UDC 615.47
DOI 10.36910/10.36910/6775-2313-5352-2025-26-01
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METHOD OF CALIBRATION OF SINGLE-CHANNEL ELECTROCARDIOGRAPHS

The article describes the method of calibration of single-channel electrocardiographs, the measurement results of which determine medical treatment strategies for patients. Therefore, it is important that the device is accurate, because incorrect measurements can lead to incorrect diagnosis and subsequent complications. Ensuring the accuracy of electrocardiograph measurement results improves the reliability of medical conclusions, and timely calibration allows you to identify problems and eliminate them before serious problems arise. The methods and means of electrocardiograph calibration, the conditions for electrocardiograph calibration and preparation for it are considered. The method of electrocardiograph calibration is described.

Keywords: *electrocardiograph, calibration, error, diagnostics, accuracy, sensitivity, pulse, signal, recording.*

Problem statement. An electrocardiograph is one of the most important measuring instruments in medical practice for diagnosing and monitoring the cardiovascular system, which allows doctors to assess the electrical activity of the heart. This allows you to detect various disorders, such as arrhythmias, ischemic changes, hypertrophy of the heart muscles and other pathologies. Therefore, ensuring the accuracy of electrocardiographs and the reliability of measurements is critical for the correct diagnosis and treatment of heart diseases. Electrocardiographs are legally regulated measuring instruments and are therefore subject to mandatory verification. The inter-verification interval of electrocardiographs is regulated by the order of the Ministry of Economic Development of Ukraine dated October 13, 2016 No. 1747 «On approval of inter-verification intervals of legally regulated measuring instruments in operation by categories» and is one year [1].

Research problem. The quality, efficiency and safety of medical services provided to citizens in medical and preventive institutions largely depend on the technical condition of medical devices. The use of faulty medical devices leads to low efficiency of the procedure or incorrect diagnosis of the patient. Therefore, it is necessary to constantly monitor the accuracy of the equipment used in medical institutions, because the accuracy of the diagnosis and the correctness of treatment, and therefore the health and life of patients, directly depend on it [2].

Analysis of recent research and publications. Electrical potentials generated by living cells, organs and tissues of humans and animals are called bioelectric and are the subject of study of one of the large sections of modern electrophysiology. Since bioelectric potentials reflect subtle physiological processes in the body, any functional and pathological changes in the studied systems and organs affect their parameters and form. The need to record these changes arises in the study of life processes, diagnostics, treatment and prevention of diseases, monitoring the condition and working capacity of a person [3].

The electrocardiogram (ECG) of healthy people largely depends on their physique, age, conditions for recording bioelectric potentials and their registration. However, on the ECG curve, it is always possible to distinguish certain teeth and intervals that reflect the sequence of excitation of the heart muscle. In the event of diseases, the amplitude of the teeth and their duration, as well as the duration of the intervals between the teeth, can change significantly [4].

Electrocardiographs are verified in accordance with the requirements of DSTU 9202:2022 “Metrology. Electrocardiographs. Verification Methodology”. The verification results are considered positive if their metrological and technical characteristics meet the requirements declared by the manufacturer. Positive results of the verification of a measuring instrument are certified by issuing a verification certificate. Verification of electrocardiographs ensures the quality of medical services and guarantees the accuracy of data, which meets modern standards and reduces risks for patients [5].

A modern electrocardiograph is a complex electronic device that has many technical characteristics. The quality of electrocardiography depends on the serviceability and accuracy of the electrocardiograph. One of the main parameters of the electrocardiograph is the sensitivity of the

signal amplification path, the speed of movement of the recording medium and the amplitude-frequency characteristic. Modern electrocardiographs have regulated errors of sensitivity and speed at the level of 5%. The amplitude-frequency characteristic affects the absence of distortions of the shape of the recorded cardiac signal curve. Electrocardiographs belong to legally regulated measuring instruments and therefore are subject to verification [6].

The purpose of the work is to develop a method for verifying single-channel electrocardiographs to ensure the accuracy of ECG measurement results and improve the reliability of medical conclusions.

Presentation of the main material. Single-channel electrocardiographs EK1K-01 with pen recording via copying tape onto chart paper are designed to measure the dependence of the difference in potentials of the electric field of the heart on time for the study and diagnosis of the state of the human cardiovascular system and establish methods and means of their primary and periodic verification.

The following operations should be performed during verification [5]:

– external inspection;
– testing;
– determination of metrological characteristics;
– determination of relative error of voltage measurement;
– determination of relative error of sensitivity setting;
– determination of relative error of recording medium speed setting;
– determination of relative error of time interval measurement;
– determination of transient characteristic emission;
– determination of common-mode signal attenuation coefficient;
– determination of internal noise level brought to the input;
– determination of recording hysteresis;
– determination of amplitude-frequency characteristic parameters;
– determination of time constant;
– determination of internal calibrator error;
– determination of input impedance;
– determination of sensitivity at additional input and its error;
– determination of sensitivity at additional output and its error.

When verifying electrocardiographs, the following verification tools should be used:

– DC source B5-43 with a voltage range of (0-10) V;
– special-form signal generator type GS-15 with a frequency range of (10-8-10-3) Hz and a voltage setting error of ±3%;
– universal oscilloscope S1-68, in which the voltage measurement error in the sensitivity range from 2 mV/cm to 50 V/cm does not exceed 5%;
– electronic frequency counter type Ch3-36 with a frequency range from 10 Hz to 50 MHz and an error of ± 2·10-5 MHz;
– universal voltmeter type B7-16A with a measurement range of (10-4-103) V;
– ruler-500 with a measurement limit of 500 mm and a division value of 1 mm;
– caliper Shts-P- 250-0.05 GOST 166-89;
– voltmeter S-50/1 with a measurement limit of 15 V, accuracy class 0,5;
– reference microscope MPB-2 with a scale division value of 0,05 mm;
– voltage divider DNS-0 with a basic error of the division coefficient ± 3%;
– low-frequency signal generator G3-56/1 or G3-109 with a frequency range of 20 Hz-200 kHz.

It is allowed to use other, newly developed, or currently in use means of verification that have been certified by state bodies or, with their permission, departmental metrological services, with a measurement error not exceeding 1/3 of the permissible error of the specified parameter.

All verification operations, except those specifically stipulated, must be carried out at:

– ambient temperature (20 ± 5) °C;
– relative humidity (60 ± 15)% at air temperature (20 ± 5) °C;
– supply voltage deviation from the nominal value ± 2%;
– atmospheric pressure (101,3 ± 4) kPa (750 ± 30 mm Hg).

The listed conditions are necessary for verification tools.

Before performing verification, install and prepare for operation the electrocardiograph being verified and the verification tools. Measuring tools used during verification must be designed in

accordance with DSTU 9202:2022 «Metrology. Electrocardiographs. Verification Methodology».

When calibrating the electrocardiograph, unless otherwise specified, the following settings must be set:

– sensitivity – 10 mm/mV.

– recording medium feed speed – 25 mm/s.

– lead switch in position – «1».

– low-pass filter – off.

The signal to the electrocardiograph input should be supplied via the KEPEV-A cable TU 16-943.053-86.

External inspection. During the external inspection, the following are checked:

– the presence of a technical description for the electrocardiograph;

– the absence of signs of corrosion and noticeable mechanical damage;

– the presence of the completeness of the electrocardiograph being verified, which is being verified;

– the absence of damage to the lead cable and the additional input and output cable.

Testing. The electrocardiograph being verified is tested no earlier than 1 minute after it is turned on.

During the test, the following are checked:

– the presence of a recording line, when the record button is pressed; in this case, the recording line should be visible on the movable carrier;

– the presence of calibration signals, setting the sensitivity by pressing the calibration button and switching the sensitivity, in this case, calibration pulses of different magnitudes should be recorded on the record, depending on the set sensitivity.

Determination of metrological characteristics. The relative error of voltage measurement is determined when connecting to the electrocardiograph input the maximum values of the equivalent electrode impedances of the electrical equivalent of the object according to the scheme (Fig. 1) by recording test rectangular pulses of positive and negative polarity with a frequency of 1 Hz, which are fed to the electrocardiograph input via the KEPEV-A cable in any of the leads in the voltage range and values of the set sensitivity specified in Table 1 (switch S3 – in the open state, S4 – in position «2»).

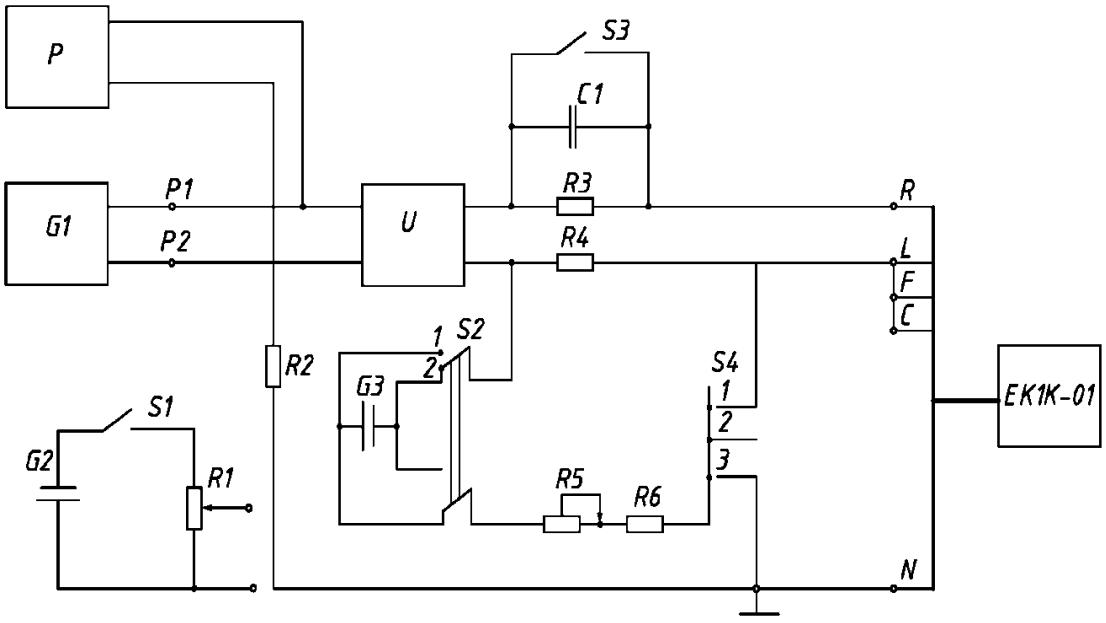

Figure 1 – Scheme for determining the voltage measurement error:
EK1K-01 – electrocardiograph under test; capacitor *C*1 – K73-9 100V-047 μF, ±10%; *G*1 – special-shaped signal generator G6-15; *G*1, *G*2 – DC power supply type B5-43; *P* – universal voltmeter type B7-16A. Resistors: *R*1 – SP4-1V-0,25-1 kΩ – A; *R*2 – S2-29V-0,25-100 Ω ± 0,4% – 1,0 A; *R*3 – MLT-0,125-51 kΩ ±5%; *R*4 – S2-29V-0,25-100 Ω ± 0,1% – 1,0 A; *R*5 – SP4-1v-0,25-470 Ω – A; *R*6 – MLT-0,125-100 Ohm ±5%; *S*1 – KMA1-1 button; *S*2 – P2T-1-1V switch, *S*3 – MT1 microtumbler; *S*4 – PR3P34 switch; *U* – DNS-0,1 voltage divider

The voltage divider U (Fig. 1) is used with a division ratio of 1:100, and pulses with an amplitude according to Table 1, but 100 times larger, with an allowable error of ±1% are fed to the input of the divider from the generator G1. The amplitude of the pulses is set by the compensation method, using an oscilloscope C1-68, a universal voltmeter of the B7-16A type and a DC power supply of the B5-43 type.

Table 1 – Voltage ranges and set sensitivity values

Set sensitivity mm/mV	Pulse amplitude at the electrocardiograph input, mV		
5	0,4		4
10	0,2		2
20	0,03	0,1	1

On the recording, the amplitude of the pulse image is measured without taking into account one width of the recording line.

The measurements are repeated with a differential supply to the leads of the lead cable and with a supply between the leads N and all other leads of the lead cable from the source G3 of a constant voltage of ±(300 ± 15) mV. Switch S4 is in positions «1» and «3» at positions «1» and «2» of the switch S2. Switch S3 is in the open state.

The relative error of voltage measurement is determined by formula (1):

$$\delta_n = \frac{U_R - U_{in}}{U_{in}} \cdot 100, \quad (1)$$

where δ_n – relative error of voltage measurement, %;

$U_R = h_n / S_n$ – range of voltage measured by the electrocardiograph, mV;

U_{in} – range of voltage supplied to the input of the electrocardiograph, mV;

h_n – linear size of the range of the registered signal, mm;

S_n – nominal value of the set sensitivity, mm/mV.

The voltage measurement error should not exceed:

– ±20% in the range from 0,1 to 0,5 mV;

– ±10% in the range from 0,5 to 4 mV.

The image of the input signal of 0,03 mV should be visible on the recording medium. Repeat the measurement by swapping the wires *R* and *L* of the lead cable.

To check the upper value of the range of registered voltages (5 mV), the switch *S*4 is set to position «2», the DC power source *G*2 with resistor *R*1 and button *S*1 is connected to points *P*1 and *P*2 instead of the generator G1 in one and the other polarities. Resistor *R*1 is used to set the voltage at points *P*1 and *P*2 (5 ± 0,025) V, using a voltmeter of type B7-16A.

With an electrocardiograph sensitivity of 5 mm/mV, shift the zero line position ±(15 ± 1) mm and press the *S*1 button, record positive and negative pulses, respectively. The signal amplitude on the record should be (25 ± 3) mm.

Determination of the relative error of sensitivity setting. The relative error of sensitivity setting is determined by applying a sinusoidal signal with a frequency of 2,5 Hz and a amplitude of 2 mV to the electrocardiograph input, according to the scheme (Fig. 1) with an electrocardiograph sensitivity of 10 mm/mV. Record 5 periods of the input signal. The measurement is repeated for sensitivities of 20 and 5 mm/mV and input signals of 1 and 4 mV, respectively.

The relative error of sensitivity setting in percent is calculated by the formula (2):

$$\delta_s = \frac{S_m - S_{in}}{S_{in}} \cdot 100, \quad (2)$$

де $S_m = h_n / U_{in}$ – measured sensitivity value, mm/mV;

h_n – linear size of the recorded signal range, mm;

U_{in} – input voltage range, mV;

S_{in} – nominal value of the set sensitivity.

The sensitivity setting error should not exceed ± 5%.

Determination of the relative error of the recording medium speed setting. The relative error of the recording medium speed setting is determined according to the scheme (Fig. 1) by applying to the electrocardiograph input a rectangular signal with a amplitude of 0.5 mV and a frequency of 2,5 Hz with a permissible deviation of ±1% at a sensitivity of 10 mm/mV and a media speed of 25 mm/s. The

frequency setting is controlled by a frequency meter of the Ch3-36 type. At least 20 periods of the input signal are recorded (Fig. 2).

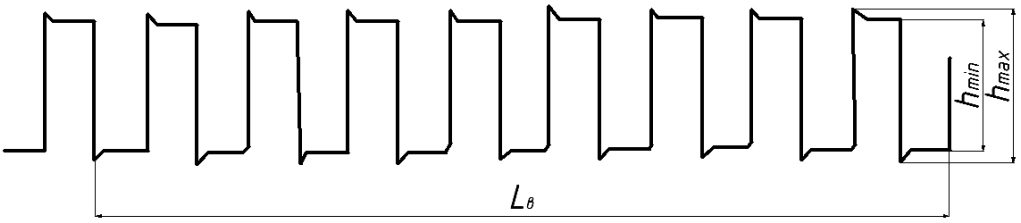

Figure 2 – Recording a rectangular signal

The relative error of the recording medium speed setting δ_v, in percent, is calculated by formula (3):

$$\delta_v = \frac{v_m - v_n}{v_n} \cdot 100, \text{ В}, \tag{3}$$

where $v_m = \frac{2L_m}{nT_n}$ – measured value of speed of movement of the recording medium, mm/s;

L_m – length of the recording section, mm, on which n/2 periods of the recorded signal fit;

n – number of half-periods of the recorded signal;

T_n– period of the signal supplied to the input of the electrocardiograph, s;

v_n – nominal value of the set speed of movement of the recording medium, mm/s.

Measurements and calculations are repeated at a speed of 50 mm/s with a test signal frequency of 5,0 Hz with a permissible deviation of ±1%. The relative error in establishing the speed of movement of the recording medium should not exceed ±5% in any recording area.

Determination of the relative error in measuring time intervals. The relative error in measuring time intervals equal to 0,1; 0,5; 1,0 s is carried out at a speed of movement of the recording medium of 25 and 50 mm/s in accordance with this method and is determined by the formula (4):

$$\delta_i = \frac{T_m - U_{in}}{T_{in}} \cdot 100, \tag{4}$$

where δ_i – relative error of measurement of time intervals, %;

$T_m = L_m / v_n$ – measured time interval, s;

L_m – linear size of the section, records on which consist of n half-periods (n = 1; 5, 10);

v_n – nominal value of the set speed of movement of the recording medium, equal to 25 and (or) 50 mm/s;

$T_{in} = n/2F$ – time interval supplied to the input of the electrocardiograph, s;

F – signal frequency, Hz.

The relative error of measuring time intervals should not exceed ±10%.

Determination of the overshoot on the transient characteristic. The overshoot is determined at a sensitivity of 10 mm/mV and a speed of movement of the recording medium of 50 mm/s in the middle position of the zero line. Test pulses with a amplitude of 1 mV and a frequency of 2,5 Hz are applied to the input of the electrocardiograph using this method with the switch *S*3 closed. The amplitude of the pulse image on the recording is measured (Fig. 3).

The overshoot on the transient characteristic is determined by the formula (5):

$$\delta_e = \frac{h^e_{\max} - h^e_{\min}}{2h_{\min}} \cdot 100, \tag{5}$$

where δ_e – the emission on the transient characteristic, %;

$h^e_{\max}$, $h^e_{\min}$ – the measured values of the linear dimensions of the recorded signal amplitudes with and without the emission, respectively, mm (Fig. 2).

The emission on the transient characteristic should not exceed 10 %.

Determination of the attenuation coefficient of the common-mode signal. The attenuation coefficient of the common-mode signal is determined by applying a sinusoidal voltage with a frequency of 50 Hz to the electrocardiograph inputs through the electrical equivalent of the object (*C*3, *R*1 and *R*2, *C*3) according to the scheme shown in Figure 3, at all positions of the lead switch.

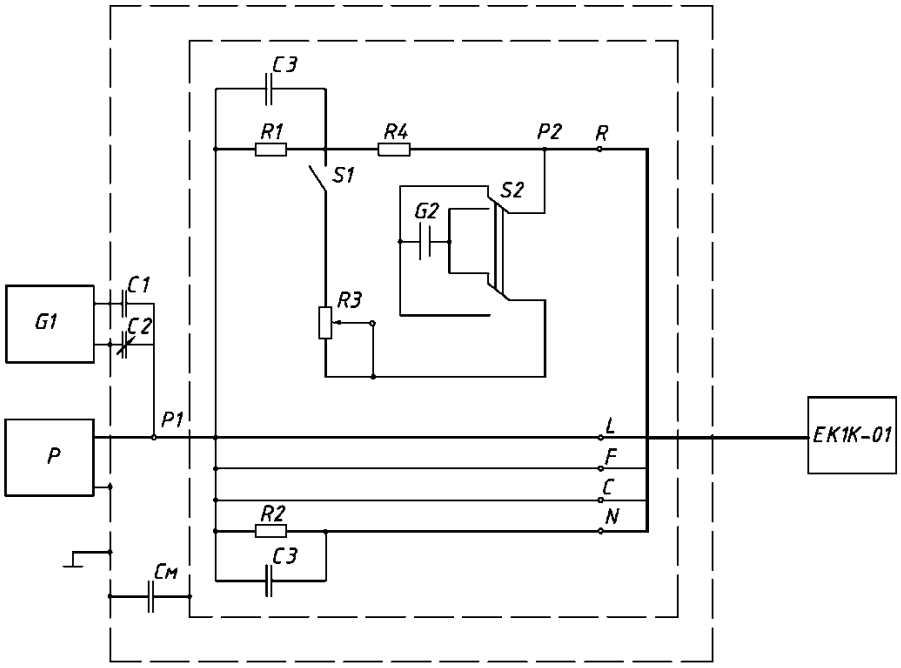

Figure 3 – Scheme for checking the attenuation coefficient of the common-mode signal: EK1K-01 – electrocardiograph being verified. Capacitors: *C*1 – KM-5b-M47-100 pF ± 10%; *C*2 – KPK-2-10-100 pF; *C*3 – K73-9-100 V-0,047 μF ± 10%; *Cm* – mounting capacitance; *G*1 – low-frequency signal generator G3-56/1; *G*2 – element 332 GOST 12333-74; *P* – voltmeter electrostatic system type C50/1. Resistors: *R*1 – MLT-0,125-51 kΩ ± 5%; *R*2 – MLT-0,125-51 kΩ ± 5%; *R*3 – SP4-1B-0,25-470 Ohm-A; *R*4 – MLT-0,125-100 Ω ± 5%; *S*1 – MT1 micro-tumbler; *S*2 – P2T-1-1B switch

The capacitance *C*2 is adjusted so that at point *P*1 the voltage relative to ground is 10 V ± 5% with the cable disconnected from the electrocardiograph and the voltage at the output of the generator *G*1 set to 20 V ± 3%.

The attenuation coefficient of common-mode signals in different taps is checked by connecting the tap cable wires in series at point *P*2 (Fig. 3) in accordance with Table 2, and while simultaneously applying a constant voltage of ± 300 kV to the input. The constant voltage of ± (300 ± 15) kV is applied by closing the switch S1 and changing the position of the switch *S*2.

Table 2 – Tap switch positions when connecting the cable

Cable connection of leads that connect to point P2	Lead switch position
R	I – aVR
L	III – aVL
F	II – aVF
C	V
N	under all conditions

The attenuation coefficient of in-phase signals is determined by the formula (6):

$$K_c = \frac{V_c}{h_n} S_n \cdot 10^R, \tag{6}$$

where K_c – attenuation coefficient of common-mode signals;

V_c – voltage range at point P1 with the lead cable disconnected $\left(V_c = 2\sqrt{2} \cdot 10\right)$, V;

h_n – linear size of the recorded signal range, mm/mV;

S_n – set sensitivity, mm/mV.

The attenuation factor of common-mode signals must be at least 28,000 in any lead.

Determination of the level of internal noise brought to the input. An electrical equivalent of the object is connected to the input of the electrocardiograph (Fig. 3), while the signal source is short-circuited. The level of internal noise is determined at a sensitivity of 20 mm/mV and a speed of 50 mm/s by directly measuring the track noise width on the recording for 10 s (defined as the excess of the zero line width without taking into account single emissions).

The level of internal noise, brought to the input, is determined by formula (7):

$$U_n = \frac{10^3 \cdot h_{mn}}{S_n}, \quad (7)$$

where U_n – internal noise level, brought to the input, μV;

h_{mn} – linear dimension of the maximum noise amplitude measured on the record, excluding the width of the recording line (single emissions are not taken into account), mm;

S_n – nominal value of the set sensitivity, mm/mV.

The noise level brought to the input should not exceed 25 μV. Determination of recording hysteresis. Recording hysteresis is determined by applying test rectangular pulses with a frequency of 0,5 Hz to the input of the electrocardiograph according to the scheme (Fig. 1) through a differential circuit consisting of a capacitor with a capacity of 0,5 μF and a resistor of 100 kΩ.The differential circuit is switched on after the voltage divider. The pulse amplitude is 2 mV with a sensitivity of 10 mm/mV. The switch *S*3 is closed, *S*4 is in position «2». The hysteresis value λ is measured on the recording (Fig. 4) without taking into account one recording line width.

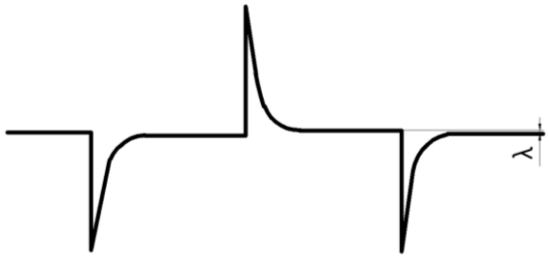

Figure 4 – Recording hysteresis

The recording hysteresis should not exceed 0,5 mm. Determination of the amplitude-frequency characteristics parameters. The amplitude-frequency characteristics parameters are determined by applying sinusoidal signals with an amplitude of 1 mV to the electrocardiograph input according to the scheme (Fig. 1) without applying a constant voltage to the input (switch *S*4 in position «2»). By changing the signal frequency from 0,1 to 75 Hz, the signal amplitude is maintained constant and a sinusoidal signal is recorded. The ratio of the linear size of the amplitude of the recorded signal at the i-th frequency to the linear size of the amplitude of the recording signal at a frequency of 10 Hz is determined by the formula (8):

$$\delta_F = \frac{A(f_i)}{A(f_0)} \cdot 100, \quad (8)$$

where δ_F – ratio of the linear size of the amplitude of the recorded signal at the ith frequency to the linear size of the amplitude of the recorded signal at a frequency of 10 Hz, %;

$A(f_i)$ – linear size of the image range of a sinusoidal signal of the i-th frequency (i = 0.1; 0.5; 1; 20; 30; 40; 50; 60; 75 Hz) on the recording, mm;

$A(f_0)$ – linear size of the image range of a sinusoidal signal with a frequency of 10 Hz on the recording, mm.

The ratio of the linear size of the amplitude of the registered signal at the i-th frequency to the linear size of the amplitude of the registering signal at a frequency of 10 Hz in the range from 0,1 to 60 Hz should be within the range from 90 to 105 %, and at a frequency of 75 Hz – from 70 to 105 %.

Determination of the time constant. The time constant is determined according to the scheme (Fig. 1), switch *S*3 is closed, *S*4 is in position «2», with a sensitivity of 10 mm/mV by applying

rectangular pulses with a amplitude of 2 mV and a frequency of no more than 0,2 Hz to the electrocardiograph input. The speed of movement of the recording medium is 50 mm/s.

The time constant τ is defined as the time for the signal to decay to level 0,37 according to Figure 5 without taking into account emissions. The image on the transient response record should be monotonic within the effective recording width, directed towards the zero line. The time constant should be at least 3,2 s.

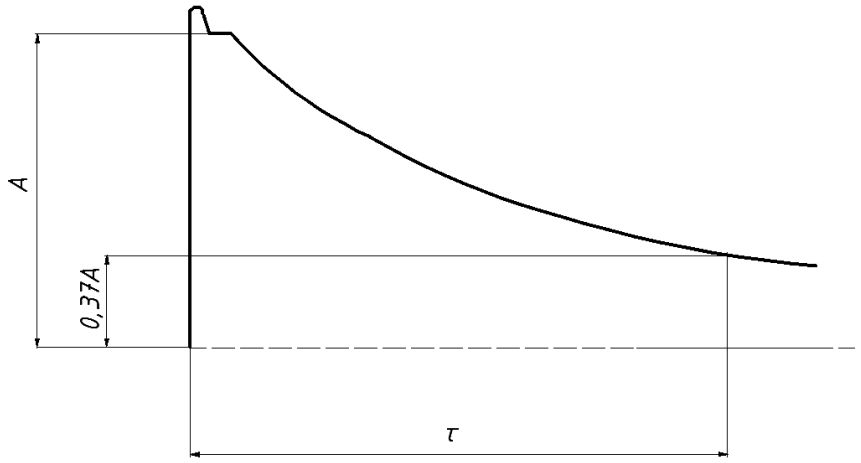

Figure 5 – Recording of the transient response

Determination of the error of the internal calibrator. The error of the internal calibrator is determined by recording the external signal and the internal calibrated signal. According to the scheme (Fig. 1), a rectangular signal with a amplitude of 1 mV and a frequency of 2,5 Hz must be applied to the input of the electrocardiograph and recorded. Then record the calibrated pulse from the internal calibrator (by pressing the appropriate button). The error of the internal calibrator in percent is determined by formula (9):

$$\delta_{i.c.} = \left| \frac{h_c - h_{es}}{h_{es}} \right| \cdot 100, \tag{9}$$

where $\delta_{i.c.}$ – error of the internal calibrator, %;

h_c – linear size of the recorded signal range of the internal calibrator, mm;

h_{es}– linear size of the recorded external signal range, mm.

The error of the internal calibrator should not exceed ±5%. Determination of input impedance. The input impedance is determined by applying to the input of the electrocardiograph a test sinusoidal signal with an amplitude of 1 mV and a frequency of 10 Hz with a permissible deviation of ±1 Hz at a sensitivity of 10 mm/mV according to the scheme (Fig. 6), switches *S*1, *S*2 are closed.

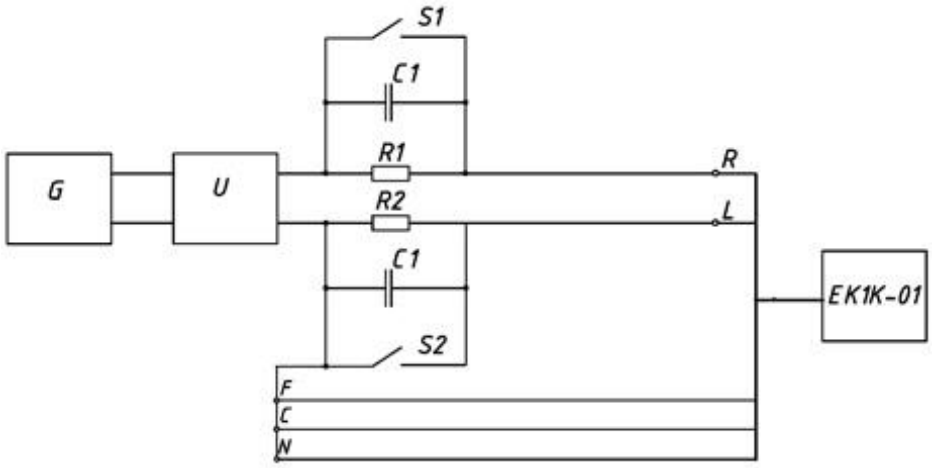

Figure 6 – Scheme for determining the total input impedance: EK1K-01 – electrocardiograph being verified; *C*1, *C*2 – capacitor K73-9-100V-4700 pF ±10%; *G* – signal generator of a special form, type G6-15; *R*1, *R*2 – resistor MLT-0,125-620 kΩ ±5%; *S*1, *S*2 – micro-tumbler MT1;
U – voltage divider, type DNS-01

Then the same signal is fed to the inputs of the electrocardiograph through additional resistors *R*1, *R*2, switches *S*1, *S*2 are open. Repeat the measurement by changing the wires *R* and *L* of the lead cable.

The input impedance is calculated by the formula (10):

$$Z_{in} = Z_2 \left| \frac{H_{n2}}{H_{n1} - H_{n2}} \right|, \tag{10}$$

where Z_{in} – input impedance, kOhm;

H_{n1} – linear size of the recorded signal range without series-connected impedance Z_2, mm;

$H_{n2} = \frac{A_{\max} + A_{\min}}{2}$ – linear size of the recorded signal amplitude with the impedance of the output Z_2 connected in series (Fig. 7), mm;

Z_2 – the value of the series impedance is 527 kOhm at a frequency of 10 Hz.

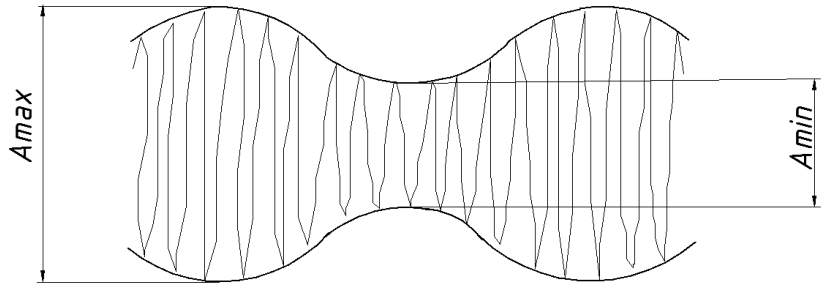

Figure 7 – Signal recording when measuring input

The input impedance must be at least 5 MΩ. Determination of the sensitivity of the additional input and its errors. The sensitivity of the additional input is determined by applying to the additional input via the TE4.853.248 cable a rectangular pulse signal with a frequency of 1 Hz and an amplitude of 1 V with a permissible deviation of ± 1% according to the scheme (Fig. 8).

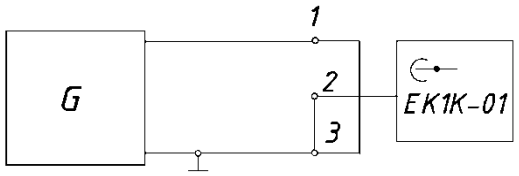

Figure 8 – Scheme for determining the sensitivity of the additional input:
EK1K-01 – electrocardiograph under test; *G* – special-shaped signal generator G6-15

The required accuracy of setting the pulse amplitude can be ensured at the output of a special-shaped signal generator of the G6-15 type by the compensation method using an oscilloscope C1-68, a universal voltmeter B7-16A and a DC power supply of the B5-43 type. The amplitude of the pulse signal image is measured on the recording and the sensitivity error at the additional input is determined by the formula (11):

$$\delta_{a.i.} = \left(\frac{h_{es}}{2U_{a.i}\xi_{n1}} - 1 \right) \cdot 100, \tag{11}$$

where $\delta_{a.i.}$ – sensitivity error for additional input,%;

h_{es} – the amplitude of the pulse signal image on the recording, mm;

$U_{a.i.}$ – the amplitude of the pulse signal image on the recording, mm;

ξ_{n1} – nominal sensitivity value for additional input ξ_{n1}= 20 mm/V.

Repeat the measurements and calculations by swapping the positions of cable wires 1 and 2 (3 – grounding wire of cable TE4.853.248). The sensitivity error for the additional input should not exceed ±5%. Determination of sensitivity by additional output and its errors. Sensitivity by additional output is determined by measuring with a voltmeter B7-16A the voltage at a load of 10 kΩ ± 5%, connected to the red and black wires of the cable TE4.853.248. The cable TE4.853.248 is connected to

the additional output of the electrocardiograph. A sinusoidal signal with an amplitude of 1 mV with a permissible deviation of 0,01 mV and a frequency of 20 Hz is applied to the input of the electrocardiograph according to the scheme (Fig. 1.)

The sensitivity error at the additional output is determined by the formula (12):

$$\delta_{a.i.} = \left(\frac{U_{a.ix.}\sqrt{2}}{U_{in}\xi_{n2}} - 1 \right) \cdot 100, \quad (12)$$

where $\delta_{a.i.}$– sensitivity error for additional output, %;

$U_{a.i.}$– voltage on the load connected to the additional output, V;

$U_{in.}$ – signal amplitude at the input of the electrocardiograph, mV;

ξ_{n2} – nominal value of sensitivity for additional output, ξ_{n2} = 1 V/mV.

The sensitivity error for the additional output should not exceed ±5%.

Conclusions. Electrocardiographs that meet the requirements of this methodology are considered suitable for use. They are subjected to branding in a way that excludes the possibility of disassembling and repairing the electrocardiograph without breaking the brand, and certificates of initial state verification are issued for them in the form established by the Law of Ukraine «On Metrology and Metrological Activities» on the procedure for conducting verification of legally regulated measuring instruments in operation and recording its results. Periodic verification is carried out by the bodies of the departmental metrological service in accordance with the established procedure at least once a year. Electrocardiographs that do not meet the requirements of this methodology are unsuitable for use, and a certificate is issued for them in the established form, indicating the reasons for unsuitability.

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МЕТОДИКА ПОВІРКИ ОДНОКАНАЛЬНИХ ЕЛЕКТРОКАРДІОГРАФІВ

В статті описано методику повірки одноканальних електрокардіографів, від результатів вимірювань яких визначають медичні стратегії лікування для пацієнтів. Тому важливо, щоб прилад був точним, адже невірні вимірювання можуть призвести до неправильного діагнозу та подальших ускладнень. Забезпечення точності результатів вимірювань електрокардіографів покращує надійність медичних висновків, а вчасна повірка дозволяє виявляти проблеми та усувати їх до виникнення серйозних неполадок. Розглянуто методи та засоби повірки електрокардіографа, умови повірки електрокардіографа і підготовки до неї. Описано методику проведення повірки електрокардіографа.

Ключові слова: *електрокардіограф, повірка, похибка, діагностика, точність, чутливість, імпульс, сигнал, запис.*