L.S. Fainzilberg, T.J. Bekler

International Research and Training Center for Information Technologies and Systems of NAS of Ukraine and Ministry of Education, Youth and Sports of Ukraine, Kyiv

SOFTWARE-HARDWARE COMPLEX FOR GENERATING ARTIFICIAL ELECTROCARDIOGRAMS WITH REALISTIC-FORM

A methodology for verification of metrological characteristics of digital electrocardiographs based on the model of generation of realistic artificial electrocardiograms in conditions of internal and external disturbances is proposed. The results of experimental investigations of portable electrocardiograph with finger electrodes are presented.

Keywords: mathematical model, electrocardiogram, metrological characteristics.

Diseases of the cardiovascular system have long been in the lead among the most dangerous diseases, and their untimely diagnosis remains one of the major causes of disability and death of working-age population. Today 3/4 of the population of Ukraine suffers from cardiovascular disease, and in 62.5% of cases it causes death, which is much higher than in developed countries [1]. In recent years, these diseases have become significantly "younger". Only in 10 years in Ukraine the incidence of coronary heart disease has doubled [2].

Quite often sudden heart attacks, including fatal, occur at work, particularly in workers whose labor conditions are associated with major physical or emotional stress. Such situations are not only painful for specific people and their families, but also generate negative economic consequences for the country, because people of working age are dying. A sudden heart attack at work can lead to erroneous actions of the operator in control of sophisticated equipment and ultimately cause serious accidents, the consequences of which are well known.

Therefore, convenient, affordable and at the same time sufficiently reliable means for rapid diagnosis that can detect the initial signs of abnormalities in the heart under the influence of physical and emotional overload are necessary not only in medical institutions but also in manufacturing and even at home.

Electrocardiography is still the most common method of functional diagnostics in cardiology. Recent decades have brought revolutionary changes in this industry: clinical and ambulatory practice widely use digital electrocardiographs with automatic interpretation of electrocardiograms (ECG).

However, according to clinicians, existing computer tools for analysis and interpretation of the ECG still do not provide the required accuracy of diagnostic results. The above primarily relates to the diagnosis of coronary heart disease. Therefore, experts are looking for new approaches to constructing methods and means of computer analysis of ECG.

As part of the tasks for the State Targeted Scientific and Technical Program

"Pattern Computer" the International Research and Training Center for Information Technologies and Systems (IRTC ITS) of NAS of Ukraine and Ministry of Education, Youth and Sports of Ukraine created and submitted for mass production to PJSC NEC "G.I. Petrovsky Kyiv Plant of Automatics" the microelectronic device FAZAGRAF®. The device implements an original method for the analysis and interpretation of the ECG, which has been proven to be effective by large-scale clinical trials [3].

The device FAZAGRAF® received certificate number 8398/2008 on state registration and license to use in medical practice and public certificate of approval of a measuring instrument UA-MI/1-2558-2009.

It is known that all measuring devices both at manufacture and during further operation are subject to metrological monitoring and verification. This requires equipment which will be able to check compliance of unit parameters to its technical specifications.

In the developed world microelectronic devices (simulators), which provide special test signals for metrological verification of digital medical devices in accordance with accepted standards, are manufactured. Table 1 shows the comparative technical specifications obtained from the analysis of modern foreign simulators for verification of digital electrocardiographs.

Table 1

Comparison of complex shape signal simulators

Тип імітатора	Standard test signals	ECG generation				PC interface	Frequency\ amplitude accuracy	USD price ≈
		Normal ECG	Arrhythmias	ST segment shift	Distortion			
Diatest (Russia) www.rudshel.ru	+	+	—	—	—	—	± 3 %/ ± 0,5 %	1300
Neyrotest7B (Russia) www.mks.ru	+	+	—	—	—	—	± 1,2 % / ± 0,2 %	400
FC12D (Spain) www.serviciencia.es	—	+	—	—	—	—	± 5 % / ± 0,2 %	200
ST - 16 (Spain) www.stelec.com	+	+	+	—	+	—	± 3%/ ± 1%	1500
Phantom 320 (Germany) www.ms-gmbh.de	—	+	+	+	+	—	—	1700
Seculife PS (Germany) http:/elizpribor.ru	—	+	+	+	+	—	± 1 % / ± 0,2 %	2100
TechPatient CARDIO (Argentina) www.heinstruments.com	+	+	+	—	+	—	± 2%/ ± 1%	400
PS420 (USA) http://assets.fluke.com	+	+	+	+	+	—	± 2%/ ± 1%	3000
MiniSim 100 (U.S.) www.netech.org	+	+	+	+	—	—	± 1 % / ± 0,5 %	2000
EHS12 (USA) www.ultramedic.com	+	+	—	—	—	—	± 2 % / ± 0,5 %	800
MS400 (China) www.contecmed.com	+	+	+	+	+	+	± 2%/ ± 1%	1000

Table 1 shows that the high cost devices have the best quality of consumer testing of modern ECG equipments. Device MS400, only of the considered, has removable memory cards, allowing the user to change the sets of signals for testing. However, this possibility raises the problem of searching for signals of required form in the required format with specified amplitude and time characteristics.

Modern systems for inspection of medical measuring devices should not only form the reference signals that provide verification of metrological characteristics of the product in accordance with accepted standards, but also generate artificial ECG simulating various forms of biological signals, including those that are rarely found in real conditions. Only with such a comprehensive testing the reliability of these diagnostic decisions can be guaranteed. Paradoxically, in Ukraine metrological services still use for checking electrocardiographs technologically inadequate equipment, such as UP-ECG and GF-05, developed in the late 70's - early 80's on outdated components, which had already exhausted their service life and require replacement.

The aim of the innovation project, implemented at the IRTC ITS in 2011 according to the Decree of the Presidium of the National Academy of Sciences of Ukraine No 129 from 25.02.2011, is the creation of software-hardware complex (SHC) for reproduction of complex shape signals, in particular artificial ECG, which are used to carry out verification of metrological characteristics and evaluation of consumer quality of devices FAZAGRAF® in their mass production at industrial enterprises.

Before proceeding to describe the basic ideas that formed the basis of the created SHC, we will give a brief description of the main functions of the FAZAGRAF® device.

GENERAL DESCRIPTION OF FAZAGRAF® DEVICE

The following requirements formed the basis of the FAZAGRAF® device:

- promptness (results must be received no more than in 1-2 minutes);
- convenience (test procedure must not be burdensome, done without removing clothes and not require other preparatory measures);
- informative (ability to detect hidden disorder symptoms in the heart under the influence of physical and emotional stress, which are underestimated with the traditional ECG diagnosis);
- accessibility (presentation of the results should be clear to the personnel that has no special medical training).

FAZAGRAF® device consists of a microprocessor sensor (Fig. 1), which provides the registration of standard 1-lead ECG and input of digitized signal into a personal computer through a standard USB port.

Fig. 1. Microprocessor sensor of **FAZAGRAF®**

Touching with fingers of the right and left hands the miniature electrodes placed on the front of the sensor is enough for ECG registration. Power supply of the sensor is provided via the USB-port. Sustainable current consumption value does not exceed 120 mA. Galvanic isolation of electrical circuits is provided in the sensor in accordance with international standards on safety of medical devices.

The main technical characteristics of the sensor are shown in Table. 2.

Table 2

Technical Specifications of FAZAGRAF® sensor

Specification	Value
Input voltage range of ECG	from 0.03 to 5 mV
Input impedance	not less than 2 MOhm
common mode attenuation ratio	5
Internal noise input voltage	not less than 10 (100 dB)
Uneven amplitude-frequency characteristics (AFC) in the frequency range from 0.5 to 40 Hz	no more than 20 mV
Boundaries of relative measurement error voltage permitted	-30 to 5%
in the interval of the measurement range from 0.1 mV to 0.5 mV	± 15%
in the interval of the measurement range from 0.5 to 4 mV	± 7%
Boundaries of relative error in the measurement of time intervals from 0.1 to 1 s, permitted	± 7%
Boundaries of relative error in the measurement of heart rate (HR) in the range of 30 to 180 b / Min	± 5%
Average time between failures	2000 h
Average performance recovery time	20 h

Processing of ECG is done by a computer program that is being executed on a personal computer, including a laptop, of such minimum configuration: OS - Windows 2000/XP, Pentium 600 MHz, 64 MB RAM, HDD 20 GB, SVGA monitor 800 × 600, USB-port.

A patented method of ECG analysis and interpretation is implemented in FAZAGRAF® [4], which provides highly informative results. The basic idea is that at each point discretely given electrocardio signal Z (t), t = 1,2, ... numerical methods to assess the rate of change in signal $\dot{Z}$ (t) are used and all subsequent processing is performed on the phase plane in coordinates Z (t) - $\dot{Z}$ (t).

Because ECG is not a periodic function, the trajectories of individual cycles are "blurred" in the phase space being drawn to some local area - an attractor in the form of limit cycle (Fig. 2).

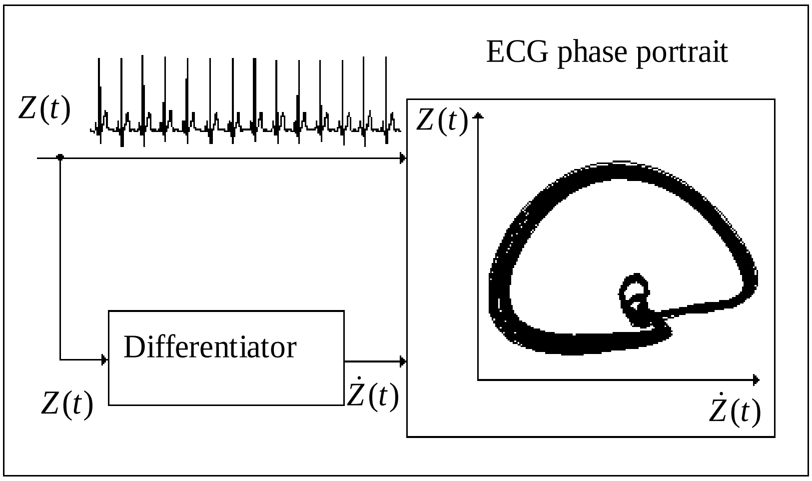

Fig. 2. ECG in two-dimensional phase space

The computer program implements all the stages of high-tech information technology in signal processing, including:

- suppression of interference of various types, including network interference, based on the original narrowband rejector [5] and random noises caused by, for example, muscle tremor, based on adaptive smoothing algorithm [6];
- evaluation of the first derivative signal based on Lagrange polynomial interpolation with appropriate regularization procedure;
- construction of ECG phase portrait and assessment of averaged phase trajectory using the Hausdorff metric [7];
- restoration of reference cardiac cycle in time domain and analysis of traditional ECG signs;
- selection of repolarization fragment of averaged phase trajectory;
- assessment of additional diagnostic parameter β_T, which characterizes symmetry of averaged phase trajectory repolarization fragment form, and implementation of diagnostic rule based on a comparison of β_T with the threshold value [3].

Value β_T is defined as the ratio of the maximum speed on the uplink and downlink laps of repolarization fragment of averaged phase trajectory, with $\beta_T = D_2/D_1$ at positive T deflection and $\beta_T = D_1/D_2$ at negative deflection T. The original

ECG computer processing algorithms in phase space, including procedures designed to automatically determine the parameter β_T, are described in [8].

For clarity and ease of information presentation of the ECG processing results are displayed on a special indicator in the form of a thermometer with a scale divided into three zones - green (NORMAL), yellow (SATISFACTORY), red (WARNING), and are accompanied by voice messages. This interpretation of the data is understandable to everyone, including domestic conditions, since it does not require any special medical knowledge. In addition, FAZAGRAF® generates a report on the test results in the form of tables and graphs of traditional and original signs of the ECG, which is stored in the database and can be printed on a printer.

It is clear that the consumer quality of the device primarily depend on the accuracy of measurement of these metrological characteristics under real operating conditions.

TEST METHODOLOGY OF METROLOGICAL CHARACTERISTICS OF FAZAGRAF®

The main idea, which is the basis of verification methodology of metrological characteristics of FAZAGRAF®, is as follows. The software-hardware complex created by the project generates complex shape artificial signals, including electrocardiograms, with specified amplitude-time characteristics of informative fragments, which are used as test signals.

The complex is built on the basis of autonomous microelectronic signal simulator ISSF-011, which connects to a personal computer via a standard USB interface. For ease of testing the composition of complex also includes specially designed accessories - transitional adapter by which a test signal from the analog output terminals of simulator goes directly to the finger electrodes of FAZAGRAF® being tested (Fig. 3).

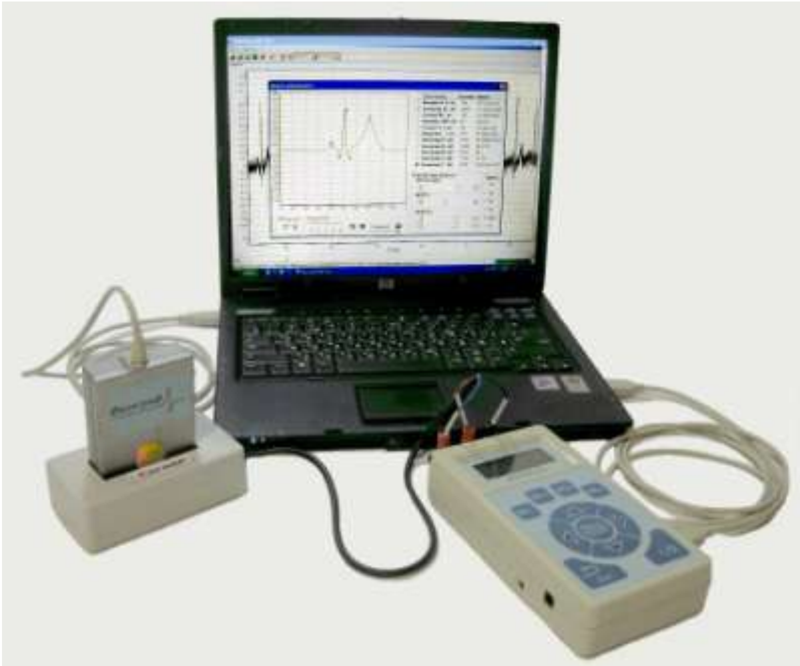

Fig. 3. S&HC structure consisting of: a personal computer (center), an adapter to connect FAZAGRAF ® (left) and signal simulator ISSF-01 (right)

Test analog signals are reproduced with a simulator in the range of infra low and low frequencies and include harmonic signals of sinusoidal, square and triangular shapes with specified amplitude and frequency characteristics as well as special signals in the form of artificial ECG, which are recorded in memory of simulator using external computer programs. Simulator ISSF-01 obtained the Certificate of State Metrological Certification No 26-02-0808 from September 16, 2011.

Evaluation of metrological characteristics of FAZAGRAF® is based on deviations of amplitude-time parameters of the average cardiac cycle automatically determined by FAZAGRAF®, from known amplitude-time parameters of reference cardiac cycle, based on which a special test signal is generated.

Special signals are generated using an original mathematical model [9], which allows to generate artificial realistic-form ECG and simulate ECG deviation from the norm, which correspond to different violations in the cardiovascular system and the real hindrances, such as network interference, muscle tremor and others.

Generating artificial ECG is done in two stages. The first stage generates a reference cardiac cycle *z(t)*. The generation model *z(t)* is based on a system of differential equations proposed in [10] which has the form

$$\dot{x} = \alpha x - \omega y, \tag{1}$$

$$\dot{y} = \alpha y + \omega x, \tag{2}$$

$$\dot{z} = -\sum_{i\in\{P,Q,R,S,T\}} a_i \Delta\theta_i \exp(-\frac{\Delta\theta_i^{\ 2}}{2b_i^2}) - (z - z_B)\,. \qquad (3)$$

In system (1) - (3) accepted designation: $a = 1\sqrt{1x^2 + y2}$, ω - angular velocity of reflectance point in the plane (x, y); $\Delta\theta_i = (\theta - \theta_i) \bmod 2\pi$; i ∈ {$P$, Q, R, S, T}, where θ ∈ [-π, π] - current angle defined by the expression

$$\theta = \begin{cases} \mathbf{arctg}\left(\frac{y}{x}\right), & \textit{если} \quad x > 0; \\ \pi + \mathbf{arctg}\left(\frac{y}{x}\right), & \textit{если} \quad y \geq 0,\ x < 0; \\ -\pi + \mathbf{arctg}\left(\frac{y}{x}\right), & \textit{если} \quad y < 0,\ x < 0; \\ \frac{\pi}{2}, & \textit{если} \quad y > 0,\ x = 0; \\ -\frac{\pi}{2}, & \textit{если} \quad y < 0,\ x = 0. \end{cases} \qquad (4)$$

In equation (3) variable $z_B = B \cdot \sin(2\pi f_B t)$ simulates the drift of isoelectric line with amplitude B and breathing frequency f_B. Parameters a_i, b_i, θ_i determine the amplitude-time characteristics of generated *P, Q, R, S, T* ECG deflections.

System (1) - (3) generates a trajectory (Fig. 4) in three-dimensional space of coordinates (x, y, z).

Cyclicity of ECG is simulated by the movement of a point in a plane (x, y) along the trajectory of variable length, which is "blurred" relative to the circle of unit radius of the attractor as a limit cycle. Every rotation along the circumference corresponds to one *R-R*-interval (cardiac cycle).

Informative fragments of each cycle of ECG are simulated by movement of reflectance point towards z. At time t, in which *P, Q, R, S, T* deflections appear, limit cycle points are determined according to the specified angles θ_P, θ_Q, θ_R, θ_S, θ_T. When approaching these angles the reflectance point moves up or down in the direction z, and after some time returns to plane (x, y).

In [10] numerical method of Runge-Kutta of fourth order fixed step quantization time to generate artificial ECG was used. Instead, we used an analytical solution of system (1) - (3), which allowed to propose a mathematical model of artificial cardiac cycle generation [9] in the form of analytical expression:

$$z(t) = \sum_{i\in\{P,Q,R,S,ST,T\}} A_i \exp\left(-\frac{(t-\mu_i)^2}{2[b_i(t)]^2}\right). \qquad (5)$$

In this expression parameters Ai, μi, bi define respectively the amplitude, time to achieve extremum and duration i ($i \in \{P, Q, R, S, T\}$) of informative fragment of reference cycle and assume that

$$b_i(t) = \begin{cases} b_i^{(1)} & npu \;\; t \le \mu_i, \\ b_i^{(2)} & npu \;\; t > \mu_i, \end{cases} \tag{6}$$

where bi (1), bi (2) - parameters that determine the form of the fragment *i*. When $b_i^{(1)} \neq b_i^{(2)}$ model (5), (6) allows the generation of asymmetric fragments of reference cycle, in particular to generate deflection *T* with varying degrees of symmetrization that carries additional diagnostic information about initial signs of heart malfunction [3].

Allowable structure of ECG reference cycle imposes additional constraints on beginning of $t_i^{(1)}$ and ending of $t_i^{(2)}$ of informative fragments in the form of ratios

$$0 \le t_P^{(1)} < t_P^{(2)} \le t_Q^{(1)} < t_Q^{(2)} = t_R^{(1)} < t_R^{(2)} = t_S^{(1)} < t_S^{(2)} = t_{ST}^{(1)} \le t_{ST}^{(2)} \le t_T^{(1)} < t_T^{(2)} \le T_0, \tag{7}$$

where

$$\begin{aligned} t_i^{(1)} &= \mu_i - 3b_i^{(1)}, \\ t_i^{(2)} &= \mu_i + 3b_i^{(2)}, \end{aligned} \tag{8}$$

and T_0 - total duration (ms) of the reference cycle associated with the frequency F_{HR} of heart rate (bpm./min) with ratio

$$T_0 = \frac{60 \cdot 1000}{F_{ЧСС}} \quad . \tag{9}$$

At the second stage using the reference *z(t)* a sequence of distorted cardiac cycles is generated, where the distortions mean independent random perturbations in the reference. Formally, the process of generating artificial ECG with *N* cycles is described by the expression [11]

$$Z_m(t) = \sum_{i \in \{P,Q,R,S,ST,T\}} \tilde{A}_i[m] \cdot \exp\left(- \frac{(t - \tilde{\mu}_i[m])^2}{2(\tilde{b}_i[m])^2} \right) + h(t), \;\; m = 1,2...N, \tag{10}$$

where

$$\begin{aligned} &\tilde{A}_i\,[m] = A_i\,(1 + \alpha_i[m]), \\ &\tilde{\mu}_i\,[m] = \mu_i\,(1 + \delta_i[m]), \\ &\tilde{b}_i[m] = \begin{cases} b_i^{(1)}(1 + \varepsilon_i^{(1)}[m]), & npu \;\; t \le \mu_i[m], \\ b_i^{(2)}(1 + \varepsilon_i^{(2)}[m]), & npu \;\; t > \mu_i[m]. \end{cases} \end{aligned} \tag{11}$$

In ratios (10), (11) $\tilde{A}_i[m], \tilde{\mu}_i[m], \tilde{b}_i^{(1)}[m], \tilde{b}_i^{(2)}[m]$ - parameters of i fragment of m loop of artificial ECG and $\alpha_i[m], \delta_i[m], \varepsilon_i^{(1)}[m], \varepsilon_i^{(2)}[m]$ - sequence of realizations of independent random variables that have zero mathematical expectation M $\{\alpha\} = 0$, M $\{\delta\} = 0$, M $\{\varepsilon^{(1)} = 0\}$, M $\{\varepsilon^{(2)} = 0\}$ divided into intervals $[-\alpha_{0i}, \alpha_{0i}], [-\delta_{0i}, \delta_{0i}], [-\varepsilon_{0i}^{(1)}, \varepsilon_{0i}^{(1)}], [-\varepsilon_{0i}^{(2)}, \varepsilon_{0i}^{(2)}]$, limited fixed numbers $\alpha_{0i}, \delta_{0i}, \varepsilon_{0i}^{(1)}, \varepsilon_{0i}^{(2)}$.

External signal distortion, including drift of isoelectric line and simulation of various types of interferences (frequency, random, pulse), are provided by an appropriate additive component of *h(t)* to the generated signal.

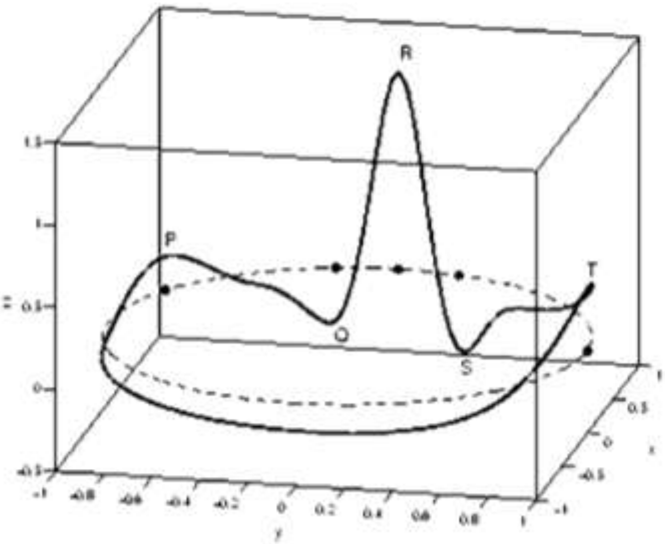

Fig. 4. The trajectory in coordinates of three-dimensional space

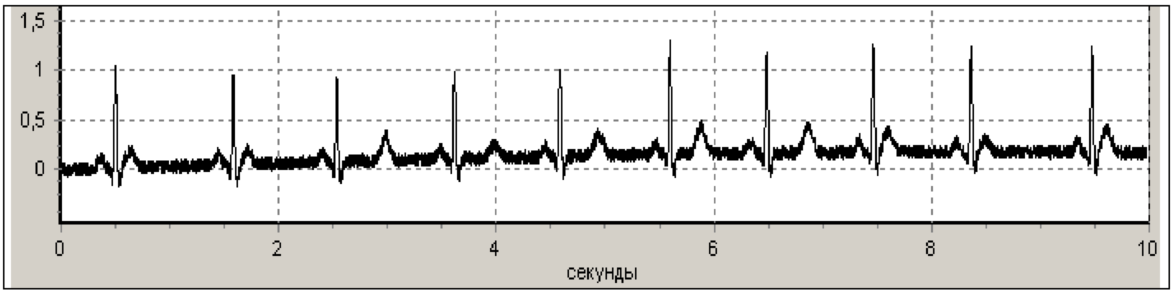

Fig. 5. Example of artificial ECG

Fig. 5 shows an example of artificial ECG, which is generated by the scheme described above. Skilled cardiologists recognize artificial ECG as real, confirming the adequacy of the proposed model and the possibility of its application for the evaluation of the effectiveness of ECG processing algorithms embedded in digital electrocardiographs, in particular for informational support of FAZAGRAF® device mass production.

EXPERIMENTAL RESEARCH

The main goal of the research was

- to test metrological characteristics of FAZAGRAF® device manufactured in an industrial enterprise;
- evaluation of the reproducibility of device characteristics for FAZAGRAF®;
- study the relationship of traditional and original ECG diagnostic signs that are automatically calculated by FAZAGRAF® .

Evaluation of metrological characteristics of FAZAGRAF® was conducted using artificial ECG, which were generated by the complex. Fig. 6 shows the scheme illustrating the operation sequence during the experiments.

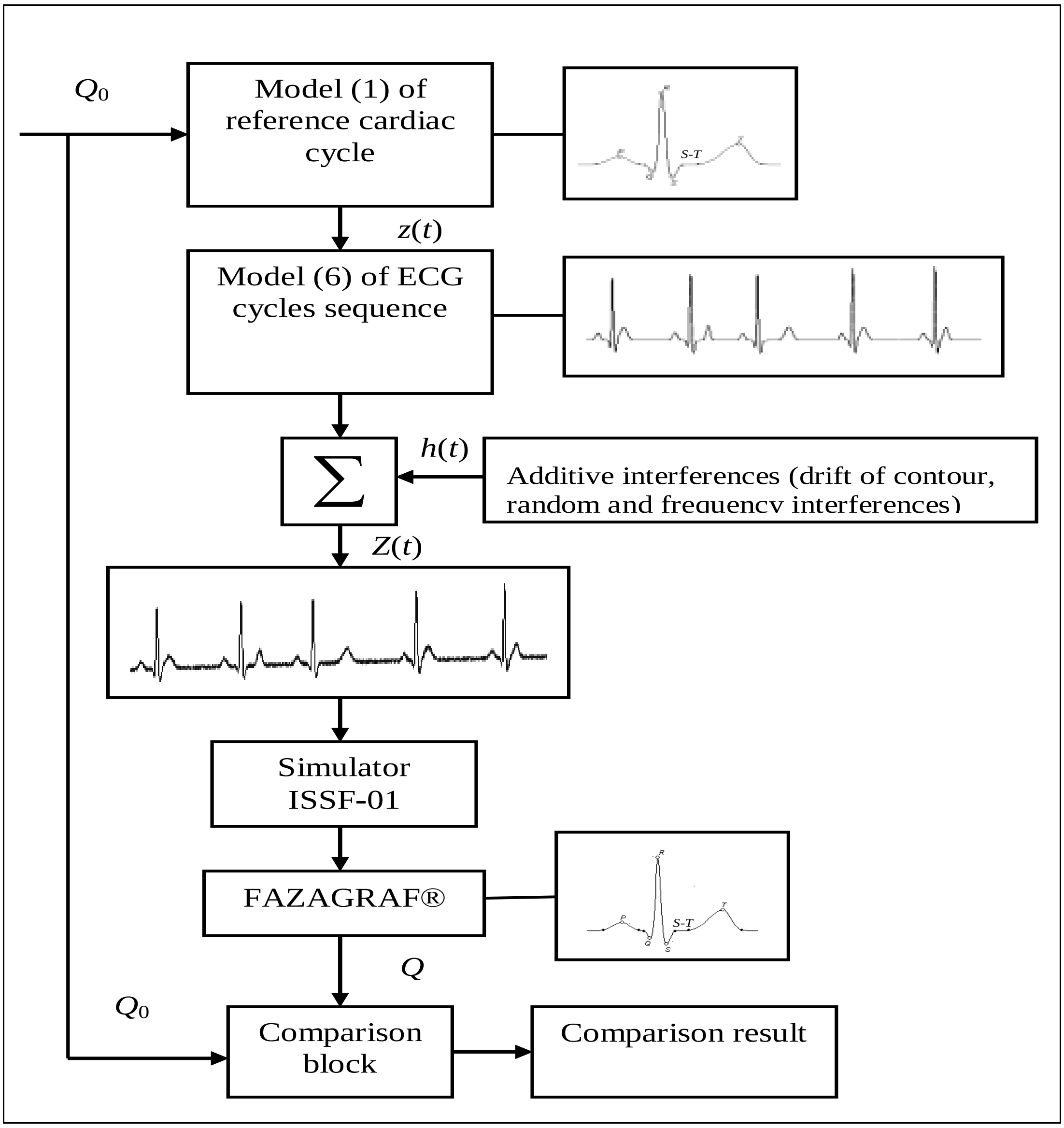

Fig. 6. Sequence of operations in testing metrological characteristics of the device FAZAGRAF ®

Decisions on compliance of metrological characteristics of given TS was taken on the basis of comparison of components of the vector of amplitude-time parameters of ECG reference cycle, on which a test signal was generated, and the vector $Q = (\tilde{A}_p, \tilde{\mu}_p, \tilde{b}_p^{(1)}, \tilde{b}_p^{(2)}, \ldots, \tilde{A}_T, \tilde{\mu}_T, \tilde{b}_T^{(1)}, \tilde{b}_T^{(2)})$ of amplitude-time parameters of ECG averaged cycle, which was automatically calculated by FAZAGRAF® by processing analog test signal fed to its input.

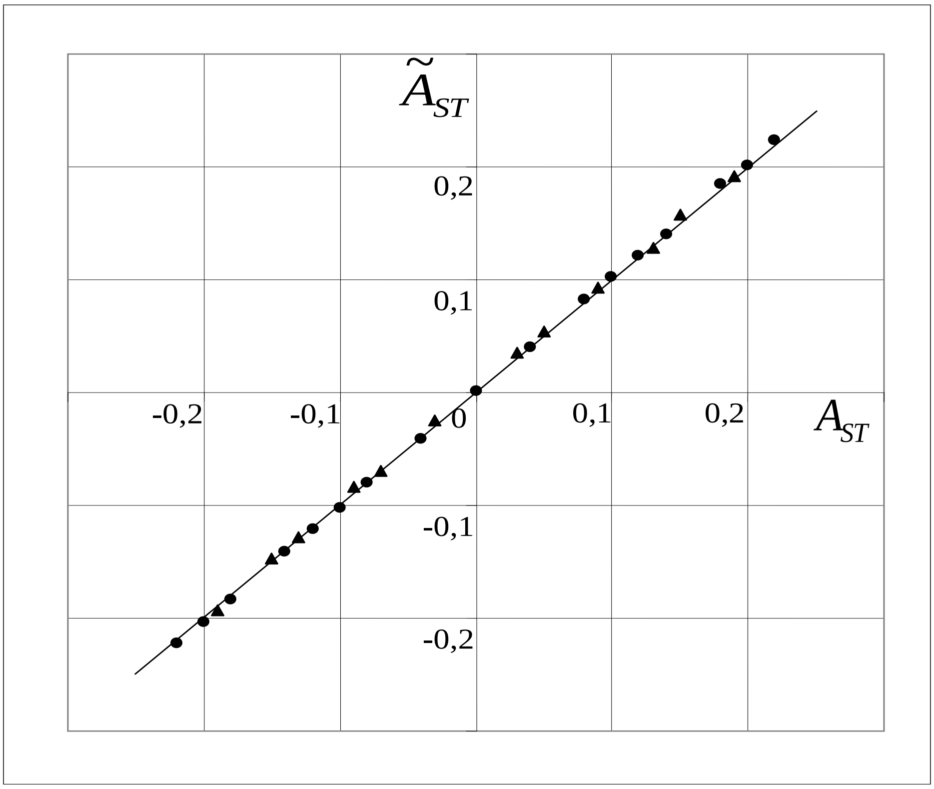

Fig. 7. Scatterogram of segment shift defined by FAZAGRAF ® device relative to the true value of this parameter

Fig. 7 shows scatterogram results of the evaluation of accuracy in detecting conventional electrocardiographic signs of myocardial ischemia [11] - the parameter that characterizes the upward movement of the ST segment (elevation) or down (depression) relative to the isoelectric line.

Experiments have confirmed the high accuracy evaluation of this feature: even at 50% distortion of the *ST* segment amplitude and 5% additive interferences the mean square deviation of *ST* segment shift from true values did not exceed 0.0031 mV.

Experiments have also confirmed the high evaluation accuracy of FAZAGRAF® of other conventional and original diagnostic signs of ECG. For example, the relative error in determining heart rate (HR) was only 0.73%, and the mean square deviation of the parameter estimates β_T, which characterizes the symmetry of T deflection in phase space - 0,021 units.

It is clear that the accuracy of determination of ECG diagnostic signs depended on the level of distortion cycles of test signals that in the experiments were 70% of the true value of the corresponding parameter of the reference cycle. For example, the relative error of automatic determination of *T* deflection symmetry distortion level ξ decreased from 4% at distortion level ξ = 70% to almost zero in the absence of distortions (Fig. 8).

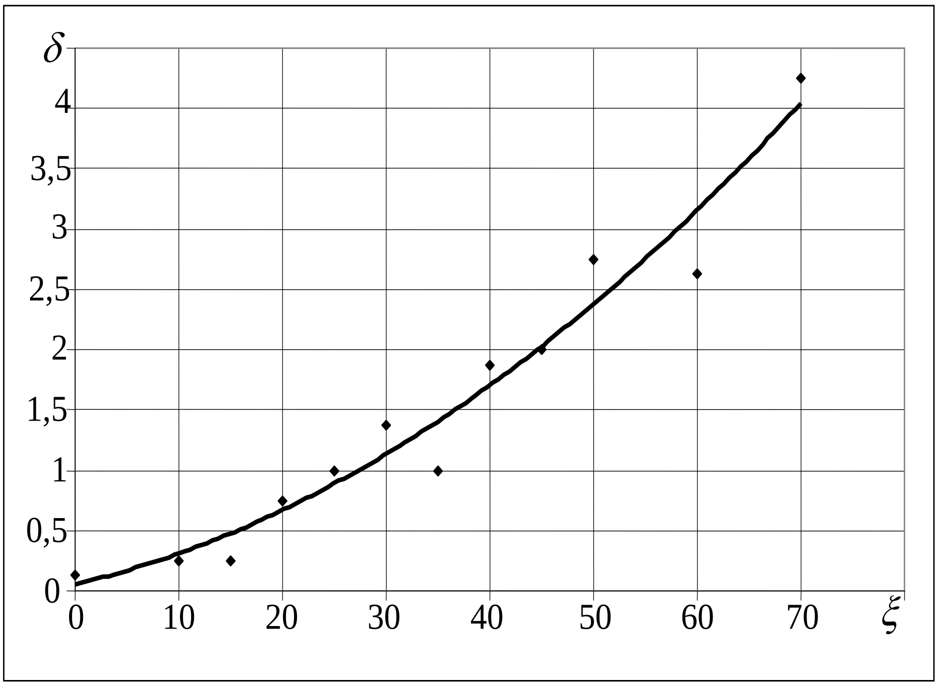

Fig. 8. Dependence of relative error form symmetry distortion level of deflection

The dependence of relative error from ξ distortion level with coefficient of determination R^2 = 0,953 is described by the regression equation

$$\delta = 0.0005\xi^2 + 0.0203\xi + 0.0538,$$

which may be taken into account in the practical use of FAZAGRAF®.

In studies it was found that with increasing duration of test signal increases accuracy of its characteristics. Especially such dependence is observed when measuring heart rate variability, such as standard deviation of R - R-intervals and tension index [12].

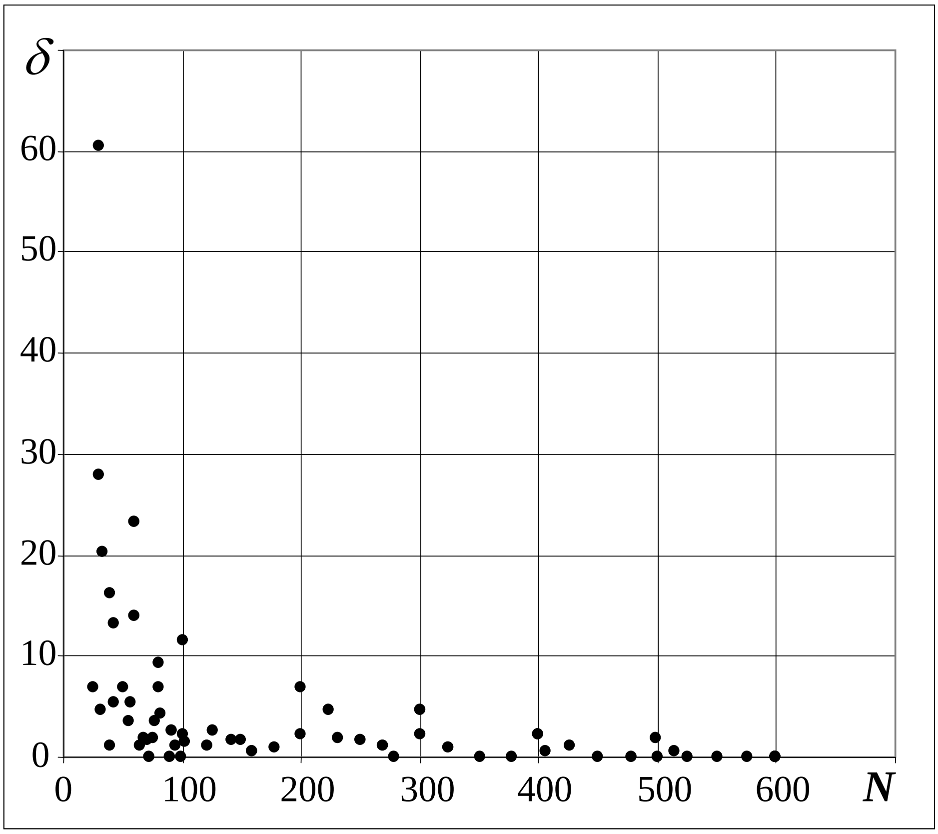

Fig. 9. Dependence of relative error of parameter determination from number of test signal cycles

Fig. 9 shows the results of experiments that illustrate the dependence of the relative error δ parameter definition SDNN (standard deviation of R - R-intervals) from the number of N cycles of test signal. As one can see, when handling more than 100 cycles the relative error δ was within 7%, while N <100 it reached 60%. This fact should be taken into account in practical use of FAZAGRAF ® in health care facilities.

The reproducibility (match) of processing results of test signals of FAZAGRAF devices from experimental batch (50 devices) manufactured in an industrial enterprise was also tested. The experiments have shown that the maximum relative standard deviation in the measurement of test signal characteristics with different devices do not exceed 0.9%, and in multiple signal processing with a single device - 0.64%, indicating high reproducibility of results.

All devices from the experimental batch provided equal and correct interpretation of real ECG with specialized test database, which accumulated signals with previously known characteristics of certain disorders of the cardiovascular system.

CONCLUSIONS

As a result of research an actual scientific applied problem was solved - a modern competitive software and hardware complex was created which provides generation and reproduction of test signals of complex shape with specified amplitude and time characteristics, in particular the formation of artificial electrocardiograms with specified diagnostic signs.

The complex is a convenient way to check metrological characteristics and consumer quality of digital electrocardiographs, including device FAZAGRAF ® both in its production and further operation.

The proposed mathematical generation models of artificial realistic-form ECG may also be useful in other areas of application. In particular, using these models statistical relationship between ECG diagnostic signs in the time domain and the phase space were constructed, which with high coefficients of determination are described by corresponding regression equation [13].

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