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LABORATORY LOCATION:
(PERMANENT LABORATORY)

BIOMEDICAL CALIBRATION LABORATORY
BELL COMM TECHNOLOGIES SDN. BHD.
2ND FLOOR, SUITE 2.02, BANGUNAN BASIC 8
LORONG 19/1A
46300 PETALING JAYA
SELANGOR
MALAYSIA

FIELDS OF CALIBRATION:

ELECTRICAL, PRESSURE, FLOW & VOLUME,
TEMPERATURE

This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).

This laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001 (see Joint ISO-ILAC-IAF Communiqué dated April 2017).

* The uncertainty covered by the CMC is expressed as the expanded uncertainty corresponding to a coverage probability of approximately 95 % and have a coverage factor of $k=2$ unless stated otherwise.

SCOPE OF CALIBRATION: ELECTRICAL

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
Measuring Instrument			Generating using Calibrator (Fluke: 5522A)
i. DC Voltage	1 V to 250 V	0.1 V	
ii. DC Current (Leakage Current)	10 μ A to 100 μ A 101 μ A to 10000 μ A	0.1 μ A 1 μ A	
iii. AC Voltage	<u>At 50 Hz</u> 1 V to 400 V	0.1 V	
iv. AC Current (Leakage Current)	<u>At 50 Hz</u> 10 μ A to 100 μ A 101 μ A to 10000 μ A	0.1 μ A 1 μ A	

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SCOPE OF CALIBRATION: ELECTRICAL

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
v. AC Current Consumption	<u>At 50 Hz</u> 1.0 A to 10 A	0.1 A	Measurement by using multimeter
vi. Resistance	0 m Ω to 2000 m Ω	1 m Ω	DC Resistor Box
	2 M Ω to 100 M Ω 190 M Ω	0.1 M Ω 1.1 M Ω	DC Resistor Box
Patient Simulator a) Frequency	0.125 Hz to 3 Hz 0.5 Hz to 3 Hz 5 Hz to 10 Hz 40 Hz to 60 Hz	0.0015 Hz 0.002 Hz 0.0081 Hz 0.042 Hz	Calibrated using Fluke 190M-2 Medical Scopemeter
b) Heart Rate	30 bpm to 200 bpm	0.2 bpm	Calibrated using Fluke 190M-2 Medical Scopemeter
c) Pulse Amplitude	0.5 mV to 5 mV	0.12 mV	Multi product Multimeter/ Fluke 190M-2 Medical Scopemeter
d) DC Voltage	1 mV to 120 mV	0.12 mV	Calibrator 5522A and Multimeter
e) Resistance	200 Ω to 2 K Ω 2 K Ω to 20 K Ω	0.4 Ω 0.06 K Ω	Calibrated using Multimeter

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SCOPE OF CALIBRATION: ELECTRICAL

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
Defibrillator Analyzer			
a) Load Resistance	25 Ω to 200 Ω	0.007 Ω	Calibrated using Multimeter/ Fluke 190M-2 Medical Scopemeter
b) Energy	2 Joules to 100 Joules 101 Joules to 360 Joules	0.13 Joules 0.20 Joules	Calibrated using Fluke 190M-2 Medical Scopemeter and Current Shunt
c) ECG Amplitude	1 mV to 5 mV	0.012 mV	Multi product Multimeter/ Fluke 190M-2 Medical Scopemeter
d) Frequency	50 mHz to 999 mHz 1 Hz to 10 Hz 11 Hz to 200 Hz	1 mHz 0.002 mHz 0.040 Hz	Calibrated using Fluke 190M-2 Medical Scopemeter
e) Heart Rate	30 bpm to 250 bpm	0.2 bpm	Calibrated using Fluke 190M-2 Medical Scopemeter
Pace Maker Analyzer			
a) Load Resistance	200 Ω 500 Ω 1000 Ω	0.01 Ω 0.03 Ω 0.07 Ω	Calibrated using Multimeter/ Fluke 190M-2 Medical Scopemeter
b) Pulse Rate	80 ppm	0.3 ppm	Calibrated using Fluke 190M-2 Medical Scopemeter
c) Pulse Width	1 ms	0.33 ms	Calibrated using Fluke 190M-2 Medical Scopemeter
d) Current, Pulse	1 mA pk 4 mA pk 10 mA pk 20 mA pk	0.002 mA pk 0.06 mA pk 0.04 mA pk 0.08 mA pk	Calibrated using Fluke 190M-2 Medical Scopemeter

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SCOPE OF CALIBRATION: ELECTRICAL

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
e) Sensitivity Amplitude	1 mV pk 5 mV pk 50 mV pk	0.07 mV pk 0.08 mV pk 0.2 mV pk	Calibrated using Fluke 190M-2 Medical Scopemeter
Electrosurgical Analyzer a) Load Resistance	50 Ω to 500 Ω	0.02 Ω	Calibrated using Multimeter/ Fluke 190M-2 Medical Scopemeter
b) RF Current	200 mA to 800 mA (up to 200 MHz)	1.6 mA	Calibrated using Fluke 190M-2 Medical Scopemeter and Current Shunt
c) RF Voltage p-p	200 V pp to 700 V pp (up to 200 MHz)	1.7 to 2 V pp	Calibrated using Fluke 190M-2 Medical Scopemeter and Current Shunt
d) RF Power	25 W to 200 W (up to 200 MHz)	0.16 W	Calibrated using Fluke 190M-2 Medical Scopemeter and Current Shunt

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SCOPE OF CALIBRATION: PRESSURE

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
Patient Simulator a) Pressure	7 mbar to 532 mbar	3.0 mbar	Calibrated using Pressure Calibrator
Ventilator Analyzer a) Low Pressure	10 mbar to 667 mbar	3.0 mbar	Calibrated using Pressure Calibrator
b) High Pressure	70 mbar to 7 bar	3.0 mbar	
c) Airway Pressure	-100 mbar to -10 mbar 10 mbar to 100 mbar	1.0 mbar 3.0 mbar	
Infusion Device Analyzer a) Pressure	70 mbar to 3.0 bar	8.0 mbar	Calibrated using Pressure Calibrator
Parameter Tester a) Pressure	-700 mbar to 7 bar	8.0 mbar	Calibrated using Pressure Calibrator

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SCOPE OF CALIBRATION: FLOW & VOLUME

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
Ventilator Analyzer a) Gas Volume	100 mL to 1000 mL 1000 mL to 3000 mL	7 mL 16 mL	Comparison with Calibration Syringe
Infusion Device Analyzer a) Liquid Volume	1 mL to 50 mL	0.15 mL	Comparison with Burette
b) Liquid Flow Rate	10 mL/h – 1000 mL/h	0.16 mL/h	Comparison with Burette and Stop Watch

SCOPE OF CALIBRATION: TEMPERATURE

Instrument Calibrated/ Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ($\pm$)*	Remarks
a) Thermocouple Type-K	33 °C to 300 °C	0.4 °C	Comparison with Temperature Calibrator
b) Thermistor	33 °C to 50 °C	0.4 °C	