Mobile Recorder for Electrical Activity of the Heart

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Abstract— The presented study is dedicated to a mobile recorder designed to keep log of electric activity of the heart and incorporated into the expert system developed to detect fatigue status of a patient. The newly designed recorder has a modular structure and its enclosure houses two double-sided printed circuit boards (PCBs), separately for the analog part (BtECG) and the digital one (BtECGradio). The analog module is responsible for measurement of electric signals received from the patients' body with their further amplification, filtration and conversion to digital form. In addition, in comprises a source of stabilized voltages for both analog and digital circuits. The digital module receives binary data, extracts its useful portion, carries out formatting of the data to form of frames required for RF communication according to the Bluetooth standard and enables wireless communication with a collaborating unit. The analog subassembly is meant to record electric potentials within the range from 0.2 to 2 mV and owing to the high level of the CMRR factor it substantially eliminates the common-mode signals. Furthermore, it enables two-stage amplification, filtration of high-frequency interferences, high-pass filtration and active, five-staged low-pass filtration. The digital module of the recorder enables RF data transmission according to the Bluetooth 4.0 standard, communication with a host unit with use of the UART and SPI interfaces (reading of RF packages from the CPU module) as well as communication with a host unit with use of the Full Speed USB 2.0 (BGAPI) protocol. Its power consumption is ultra low and the communication sessions is controlled by a microprocessor of the 8051 architecture. The digital module also enables the user to embed own application and to debug them via the CC Debugger Connector link. The base chip for development of the digital module is the BLE112 Bluetooth Smart module from Bluegiga.

1. INTRODUCTION

1.1. Parameters of ECG Mobile Recorders

In the area of recording and analysis of ECG signal there are available the mobile devices with the parameters similar to the ambulatory solutions. Regardless of the necessary miniaturisation and the battery power supply they are produced in the version of one, three, seven as well as classical twelve leads.

The structures of portable [11] type can be divided into the classes: eventholters and continuous recording devices (several hours). They record the electrocardiogram onto the integrated carrier (e.g., Flash memory [11]), which is then reproduced and analysed by a cardiologist. More advanced solutions have the embedded algorithms for ECG signal processing in the real time [12]. They have the function of fast communication with the portable devices (notebooks, palmtops, smartphones), they take advantage of the computing power from the cooperating microcomputers and GPRS modules for the packet data exchange (in GSM networks) as well as they demonstrate the analysis results in the embedded displays.

From the technical point of view, the mobile devices for ECG signal recording and analysing can be described by means of the group of coherent parameters. They result directly from the structure, and indirectly from the apparatus configuration. The set of parameters which are the most essential for a design engineer as well as for a user include: number of leads, types of leads (Einthoven's: I, II, III; Goldberger's: aVR, aVL, aVF, Wilson's: V1, V2, V3, V4, V5, V6; modified [4] MCL1; 12-lead Mason-Likar variant), input impedance (10–100 MΩ), input dynamic range [1], CMRR [3, 8] (1), amplification [1], transfer bandwidth [2], converter resolution, sampling frequency, measured heart rate zone (bpm), quantum processing, transmission/interface, method for device power supply, battery capacity, data memory, certificate/approval.

$$CMRR = 20 \cdot \log\left(\frac{A_D \cdot V_{CM}}{V_{OUT}}\right) \tag{1}$$

where: A_D — differential gain, V_{CM} — common voltage applied to both differential inputs, V_{OUT} — output voltage appearing as response to the application of common voltage V_{CM}.

Additionally, it is required from the portable recorders to meet the electromagnetic compatibility prerequisite. The implementations and test results of special hood shielding for electrical equipment are well known [13–20].

Moreover, modern portable bio expert system bases on built-in advanced algorithms e.g. for drivers conditions estimation [21, 22].

1.2. Mobile System Criteria

While defining the concept of mobile system or electrocardiographic device you need specify the set of the most important features which should characterise such system. According to its purpose, we can describe it as: personal and non-ambulatory packet enabling long-term recording of ECG signal, recording on request or signal automatic analysis in the real time.

The minimum technical requirements are defined with the group of parameters such as: overall dimensions — the accepted size should not be bigger than the size of typical mobile phone, weight of ca. 100 g, L/W/H: 110/50/15 mm; number of leads — 1–12 depending on the diagnostic needs; types of leads — allowing free movement and enabling self-assembling; input impedance — 10 MΩ and more; input dynamic range — from a few to several millivolt; CMRR — 60–120 dB; transfer bandwidth — 0.05–100 Hz; converter resolution — 10 bites and more, at present reaching 24 bits; sampling frequency — 200 Hz and more, measured heart rate zone — from several bpm at the lower limit up to two hundred and more at the upper limit; transmission/interface — at least one from the cable groups: USB, RS232, PSTN and one wireless: Bluetooth [10], IrDA, GSM/GPRS, WiFi; power supply from battery or rechargeable battery with the possibility for replacement or cell recharging; safe supply voltage — a few volts; battery capacity — they allow continuous operation for the time of carrying out at least one measurement/diagnostic cycle; data memory (non-volatile memory, e.g., flash memory card) — they allow continuous recording of data or analysis results during one measurement/diagnostic cycle, certificate/approval — the device should meet the requirements of the standards PN-EN 60601 [9] (according to 93/42/EEC) and be admitted to trading on domestic/European market [7].

There is no sharp line in the classification parameters of ECG mobile devices. They result largely from the features of the newest range of products, possibilities of modern technologies and customers expectations.

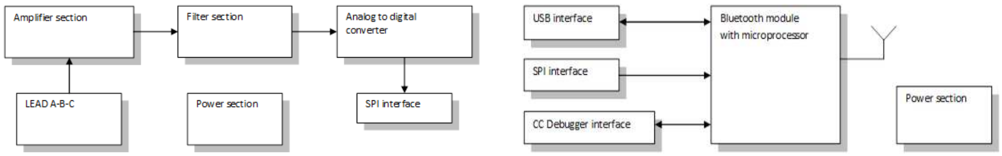
1.3. Design Trends

The development of mobile devices for recording and analysing of ECG signal is stimulated with the need for miniaturisation, capacity increase, uncomplicated and interactive operation as well as the possibility for fast data exchange.

As far as the overall dimensions are concerned the standard are the devices not bigger than typical mobile phone or smartphone (less than 120/70/20 mm and not heavier than 100–150 g). The direction of capacity increase is first of all: computing power sufficient for parallel recording and analysing signals from many (even twelve) leads, algorithms realising the detection and classification of disturbances and incidents, based on the wide range of designated indicators (HR, HRV, HRT, QRS complexes, ST segments, QT, T-waves, VCG, TVCG), support for memory cards with great capacity (2 GB and more) or suitable size of the embedded memory, time of operation while using one set of the supply source from a few days up to a week.

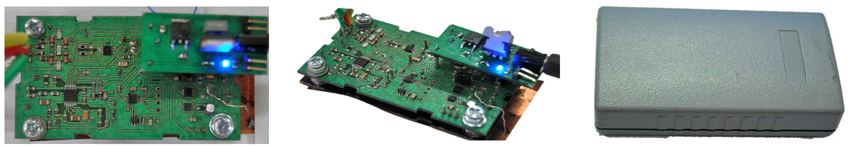
While offering the solutions to individual customers, the producers reduce the number of leads. This way they shorten time needed for taking out the device from the box up to obtaining the first results of analysis or records of crucial segments of ECG signal. The ambulatory set of twelve skin electrodes is replaced with three basic ones or completely reduced thank to the application of the electrodes located on the device/attachment housing.

The communication with patient is provided by character or graphic displays presenting the analysis results, signal tracing (from one or a few channels simultaneously), or the values of indicators. The operation is via some key buttons on the device housing, and the advanced configuration by means of a computer and dedicated application. It is essential from the data transmission/exchange point of view to provide fast and compatible interface. The embedded USB connection (or fallen out of use RS232) is a standard. For remote observation (e.g., patient in the movement) or monitoring at a distance (under organised system of medical diagnostics/assistance) WiFi, Bluetooth and GSM/GPRS modules are used.



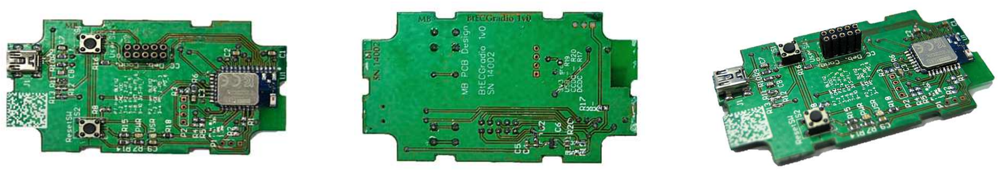
(a) (b)

Figure 1: Mobile recorder block diagrams. (a) Block diagram of BtECG module. (b) Block diagram of BtECGradio module.



(a) (b) (c)

Figure 2: (a) Top and (b) side view of BtECG module with (c) device's cover.



(a) (b) (c)

Figure 3: (a) Top, (b) bottom and (c) side view of BtECGradio module device.

2. MOBILE RECORDER FOR HEART'S ACTIVITY

The designed under research work the mobile recorder for the heart's electrical activity is of modular construction. In one housing there are two bilateral printed circuits (PCB) separately for analogue part — BtECG and digital one — BtECGradio.

The analogue module (Figures 1(a) and 2) is responsible for taking/measuring the electrical signal from patient's body, its amplification, filtration and conversion to the digital form. Additionally, it provides the source of stabilised voltage (voltages) both for analogue and digital systems.

The digital module (Figures 1(b) and 3) receives binary data, separates the useful part, formats the data to the form of frames required under the radio communication of Bluetooth 4.0 standard and ensures the wireless connection with the cooperating device.

2.1. BtECG — The Analogue Module

The recorder analogue component provides: high CMRR coefficient (80–100 dB); rail-to-rail output; JFET inputs with large capacity (of 5 pF), small polarisation current and with no noise current (proper for high impedance of the source); recording of potentials from the range of 0.2–2 mV; rejection of common-mode signals (interference on the line or high frequency EMI); amplification of the useful signal ($G = 14$) as well as wide range of output dynamics enabling to obtain high amplification at the next stage; filtration of high frequency interference (natural RC filter); high pass filtration ($f_g = 0.033\,\mathrm{Hz}$) — elimination of DC offset formed between the electrodes; 50 times amplification ($G = 50$), forming the signal at the level 0–5 V; active five-stage low-pass filtration ($f_g = 157\,\mathrm{Hz}$); analogue-digital conversion; stabilised supply voltage: 3.3 V (for digital part — Bluetooth module), $+/-5\,\mathrm{V}$ (for differential amplifier), 5 V (for analogue-digital converter) and 2.5 V (for operational amplifier).

The integrated circuits and binary elements used in the study carry out the functions specified above, respectively: AD8220 — Analog Devices (a, b, c, d, e, f, g), RC (g, h), AD8618 (i, j), AD7685 Analog Devices (k), OP2177 (e), ADR4350 (k), TPS61027 and TPS63031 — Texas Instruments (l).

2.2. BtECGradio — The Digital Module

The recorder digital module provides: radio data transmission in Bluetooth 4.0 standard; communication with the analogue module BtECG — interface USART 0 SPI; communication with host (RF packets reading from CPU module) — interface USART 1 SPI; communication with host (BGAPI) — interface Full speed USB 2.0; ultra-low current consumption (transmission: 27 mA, rest: 0.4 μA); communication control based on the architecture processor 8051; establishment of own applications and debugging on CC Debugger Connector; light signalling of power supply (PWR LED) and user's signalling (USR LED); reset switch (Reset SW) and user's switch (User SW); configurable power supply modes 3.3 V from: BtECG, CC Debugger Connector or USB (stabilised from 5 V).

The basic element of the digital module is BLE112 system produced by Blue Giga. It carries out all above-mentioned functions with the power supply tolerance from 2 to 3.6 V.

3. CONCLUSION

The requirements for electronic medical devices include not only technical parameters but also reliability and user safety. They are defined by restrictive criteria: production of devices out of the highest quality components, design and assembly according to the international standards as well as application of the latest technical concept [6].

The main functionality of the heart activity monitoring device is based on the differential amplifier. It is the first rate of amplification and separation of the useful signal part from the interference (of summation signal). Despite its apparent simple construction, its production process is very demanding and obtaining of the module (in the form of integrated circuits — IC) with acceptable parameters is very expensive.

The presented design and practical realisation of the recorder meet the requirements of the mobile device for medical diagnostics. The battery power supply protects patient from accidental electrocution, the wireless interface guarantees safety communication in the range of at least 10 m, Bluetooth applied under fourth version minimises the current consumption, the selected ICs parameters are high for the mobile version, and the modular construction enables fast diagnosis and defect repair.

The practical engineering conclusions resulting from the design experience for the above-presented device are as follows:

- oscilloscope measuring probes with too low resistance and large volume are a burden of the tested system,
- tested device requires separate connection in relation to the return electrode of the earthing potential (shield) [7, 8],
- in order to avoid the negative potential tides of the oscilloscope to zero potential of the tested device, you should use the measurement differential method (negative potential of two probes are independently shorted), lack of such solution results in the saturation of amplifiers (the difference of potentials at the input of operational amplifier must not exceed 50 mV, at the differential amplifier output capacity $+/-5\,\mathrm{V}$).

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