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ELECTROCARDIOGRAM (ECG) EQUIPMENT CALIBRATION TEST LABORATORY OF NURSES STIKES AL INSYIRAH NEW PEKANBARU

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ABSTRACT

Heart disease is one of the many deadly diseases. The death rate of people due to heart disease in Indonesia is 29.1% or 17.1 million%/year. To reduce the lack of death rates caused by heart disease, by checking heart health using electrocardiogram modalities. The process of the heart's electrical activity is monitored and displayed in a graph on the monitor screen. ECG is used not only in hospitals but also in nursing laboratories as a clinical practice aid for nursing students. All medical devices must be calibrated regularly. This study shows the ECG calibration process with the aim of getting the results of whether the ECG in the STIKES Al-Insyirah Pekanbaru lab is suitable for use. The electrocardiogram used with the GE brand, type Mac 600. The method used is a direct comparison method with an electrocardiogram simulator. The test results get a voltage level calibration value with a tolerance of 5% with a value of 5.10, and 20 mm/mV. The value of the recording rate has a tolerance of 100-104 mm. while the ECG signal calibration obtained measurement results of 10 mm and is still within the tolerance limit.

Keywords: Electrocardiogram, ECG, Health, Calibration, Heart

INTRODUCTION

The heart is one of the vital organs in the human body, which functions as a blood pump to meet the needs of oxygen and nutrients throughout the body. Thus we must always do a heart check early, to avoid any heart disease.

ECG is a test to measure and record the electrical activity of the heart using an electrical impulse detector (ECG) (Library2011). This tool can interpret electrical impulses and convert them into graphs that are displayed on the monitor screen [7]. This examination is safe, fast, and painless because it is carried out without a current and without incisions (non-invasive) (Putri2016).

An EKG is performed if there are symptoms of heart disease such as chest pain, shortness of breath, fatigue, weakness, palpitations, and arrhythmias (tachycardia or bradycardia) (Ahmad2017). Tests are performed to detect heart-related health problems such as heart attack, coronary artery disease, electrolyte imbalance, addiction, and drug side effects, as well as to evaluate the effectiveness of the pacemaker used.

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Inaccurate EKG equipment causes inaccurate results of recording the heart's electrical activity [1]. It is necessary to periodically test the ECG device and calibrate it [3]. Calibration aims to support the applied quality system (Ktangante 2011). By calibrating, it can be seen how far the difference (deviation) is from the correct measuring value, measuring value on the basic principles of calibration: measuring object, measuring standard (standard calibration tool), operator/technician. Calibration results: value of measuring object, value of correction/deviation [6]. The study conducted tests on the Electrocardiogram device with the GE brand, Mac 600 type. To determine the feasibility of the instrument by periodically recalibrating the electrocardiogram, as well as recording the performance of the device with chart control to shorten the time.

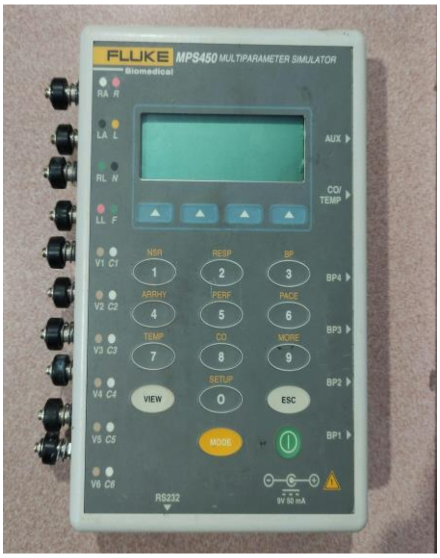

Figure 1. Fluke MPS450 ECG Simulator

RESEARCH METHODS

In this study, calibration of the Electrocardiogram (ECG) instrument with the GE brand, Type Mac 600, calibration was carried out on May 30, 2022 at the TREM LAB. A direct comparison method is required to calibrate the electrocardiogram. Calibration was carried out under environmental conditions of 25.2℃ ± 3℃ for room temperature and 58.4%RH ± 60.5% RH for humidity in the room. calibration, requires several stages of testing, namely, visual observation, calibration of the voltage level or amplitude, calibration of the recording rate, calibration of the sinusoidal signal and also the ECG signal. The research method is shown in the flowchart as follows:

Figure 2. Research Flow Chart

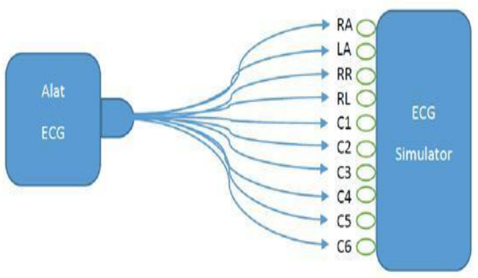

Figure 3. Electrocardiograph Calibration Flow Chart

Model calculation method
Mathematical calibration Recording Rate /
paper speed (V)

C = lstd – luut – ldrift std Where,
C : Correction of speed indication
on the measuring instrument (UUT)
lstd : Long value on standard tool
luut : The value of the length on the tool that
measured (UUT)
ldrift : drift standard
In carrying out the Calculation Analysis of uncertainty, it is necessary to know in advance about the source of uncertainty, the sensitivity coefficient is obtained from the mathematical model above, where the mathematical model has a first derivative value of 1, also regarding the degrees of freedom in each source of Type B uncertainty with a determined reliability value of 10 is = 50, Calculate the combined uncertainty, effective degrees of freedom and stretch uncertainty.

Table 1. Uncertainty Budget Amplitude

No.	Komponen	Satuan	U	Pembagi	U_i
1.	Pengukuran Berulang	Mm	∂	$\sqrt{n}$	$\frac{\partial}{\sqrt{n}}$
2.	Sertifikat Mistar	Mm	$U_{Sertf\ stand2}$	K	$\frac{U_{Sertfstd}}{K}$
3.	Drift Mistar	Mm	U_{drift2}	$\sqrt{3}$	$\frac{U_{drift}}{\sqrt{3}}$
4.	Resolusi Alat	Mm	$U_{resolusi}$	$\sqrt{3}$	$\frac{U_{res}}{\sqrt{3}}$

Table 2. Uncertainty Budget Recording Rate

No.	Komponen	Satuan	U	Pembagi	U_i
1.	Pengukuran Berulang	Mm	∂	$\sqrt{n}$	$\frac{\partial}{\sqrt{n}}$
2.	Sertifikat Mistar	Mm	$U_{Sertf\ stand2}$	K	$\frac{U_{Sertfstd}}{K}$
3.	Drift Mistar	Mm	U_{drift2}	$\sqrt{3}$	$\frac{U_{drift}}{\sqrt{3}}$
4.	Resolusi Alat	Mm	$U_{resolusi}$	$\sqrt{3}$	$\frac{U_{res}}{\sqrt{3}}$

The work is carried out according to the quality procedures that have been determined in the work method, then the calibration worksheet containing the raw data is checked by the R&D section and then the reporting process is carried out in the certificate section. The reporting process is carried out by calculating the data in an available excel document called a Budget Uncertainty (BK).

Figure 4. Performance Measurement of Electrocardiograph (ECG)

Figure 4 is a measurement of the performance of the GE Brand Electrocardiogram (ECG), MAC 600 type.

RESULTS AND DISCUSSION

The data from the calibration of the electrocardiogram instrument is divided into 7 tables, namely, data on facilities and equipment, data on measuring instruments used, environmental conditions, physical and functional testing of the electrocardiogram, electrical safety test of the electrocardiogram instrument, measuring the performance of the electrocardiogram, and uncertainty analysis in measuring the performance of the electrocardiogram.

Data Collection of Facilities and Tools

Data collection of facilities and equipment is the first step in performing instrument calibration (ECG). Data collection is carried out to ensure that the tools and facilities used are in accordance with applicable procedures and to avoid errors in reporting and labeling the status of the equipment. Data collection includes owner status, tool brand, type, serial number, date of calibration, place of calibration, room, and calibration officer.

Table 3. Data of Facilities and Tools

Name of the owner	STIKES AL-INSYIRAH PEKANBARU
Brand	GE
Model/Type	MAC 600
No. Series	SS518210006PA
Calibration Date	May 30, 2022
Calibration Site	TREM LAB
Room	CLINICAL EQUIPMENT LAB
Calibration Officer	Dilken

Measuring tools used

Data collection of measuring instruments used includes the brand, type and series of tools. Measuring tools used in insulation resistance and can also simulate an electrocardiogram (ECG) signal. Leakage current standard, the test power used to test the safety (safety) of an electrically based health or hospital equipment. Withstand earth protection (Protective Earth Resistance), power commonly used in testing medical equipment for safety is referred to IEC 60601-1 series : Medical Electrical Equipment. electricity based disease.

Table 4. Measuring Instrument Data

No	Tool's name	Brand	Type	Series
1	*ONE*	Fluke	615	1522012
2	*ECG*Simulator	Fluke	MPS450	149205
3	Steel Ruler	-	-	S19008754
4	*Thermohygrometer*	Greisinger	GFTB 100	021210-01

Figure 5. Electrical Safety Analyzer

In Figure 5. There is an Electrical Safety Analyzer, which is a test tool used to test the safety of an electrically based health or hospital equipment. Tests that can be done are leakage current, protective earth resistance, insulation resistance and can also simulate electrocardiogram (ECG) signals. Standards commonly used in testing medical equipment for safety are referred to IEC 60601-1

Figure 6. ECG Simulator

In figure 6. There is an ECG Simulator tool which is a tool to record the electrical activity of the heart at a certain time (during the examination). The electrocardiograph does not directly assess cardiac contractility, but it can provide a comprehensive indication of the rise and fall of cardiac contractility. The ECG consists of a differential bioelectric amplifier. The electrocardiogram works on the principle of measuring the difference in electrical potential. The human body produces electricity even in very small amounts. If there is electricity, then there must be a potential difference or electric voltage. This electric voltage can describe or illustrate the state of the human heart beat.

Figure 7.Thermohygrometer

In Figure 7 there is a Thermohygrometer which is a tool used to measure temperature and humidity in a room. This tool has two measurement indicators, namely a thermometer and a hygrometer. A thermometer is a tool used to measure temperature (temperature), or changes in temperature. The term thermometer comes from the Latin thermo meaning heat and meter meaning to measure. The most commonly seen unit of measurement is the degree Celsius (C). Hygrometer is a tool used to calculate the percentage of water vapor (dew) in the air, or more simply a tool to measure the level of humidity in the air. The unit of measurement for Hygrometer is Percentage (%). The higher the percentage, the higher the humidity, and vice versa.

Environmental Condition Measurement Results

Measurement of environmental conditions was carried out using a Thermohygrometer. Measurements include room temperature, room humidity, input voltage LN, N-Earth, and L-earth. When compared with the data obtained in table 5, the environmental conditions do not meet the requirements for calibration data collection and this will certainly affect the quality of the ECG performance measurement data.

Table 5. Measurement of Environmental Conditions

Parameter	MEASURED	
1.Room Temperature	Starting : 25.4	End : 25.6
2. Room Humidity	Initial : 49%	End : 49%
3. Input Voltage LN	208.1 Vac	Vdc
N-Earth Input Input Voltage	209.1 Vac	
Input Voltage L-earth	1.8 Vac	

Physical Test Results and Functions of Electrocardiogram (ECG) Equipment

In table 6, the physical test and the function of the tool include the body and surface of the tool, the tool contact box, the main power supply cable, safety fuse, switch and control buttons, tubes and hoses after observations are functioning properly.

Table 6. Physical Test and Tool Function

No	Parameter	Examination Limits	Observation result
1	Body and Surface	The enclosure is intact, clean, tightly attached to one another and has no traces of falling liquid or other disturbances.	1
2	Toolbox	Check if there is interference in the box (AC-Power). The movement of the box box to ensure its safety. Shake the box to make sure there are no bolts.	1
3	Main supply cable	Check the cable for any visible damage, or peeling of the insulation.	1
4	Safety fuse	Check the fuse located on the outside of the circuit, whether the resistance value and type are in accordance with the specifications written on the tool. The safety fuse must work properly.	1

Electrical Safety Test Results

Electrical safety measurement is divided into 5 parameters. All parameter measurement results have met the existing requirements.

Table 7. Electrical Safety Test

No.	Parameter	Measured		Threshold
1	Insulation resistance	OL	MΩ	> 2 MΩ
2	Direct method equipment leakage current (class I type B/BF/CF)	93.3	□	≤500
3	Applied part leakage current-direct method (CF)	0.0	□	≤50
4	Protective earth resistance:	0	mΩ	≤300 MΩ
5	Using DC power source			

Tool Performance Measurement Results Electrocardiogram (ECG) Visual observation 12 leads

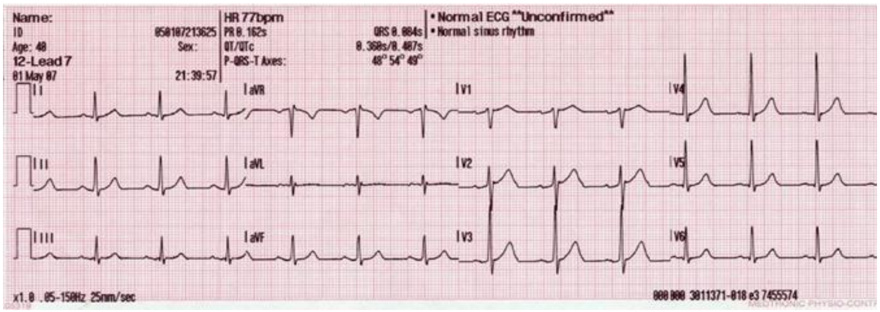

Figure 8. Normal appearance of a sine wave rhythm on a 12 lead ECG

Table 8. Input : 60 BPM, Vpaper : 25 mm/sec

LEAD	I	II	III	AVL	AVF	AVR	V1	V2	V3	V4	V5	V6
Observation Results	1	1	1	1	1	1	1	1	1	1	1	1

Table 9 is the result of direct calibration/raw data direct reading of visual observation parameters. Based on the results obtained, it shows that visually it has good results and is clearly visible and there is no vibration. The results of the calibration of the voltage/amplitude level are shown in table 10, the measurements were carried out 3 times, with a tolerance value of ± 5% on each measurement.

Table 9. Calibration of Voltage Level at Recording Rate of 25 mm/s and Input Amplitude ECG Simulator 1 mV Resolution : 1

ECG Gain Setting (mm/m)	Input Pulse Height Amplitude (mm)	Measurement results					5% tolerance±
		I	II	II	IV	V	
5	5	5	5	5	5	5	4.75 - 5.25
10	10	10	10	10	10	10	9.5 - 10.5
20	20	20	20	20	20	20	19 – 22

For the calibration results at the recording rate in table 10 has a value of width pulse/standard value of 100 mm with measurement results that have a tolerance of 5% ± 100 - 107 which means it has a small error value

Table 10. Record Rate Calibration at 25 mm/s and 50 mm/s

ECG Simulator settings (bpm)	ECG Simulator Pulse Width (mm)	Measurement results					Allowable deviation ± 5%
		I	II	III	IV	V	
120	100.0	104	104	104	104	104	100 – 107
120	100.0	100	100	100	100	100	

The next table is table 11. The results of the calibration of the ECG signal with a tolerance value of ± 5%.

Table 11. Normal ECG signal calibration at position : 60 BPM, ECG Simulator Amplitude 2mV, gain 20 mm/mV

Recording Rate (mm/s)	RS Amplitude Height (mm)	Measurement results					Allowable deviation
		I	II	III	IV	V	
25	10	7	7	7	7	7	± 5%

Based on the measurement results in tables 8 to 11, it shows that the calibration results have accurate measurements with tolerances for each measurement parameter. The next step is to analyze the calibration results with calibration calculations on the uncertainty budget of each parameter.

Calibration Test Analysis

From the results of the calibration calculation in the uncertainty budget for each calibration stage:

Table 12. Analysis of Voltage Level Calibration Results

UUT settings (mm/mV)	Measurement Results (mm/mV)	Correction Result (mm/mV)	Uncertainty	Tolerance
5	5	8.85	2.20	5%
10	10	9.84	2.20	5%
20	20	19.84	2.20	5%

Table 13 is an analysis of the results of the calibration of the voltage level measurement, based on table 1, it is found that the uncertainty of the voltage/amplitude level calibration measurement is 2.20 for each measurement repeated 3

Table 13. Analysis of Recording Rate Calibration Results

UUT settings (mV)	Standard settings	Measurement result (mm/mV)	Correction result (mm/mV)	Uncertainty	Tolerance (%)
25	120	104	103.72	1.1	5%
50	120	100	100.25	1.1	5%

The results of the analysis of the calibration results on the recording rate on the measurement results carried out to analyze the results of the recording rate calibration on the measurement results 2 times obtained 104 mm/mV and 100 mm/mV the uncertainty value is 1.1. while in Table 14 the analysis of the calibration results on the ECG signal with a measurement result of 7 mm and the correction result is 6.84 mm/mV the uncertainty value is 0.68.

Table 14. Analysis of ECG Signal Calibration Results

UUT settings (mV)	ECG gain (mm/mV)	Measurement result (mm)	Correction result (mm/mV)	Uncertainty	Toleranc e%
2	20	7	6.84	0.68	5%

CONCLUSION

Based on the results of calibration and analysis of uncertainty in each measurement parameter, namely the calibration of voltage levels, recording rates, ECG signals with a tolerance value of 5%, it can be concluded that the Electrocardiogram (ECG) medical device is declared suitable for use.

SUGGESTION

Always make repairs to the electrocardiogram device and calibrate it regularly so that the correct measurement results are obtained and there is no error in performing the examination using the electrocardiogram.

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