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



# Certificate of Calibration

| | |
|---|---|
| **Equipment :** | Electrical Safety Analyzer |
| **Model :** | ESA615 |
| **Serial No. :** | 2856013 |
| **ID No. :** | ELSA004 |
| **Manufacturer :** | FLUKE BIOMEDICAL |
| **Submitted by :** | National Healthcare Systems Co.,Ltd.<br>2301/2 New Petchburi Soi 47 (Soonvijai),<br>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

( ) Pornthippa Tameyakul
(✓) Surin Yenprasert
( ) Nattachai Sawangkunnopchai

**Issue date :** 26 December 2023

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

**Received order :** 8 December 2023
**Condition as received :** Used item
**Calibration date :** 12 December 2023
**Reference :** 2312-0182WSC-17



**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 :-

| Instrument | Model | Serial No. | Cert. No. | Due date |
|---|---|---|---|---|
| 1) Multi-Product Calibrator | 5502A | 2737801 | 23E3267 | 12 Oct 2024 |
| 2) Digital Multimeter | 34410A | MY53002082 | 23EH17 | 28 Aug 2024 |
| 3) Decade Resistance Box | HARS-X-6-0.001. | E1-23096027 | 20230307-82837 | 07 Mar 2024 |
| 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 ( ± µA ) |
|---|---|---|---|---|
| - | open | 0.6 | 0.6 | 0.11 |
| RA & LL | 20.00 | 19.5 | -0.5 | 0.11 |
| RA & LA | 20.00 | 19.5 | -0.5 | 0.11 |
| RA & RL | 20.00 | 19.5 | -0.5 | 0.11 |
| RA & V1 | 20.00 | 19.5 | -0.5 | 0.11 |

**UUC* :** Unit Under Calibration

**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 ( ± μA ) |
|---|---|---|---|
| open | 0.6 | 0.6 | 0.11 |
| 10.00 | 9.5 | -0.5 | 0.11 |
| 50.00 | 49.6 | -0.4 | 0.11 |
| 100.00 | 99.8 | -0.2 | 0.11 |
| 500.0 | 501 | 1 | 0.68 |
| 1000.0 | 1003 | 3 | 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 ( ± μA ) |
|---|---|---|---|
| open | 0.6 | 0.6 | 0.11 |
| 10.00 | 9.5 | -0.5 | 0.11 |
| 50.00 | 49.6 | -0.4 | 0.11 |
| 100.00 | 99.8 | -0.2 | 0.11 |
| 500.0 | 501 | 1 | 0.68 |
| 1000.0 | 1003 | 3 | 0.68 |

**UUC* :** Unit Under Calibration

**Result of calibration :** Without adjustment
**Function :** Earth leakage current
**Port of UUC* :** Mains ground & Earth (outlet)

| Standard Reading ( μA ) | UUC* Reading ( μA ) | UUC* Error ( μA ) | Uncertainty ( ± μA ) |
|---|---|---|---|
| 996.858 | 1000 | 3.142 | 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 ( ± Ω ) |
|---|---|---|---|
| 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 | 1.004 | 0.00261 | 0.0087 |
| 1.50139 | 1.505 | 0.00361 | 0.0097 |
| 2.00166 | 2.006 | 0.00434 | 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 ( ± 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)

| Applied Resistance ( MΩ ) | UUC* Reading ( MΩ ) | UUC* Error ( MΩ ) | Uncertainty ( ± MΩ ) |
|---|---|---|---|
| 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 | 49.8 | -0.2 | 0.14 |
| 100 | 99.2 | -0.8 | 0.24 |

**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 ( ± 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 %.

-o0o-