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 :	Vital Signs Simulator
Model :	ProSim 8
Serial No. :	2848050
ID No. :	VTSS004
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

( ) 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-11

Procedure used :-

Calibration was conducted using in-house calibration procedure : CP-MD15, according to direct measurement method with Oscilloscope and Digital Multimeter. Performed pressure measurement by using in-house calibration procedure : CP-MD04 based on Guideline DKD-R 6-1 edition 03/2014, according to comparison method against Digital Manometer, using clean air as pressure media.

SpO2 Simulation testing was conducted using in-house testing procedure : WI-MD06 based on Service Manual of UUT, according to comparison method.

Conditions of this result of calibration

1. Reference standard instrument :-

Instrument	Model	Serial No.	Cert. No.	Due date
1) Oscilloscope	DSO-X2012A.	MY51290571	23E1507	9 May 2024
2) Digital Multimeter	34410A	MY53002082	23EH17	28 Aug 2024
3) Digital Manometer	767363.	91P330788	MP-0115-23	6 Jun 2025
4) Vital Signs Simulator	ProSim 8.	5978505	23MD1630	1 Nov 2024
5) Pulse Oximeter	PM10N	MBP 2118625	23MD40	10 Jan 2024
6) Pulse Oximeter	SPECTRO2 10	4050883	23MD1075	7 Aug 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 : ECG Simulation **Port of UUC* :** High level output

UUC* Setting (BPM)	Standard Reading (Hz)	Convert to Heart rate (BPM)	UUC* Error (BPM)	Uncertainty (± BPM)
30	0.5000	30.0	0.0	0.015
60	1.0000	60.0	0.0	0.015
120	2.000	120.0	0.0	0.046
180	3.000	180.0	0.0	0.16
240	4.00	240.0	0.0	0.38
300	5.00	300.0	0.0	0.38

Scale and conversion factor is 1 Hz = 60 BPM

UUC* : Unit Under Calibration

Result of calibration : Without adjustment

Function : IBP / Static

Port of UUC*	UUC* Setting (mmHg)	Standard Reading (mV)	Convert to Pressure (mmHg)	UUC* Error (mmHg)	Uncertainty (± mmHg)
IBP 1	0	0.00000	0.000	0.000	0.18
	50	1.23846	49.538	0.462	0.18
	100	2.48378	99.351	0.649	0.18
	240	5.96888	238.755	1.245	0.18
IBP 2	50	1.23936	49.574	0.426	0.17
	100	2.48790	99.516	0.484	0.17

Scale and conversion factor is 1 mmHg = 0.025 mV

Result of calibration : Without adjustment

Function : Temperature output **Port of UUC* :** TEMP

UUC* Sensor type	UUC* Setting (°C)	Standard Reading (kΩ)	Convert to Temp. (°C)	UUC* Error (°C)	Uncertainty (± °C)
YSI 400 @ 25°C = 2252 Ω	37.0	1.35768	36.952	0.048	0.0051
	40.0	1.20150	39.963	0.037	0.0054
YSI 700 T1 @ 25°C = 6000 Ω	37.0	3.60339	37.035	-0.035	0.0037
	40.0	3.19138	40.028	-0.028	0.0039
YSI 700 T2 @ 25°C = 30000 Ω	37.0	18.2105	36.992	0.008	0.0046
	40.0	16.1580	39.982	0.018	0.0048

Result of calibration : Without adjustment

Calibration step : ECG / Performance / Pulse amplitude

Port of UUC* : High level output

UUC* Setting (mV)	Standard Reading (mV)	UUC* Error (mV)	Uncertainty (± mV)
0.5	0.4961	0.0039	0.0042
1.0	0.9980	0.0020	0.0042
2.0	1.9976	0.0024	0.0042

UUC* : Unit Under Calibration

Result of calibration : Without adjustment

Function : Baseline respiration

Port of UUC* : LL & RA

UUC* Nominal value (kΩ)	Standard Reading (kΩ)	UUC* Error (kΩ)	Uncertainty (± kΩ)
0.5	0.49702	0.00298	0.00010
1.0	1.00442	-0.00442	0.00015
1.5	1.51043	-0.01043	0.00030
2.0	2.01698	-0.01698	0.00036

Result of calibration : Without adjustment

Function : Baseline respiration

Port of UUC* : LA & RA

UUC* Nominal value (kΩ)	Standard Reading (kΩ)	UUC* Error (kΩ)	Uncertainty (± kΩ)
0.5	0.49273	0.00727	0.000080
1.0	1.00013	-0.00013	0.00013
1.5	1.50617	-0.00617	0.00031
2.0	2.01243	-0.01243	0.00036

Result of calibration : Without adjustment

Calibration step : ECG / Performance wave

Port of UUC* : RA & LL

UUC* Setting		Standard Reading	UUC* Error	Uncertainty
Waveform	(Hz)	(Hz)	(Hz)	(± Hz)
Triangle wave	2.0	1.9998	0.0002	0.00077
Square wave	2.0	2.0000	0.0000	0.00063

UUC* : Unit Under Calibration

Result of calibration : Without adjustment

Function : Static pressure measurement

Mode : Manometer

Applied Pressure (mmHg)	Mean of UUC* Reading (mmHg)	UUC* Error (mmHg)	Uncertainty (± mmHg)
0.00	0.0	0.0	0.25
50.00	49.9	-0.1	0.25
100.00	99.9	-0.1	0.25
150.00	149.9	-0.1	0.25
200.00	199.9	-0.1	0.25
250.00	249.7	-0.3	0.25
300.00	299.6	-0.4	0.25
350.00	349.5	-0.5	0.25
400.00	399.5	-0.5	0.25

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 %.

Result of testing : Without adjustment

Function : SpO2 Simulation

This equipment was connected to the SpO2 Module Model: ProSim SPOT, S/N: 2842081

UUT* Setting (BPM)	Measure Value (BPM)	UUT* Deviation (BPM)	Tolerances Limits (± BPM)	Result
240	240	0	2	Pass
180	180	0	2	Pass
120	120	0	1	Pass
80	80	0	1	Pass
60	60	0	1	Pass
30	30	0	1	Pass

UUT* : Unit Under Testing

Result of testing : Without adjustment

Cert. No.: 23MD1863

Function : SpO2 Simulation

This equipment was connected to the SpO2 Module Model: ProSim SPOT, S/N: 2842081

Type setting : Nellcor

Ambient light : Off

UUT* Setting ($\%SpO_2$)	Measure Value ($\%SpO_2$)	UUT* Deviation ($\%SpO_2$)	Tolerances Limits ($\pm \%SpO_2$)	Result
99	99	0	1	Pass
95	95	0	1	Pass
90	90	0	1	Pass
85	85	0	2	Pass
80	80	0	2	Pass
75	75	0	2	Pass

Type setting : BCI

Ambient light : Off

UUT* Setting ($\%SpO_2$)	Measure Value ($\%SpO_2$)	UUT* Deviation ($\%SpO_2$)	Tolerances Limits ($\pm \%SpO_2$)	Result
99	99	0	1	Pass
95	95	0	1	Pass
90	90	0	1	Pass
85	85	0	2	Pass
80	81	-1	2	Pass
75	76	-1	2	Pass

Note : Tolerances limits according to TPA Medical Equipment Calibration Laboratory specification.

UUT* : Unit Under Testing

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