



TECHNOLOGY PROMOTION ASSOCIATION (THAILAND-JAPAN)
CORPORATE SERVICES 3 : EQUIPMENT CALIBRATION AND TESTING SERVICES

534/4 PATTANAKARN ROAD SOI 18, SUANLUANG, SUANLUANG BANGKOK 10250

TEL. 0-2717-3000-29 FAX. 0-2719-9484

Cert. No.: 23MD774

Page.: 1 of 5

Certificate of Calibration

Equipment : Electrical Safety Analyzer

Model : ESA615

Serial No. : 3494034

ID No. : ELSA002

Manufacturer : Fluke Biomedical

Submitted by : National Healthcare Systems Co.,Ltd.
2301/2 New Petchburi Soi 47 (Soonvijai),
Bangkapi, Huaykwang, Bangkok 10310

Place of calibration : TPA Medical Equipment Calibration Lab.

Ambient temperature : (23 ± 2) °C

Relative humidity : (50 ± 15) %

Calibrated by : Natjika Kaewmadeengam

Approved by :



Approved signatory

- () Malee Butkruea
(☒) Surin Yenprasert
() Nattachai Sawangkunnopchai

Issue date : 19 June 2023

The Uncertainties are for a confidence probability of approximately 95%.

This certificate may not be reproduced other than in full, except with the prior written approval of the head of Calibration and Testing Equipment Services.

A 0011293



Received order : 6 June 2023
Condition as received : Used item
Calibration date : 7 June 2023
Reference : 2306-0124WSC-3

Cert. No.: 23MD774

Page.: 2 of 5

Procedure used :-

Calibration was conducted using in-house calibration procedure : CP-MD06 and CP-MD09, according to directed measurement method.

Conditions of this result of calibration

1. Reference standard instrument :-

<u>Instrument</u>	<u>Model</u>	<u>Serial No.</u>	<u>Cert. No.</u>	<u>Due date</u>
1) Multi-Product Calibrator	5502A	2737801	22E1373	25 Oct 2023
2) Digital Multimeter	34410A	MY53002082	22E2922	1 Sep 2023
3) Decade Resistance Box	HARS-X-6-0.001	E1-14364931	22E2800	22 Aug 2023
4) High Resistance Tester	HRRS-Q-4-100K	B2-1434646	ER-0155-22	23 Dec 2024
5) Oscilloscope	DSO-X2012A	MY61410106	23E41	9 Jan 2024

2. The certificate is valid only to the item calibrated on date and place of calibration.

3. This result of calibration was made on requested at the point specified by customer.

4. This certification is traceable to the International System of Units, through :-

- National Institute of Metrology (Thailand), through Technology Promotion Association (Thailand-Japan)
- National Institute of Metrology (Thailand)

Result of calibration : Without adjustment

Function : Patient aux current

Port of UUC*	Applied DC Current (μA)	UUC* Reading (μA)	UUC* Error (μA)	Uncertainty (\pm μA)
-	open	0.4	0.4	0.11
RA & LL	20.00	19.7	-0.3	0.11
RA & LA	20.00	19.7	-0.3	0.11
RA & RL	20.00	19.7	-0.3	0.11
RA & V1	20.00	19.7	-0.3	0.11

UUC* : Unit Under Calibration



Cert. No.: 23MD774

Page.: 3 of 5

Result of calibration : Without adjustment

Function : Patient leakage current

Port of UUC* : Lead RA & Earth (outlet)

Applied DC Current (μA)	UUC* Reading (μA)	UUC* Error (μA)	Uncertainty ($\pm \mu\text{A}$)
open	0.4	0.4	0.11
10.00	9.7	-0.3	0.11
50.00	49.8	-0.2	0.11
100.00	99.9	-0.1	0.11
500.0	501	1	0.68
1000.0	1002	2	0.68

Result of calibration : Without adjustment

Function : Enclosure leakage current

Port of UUC* : Red connector & Earth (outlet)

Applied DC Current (μA)	UUC* Reading (μA)	UUC* Error (μA)	Uncertainty ($\pm \mu\text{A}$)
open	0.4	0.4	0.11
10.00	9.7	-0.3	0.11
50.00	49.8	-0.2	0.11
100.00	99.9	-0.1	0.11
500.0	501	1	0.68
1000.0	1002	2	0.68

UUC* : Unit Under Calibration



Result of calibration : Without adjustment

Cert. No.: 23MD774

Function : Earth leakage current

Page.: 4 of 5

Port of UUC* : Mains ground & Earth (outlet)

Standard Reading (μA)	UUC* Reading (μA)	UUC* Error (μA)	Uncertainty ($\pm \mu\text{A}$)
998.550	1000	1.450	0.87

Result of calibration : Without adjustment

Function : Protective earth resistance

Port of UUC* : Red connector & Earth (outlet)

Applied Resistance (Ω)	UUC* Reading (Ω)	UUC* Error (Ω)	Uncertainty ($\pm \Omega$)
0.00076	0.000	-0.00076	0.0087
0.22085	0.222	0.00115	0.0087
0.50062	0.502	0.00138	0.0087
1.00139	1.005	0.00361	0.0087
1.50139	1.508	0.00661	0.0097
2.00166	2.008	0.00634	0.0097

Result of calibration : Without adjustment

Function : Mains voltage / Point to point

Port of UUC* : Red connector & Black connector

Applied voltage @ 50 Hz (V)	UUC* Reading (V)	UUC* Error (V)	Uncertainty ($\pm \text{V}$)
220.000	220.0	0.000	0.15

UUC* : Unit Under Calibration



Result of calibration : Without adjustment

Function : Insulation @ 500 VDC (A.P.-PE)

Port of UUC* : Lead RA & Earth (outlet)

Cert. No.: 23MD774

Page.: 5 of 5

Applied Resistance ($M\Omega$)	UUC* Reading ($M\Omega$)	UUC* Error ($M\Omega$)	Uncertainty ($\pm M\Omega$)
2	2.0	0.0	0.058
5	5.0	0.0	0.059
10	10.0	0.0	0.063
20	19.9	-0.1	0.074
50	49.7	-0.3	0.14
100	99.0	-1.0	0.27

Result of calibration : Without adjustment

Function : ECG Wave simulation

Port of UUC* : Lead LL & Lead RA

UUC* Setting (BPM)	Standard Reading (Hz)	Convert to ECG (BPM)	UUC* Error (BPM)	Uncertainty (\pm BPM)
30	0.5000	30.0	0.0	0.18
60	1.000	60.0	0.0	0.15
120	2.000	120.0	0.0	0.28

Scale and conversion factor is 1 Hz = 60 BPM

UUC* : Unit Under Calibration

The reported uncertainty of measurement was based on a standard uncertainty multiplied by a coverage factor ($k = 2$), providing a level of confidence of approximately 95 %.

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