



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.: 23MD775

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Certificate of Calibration

Equipment : Defibrillator / Transcutaneous Pacer Analyzer

Model : IMPULSE 7000DP

Serial No. : 2079335

ID No. : DEFA002

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.

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Received order : 6 June 2023
Condition as received : Used item
Calibration date : 7 June 2023
Reference : 2306-0124WSC-5

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Procedure used :-

Calibration was conducted using in-house calibration procedure : CP-MD05 & CP-MD06 base on Service Manual of UUC, according to direct measurement method for resistance, DC voltage and frequency. The energy measurement perform by indirect 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) Digital Multimeter	8846A	5339019	23EH1	26 Apr 2024
2) 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)

Result of checking : Without adjustment

Test description	Result
Firmware version	2.06
Visual inspection	Pass
Battery capacity	After charge 6 hours = 65 %
Battery charge indicator status	Pass
Fan test ON / OFF	Pass
Key test	Pass
Active test	Pass



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Result of calibration : Without adjustment

Calibration step	Port of UUC*	UUC* Nominal Value	Standard Reading	UUC* Error	Uncertainty	Tolerances Limits
Defib. Load Resistance	Apex & Sternum	(Ω) 50	(Ω) 49.9514	(Ω) 0.0486	($\pm \Omega$) 0.011	($\pm \Omega$) 0.50
Pacer Load Resistance	Pacer (+) & (-)	(Ω) 50	(Ω) 50.1840	(Ω) -0.1840	($\pm \Omega$) 0.011	($\pm \Omega$) 1.0
		100	99.8810	0.1190	0.017	2.0
		150	149.905	0.095	0.030	3.0
		250	249.358	0.642	0.041	5.0
		450	448.439	1.561	0.064	9.0
		850	846.907	3.093	0.11	17.0
		1500	1494.00	6.00	0.30	30.0

UUC* : Unit Under Calibration



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Result of calibration : Without adjustment

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Calibration step	Port of UUC*	UUC* Nominal Value	Standard Reading	UUC* Error	Uncertainty	Tolerances Limits
Lead 1 ECG Voltage	RA & LA	(mV)	(mV)	(mV)	(± mV)	(± mV)
		7.0000	7.0457	-0.0457	0.0044	0.49
		0.7000	0.7024	-0.0024	0.0041	0.049
Lead 1 Attenuator IN	RA & LA	(mV)	(mV)	(mV)	(± mV)	(± mV)
		-6.7000	-6.6787	-0.0213	0.0044	0.335
Lead 1 Attenuator OUT	RA & LA	(V)	(V)	(V)	(± V)	(± V)
		-0.4690	-0.4666	-0.0024	0.00010	0.023
Lead 1 Voltage Ratio	RA & LA	(V / V)	(V / V)	(V / V)	(± V / V)	(± V / V)
		10.0000	10.0910	-0.0910	0.016	0.300
Lead 2 ECG Voltage	RA & LL	(mV)	(mV)	(mV)	(± mV)	(± mV)
		10.0000	9.9963	0.0037	0.0046	0.20
		1.0000	0.9998	0.0002	0.0041	0.020
Lead 2 Attenuator IN	RA & LL	(mV)	(mV)	(mV)	(± mV)	(± mV)
		-10.0000	-10.0730	0.0730	0.0045	0.500
Lead 2 Attenuator OUT	RA & LL	(V)	(V)	(V)	(± V)	(± V)
		-0.7000	-0.7025	0.0025	0.00010	0.035
Lead 2 Voltage Ratio	RA & LL	(V / V)	(V / V)	(V / V)	(± V / V)	(± V / V)
		10.0000	10.0400	-0.0400	0.016	0.300

UUC* : Unit Under Calibration

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Result of calibration : Without adjustment

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Calibration step	Port of UUC*	UUC* Nominal Value	Standard Reading	UUC* Error	Uncertainty	Tolerances Limits
Lead 3 ECG Voltage	LA & LL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		3.000	2.9510	0.0490	0.0042	0.21
		0.300	0.2978	0.0022	0.0041	0.021
Lead 3 Attenuator IN	LA & LL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-3.300	-3.3960	0.0960	0.0042	0.165
Lead 3 Attenuator OUT	LA & LL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.231	-0.23591	0.00491	0.000087	0.012
Lead 3 Voltage Ratio	LA & LL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0372	-0.0372	0.016	0.300
Lead V1 ECG Voltage	V1 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		10.000	10.0077	-0.0077	0.0046	0.70
		1.000	0.9986	0.0014	0.0041	0.070
Lead V1 Attenuator IN	V1 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-6.700	-6.7157	0.0157	0.0044	0.335
Lead V1 Attenuator OUT	V1 & RL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.469	-0.4683	-0.0007	0.000092	0.023
Lead V1 Voltage Ratio	V1 & RL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0670	-0.0670	0.016	0.300
Lead V2 ECG Voltage	V2 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		10.000	9.9430	0.0570	0.0046	0.70
		1.000	0.9925	0.0075	0.0041	0.070
Lead V2 Attenuator IN	V2 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-6.700	-6.7150	0.0150	0.0044	0.335
Lead V2 Attenuator OUT	V2 & RL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.469	-0.4688	-0.0002	0.000092	0.023
Lead V2 Voltage Ratio	V2 & RL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0670	-0.0670	0.016	0.300

UUC* : Unit Under Calibration

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Result of calibration : Without adjustment

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Calibration step	Port of UUC*	UUC* Nominal Value	Standard Reading	UUC* Error	Uncertainty	Tolerances Limits
Lead V3 ECG Voltage	V3 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		10.000	9.9940	0.0060	0.0046	0.70
		1.000	1.0013	-0.0013	0.0041	0.070
Lead V3 Attenuator IN	V3 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-6.700	-6.75067	0.05067	0.0044	0.335
Lead V3 Attenuator OUT	V3 & RL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.469	-0.4688	-0.0002	0.000092	0.023
Lead V3 Voltage Ratio	V3 & RL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0285	-0.0285	0.016	0.300
Lead V4 ECG Voltage	V4 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		10.000	9.9647	0.0353	0.0046	0.70
		1.000	0.9944	0.0056	0.0041	0.070
Lead V4 Attenuator IN	V4 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-6.700	-6.7200	0.0200	0.0044	0.335
Lead V4 Attenuator OUT	V4 & RL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.469	-0.4685	-0.0005	0.000092	0.023
Lead V4 Voltage Ratio	V4 & RL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0680	-0.0680	0.0156	0.300
Lead V5 ECG Voltage	V5 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		10.000	9.9720	0.0280	0.0046	0.70
		1.000	0.9958	0.0042	0.0041	0.070
Lead V5 Attenuator IN	V5 & RL	(mV)	(mV)	(mV)	(\pm mV)	(\pm mV)
		-6.700	-6.7570	0.05700	0.0044	0.335
Lead V5 Attenuator OUT	V5 & RL	(V)	(V)	(V)	(\pm V)	(\pm V)
		-0.469	-0.4688	-0.0002	0.000092	0.023
Lead V5 Voltage Ratio	V5 & RL	(V / V)	(V / V)	(V / V)	(\pm V / V)	(\pm V / V)
		10.000	10.0629	-0.0629	0.016	0.300

UUC* : Unit Under Calibration

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Result of calibration : Without adjustment

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Calibration step	Port of UUC*	UUC* Nominal Value	Standard Reading	UUC* Error	Uncertainty	Tolerances Limits
Lead V6 ECG Voltage	V6 & RL	(mV) 10.000	(mV) 10.0090	(mV) -0.0090	(± mV) 0.0046	(± mV) 0.70
		1.000	0.9990	0.0010	0.0041	0.070
Lead V6 Attenuator IN	V6 & RL	(mV) -6.700	(mV) -6.7230	(mV) 0.0230	(± mV) 0.0044	(± mV) 0.335
Lead V6 Attenuator OUT	V6 & RL	(V) -0.469	(V) -0.4676	(V) -0.0014	(± V) 0.000092	(± V) 0.023
Lead V6 Voltage Ratio	V6 & RL	(V / V) 10.000	(V / V) 10.0701	(V / V) -0.0701	(± V / V) 0.016	(± V / V) 0.300
Apex-Sternum ECG Voltage	Apex & Sternum	(mV) 7.0000	(mV) 6.9353	(mV) 0.0647	(± mV) 0.0044	(± mV) 0.49
		0.7000	0.6935	0.0065	0.0041	0.049
Apex-Sternum Voltage Ratio	Apex & Sternum	(V / V) 10.0000	(V / V) 10.0484	(V / V) -0.0484	(± V / V) 0.016	(± V / V) 0.300
Scope Output Volt. Peak to Peak	Scope Output	(V) 8.0000	(V) 7.9080	(V) 0.0920	(± V) 0.00029	(± V) 0.40
Scope Output Volt. RMS	Scope Output	(V) 0.8839	(V) 0.8723	(V) 0.0116	(± V) 0.00029	(± V) 0.0442
Hi Level ECG Volt. Peak to Peak	High Level ECG	(V) 8.0000	(V) 7.9210	(V) 0.0790	(± V) 0.00029	(± V) 0.40
Hi Level ECG Volt. RMS	High Level ECG	(V) 0.8839	(V) 0.8738	(V) 0.0101	(± V) 0.00029	(± V) 0.0442

Note : Tolerances limits according to manufacturer specification.

UUC* : Unit Under Calibration



Result of calibration : Without adjustment

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Function : Biphasic energy measurement

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Port of UUC*	Applied Energy	UUC* Reading	UUC* Error	Uncertainty
	(Joules)	(Joules)	(Joules)	(\pm Joules)
Apex & Sternum	5.09	5.0	-0.09	0.061
	50.97	50.6	-0.37	0.14
	101.66	100.9	-0.76	0.28
	152.63	151.3	-1.33	0.39
	203.81	201.9	-1.91	0.55
	307.46	303.9	-3.56	0.78
	368.91	364.2	-4.71	0.93

Result of calibration : Without adjustment

Function : ECG Simulation

Port of UUC*	UUC* Setting	Standard Reading	Convert to Heart rate	UUC* Error	Uncertainty
	(BPM)	(Hz)	(BPM)	(BPM)	(\pm BPM)
High Level ECG Output	30	0.500	30.0	0.0	0.015
	60	1.000	60.0	0.0	0.015
	90	1.500	90.0	0.0	0.017
	120	2.000	120.0	0.0	0.015
	240	4.000	240.0	0.0	0.15
	300	5.000	300.0	0.0	0.15

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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