Since the sum of the three signals affects the inputs of the biopotential amplifiers, they should be considered in more details.

Firstly, the largest amplitude is the signal of network interference frequency – 50 Hz (in Russia). It is suppressed by the use of a differential (instrumental) amplifier at the input.

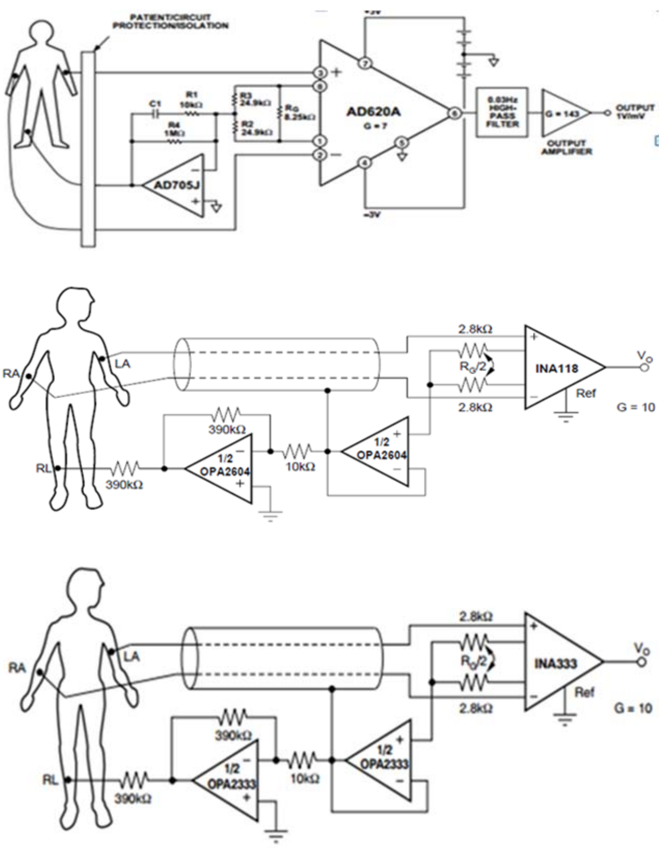

Fig. 6. Typical schemes of biopotential amplifiers (preamplifiers)

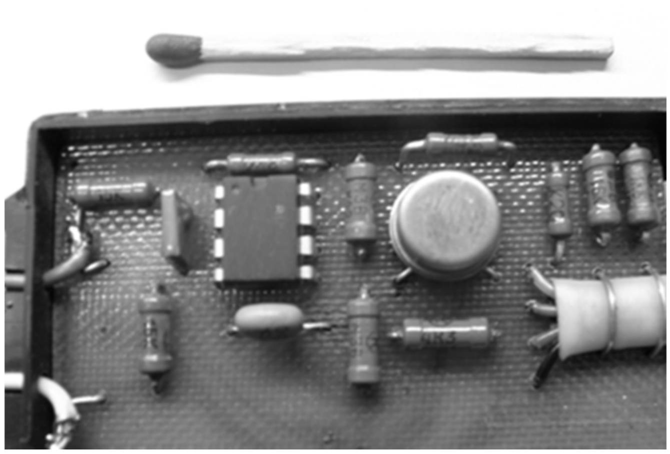

Fig. 7. Implementation of a typical scheme board of biopotential amplifier

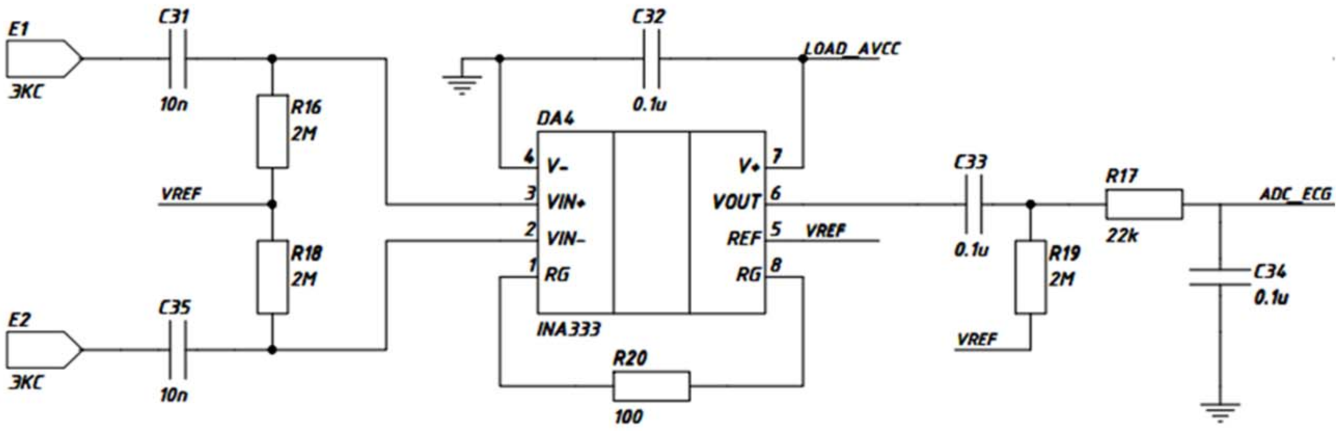

Fig. 8. Biopotential amplifier Principal Scheme of biotelemetric System's Prototype

Secondly, the signals coming from the electrodes can have a constant component up to 300 mV and unpredictable polarity (polarization potential). To eliminate its effect, the gain of the input amplifier is limited by a value that does not allow saturation of the output of the input amplifier when a useful signal is applied.

Thirdly, the input itself receives a bioelectric signal of several millivolts.

Thus, at the output of the input amplifier there will be an amplified polarization potential plus a useful biopotential, the value of which rarely exceeds 5 mV. In Fig. 6, it is seen that to amplify a useful signal, an amplification of 500-1000 is required (depending on the amplifier supply voltage). It is necessary to remove the amplified polarization potential. The top typical scheme shows that for this purpose, after the input amplifier, the high-pass filter is applied that passes signals with a frequency higher than 0.05 Hz for the electrocardiographic (ECG) signal. For the electromyographic (EMG) signal, the high-pass filter filter will transmit frequencies above 10 Hz or a different frequency (depending on the purpose of the research).

In Fig. 6 is shown that at least 2 amplifiers - 1 instrumental and 1 ordinary operational amplifier (OA) - are needed to realize 1 channel of the biopotential amplifier (see Fig. 7). This contradicts to minimize the quantity of elements per gain channel. To solve this problem the principal scheme represented in Fig. 8 was developed. The common-mode signal is suppressed by IA with a help of the differential amplifier, the electrode potential does not pass to the input of the IA due to the high-pass filters formed by elements C31, C35 and R16, R18. Thus, only the biopotential is applied to the inputs of the IA, the gain of which is determined by the magnitude of the gain of the IA given by the resistor R20. In our case, the gain is 1000. The received amplified signal is applied through the low-pass filter on the elements R17, C34 to the input of the microcontroller ADC.

The implementation of the model of the biopotential amplifier is shown in Fig. 10. The match head is located side by side to compare the sizes with the previous version (Fig. 7). All elements of the principal scheme (Fig. 8) are located at the minimum distance from the IA terminals of the INA333 type.

An example of an electrocardiogram (ECG) signal, taken with the above amplifier at one IA, is shown in Fig. 10.

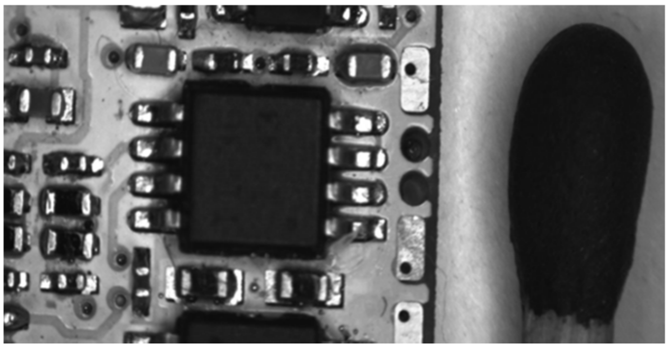

Fig. 9. Implementation of the biopotential amplifier circuit of the biotelemetric system model

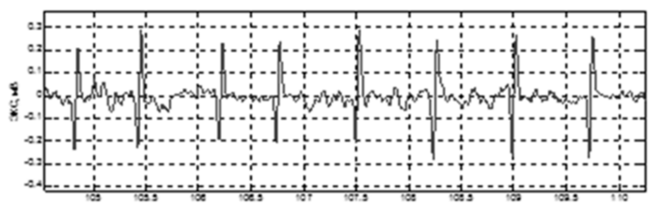

Fig. 10. Electrocardiogram (ECG) signal recorded on the surface of the body

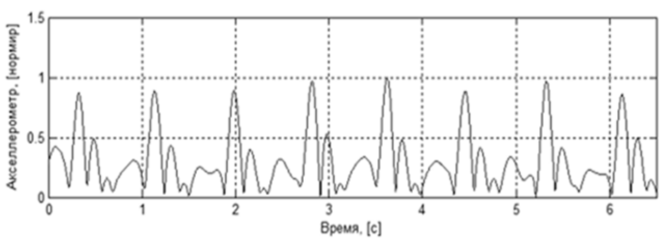

Fig. 11. The pulse wave signal recorded by accelerometer

Assembling this amplifier, it is necessary to pay attention to the identity of the values of the elements of the input high-pass filters, since the suppression of in-phase interference depends on this.

As an example, showing the possibility of non-standard application of the accelerometer, Fig. 11 shows the pulse wave signal. It was obtained by placing the accelerometer directly on an aorta. It can be seen that without the electrical contact with an artery, it is possible to obtain the value of the heart rate. It remains possible to determine the orientation of the accelerometer itself (and hence the body of the biological object) in the gravitational field of the Earth.

Thus, we considered some peculiarities in the development of the model of the implantable biotelemetric system, which allowed us to obtain additional possibilities.

We also considered the option of constructing the prototype of the receiving module of the biotelemetric system. Its physical configuration is shown in Fig. 12. Since the dimensions and power consumption issues are not so relevant for this model, the components were chosen on the basis of minimizing the nomenclature of the latter. As the receiver and microcontroller were used the chip CC430F5137 [6], in Fig. 12 it is located in the center of the printed circuit board at the bottom. At the top left there is the USB channel controller, made for connecting the receiver with any personal computer. The prototype of the receiving module of the implantable biotelemetric System is connected to a personal tablet type computer. As the receiving antenna, a standard ISM whip antenna is used. Simultaneously with the visualization of the received data, it is possible to register them on internal or external drives of a personal computer.

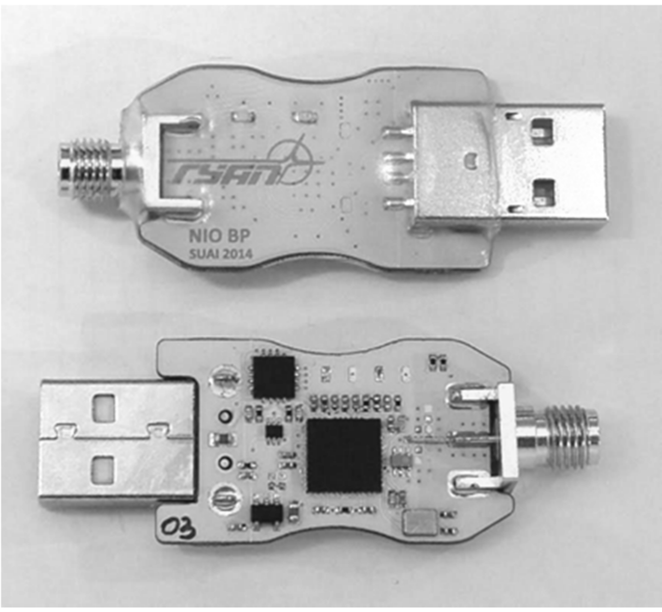

Fig. 12. Prototype of the receiving module of the implantable biotelemetric System

V. Conclusion

Currently, a significant drawback of existing implantable devices is the need to extract them from the body of the observation object to replace the source of energy supply. Energy supply sources are an obstacle to the further miniaturization of implantable devices. In the most common currently implantable devices, the battery takes 85 - 90% of the device volume. The same trend continues with the mass of the device. This article considers the task of minimizing dimensions and increasing the operating time of implantable devices, as well as the possibility of their contactless charging, which does not require the extraction of the system from a biological object. Conducted studies of the global market for these products confirm the relevance and increased interest in the studied problem. The results of the research can be applied in the field of medicine, pharmacology and human physiology. It is assumed that they will be used to create a system for charging power sources (batteries, capacitors) sealed devices intended for implantation into biological objects.

Thus, we have considered some issues related to the development and construction of an implantable biotelemetric System models, which allowed us to obtain additional opportunities. Issues of circuit implementation of the elements responsible for the formation of pulsed power supply of individual modules of the biotelemetric system are solved by switching the cascades of the digital outputs of the microcontroller to Push-Pull mode. In this case, the total current delivered to the modules power supply should not exceed 48mA for the CC430F5137 microcontroller. This allows you to reduce the number of elements placed on the PCB, and, accordingly, reduce the size of the latter or place additional modules to enhance the functionality of the system. Further work will be aimed at improving the software, design and solving problems related to the issues of the packaging of the implantable part of the biotelemetric System with extended functional capabilities.

Acknowledgment

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