TESTER FOR METROLOGICAL CHECKING OF ECG INSTRUMENTS

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According to the regulations of the State Agency of Standardization and Metrology it is obligatory to check metrological characteristics of ECG instruments regularly once per year and every time after repairmen. The paper describes the specific features and realization of a microprocessor-based tester for checking metrological characteristics of ECG instruments. This includes the determination of: the relative error in voltage measurement; the relative error in time-interval measurement; the relative error in speed of paper movement; the frequency response of input amplifiers. The tester must generate sine-wave and pulse signals in shape with number of fixed amplitudes and frequencies. The output of the tester is necessary to be symmetrical with additional possibility to simulate electrode/skin impedance and electrode polarization events. The tester can operate in automatic and manual mode, generating signal with determined parameters. The applied software is organized as a set of programs with simple user interface.

INTRODUCTION

The ECG instruments are widely used in clinical practice for functional diagnostic of heart function. As they record ECG signals containing personal diagnostic data it is very important to keep their parameters within the determined limits. According to the regulation of the State Agency of Standardization and Metrology it is obligatory to check metrological characteristics of ECG instruments at the beginning of their exploitation, then regularly once per year and every time after repairmen. In order to simplify the process of checking and to avoid connecting a set of different generators, cables and electronic circuits it is reasonable to use a single tester, which generates all necessary signals.

The specific features and realization of a universal microprocessor-based tester for metrological checking of ECG instruments is described further in this paper. Special attention is paid on the output circuits, which must simulate the specific features and the parasitic events of ECG-to-human body connection. The algorithm for measurement and calculation of the controlled errors and characteristics of ECG instrument is described.

STUCTURE AND FEATURES OF THE TESTER

The tester must generate sine-wave and pulse signals in shape with number of fixed amplitudes and frequencies. The output of the tester is necessary to be symmetrical with additional possibility to simulate electrode/skin impedance and electrode polarization events. The block diagram of the tester, illustrated on Figure 1, consists of: microprocessor-based signal generator with programmable shape, frequency and amplitude; single-ended to symmetrical output converter; differential amplitude divider; electrode/skin impedance equivalent circuit; electrode polarization simulator.

The signal generator with programmable shape, frequency and amplitude is based on MC68HC11 microcontroller [1]. The sine-wave signal is synthesized digitally with 128 samples/period stored in a look-up table in EPROM. For digital to analog conversion a 10-bit DAC with current output is used. The conversion of current to voltage and low-pass filtration of the signal is implemented by additional operation amplifier. The amplitude of the pulse signal is controlled digitally with step of 5mV. The user interface is organized with simple keyboard and LED indicators. The applied software is organized as a set of programs and sub-programs. The programs are responsible for signal shapes. The sub-programs control the signal amplitude or frequency. The tester can operate in automatic and manual modes. In automatic mode it generates the signal with selected waveform and changes the frequency or amplitude within a pre-determined interval. In manual mode after selection of the numbers of program and sub-program the tester generates signal with fixed frequency and amplitude. The output of the generator is single-ended.

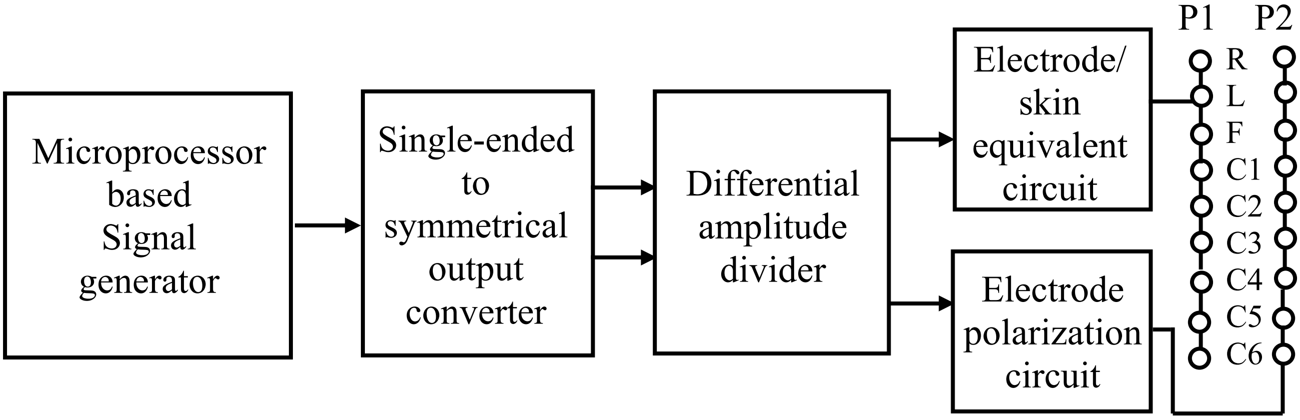

Figure 1. Block diagram of tester for metrological checking of ECG instruments.

The output circuit of the tester must imitate the parameters and the specific conditions of recorded bio-potentials [2]. This is the peculiarity that makes the developed tester different from popular signal generators. First, the output of microprocessor-based signal generator must be converted from single-ended to symmetrical. Then, the amplitudes of the test signals must be reduced to the range of milivolts, in order to resemble the amplitude of bio-potentials recorded by ECG instruments. And finally, the parasitic events which arise on the connection between recording electrodes and human skin have to be simulated. On Figure 2 the electrical circuit of the tester's output is presented. The single-ended to symmetrical output converter is realized with operation amplifiers A1 and A2. Op amp A2 is in inverting configuration with gain equal to -1. This way at the output of converter the amplitudes of the signals are doubled in respect to the input signals. With resistors R2 and R3 the amplitude divider with differential input and differential output is designed. The ratio of input and output amplitude of the signal is 1000:1. The electrode/skin impedance is simulated with Rel and Cel, connected in parallel. For simulation of electrode polarization a single battery is used. By means of resistor divider R4-R5 the value of 300mV is fixed for maximum of the polarization potential. The sign of polarization potential (+300mV or -300mV) is set by switch S2. The two outputs of the tester are connected to the number of terminals (one terminal for each patient cable of ECG instrument).

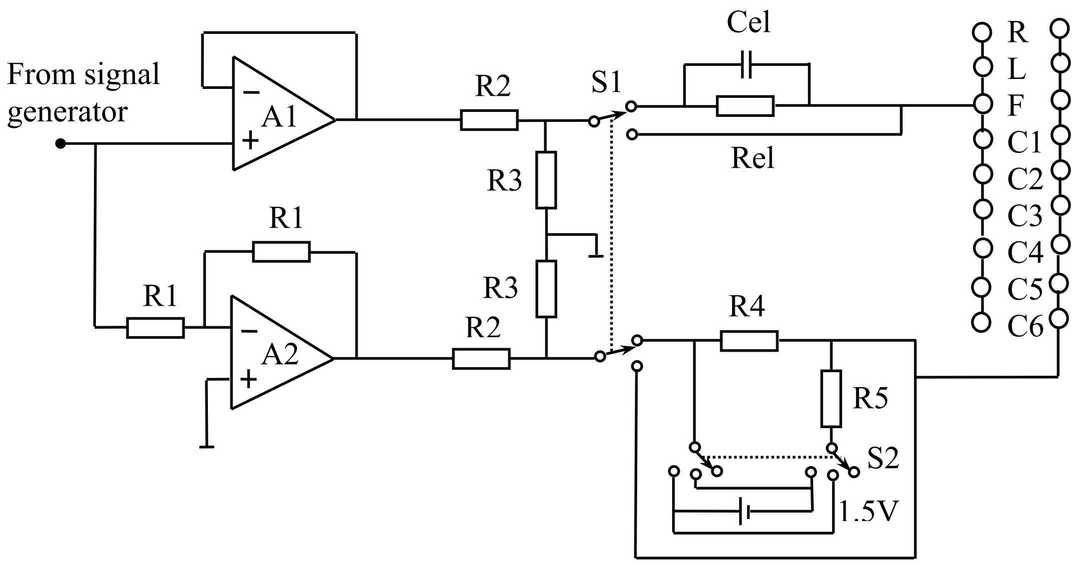

Figure 2. Electrical circuit of the tester's output.

METROLOGICAL CHECKING

The metrological checking includes the determination of: the relative error in voltage measurement; the relative error in time-interval measurement; the relative error in speed of paper movement; the frequency response of input amplifiers [3]. A set of measurements is performed for every parameter.

Determination of relative error in voltage measurement

For determination of relative error in voltage measurement a number of scenarios are performed, because it is necessary to check all amplifier channels in ECG instrument, with all possible sensitivity settings. The various connections of patient cables to the tester outputs and corresponding ECG leads, which can be recorded, are illustrated in Table 1.

Table 1

Selection of ECG lead	Patient cable connected to tester output, named P1	Patient cables connected to tester output, named P2
I, II, aVR, aVL, aVF	R	All the rest
I, III, aVR, aVL, aVF	L	All the rest
II, III, aVR, aVL, aVF	F	All the rest
V1-V6	Ci (i=1-6)	All the rest

For these measurements the tester must generate pulse signal with fixed frequency of 10Hz and different amplitudes, depending on the selected sensitivity of recording, as it is shown in Table 2.

Table 2

Selected sensitivity of ECG instrument, [mm/mV]	The amplitude (peak-to-peak) of the pulse signal, generated by tester, [mV]		
5	0,4	2	4
10	0,2	1	2
20	0,1	0,5	1

All these measurements are performed for the three positions of switch S2 in order to simulate the maximum value of (±300mV) in electrode polarization.

Finally, the relative errors in voltage measurement are calculated employing the relation:

(1) $\delta u = ((hu/S - Uin)/ Uin).100[\%]$

where:

hu is the peak-to-peak value of pulses height recorded by ECG instrument [mm];
S is the selected sensitivity of ECG [mm/mV];
Uin is the peak-to-peak value of the signal, generated by the tester at the input of ECG [mV].

Determination of relative error in time-interval measurement

For determination of relative error in time interval measurements the tester must generate pulse signal with fixed amplitude of 1mV (peak-to-peak) and different frequencies, as shown in Table 3. The measurements are performed for two speeds of paper and 10mm/mV selected sensitivity of ECG recording for one of the pre-cordial leads (V1-V6). Connection of patient cables of ECG instrument to the tester outputs are according to the chosen for recording pre-cordial lead, in agreement with Table 1 (last raw).

Table 3

Frequency of input signal, [Hz]	0,78	1,56	3,12	6,25	6,25	12,5	25	50
Time interval for three periods, [s]	3,84	1,92	0,96	0,48	0,48	0,24	0,12	0,06
Speed of paper [mm/s]	25				50			

The relative errors in time interval measurement are calculated employing the following relation:

(2) $\delta_T = ((Lmes/V - Tin)/ Tin).100[\%]$

where:

Lmes is the recorded length for three periods of input pulse signal [mm];
V is the selected speed of paper [mm/s];
Tin is the time interval for three periods of pulse signal, generated by the tester [s].

Determination of relative error in speed of paper movement

The arrangements for determination of relative error of paper speed require pulse signal generated by the tester with fixed frequency of 10Hz and amplitude of 1mV (peak-to-peak). The sensitivity of ECG recording is necessary to be chosen 10mm/mV and selected for recording to be one or several pre-cordial leads. The patient cables R, L and F have to be connected to the output P1 of the tester and the pre-cordial cables (C1-C6) of ECG to the other output (P2). The tests and measurements are performed for all speeds of paper and the relative errors are calculated employing the relation:

(3) $$\delta v = ((Lmes/n.Tin - V)/V).100[\%]$$

where:
Lmes is the recorded length for **n (n≥10)** periods of input pulse signal [mm];
Tin is the period of input signal [s];
V is the selected speed of paper [mm/s].

Determination of the frequency response of input amplifiers

For determination of the frequency response of input amplifiers of ECG instrument the tester have to generate sine-wave signal with fixed amplitude of 1mV (peak-to-peak) and a number of frequencies in the range from 0,5Hz to 100Hz. The sensitivity of ECG recording is set to 10mm/mV and selected for recording have to be one or several pre-cordial leads. The patient cables R, L and F have to be connected to the output P1 of the tester and the pre-cordial cables (C1-C6) to the other output (P2). The paper speed of ECG recorder should be set to 25mm/s for f≤10Hz and 50mm/s for the higher frequencies. An example of recorded signals for determination of frequency response of input amplifiers is illustrated on Figure 3. To determine the frequency response of input amplifiers in ECG instrument the amplitudes of recorded signals for all tested frequencies are normalized in respect to the amplitude of recorded signal for f=10Hz.

CONCLUSIONS

The described tester is designed in accordance with the regulations and methods for metrological checking of ECG instruments issued by the State Agency of Standardization and Metrology. The signal generator is designed as a universal device and it is easy to add new applied programs in order to generate signals with more complicated shapes and variety of parameters. This design practically allows employing the tester for checking of parameters and characteristics of other biomedical instruments used in functional diagnostic for recording bio-potentials like Electroencephalographs, Electromyographs, etc.

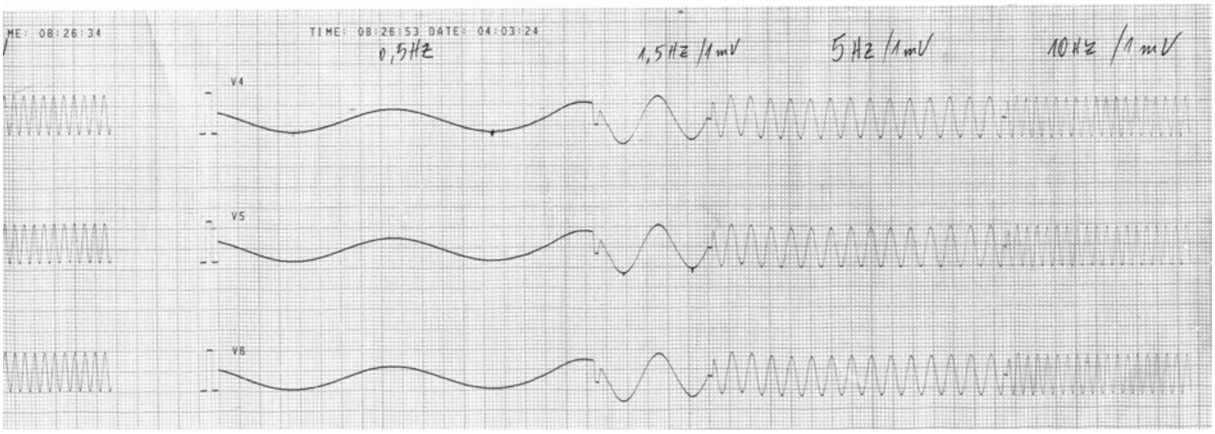

Figure 3. Signals recorded by checked ECG instrument for determination of frequency response of input amplifiers.

REFERENCES

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