Alternative Framework to Calibrate Signal Processing Medical Diagnostic Equipment

¹Myangad Tungalag(Doctoral Candidate),²Liu Baolin (Prof., Ph.D), ³Ambarish Pandey (Prof., PhD)

¹University of Shanghai for Science and Technology, China, ²University of Shanghai for Science and Technology, China, ³Royal International University, Mongolia

¹tungalag@must.edu.mn²blliuk@163.com³ambarish@royalacademy.edu.mn

Abstract – SinceMongolia is not a manufacturer of medical equipment, it has to be dependent on import of diagnostic equipment. Though these are highly expensive equipment yet there is no quality and compatibility assurance. For this reason, it is essential for the healthcare industry to develop optimal methods and methodologies, working standards and special requirements that can be used to control the utilization of Organization. From among the medical diagnostic the equipment and its availability for diagnostic analysis. In order to provide normal technical functioning and keep the metrological indicators of the diagnostic equipment within appropriate limits for the purpose of getting the right provisions of the diagnostic accuracy, the technical preparedness of the equipment should be regularly monitored for a certain period before conducting diagnosis. This should be done in accordance with related laws and regulations developed by the International Metrology equipment, authors have chosen Electrocardiogram as a subject of this research work and studied how to resolve the issue of express investigation of the equipment, readiness for the diagnosis.

Index Terms: Electrocardiogram, Diagnostics, Signal, Metrology, ECG, Calibration, Tools and equipment

I. INTRODUCTION

The Healthcare industry is the area that the countryshould pay utmost attention to develop. High technology equipment with stable function and good quality are a few of the major constitutes of modern medical service. The Electrocardiogram (ECG) is diagnostic equipment which is commonly used for medical diagnostics in many countries. The ECGs can be dependent on their operation principles, technical characteristics, design and the base of the elements used in production; different manufacturers produce the equipment with different technical characteristics. In Mongolia; during 1965 – 2010, 31 types of ECG are used which are produced by 41 manufacturer in 19 countries from 1965 to 2010. Those equipment were either imported or supplied under grants through various organizations. Being a developing country, more serious attention should be paid to this issue.Now it is necessary to strengthen technical control on metrological equipment that essentially affects he diagnoses and to develop a comprehensive methodology for equipment control.

II. STRATEGY

Before using the diagnostic equipment, it is important to inquire technically normal functioning of the equipment and to check its readiness for diagnosis. A case of heart bio-electrocardiogram equipment was studied for this purpose. According to the MNS OIML5139:2002 international standard [1], there are 16 requirements for normal functioning of heart bioelectrocardiogram equipment should be considered, however, these are not feasible in terms of time and training. This paper is to provide a practical solution to calibrate the machine before using for diagnosis.

For this, a specially processed control signal is given to the input of the heart bio-electric cardiogram equipment and the readiness of the equipment can be checked out within a short period of time by comparing result of control signals with the test records. Therefore, development of the control signal options for bio-cardiogram equipment is required. For this reason, it is needed to get common pattern of the Mongolian people's ECGs. ECGs of people from different parts of the country were analyzed in order to get the average pattern. In doing so, 3000 ECGs were recorded, examined and confirmed by the professionals were used as reference of this research paper. An Honorary Doctor in Mongolia Dr. A.Ulziikhutag [2], has divided the Mongolia's landscape into the following zones: 1-Dornod elevations, 2-Khentii mounts, 3-Govi-Altai middle height mounts, 4-Khangai middle height mounts; and determined the ECG sketch.

Bio-electric signal of a normally functioning heart is presented as a curve consisting of five basic grinders of P, Q, R, S and T (Figure 1).

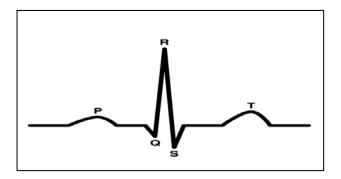


Figure 1. Positions of the ECG curve grinders of normal functioning hearts.

The corresponding amplitudes expressed in millimeters are shown in Table 1

Connection	Zone 1	Zone 2	Zone 3	Zone 4	Average
Ι	$_{0.10} \pm _{0.01}$	$_{0.10} \pm _{0.01}$	$_{0.26} \pm _{0.02}$	$_{0.27} \pm _{0.01}$	0.18
П	$_{0.12} \pm _{0.01}$	$_{0.13} \pm _{0,01}$	$_{0.31} \pm _{0.01}$	$_{0.32} \pm _{0.01}$	0.22
III	$_{0.30} \pm _{0.01}$	$_{0,29} \pm _{0,01}$	$_{0.42} \pm _{0.02}$	$_{0.47} \pm _{0.01}$	0.37
aVR	$_{0.10} \pm _{0.01}$	$_{0.10} \pm _{0.01}$	$_{0.26} \pm _{0.02}$	$_{0.27} \pm _{0.01}$	0.19
aVL	$_{0.11} \pm _{0.01}$	$_{0.11} \pm _{0,01}$	$_{0.28} \pm _{0.01}$	$_{0.30} \pm _{0.02}$	0.20
aVF	$_{0.21} \pm _{0.02}$	$_{0.25} \pm _{0,02}$	$_{0.33} \pm _{0.01}$	$_{0.39} \pm _{0.02}$	0.29
\mathbf{V}_1	$_{0.12} \pm _{0.01}$	$_{0.13} \pm _{0,01}$	$_{0.31} \pm _{0.01}$	$_{0.32} \pm _{0.01}$	0.21
\mathbf{V}_2	$_{0.10} \pm _{0.01}$	$_{0.12} \pm _{0,01}$	$_{0.31} \pm _{0.01}$	$_{0.30} \pm _{0.01}$	0.20
V ₃	0.12 ± 0.01	$_{0.11} \pm _{0.01}$	$_{0.24} \pm _{0.02}$	0.29 ± 0.01	0.16
V_4	$_{0.10} \pm _{0.01}$	0.10 ± 0.01	$_{0.17} \pm _{0.01}$	$_{0.19} \pm _{0.01}$	0.14
V 5	$_{0.26} \pm _{0.02}$	$_{0.37} \pm _{0.02}$	$_{0.48} \pm _{0.02}$	$_{0.50} \pm _{0.02}$	0.40
V_6	$_{0.30} \pm _{0.01}$	$_{0.35} \pm _{0.02}$	$_{0.47} \pm _{0.02}$	$_{0.51} \pm _{0.02}$	0.41
Average	0.19	0.21	0.34	0.37	0.277

Table1. Q grinder amplitudes of the E	ECG signals of people from 4 zones
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Table 2. R grinder amplitudes of the ECG signals of people from 4 zones

Connection	Zone 1	Zone 2	Zone 3	Zone 4	Average
I	$_{4.17} \pm _{0.14}$	$_{4.43} \pm _{0.17}$	$_{5.70} \pm _{0.14}$	$_{5.91} \pm _{0.15}$	5.05
II	$_{6.74} \pm _{0.19}$	$_{7.47} \pm _{0.21}$	$_{8.87} \pm _{0.21}$	9.25 ± 0.18	8.08
III	6.22 ± 0.17	$_{6.26} \pm _{0.16}$	$_{4.47} \pm _{0.17}$	$_{4.91} \pm _{0.16}$	5.46
aVR	1.84 ± 0.06	$_{2.22} \pm _{0.07}$	1.06 ± 0.05	1.15 ± 0.05	1.57
aVL	1.98 ± 0.12	1.92 ± 0.12	$_{2.51} \pm _{0.15}$	$_{2.47} \pm _{0.13}$	2.22
aVF	$_{7.81} \pm _{0.15}$	8.26 ± 0.16	$_{6.17} \pm _{0.16}$	$_{6.56} \pm _{0.14}$	7.20
V_1	$_{4.91} \pm _{0.13}$	$_{4.10} \pm _{0.12}$	$_{3.04} \pm _{0.11}$	$_{2.45} \pm _{0.09}$	3.60
V_2	$_{7.35} \pm _{0.13}$	$_{7.53} \pm _{0.13}$	$_{6.03} \pm _{0.16}$	$_{6.12} \pm _{0.14}$	6.76
V ₃	8.95 ± 0.17	$_{9.15} \pm _{0.18}$	$_{9.70} \pm _{0.17}$	10.0 ± 0.17	9.45
V_4	10.15 ± 0.17	11.4 ± 0.17	11.3 ± 0.18	$_{13.4} \pm _{0.19}$	11.56
V ₅	$_{9.62} \pm _{0.18}$	10.4 ± 0.17	11.3 ± 0.18	$_{12.2} \pm _{0.15}$	10.88
V ₆	8.50 ± 0.16	$_{8.75} \pm _{0.18}$	10.6 ± 0.19	10.9 ± 0.15	9.69
Average	6.5	6.82	6.73	7.11	7.233

Connection	Zone 1	Zone 2	Zone 3	Zone 4	Average
Ι	4.22 ± 0.13	$4.31 \pm .12$	1.93 ± 0.13	1.49 ± 0.11	2.99
II	2.76 ± 0.13	$_{2.70} \pm _{0.13}$	$_{2.56} \pm _{0.15}$	$_{2.37} \pm _{0.10}$	2.60
III	$_{0.84} \pm _{0.09}$	$_{0.87} \pm _{0.10}$	$_{2.65} \pm _{0.16}$	$_{2.50} \pm _{0.14}$	1.72
aVR	$_{6.07} \pm _{0.13}$	$_{6.43} \pm _{0.17}$	$_{7.87} \pm _{0.17}$	$_{8.54} \pm _{0.15}$	7.23
aVL	$_{3.32} \pm _{0.15}$	$_{3.59} \pm _{0.15}$	$_{3.43} \pm _{0.14}$	$_{2.50} \pm _{0.13}$	3.21
aVF	$_{0.44} \pm _{0.07}$	$_{0.56} \pm _{0.07}$	$_{1.82} \pm _{0.12}$	$_{2.06} \pm _{0.11}$	1.22
V_1	$_{7.26} \pm _{0.14}$	$_{7.26} \pm _{0.15}$	8.92 ± 0.16	9.09 ± 0.14	8.13
V_2	10.8 ± 0.25	$_{11.1} \pm _{0.27}$	$_{12.8} \pm _{0.28}$	$_{13.6} \pm _{0.25}$	12.10
V ₃	10.2 ± 0.21	10.2 ± 0.23	$_{9.94} \pm _{0.21}$	10.3 ± 0.20	10.16
V_4	$_{7.75} \pm _{0.19}$	$_{8.16} \pm _{0.18}$	$_{6.17} \pm _{0.19}$	$_{6.0} \pm _{0.17}$	7.02
V ₅	5.46 ± 0.17	5.83 ± 0.17	$_{3.41} \pm _{0.13}$	3.06 ± 0.14	4.44
V_6	3.01 ± 0.17	3.07 ± 0.16	1.80 ± 0.14	1.08 ± 0.20	2.24
Average	5.12	5.34	4.76	5.22	5.534

TABLE 3. S grinder amplitudes of the ECG signals of people from 4 zones

Table 4. T grinder amplitudes of the ECG signals of people from 4 zones

Connection	Zone 1	Zone 2	Zone 3	Zone 4	Average
I	1.23 ± 0.06	$_{1.35} \pm _{0.08}$	$_{2.08} \pm _{0.07}$	$_{2.00} \pm _{0.06}$	1.67
II	2.53 ± 0.08	2.51 ± 0.09	2.48 ± 0.08	2.50 ± 0.07	2.50
III	1.65 ± 0.07	1.81 ± 0.07	1.10 ± 0.07	1.29 ± 0.08	1.46
aVR	2.35 ± 0.06	$_{2.30} \pm _{0.05}$	$_{2.32} \pm _{0.06}$	$_{2.29} \pm _{0.06}$	2.32
aVL	0.48 ± 0.05	0.51 ± 0.5	0.63 ± 0.06	0.67 ± 0.05	0.57
aVF	2.00 ± 0.07	2.07 ± 0.07	$_{1.29} \pm _{0.06}$	1.43 ± 0.05	1.70
\mathbf{V}_1	0.33 ± 0.09	0.35 ± 0.08	$_{0.11} \pm _{0.09}$	0.20 ± 0.07	0.25
V ₂	1.73 ± 0.12	1.95 ± 0.11	$_{3.06} \pm _{0.13}$	$_{3,33} \pm _{0,13}$	2.52
V 3	$_{3.55} \pm _{0.11}$	$_{3.85} \pm _{0.11}$	$_{4.98} \pm _{0.10}$	$_{5.29} \pm _{0.09}$	4.42
V_4	$_{4.28} \pm _{0.13}$	$_{4.39} \pm _{0.14}$	$_{4.82} \pm _{0.13}$	5.23 ± 0.13	4.68
V 5	$_{2.86} \pm _{0.09}$	$_{2.91} \pm _{0.09}$	$_{3.65} \pm _{0.12}$	$_{3.77} \pm _{0.11}$	3.30
V ₆	1.80 ± 0.08	1.90 ± 0.09	$_{2.43} \pm _{0.10}$	$_{2.48} \pm _{0.10}$	2.15
Average	2.07	2.12	2.41	2.54	2.101

Table 5. Amplitudes of Q,R,S,T grinders of Mongolians' ECG signals

	Ι	Π	III	aVR	aVL	aVF	V_1	V_2	V ₃	V_4	V ₅	V ₆	Averag e
R	5.05	8.08	5.46	1.57	2.22	7.2	3.6	6.76	9.45	11.56	10.88	9.69	7.233
S	2.99	2.6	1.72	7.23	3.21	1.22	8.13	12.1	10.16	7.02	4.44	2.24	5.534
Т	1.67	2.5	1.46	2.32	0.57	1.7	0.25	2.52	4.42	4.68	3.3	2.15	2.101

The study shows that the heart electric signals can be designed by using several methods; and Q,R,S,T grinders are used as analog signals.

The analog signal has values that are continual during a given time. In other words, it has endless values for a

given period of time. There are two determinants of analog signals. They are:

1. Frequency: Number of waves that are isochronous, i.e. it is expressed by the number of the cycles for a second.

2. Amplitude: Shows the speed of the waves within the given period of time. This determines the magnitude and noise of the signals.

III.SIGNAL PROCESSING

The availability of the ECGs is required to be checked in accordance with 16 technical requirements among which the following must be regularly inspected before ECG:

1. Relative error on voltage measuring (by the signal amplitude of voltage with linear growth)

- 2. Relative error on sensitivity (by sinusoid signals)
- 3. Relative error on measuring the time of pulse duration (by rectangle pulses)
- 4. Baseline deviation (by zero line lasting for 60 seconds)

The description of the signal combination to be used for checking the above indicators can be presented as the curve shown in Figure 2. The idea is to take this as the control signal for the evaluation of technical availability of ECG, to get a signal of same form, size and rate of change and to develop a control signal for testing. Shown in a coordinate system (Figure 2).

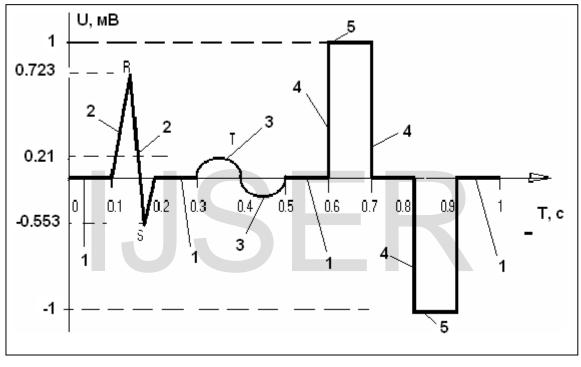


Figure 2. Control signal for checking technical availability of ECG

Authors have considered that the control signal for ECG should have common characteristics of heart bioelectric cardiogram including linear function of RS grinder, parabolic function of T grinder, as well as 1mB signal of rectangle form used for each channel. Mathematical processing was done for the heart bioelectric cardiogram records taking into consideration that the signal for checking particular equipment shall have the same parameters and characteristics with the input signal of the equipment. We intended to get a suitable option of control signals using coordinate method to express the heart bio-electric records through mathematical functions. Configuration was made in the following way: the beginning of the coordinates would coincide with the beginning of a whole period of a ECG, i.e. the starting point of the heart bio-electric signal would place on the X-axis. A period of the control signal is described at the

coordinate system by the first and final coordinates of the elements. If each element with number "i" is expressed by 6 measurements of b_i , x_i , y_i , x_{i+1} , y_{i+1} ; then the first and final coordinatesof the control signal elements will be x_i , y_i and x_{i+1} , y_{i+1} . For the parabolic elements, the coordinates of the extreme point will be determined as a_i (Y-axis) and b_i (X-axis). For the linear elements, a_i and b_i equal to zero, so the equation for the control signal elements can have the following form:

For parabola:

$$y = \frac{y_i - a_i}{(x_i - b_i)^2} \cdot (x - b_i)^2 + a_i$$
(1)

For linear:

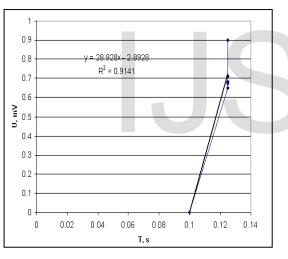
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$$y = y_i + \frac{y_{i+1} - y_i}{x_{i+1} - x_i} \cdot (x - x_i)$$
(2)

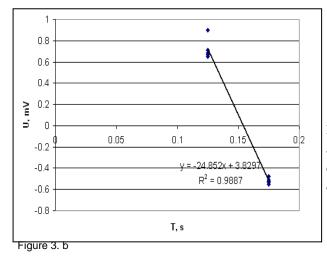
In order to develop an algorithm for the control signal, each part is required to be expressed in the form of linear and quadratic function. Therefore, let's name each part of the control signal as "element", write corresponding functions for lines and parabolas and develop algorithm. Time zones are classified as follows:

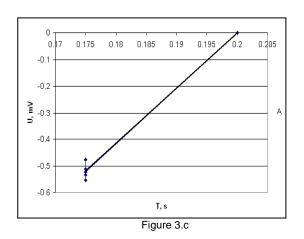
1.	Zone 1	-	(0.100 sec - 0.125sec)
2.	Zone 2	-	(0.175sec - 0.200 sec)
3.	Zone 3	-	(0.300 sec - 0.400 sec)
4.	Zone 4	-	(0.400 sec - 0.500 sec)
5.	Zone 5	-	(0.600 sec - 0.700 sec)
6.	Zone 6	-	(0.700 sec - 0.800 sec)
7.	Zone 7	-	(0.800 sec - 0.900 sec)
8.	Zone 8	-	(0.900 sec - 1.000 sec)

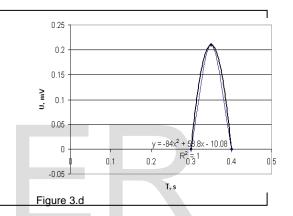
Mathematical descriptions and forms corresponding to each zone are shown in Figure 3.a-3.e.











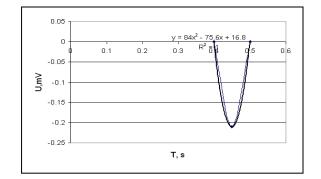


Figure 3.e Figure 3 - Elements of a sample control signal

Here:

a and b – determine the function of R grinderc - determines the function of S grinderd and e - determine the function of T grinder.

The sample control signal consists of 3 parts including grinder part described in a combination form, harmonic part and the part of rectangle pulses. A condition similar as much as possible to the description of a whole period of common ECG was considered when the order of placing these parts was set up.

The purpose of developing the sample control signal is to evaluate technical characteristics and availability of the ECGs, so these parts were transformed into clear rectangular pulses, clear linear and half-circle forms. After that, algorithm for the sample control signal development program was written considering the above 3 basic parts to have a linear part to be described on the zero line between them with the given order. Descriptions of eight functions in total were included in the algorithm and it was completed like a y=0 line to be drawn on the zero line between the functions. The block scheme of the developed algorithm is shown in Figure4.

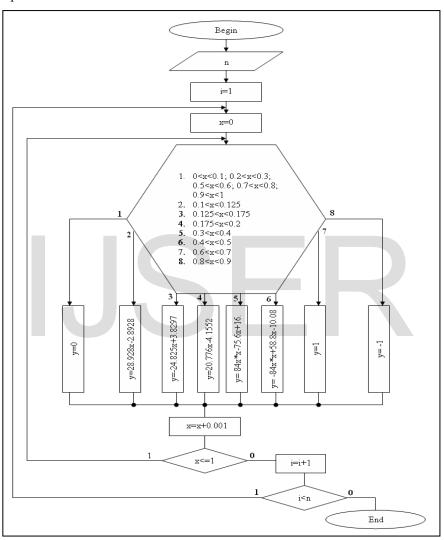


Figure 4. Algorithm for sample control signal

To form out a sample control signal for a whole period, the equations corresponding to x-values along the X-axis shall be drawn using optional operator until a whole period finishes and this shall be repeated until "n" periods finish.

CONCLUSION

The data used in this research paper are the resultsfrom the professional measurement that made for analyzing various ECGs from different parts of Mongolia and to use for diagnosis. Therefore, it can be said that one could get true and objective data covering not only ECGs, but also the results of clinical examinations and diagnostics in general. Mathematical processing was done for these data and optimal option of the sample control signal for monitoring the normal functioning of heart bioelectric cardiogram equipment was developed. The methodology of the evaluation of the function of ECG equipment being checked by the sample signal allows quick evaluation of the equipment going to be used.

Inspection of normal technical functioning and determination of the equipment's readiness for diagnosis have practical significance. Because there are various medical equipment produced in different countries with different technologies are used in Mongolia, these methods are very important to improve medical diagnostics and treatments.

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