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PORTABLE ELECTROCARDIOGRAPH WITH GSM MODULE FOR TELEMEDICINE

Urgency of the research. *The principles of telemedicine need to be put into practice of emergency medical care and family medicine, so there is a need for diagnostic medical equipment with the ability of data transfer and remote consulting with subject matter experts.*

Target setting. *Currently, ECG testing consumes the time to prepare the device for work, needs for the personal computer as the additional equipment and requires highly skilled staff. The development of portable electrocardiographic equipment with built-in means of communication is a task of current importance for biomedical engineering.*

Actual scientific researches and issues analysis*. The current researches in the development of portable cardiograph for primary preclinical diagnostics are focused on the choice of optimal design parameters of device and the incensement of noise immunity of medical equipment.*

Uninvestigated parts of general matters defining. *This article focuses on the design development of the portable electrocardiograph with built-in GSM module for operation in telemedicine systems.*

The research objective *is the design of the portable electrocardiograph for telemedicine that has a convenient interface for device control, is equipped with means of communication with cardiac care centers, has universal ports for information output to external drives and connection of additional devices, is as ergonomic as possible, meets safety, reliability and energy efficiency requirements.*

The statement of basic materials. *The main design requirements to portable electrocardiographic equipment are formulated. The basic functional units of the device are chosen and its electronic block diagram is synthesized. The computer simulation of processes and parameters of the circuitry of the instrumentation amplifier functionality at given operating temperatures proves the validity of proposed circuit design. The constructive implementation of the schematic diagram is designed. The device constructive parameters that meet the requirements of telemedicine most closely are defined.*

Conclusions. *The key features of the designed portable electrocardiograph with GSM module are: the embodiment in folding form-factor, the availability of GSM module, the constant connection of ECG electrodes via integrated ECG cable. The embodiment in folding form-factor optimizes ergonomic characteristics of the device. The replacement of non-integral ECG cable with integrated one reduces the intensity of internal noise and reduces time to prepare the device for work. Built-in GSM module provides affordable communication with specialized medical facilities, thus reducing the duration of the diagnostics and increasing the efficiency of the medical care in non-ambulatory out-hospital an outpatient setting.*

Keywords: *electrocardiography; portable electrocardiograph; telemedicine; GSM module; data transfer; folding form-factor; integrated ECG cable.*

Fig.: 4. References 17.

Urgency of the research. The cardiovascular disease (CVD) is the most common type of noncommunicable diseases worldwide. According to the WHO, deaths from CVD make up 31% in the structure of all-cause mortality. This issue is extremely relevant for Ukraine too that takes the first place among European countries in terms of incidence and mortality from CVD [1]. The concept of combating CVD provides a universal health coverage that includes the mandatory electrocardiography in Ukraine. It can take two forms: the routine testing carried out in an outpatient setting and unscheduled non-ambulatory express-ECG in providing the emergency medical care or in suspected case of CVD.

The portable electrocardiograph with the function of data transfer to the specialized medical facilities is necessary for a real-time unscheduled assessment of the patient's condition. It is proven that preclinical diagnostics and immediate care in case of acute manifestations of the CVD increase the effectiveness of further treatment.

The urgency of this research is to develop the design of the portable electrocardiograph (PEC) intended for use in telemedicine – in family medicine and in emergency medical care.

Target setting. The electrocardiographic equipment is generally a kit consisting of electronic unit of monoblock form-factor, standard ECG electrodes, the shielded ECG cable. ECG testing data are saved as printout on ECG-paper or by transferring on the computer. As a result, ECG testing consumes time to prepare the device for work, needs the personal computer as the additional equipment and requires highly skilled staff. The development of portable electrocardiographic equipment with built-in means of communication is a task of current importance for biomedical engineering.

Actual scientific researches and issues analysis are devoted to the selection of optimal design parameters of the portable electrocardiograph and the incensement of its noise immunity. The design of the proposed PEC is determined by the following parameters: method of registration of biopotentials, number of recorded leads, interface type for the device, method of data displaying, type of ports for data transfer, type of the power source.

The method of registration of biopotentials plays an important role. Simplest single-channel devices include integrated capacitive ECG sensors [2]. The disadvantages of such devices are signal distortion because of the variable skin-electrode resistance and high sensitivity to mechanical movement upon contact that reduce accuracy of received data [3]. In order to take an ECG test, the aforementioned devices should be pressed against the chest or they should be firmly squeezed with the palms of both hands. This method is convenient for monitoring or self-monitoring of the well-being, but it cannot be used in emergency medical care, especially if the patient is unconscious. In terms of interference minimization and convenience of information acquisition, PECs equipped with electrodes fixed to the patient's body are preferred [4]. Out of two designs used, the clamp ECG electrodes are more convenient to use rather than the suction cup ECG electrodes [5].

The number of recorded leads for electrocardiographs of different designs varies from 1 to 12 [6]. This parameter is not considered as the primary one for the express-ECG [5]. In order to determine the critical deviations of the cardiovascular system functionality the registration of biopotentials from three leads according to the Einthoven principle is enough [7]. An increase in the number of leads affects the amount of interference and the energy intensity of the device, and it also increases the testing preparation phase for the patient.

PEC tor express-diagnostics in non-ambulatory setting must have both a user-friendly visual interface and an ergonomic way of interacting with the device [8]. Practically all the devices, which are in service, are controlled via the button interface with the dialogue window on the liquid crystal display, that simplifies the handling of the device, increases the device's strength and minimizes system energy consumption [5, 7].

A number of PECs provide a function to print the cardiogram on a thermal paper directly at the place of diagnostics, which is convenient for diagnosis and saving of the results of the testing [5]. On the other hand, the use of the thermal paper involves the design of the thermal printing compartment with the possibility of paper replacement, the allocation of volume to house the heat source and the support shaft. Not only do these elements significantly complicate the design, but also affect the power consumption and resistance of the device to the shock loads.

Energy efficiency and autonomy are significant factors to be considered in the development of portable medical equipment in general and equipment for telemedicine in particular [4; 9]. To implement them, the device must have a low power consumption and stay operational at the testing place, regardless of the availability or absence of electrical powerlines.

Uninvestigated parts of general matters defining. The disadvantage of standard electrocardiography methods is the signal distortion, as a result of the electromagnetic interference [3]. Connectors and connecting cables, the human body, the PEC computing module generate electromagnetic distortions [10]. In addition, an important factor is the mechanical strength of the connectors in operating conditions with a large number of pairing cycles [11]. One of the aspects of PEC development is crosstalk level reduction and durability improvement of the equipment by reducing the number of cables and connectors in structural design of the device.

The built-in GSM module is a key design element in the development of portable electrocardiograph for telemedicine. It provides an opportunity of transferring diagnostics results and receiving instructions from specialists, reducing the time interval between taking a cardiogram and diagnosis [12 – 14]. The LAN port should be considered as an alternative to the GSM module – a less expensive, but a rather quick method of an access to the cardiology network [14]. However, at the same time, a place of a patient's testing should have access to the Internet, and the PEC kit must come with an appropriate cable.

There is a need to study the dynamics of cardiologic indications; therefore, it is important to save this information by transferring it to external storage devices or a computer [12]. The prevalence of the USB connector as a generally accepted method of the data transfer explains why it is a feature in PECs, but it requires certain design changes, taking into account the ergonomics of the device [2, 7]. The use of the SD card provides an ability to store up to 2 terabytes of cardiac imaging protocols [15]. However, the SD card port is less common than USB, which explains the need for an external storage devices reader.

The research objective is the design of portative electrocardiograph for telemedicine that has a convenient interface for device control, is equipped with means of communication with cardiac care centers, has universal ports for information output to external drives and connection of additional devices, is as ergonomic as possible, operates in compliance with safety, reliability and energy efficiency requirements.

The statement of basic materials. The designed PEC is focused on the potential use in Ukraine and bordering countries of Eastern Europe. The ambient temperature is the main external factor that has a destabilizing effect on the operation of the device. Taking into account the specifics of work of family doctors and emergency medical care teams, it is assumed that the device will be used indoors, while the operating temperature can vary in the range from + 1 to + 40° C.

The main functional units of the designed PEC are:

– PIC24FJ256DA106 microcontroller;
– HJ070NA-13A color liquid crystal display with the touch screen;
– SMD-KAAG15008C micro dynamic speaker;
– PJ-002A-SMT tonometer port;
– SIM900D mobile communication module;
– 220V power supply unit;
– JiNWo NiMh 9.6V 4000mAh rechargeable battery.

In this paper the electronic block diagram is synthesized (fig. 1). The range of heart bioelectric potentials recorded by the device is 0.03 to 5.0 mV. Signals from the ECG electrodes are sent to the lead selector switch. The selection of the current lead is done by the microcontroller through the user menu on the display of the cardiograph. Then the signal enters the circuitry of the instrumentation amplifier, which amplifies the voltage difference that is present in the electrodes. After the signal passes the low-pass filter with a double T-bridge and the cut-off frequency of 10 Hz, it enters the inverter that creates the waveforms of standard form on the display. The inverter is driven by the microcontroller. The tuning resistor located in the signal regulator block sets the signal strength. The diffuser loudspeaker sounds an indication of the cardiography completion and of other performed processes.

The USB with an antenna module is connected to the microcontroller to download reference cardiograms and save the testing results to a portable storage. According to the technical requirements of the GSM module, this structural unit includes the separate power supply circuitry and the SIM card slot.

The touch panel display driven by the microcontroller is intended to create user menu via software and optimize PEC button interface.

The proposed cardiograph model contains the port for connecting an electronic tonometer to supplement the electrocardiogram with blood pressure readouts that is an integral part of ECG diagnostics.

Operation of the device in the autonomous mode is provided by a built-in battery, which is charging through the power supply unit from a standard 220 V power line.

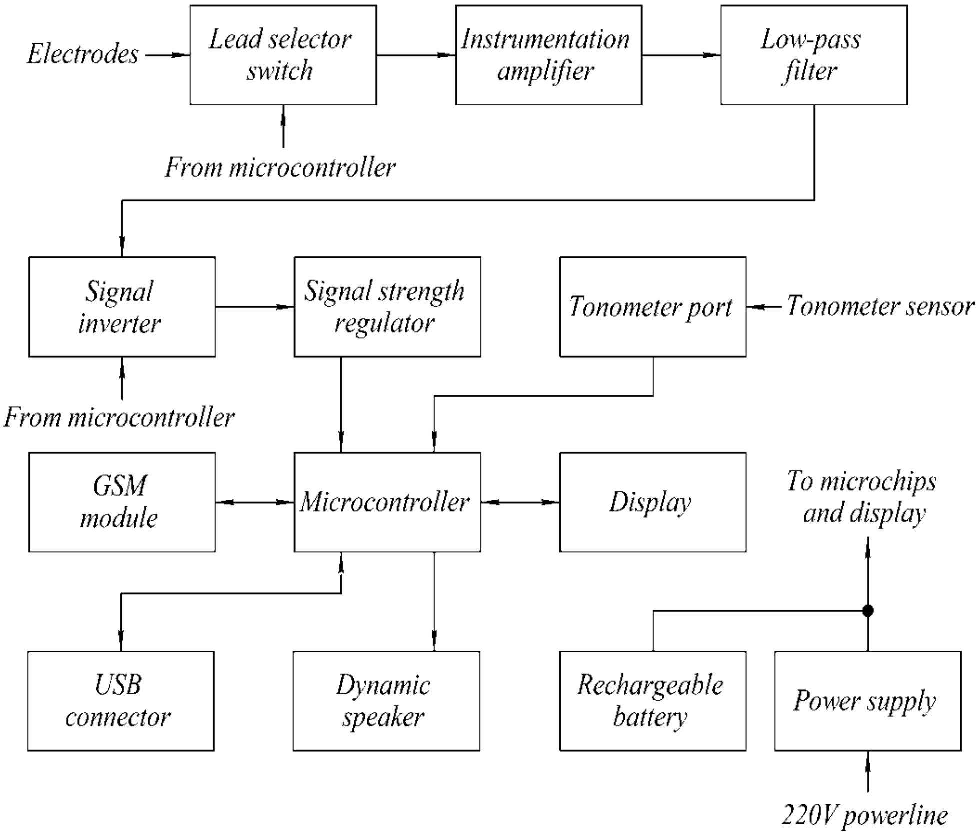


Fig. 1. The portable electrocardiograph: block diagram

Verification of the signal conversion efficiency by the designed electronic unit was produced by the computer simulation of the circuitry section. The circuitry of the instrumentation amplifier, which is the input circuitry of the schematic diagram of designed PEC, is selected as the object of the simulation. The reliability of signal travel through this section is of utmost importance during the ECG-testing [16]. The ranges of cardiometry data deviations at various values of the ambient temperature are the output parameters of simulation [17].

The given tasks were solved in the OrCad 9.2 system. The model of the cascade of PEC instrumentation amplifier was constructed in electronic circuit simulator Pspice Schematics and the relations of its electrical characteristics at specified operating temperatures were determined.

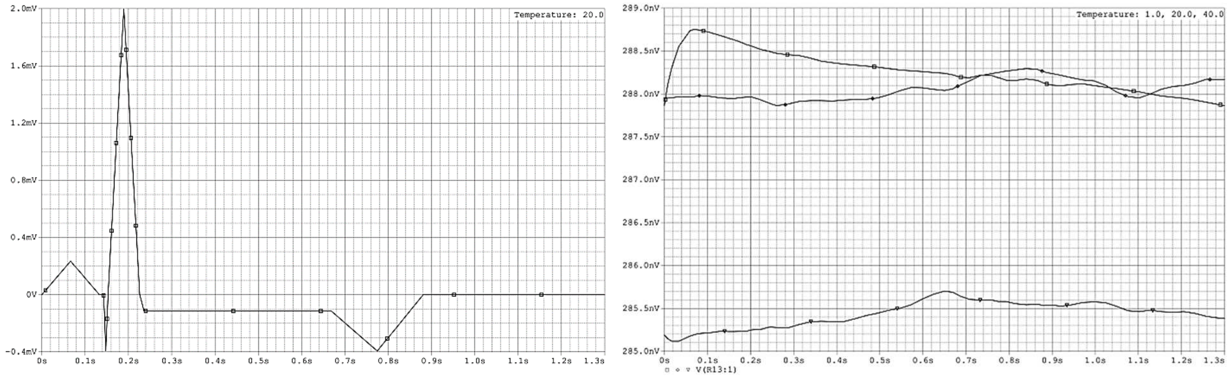
The temperature values for the simulation are selected by:

– extreme values of operating temperature +1 and + 40° C in the macroclimatic modification of the device for a moderate and cold climate (according to GOST 15150) when it is operated by emergency medical care teams;

– the mean value of operating temperature is + 20° C, which corresponds to the standard temperature in the family doctor’s office (according to DSTU B EN 15251:2011).

The simulation condition is introduced, that assumes the circuitry operates in the mode of the 1st lead biopotential aquisition according to Einthoven. The simulation was carried out for the condition of the inverted test signal, which simulates the cardiac waveform. In PSpice software the test signal is simulated by the piecewise-linear voltage source VPWL (fig. 2*a*).

The simulated section of the circuitry has a property of amplifying the difference of the input signals. Thus, ideally, the output should be represented by a straight line $f(t) = 0$ when applying the same signals to the inputs. The actual result of the simulation of the operation of the cascade of the PEC instrumentation amplifier for three given values of operating temperatures are the curves of internal interference (fig. 2*b*).

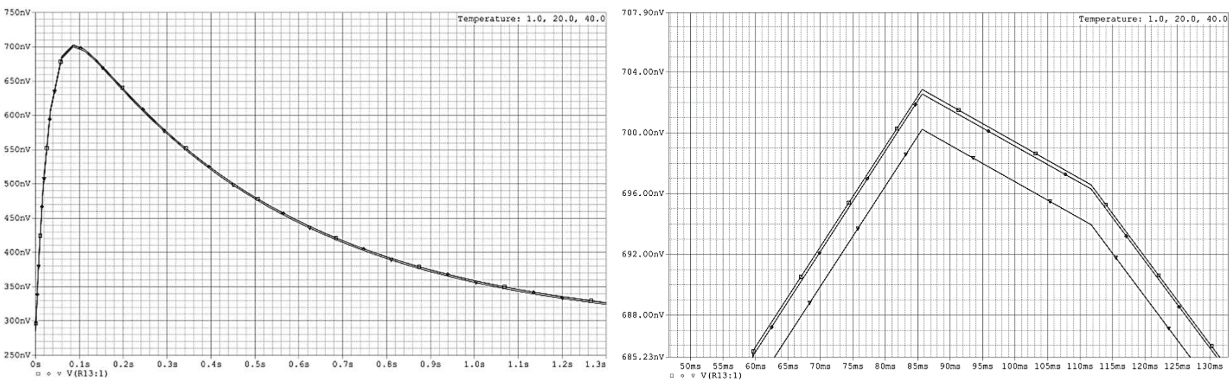


a *b*

Fig. 2. The simulation of the signal travel through the instrumentation amplifier circuitry:
a – test signal simulating cardiac waveform; b – the range of deviation of the test signal

According to simulation results of the signal travel through the circuitry of the instrumentation amplifier, the internal noise level of the circuitry reproduced by the software does not exceed 300 nV. Obtained values of the internal noise level are significantly less than margin of error of ± 25 μV. The nature of the curves shows that the affect of noise changes insignificantly with an increasing temperature in the studied range.

According to the simulation results, stabilization of the system occurs within 3 s (fig. 3*a*). In this case the primary voltage surge in the circuitry reaches values of 700 nV. (fig. 3*b*). The obtained voltage value does not endanger the equipment, since the electronic components can withstand surges of up to several volts, while the stabilization time is comparable to the period of the cardiac waveform. Thus, by means of complex computer simulation, the efficiency of signal conversion by a circuitry of the instrumentation amplifier in the given range of operating temperatures is confirmed.



a *b*

Fig. 3. The transient simulation in PEC circutry:
a – transient response in 5 s. range; b – the scaled peak of the transient waveform with visible temperature fluctuations

For the designed PEC the folding form-factor is proposed. The case and the cover connected by hinges are the major structural elements of the device (fig. 4).

The cover serves as the frame for the color LCD touch screen. The printed circuit board with the processor module and the GSM module are placed behind the display. There is also the low-profile micro speaker. The USB connector is located on the side of the cover.

The case contains the tonometer port, battery and power supply. The case design houses a removable insert with pockets for placing the ECG electrodes kit in transport position, while simultaneously hides the implementation of the wired connections of the tonometer port, battery and power supply. To prevent an accidental loss of the ECG electrodes from insertion pockets and to prevent damage to other parts of the device, the Velcro tape reliably fixing their position is featured. The electrical safety of the battery and power supply elements meets the requirements of IEC 60601-1: 2005.

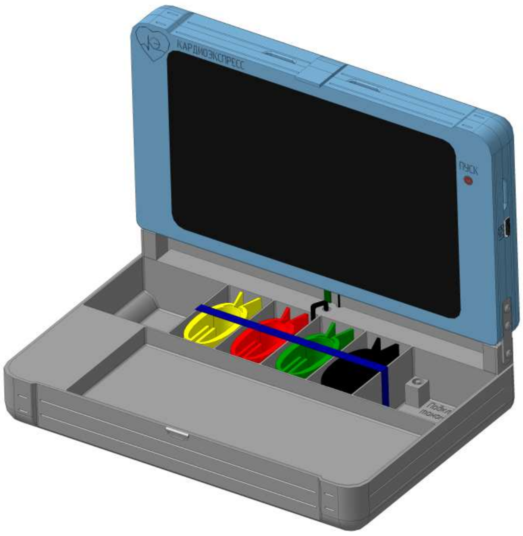


Fig. 4. The portable electrocardiograph: 3D-model

The designed PEC model is proposed to be equipped with four standard ECG electrodes of clamp design. Sensors of this type are firmly fixed to the body and they provide high accuracy acquisition of the standard 3-lead ECG. For practical purposes color and letter marking of the electrodes meets the requirements of ANSI/AAMI EC13, EC53 and IEC 60601-2-47. ECG electrode conductors are assembled into a single shielded ECG cable, permanently connected to the adapter located in the case. This omits the operation of connecting the cable, thus reducing the level of electromagnetic noise and the time spent to get the device into the operating position.

The cover and the case are connected with hinges. The proposed design solution minimizes the volume of PEC during transportation and allows an ergonomic adjustment of the device for the user's needs. The maximum angle of the device opening is 135°. During transportation, the PEC is locked with a latch. The cable of the ECG electrodes is connected to the processor module located in the cover, by means of an adapter with a flexible loop.

Conclusions. In the arrangement of the functional elements of the personal electrocardiograph, technical solutions are proposed that are not applicable in electrocardiographs produced by domestic manufacturers. The key design features of the developed PEC model:

– the folding form-factor provides the most ergonomic placement of structural elements, as well as protects the LCD touch screen from damage;

– the built-in GSM module ensures ECG data transfer to cardiologic care centers;

– the color LCD touch screen creates an optimal user interface;

– the electronic tonometer port expands the possibilities of express-diagnostics;

– the absence of a thermal printing unit reduces energy consumption and weight of the device, thus increasing its mobility.

The structural implementation of the electrical circuit is characterized by an innovative approach to the placement of the device functional elements. The implementation of the device in folding form-factor improves ergonomic characteristics of the device. The biopotential measurement in three leads fully suits the requirements of primary preclinical diagnostics in non-ambulatory settings. Replacing the removable cable with an integrated one reduces the level of induced internal noise and also reduces the time taken to bring the device to operating condition. The built-in GSM module provides a reliable communication channel with specialized medical institutions. The use of a 7-inch color touch-sensitive liquid crystal display coupled with a virtual user interface expands the capabilities of the device.

Implementation of the proposed PEC model will make it possible to provide emergency medical care services and family medicine services with equipment for express-ECG, which in turn will reduce the number of CVD deaths in Ukraine, as well as facilitate monitoring of patients who undergo respective outpatient treatment.

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ПОРТАТИВНИЙ ЕЛЕКТРОКАРДІОГРАФ ІЗ GSM МОДУЛЕМ ДЛЯ ТЕЛЕМЕДИЦИНИ

Актуальність теми дослідження. *Необхідність впровадження в практику принципів телемедицини обумовлює потребу створення діагностичної медичної апаратури, що реалізує можливість передачі даних і дистанційного консультування з профільними фахівцями при наданні екстреної медичної допомоги та в сімейній медицині.*

Постановка проблеми. *Електрокардіографічне обладнання як правило представляє собою комплекс, що складається з електронного блоку в форм-факторі моноблок, комплекту знімних ЕКГ електродів і ЕКГ кабелю. Кардіодані зберігаються друкуванням на термопапері або передачею на персональний комп'ютер. Таким чином, проведення ЕКГ вимагає витрат часу на приведення приладу в робочий стан, додаткового обладнання у вигляді персонального комп'ютера і високої кваліфікації лікаря для інтерпретації результатів. Проєктування портативної електрокардіографічної техніки з вбудованими засобами зв'язку є актуальним завданням біомедичної інженерії.*

Аналіз останніх досліджень і публікацій. *Сучасні дослідження в області проєктування портативного обладнання для первинної діагностики серцево-судинних захворювань присвячені вибору оптимальних конструктивних параметрів і підвищенню завадостійкості медичної техніки.*

Виділення недосліджених частин загальної проблеми. *Стаття присвячена розробці конструкції портативного електрокардіографа з вбудованим GSM модулем для експлуатації в системах телемедицини.*

Постановка завдання. *Актуальним завданням є проєктування портативного електрокардіографа для експрес-діагностики серцево-судинних захворювань, що має зручний інтерфейс для управління приладом, забезпеченого засобами зв'язку з центрами кардіологічної допомоги, із універсальними портами для виведення інформації на зовнішні накопичувачі й підключення додаткових пристроїв, максимально ергономічного, такого, що задовольняє вимогам безпеки, надійності та енергоефективності.*

Виклад основного матеріалу. *Сформульовано основні вимоги до портативної електрокардіографічної техніки. Обрані основні функціональні одиниці приладу і синтезована його схема електрична структурна. Комп'ютерне моделювання процесів і параметрів функціонування каскаду інструментального підсилювача приладу при заданих значеннях робочих температур підтвердило обґрунтованість запропонованих схемотехнічних рішень. Розроблена конструктивна реалізація електричної схеми. Визначено конструктивні характеристики приладу, які найбільш повно відповідають вимогам телемедицини.*

Висновки. *Характерними особливостями спроєктованого портативного електрокардіографа є виконання в розкладному форм-факторі, наявність GSM модуля і постійне підключення ЕКГ електродів через інтегрований ЕКГ кабель. Виконання в розкладному форм-факторі оптимізує ергономічні характеристики приладу. Заміна знімного кабелю інтегрованим знижує рівень наведених внутрішніх шумів, а також скорочує час приведення приладу в робочий стан. Наявність вбудованого GSM модуля забезпечує доступний зв'язок зі спеціалізованими медичними установами, скорочує тривалість діагностики і підвищує ефективність медичної допомоги в неамбулаторних умовах.*

Ключові слова: *телемедицина, електрокардіографія, портативний електрокардіограф, GSM модуль, передача даних, розкладний форм-фактор, інтегрований ЕКГ кабель.*

Рис. 4. Бібл. 17.

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