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. :	2541031
ID No. :	VTSS002
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.

Received order : 6 June 2023
Condition as received : Used item
Calibration date : 7 June 2023
Reference : 2306-0124WSC-8

Procedure used :-

Calibration was conducted using in-house calibration procedure : CP-MD06 and CP-MD07, 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	MY61410106	23E41	9 Jan 2024
2) Digital Multimeter	34410A	MY53002082	22E2922	1 Sep 2023
3) Digital Manometer	767363	91N232251	MP-0125-22	8 Aug 2024
4) Vital Signs Simulator	ProSim 8	2730880	22MD1694	20 Dec 2023
5) Pulse Oximeter	PM10N	MBP 2118625	23MD40	10 Jan 2024
6) Pulse Oximeter	SPECTRO2 10	4050883	22MD1014	11 Aug 2023

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	0.5001	30.0	0.0	0.016
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	0.15
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

Cert. No.: 23MD777

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	1.24144	49.658	0.342	0.18
	100	2.49270	99.708	0.292	0.18
	240	5.99440	239.776	0.224	0.18
IBP 2	50	1.25302	50.121	-0.121	0.17
	100	2.50744	100.298	-0.298	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	1.35483	37.003	-0.003	0.0051
	40.0	1.19633	40.070	-0.070	0.0055
YSI 700 T1 @ 25°C = 6000 Ω	37.0	3.61118	36.982	0.018	0.0037
	40.0	3.19606	39.991	0.009	0.0038
YSI 700 T2 @ 25°C = 30000 Ω	37.0	18.1966	37.011	-0.011	0.0046
	40.0	16.1441	40.004	-0.004	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	0.4956	0.0044	0.0042
1.0	0.9995	0.0005	0.0042
2.0	1.9998	0.0002	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	0.49787	0.00213	0.000080
1.0	1.00351	-0.00351	0.00013
1.5	1.50924	-0.00924	0.00030
2.0	2.01448	-0.01448	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	0.49800	0.00200	0.000090
1.0	1.00349	-0.00349	0.00013
1.5	1.50887	-0.00887	0.00030
2.0	2.01455	-0.01455	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	2.000	0.000	0.00063
Square wave	2.0	2.000	0.000	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	50.0	0.0	0.25
100.00	99.9	-0.1	0.25
150.00	149.8	-0.2	0.25
200.00	199.8	-0.2	0.25
250.00	249.6	-0.4	0.25
300.00	299.6	-0.4	0.25
350.00	349.5	-0.5	0.25
400.00	399.4	-0.6	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 Test Module Model : ProSim SPOT , S/N : 2556046

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.: 23MD777

Function : SpO2 Simulation

This equipment was connected to the SpO2 Test Module Model : ProSim SPOT , S/N : 2556046

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	75	0	2	Pass

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

UUT* : Unit Under Testing

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