



SCOPE OF ACCREDITATION

Laboratory Name :

DEPARTMENT OF BIOMEDICAL ENGINEERING, CHRISTIAN MEDICAL COLLEGE, #4, IDA SCUDDER ROAD, VELLORE, TAMIL NADU, INDIA

Accreditation Standard Certificate Number Validity

ISO/IEC 17025:2017 CC-3631 07/07/2023 to 06/07/2025

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S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrument	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
		1.0	Site Facility		
1	MECHANICAL- ACCELERATION AND SPEED	Centrifuge, RPM Indicator of Shaker and Mixer	Using Digital Tachometer by Comparison method	50 RPM to 13300 RPM	9.3%
2	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Breath Rate - BiPAP	Using Gas Flow Analyzer by Direct Method	8 BPM to 30 BPM	1.56 % to 1.25 %
3	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Earth Resistance of Patient Monitor, Fetal Monitor, Syringe Pump, Electrosurgical Unit, Infusion Pump, Ventilator, BiPAP, ECG, Defibrillator, Anaesthesia Machine, Radiant Warmer, Autoclave, Baby Incubator, Dialysis Machine, EEG	Using Electrical Safety analyser by Direct Method	0.098 ohm to 1.8 ohm	0.021 ohm





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4	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Earth/Enclosure Leakage Current of Patient Monitor, Fetal Monitor, Syringe Pump, Electrosurgical Unit, Infusion Pump, Ventilator, BiPAP, ECG, Defibrillator, Anaesthesia Machine, Radiant Warmer, Autoclave, Baby Incubator, Dialysis Machine, EEG	Using Electrical Safety analyser by Direct Method	0.1 mA to 0.8 mA	2.52 % to 1.82 %
5	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Inspiratory Pressure - BiPAP	Using Gas Flow Analyzer by Direct Method	8 cmH2O to 20 cmH2O	1.16cmH2O





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6	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Insulation Resistance of Patient Monitor, Fetal Monitor, Syringe Pump, Electrosurgical Unit, Infusion Pump, Ventilator, BiPAP, ECG, Defibrillator, Anaesthesia Machine, Radiant Warmer, Autoclave, Baby Incubator, Dialysis Machine, EEG	Using Electrical Safety analyser by Direct Method	10 Mohm to 100 Mohm	4.81 % to 8.97 %
7	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Load Current of Patient Monitor, Fetal Monitor, Syringe Pump, Electrosurgical Unit, Infusion Pump, Ventilator, BiPAP, ECG, Defibrillator, Anaesthesia Machine, Radiant Warmer, Autoclave, Baby Incubator, Dialysis Machine, EEG	Using Electrical Safety analyser by Direct Method	0.1 A to 15 A	0.28A





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8	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Occlusion Pressure - Infusion Pump	Using Infusion Analyzer by Direct Method	300 mmHg to 900 mmHg	23.06 % to 4.18 %
9	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Occlusion Pressure - Syringe Pump	Using Infusion Analyzer by Direct Method:	150 mmHg to 900 mmHg	22.13 % to 3.41 %
10	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Patient Leakage Current of Patient Monitor, Fetal Monitor, Syringe Pump, Electrosurgical Unit, Infusion Pump, Ventilator, BiPAP, ECG, Defibrillator, Anaesthesia Machine, Radiant Warmer, Autoclave, Baby Incubator, Dialysis Machine, EEG	Using Electrical Safety analyser by Direct Method	1 uA to 8 mA	11.78 % to 1.17 %
11	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Positive End Expiratory Pressure - BiPAP	Using Gas Flow Analyzer by Direct Method	4 cmH2O to 10 cmH2O	0.59cmH2O





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12	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Volume - Infusion Pump	Using Infusion Analyzer by Direct Method	1 ml to 1200 ml	5.29 % to 2.31 %
13	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Volume - Syringe Pump	Using Infusion Device Analyzer by Comparison Method:	1 ml to 50 ml	5.05 % to 1.31 %
14	MEDICAL DEVICES- IMAGING/PLOT TERS	ECG Rate - ECG Machine	Using Vital sign patient simulator by Direct Method:	30 BPM to 296 BPM	2.63 % to 1.8 %
15	MEDICAL DEVICES- MONITORING UNIT	ECG Rate - Fetal Monitor	Using Vital Sign Simulator by Direct Method	30 BPM to 240 BPM	2.63 % to 1.81 %
16	MEDICAL DEVICES- MONITORING UNIT	ECG Rate - Patient Monitor	Using Vital Sign Simulator by Direct method	30 BPM to 300 BPM	2.63 % to 1.8 %
17	MEDICAL DEVICES- MONITORING UNIT	IBP - Patient Monitor	Using Vital Sign Simulator by Direct Method	0 mmHg to 120 mmHg	1.29 mmHg to 5.45 mmHg
18	MEDICAL DEVICES- MONITORING UNIT	NIBP - Patient Monitor	Using Vital Sign Simulator by Direct Method	15 mmHg to 200 mmHg	4.46 % to 1.85 %





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19	MEDICAL DEVICES- MONITORING UNIT	Pulse Rate - Patient Monitor	Using Vital Sign Simulator by Direct Method	30 brpm to 240 brpm	3.85 % to 2.64 %
20	MEDICAL DEVICES- MONITORING UNIT	Respiration Rate - Patient Monitor	Using Vital Sign Simulator by Direct Method	12 brpm to 100 brpm	7.61 % to 5.93 %
21	MEDICAL DEVICES- MONITORING UNIT	SPO2 - Patient Monitor	Using Vital Sign Simulator by Direct Method	70 % to 100 %	11.27 % to 8.07 %
22	MEDICAL DEVICES- MONITORING UNIT	Temperature - Patient Monitor	Using Vital Sign Simulator by Direct Method	30 °C to 42 °C	0.62 °C to 0.69 °C
23	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Breath Rate - Ventilator	Using Gas Flow Analyzer by Direct Method	6 BPM to 40 BPM	1.39 % to 1.73 %
24	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Charging Time/ Sync Time - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	38 ms to 5 s	4.73 % to 3.86 %





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25	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	ECG Rate - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method:	30 BPM to 300 BPM	2.46 % to 1.54 %
26	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	2 J to 270 J	9 % to 3.67 %
27	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	High Frequency Leakage Current - Electrosurgical Unit	Using Electrosurgical Analyzer by Direct Method	10 miili Ampere to 100 miili Ampere	16.93 % to 4.65 %
28	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Inspiratory Oxygen Concentrator - Ventilator	Using Gas Flow Analyzer by Direct Method	21 % to 100 %	14.77 % to 3.02 %
29	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Power - Electrosurgical Unit	Using Electrosurgical Analyzer by Direct Method	1 watt to 300 watt	1.22 watt to 16.08 watt





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30	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Current - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	8 mA to 200 mA	2.61 % to 2.32 %
31	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	30 PPM to 180 PPM	1.00 % to 0.64 %
32	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Positive End Expiratory Pressure - Ventilator	Using Gas Flow Analyzer by Direct Method	0 cmH2O to 40 cmH2O	0.58cmH2O
33	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Tidal Volume - Ventilator	Using Gas Flow Analyzer by Direct Method	2 ml to 1500 ml	6.86 % to 4.1 %





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34	THERMAL- TEMPERATURE	Temperature Indicator of Deep Freezer, Freezer, Hot air oven, Incubator, water Bath, Refrigerator, Chiller, Sterilizer, Cold Room, Refrigerator Centrifuge	Using Digital Thermometer with Sensor by Comparison method	-80 °C to +110 °C	0.75°C

* CMCs represent expanded uncertainties expressed at approximately the 95% level of confidence, using a coverage factor of k = 2.