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Development of Hardware and Software for Generating Test ECG Signals

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Existing techniques for the synthesis of ECG signals were reviewed. The optimum technique for an ECG signal generator was identified. Software for synthesizing calibration signals with the option of cardiac waveform adjustment was developed. A circuit for matching the generated signal to the electrocardiograph machine was proposed.

Introduction

The operation of contemporary electrocardiograph machines cannot be verified using standard (for example, harmonic) signals. This produces the need to develop specialized devices generating specific test signals for checking functionality of electrocardiograph machines. Such devices can be used for checking the operability of equipment in medical settings and for the purpose of teaching students in medical schools.

The aim of this work was to develop a hardware and software system for generating test ECG signals. The following tasks were addressed:

– review of existing methods for generating cardiac waveforms;

– development of hardware;

– development of software.

Materials and Methods

The functional characteristics of test ECG signal generators should meet the requirements of the State Standard GOST R IEC 60601-2-51-2011 for test techniques and characteristics of test signals. All test signals should meet the following requirements:

– signals should contain a single ECG-like cycle repeated an infinite number of times;

– signals should have a sampling frequency of 1 kHz or 500 Hz with an amplitude resolution of 1-5 μV;

– all waveforms should be ECG-like.

Cardiac waveform synthesis algorithms. There are two approaches to testing electrocardiograph machines. The first uses a database of real ECG traces, such as Physionet [2]. This method is not always suitable, as real signals are mostly noisy and require preprocessing. The second approach involves generating synthetic waveforms using specific mathematical models. The generated waveforms can reproduce ideal ECG traces or cardiac waveforms with any desired abnormality.

There are many mathematical models for synthesizing various artificial cardiac waveforms. Creating a signal in real time economizes on memory space and "encodes" data for subsequent reproduction by an algorithm. It should be noted that there has been extensive research in the field of cardiac waveform synthesis. Its findings are actively used not only for generating test signals, but also in studies of ECG signal (ECS) processing.

Dynamic models are now quite well known and widely used in practice. Such models require large numbers of computations and setting of numerous parameters. They provide precise specification of cardiac waveform, as, for example, the dynamic model based on three linked differential equations [3]. In addition, dynamic models allow heart rate (HR) to be controlled during the signal generation process [4, 5]. Models representing ECS as a nonlinear dynamic system are also used [6]. These models are quite complex and allow reference cardiac signals to be generated.

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Other methods for modeling ECS use polynomials and rational functions [7, 8] or Fourier series [9, 10]. These models contain mathematical descriptions of each separate wave of the cardiac waveform, allowing the shapes of each individual part of the ECS to be defined. Different models allow different "realistic" signal features to be added using different computational capacities. Thus, faster models based on linear and quadratic interpolations [7, 11] are unable to recreate some pathologies in which certain elements are approximated by Gaussian functions [7, 12].

It should be noted that the latter methods do not provide convenient alteration of HR in synthesized cardiac signals. The problem is that changes in frequency have different effects on different waves. In the case of dynamic models, changes in HR require modification of 1-2 parameters, while models specified using polynomials require more parameters to be modified (sometimes more than 16) [4, 7].

Our review showed that the requirements for a test ECS generator are specified on the basis of the requirements for test signal shape, as indicated in [1]. Consideration of methods for ECS generation led to the conclusion that calibration ECG signals are best generated using the simplest functions (linear or quadratic), as these quite easily generate the required waveforms using relatively small computational resources.

Existing cardiac signal simulators were also considered. The main problem here is that the Russian market lacks devices of this type made in Russia and providing the same functionality as those available from foreign manufacturers or having anything novel to offer. However, there are several Russian ECS simulators on the market, e.g., the Neurotest-7B [13]. Considering this device specifically, it has a total of four generation modes suitable for testing electrocardiograph machines, which is very few as compared with any non-Russian analog (which can have more than 30 modes). The Russian company OOO Altonika holds patents for a device with impressive functionality for simulating human biosignals for testing electrocardiograph machines [14]. Unfortunately, this device is currently unavailable.

During consideration of methods for synthesizing cardiac signals, it was noted that methods using the simplest functions were excellent for rapid generation of test signals for electrocardiograph machines. In this work, we use the method described in [7]. It uses a Gaussian monopulse to generate the Q and R waves, while simple linear and trigonometric functions are used to generate the other parts of the waveform.

The simplest part is the TP interval. It is an isoline:

$$B(k) = 0;\ 0 \le k \le K_B.$$

The PR segment starts at the end of the P wave and ends at the beginning of the QRS complex. This is usually an isoline:

$$P_Q(k) = 0;\ 0 \le k \le K_{PQ}.$$

Displacement of the ST segment is an important marker of cardiac anomalies. This segment can be represented as a straight slope relative to the isoline:

$$S_T(k) = -S(K_S - K_{CS})k/s_m + S(K_S - K_{CS});\ 0 \le k \le K_{ST}.$$

The P and T waves can be approximated by a harmonic function. Symmetry is important for the T wave, so modeling of the transition from the T wave to the TP interval uses function I:

$$P(k) = -(A_P/2)\cos[(2\pi k + 15)/K_P] + (A_P/2);\ 0 \le k \le K_P;$$

$$T(k) = -A_T\cos[(1.48\pi k + 15)/K_T] + S_T(K_{ST}) + A_T;\ 0 \le k \le K_T;$$

$$I(k) = T(K_T)/(k + 10)s_I;\ 0 \le k \le K_I.$$

The Q and S waves are modeled using a Gaussian monopulse, while for the R wave a sine function is used:

$$Q(k) = -A_Q(0.1 - 0.1K_Q + 0.1)(19.78\pi/K_Q) \times \exp\{-2[6\pi/K_Q(0.1 - 0.1K_Q + 0.1)]^2\};\ 0 \le k \le K_Q;$$

$$R(k) = A_R\sin(\pi k/K_R);\ 0 \le k \le K_R;$$

$$S(k) = -A_S(1.978\pi k/K_S)\exp[-2(6\pi\cdot 0.1k/K_Q)^2];\ 0 \le k \le K_S - K_{CS}.$$

A total of 17 coefficients have to be specified to describe the ECS, among which coefficients K designate the durations of intervals and coefficients A specify wave amplitudes. The authors of [7] recommended applying a Savitzky–Golay smoothing filter with a window size of 7 to smooth the sharp boundaries between segments. The filter formula is as follows:

$$H_f(k) = [-2H(k-3) + 3H(k-2) + 6H(k-1) + 7H(k) + 6H(k+1) + 3H(k+2) - 2H(k+3)]/21,$$

where H is the ECS synthesized and H_f is the signal after filtering.

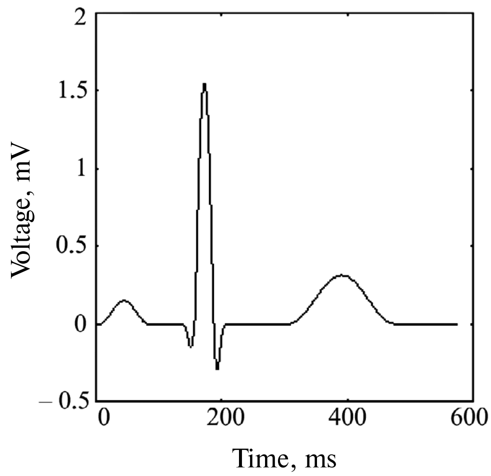

Fig. 1. Synthesized ECS.

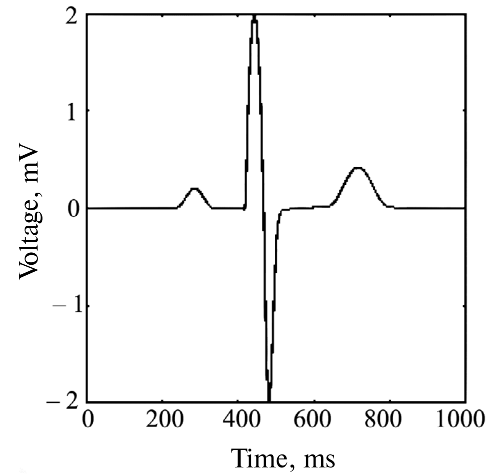

Fig. 2. Synthesized calibration ECS CAL20000.

This method was run in MATLAB to test its correct functioning. We used this language because it allows fast operations on vectors and because data can easily be presented as plots. Application of the method yielded the signal shown in Fig. 1.

A total of 16 calibration signals were then synthesized as specified by the State Standard [1]. Configurations of the QRS complex (i.e., which waves were needed) were indicated for calibration signals, along with the amplitude of the ST segment, HR, and QRS amplitude. As calibration ECS had to be similar in shape to the real ECG, these were synthesized with due regard for the criteria of normal ECS given in [15, 16].

Normal ECS have the following properties: P wave duration is up to 0.1 s; PQ interval duration, 0.12-0.2 s; QRS complex duration, 0.06-0.1 s; ST segment duration, 0.25-0.34 s; T wave duration, 0.1-0.25 s; QT interval duration, 0.35-0.44 s.

As some calibration signals require the ST segment to be offset by 300 mV, we add two parameters K_{CR} and K_{CT} specifying the number of computation points for the R and T waves, to make the transition smoother:

$$R(k) = A_R \sin(\pi k/K_R);\ 0 \le k \le K_{CR};$$

$$T(k) = -A_T \cos[(1.48\pi k + 15)/K_T] + S_T(K_{ST}) + A_T;\\ 0 \le k \le K_{CT}.$$

An additional condition is introduced to provide more flexible tuning of the ST segment, this allowing the initial level of the ST segment to be set. If the S wave is absent (i.e., if $K_S = 0$), then S_T is computed as:

$$S_T(k) = A_S k/s_m + A_S;\ 0 \le k \le K_{ST}.$$

Thus, coefficients for 16 calibration signals were computed for this method (with some modifications). Figure 2 shows one such signal as an example.

Discussion

This study generated ECS using trigonometric functions and Gaussian monopulses. This method was initially run in MATLAB, after which a number of modifications were introduced to allow the method to synthesize the 16 calibration signals specified by the State Standard GOST R IEC 60601-2-51-2011. This yielded coefficients allowing synthesis of calibration signals using a total of 19 4-byte coefficients.

A virtual instrument was then developed in LabVIEW allowing the user to generate calibration cardiac signals using an NI-9381 input–output module, as well as cardiac signals with arbitrary waveforms specified at the user's discretion. This virtual instrument operates using the method investigated in MATLAB and allows signals for each lead to be followed.

Summary and Conclusions

The aim of the present work was to develop and test hardware and software for generating test signals for electrocardiograph machines. Literature was reviewed to identify the requirements for such devices. Possible approaches to cardiac signal generation were studied and the optimum approach was selected.

The requirements formulated were used to determine the block structure of the device. An implementation option was selected and computed for each unit of the device.

The hardware part of the device was developed, this being able to match the signal generated by the input–output module to the electrocardiograph machine. Software for generating calibration signals for electrocardiograph machines and ECS of any desired configuration was also developed. The ECS synthesis method used here can be employed to generate test signals using a microcontroller, as the method allows signals of more than 1000 points in length to be specified using 76 bytes, which significantly economizes on memory for storing large numbers of signals.

REFERENCES

1. GOST R IEC 60601-2-51-2011: Medical Electrical Equipment. Part 2-51. Particular Requirements for Safety, Including Essential Performance, of Recording and Analysing Single-Channel and Multichannel Electrocardiograph Machines[in Russian].
2. Physionet. The Research Resource for Complex Physiologic Signals; https://www.physionet.org/ (accessed March 15, 2020).
3. McSharry, P. E., Clifford, G., Tarassenko, L., and Smith, L. A., "A dynamical model for generating synthetic electrocardiogram signals," IEEE Trans. Biomed. Eng., **50**, 289-294 (2003).
4. Kazakov, D. V., "A quasiperiodic two-component dynamic model for synthesis of cardiac signals using time series and the fourth-order Runge–Kutta method," Komp. Issled. Model., **4**, 143-154 (2012).
5. Yakushenko, E. S., "A program for modeling the ECG in LabVIEW," Biotekhnosfera, No. 3, 64-67 (2012).
6. Pipin, V. V., Ragul'skaya, M. V., and Chibisov, S. M., "Dynamic models and ECG reconstruction in heliogeophysical fluctuations," Vestnik RUDN Ser. Med., No. 2, 25-30 (2010).
7. Dolinsky, P., Andras, I., Michaeli, L., and Grimaldi, D., "Model for generating simple synthetic ECG signals," Acta Electrotech. Informat., **18**, 3-8 (2018).
8. Sayadi, O., Shamsollahi, M. B., and Clifford, G. D., "Synthetic ECG generation and Bayesian filtering using a Gaussian wave-based dynamical model," Physiol. Meas., **31**, 1309-1329 (2010).
9. Shishkin, M. A., Butova, O. A., Fetyukhina, L. V., Akhiezer, E. B., and Dunaevskaya, O. I., "A MATLAB model of an ECG signal generator based on frequency transformation," Visn. NTU KhPI Ser. Novi Rishen. Suchast. Tekhnol., No. 26, 140-147 (2018).
10. Kubicek, J., Penhaker, M., and Kahankova, R., "Design of a synthetic ECG signal based on the Fourier series," in: Int. Conf. on Advances in Computing, Communications and Informatics, New Delhi, India (2014), pp. 1881-1885.
11. Kovacs, P., "ECG signal generator based on geometrical features," Ann. Univ. Scient. Budapest. Sect. Comput., No. 37, 247-260 (2012).
12. Abramov, M. V., "Use of exponents for approximation of cardiological series based on the ECG," Vestn. Kibernet., No. 9, 85-91 (2010).
13. The Neurotest 7 Multifunctional Special Waveform Signal Generator: Technical Specifications Booklet [in Russian]; https://mks.ru/netcat_files/209_51.pdf (accessed March 15, 2020).
14. Briko, A. N., Davydov, D. V., Egorov, A. I., and Filimonov, P. V., A Device Simulating Human Biosignals for Testing Electrocardiograph Machines [in Russian], RF Patent No. 184385 (2018).
15. Orlov, V. N., Handbook of Electrocardiography [in Russian], MIA, Moscow (2007).
16. Hampton, J., The ECG Made Easy [Russian translation], Meditsinskaya Literatura, Moscow (2006).