



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

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

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-3631

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Validity

07/07/2025 to 06/07/2029

Last Amended on

20/08/2025

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)(±)
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	4.65 % to 0.51 %
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Breath Rate - BiPAP	Using Gas Flow Analyzer by Direct Method	8 BPM to 30 BPM	1.55 % to 7.75 %
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Earth Resistance of BP Apparatus (Sphygmomanometer),Nebulizer (Electric),Syringe Pump,Infusion Pump,Enteral Feeding Pump,CPAP,BiPAP,Boyles Apparatus,Anesthesia Machine	Using Electrical Safety analyser by Direct Method	0.098 ohm to 1.8 ohm	0.032 ohm
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Earth/Enclosure Leakage Current of BP Apparatus (Sphygmomanometer),Nebulizer (Electric),Syringe Pump,Infusion Pump,Enteral Feeding Pump,CPAP,BiPAP,Boyles Apparatus,Anesthesia Machine,Incubator	Using Electrical Safety analyser by Direct Method	10 µA to 0.8 mA	2.91 µA to 9.75 µA



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5	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Infusion Pump (Flow)	Using Infusion Analyzer by Direct Method	60 ml/hr to 1000 ml/hr	2.38 % to 2.45 %
6	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Inspiratory Pressure - BiPAP	Using Gas Flow Analyzer by Direct Method	8 cmH2O to 20 cmH2O	0.10 cmH2O to 0.58 cmH2O
7	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Insulation Resistance - 500 V DC of Nebulizer (Electric),Syringe Pump,Infusion Pump,Enteral Feeding Pump,CPAP,BiPAP,Bo yles Apparatus,Anesthesi a Machine,Patient Conditioning Equipment,Incubator	Using Electrical Safety analyser by Direct Method 500 V DC	10 Mohm to 100 Mohm	8.97 % to 12.87 %
8	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Load Current of Syringe Pump,Infusion Pump,Enteral Feeding Pump,CPAP,BiPAP,Bo yles Apparatus,Anesthesi a Machine,Patient Conditioning Equipment,Incubator	Using Electrical Safety analyser by Direct Method	0.2 A to 15 A	29.7 %



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9	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Occlusion Pressure - Infusion Pump	Using Infusion Analyzer by Direct Method	300 mmHg to 900 mmHg	11.99 % to 3.04 %
10	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Occlusion Pressure - Syringe Pump	Using Infusion Analyzer by Direct Method:	150 mmHg to 900 mmHg	28.81 % to 3.76 %
11	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Patient Leakage Current of Nebulizer (Electric),Syringe Pump,Infusion Pump,Enteral Feeding Pump,CPAP,BiPAP,Bo yles Apparatus,Anesthesi a Machine,Patient Conditioning Equipment,Incubator	Using Electrical Safety analyser by Direct Method	10 μ A to 8 mA	2.91 μ A to 2.99 μ A
12	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Positive End Expiratory Pressure - BiPAP	Using Gas Flow Analyzer by Direct Method	4 cmH2O to 10 cmH2O	0.58 cmH2O to 0.11 cmH2O
13	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Syringe Pump (Flow)	Using Infusion Analyzer by Direct Method	60 ml/hr to 400 ml/hr	2.41 % to 1.21 %
14	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DE VICES	Volume - Infusion Pump	Using Infusion Analyzer by Direct Method	1 ml to 400 ml	6.51 % to 2.31 %



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15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Syringe Pump	Using Infusion Device Analyzer by Comparison Method:	1 ml to 50 ml	7.19 % to 1.79 %
16	MEDICAL DEVICES-IMAGING/PLOTTERS	Earth / Enclosure Leakage of Trans illuminator light source, EEG, Fetal Doppler, ECG, X-Ray Diagnostic Equipment	Using Electrical Safety analyser by Direct Method	10 μ A to 0.8 mA	2.91 μ A to 9.75 μ A
17	MEDICAL DEVICES-IMAGING/PLOTTERS	Earth Resistance of Trans illuminator light source, EEG, Fetal Doppler, ECG, X-Ray Diagnostic Equipment	Using Electrical Safety analyser by Direct Method	0.098 ohm to 1.8 ohm	0.032 ohm
18	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Rate - ECG Machine	Using Vital sign patient simulator by Direct Method:	30 BPM to 296 BPM	3.21 % to 1.75 %
19	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance - 500 V DC - Trans illuminator light source, EEG, Fetal Doppler, ECG, X-Ray Diagnostic Equipment	Using Electrical Safety analyser by Direct Method 500 V DC	10 M ohm to 100 M ohm	8.97 % to 12.87 %
20	MEDICAL DEVICES-IMAGING/PLOTTERS	Load Current of Trans illuminator light source, EEG, Fetal Doppler, ECG, X-Ray Diagnostic Equipment	Using Electrical Safety analyser by Direct Method	0.2 A to 15 A	29.7 %



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21	MEDICAL DEVICES-IMAGING/PLOTTERS	Patient Leakage Current of Trans illuminator light source, EEG, Fetal Doppler, ECG, X-Ray Diagnostic Equipment	Using Electrical Safety analyser by Direct Method	10 μ A to 8 mA	2.91 μ A to 2.99 μ A
22	MEDICAL DEVICES-MONITORING UNIT	Earth / Enclosure Leakage of Patient Monitors, Apnea Monitors, Fetal Monitor, Therapeutic Stimulator, Weighing Scale, Hematology Analyser	Using Electrical Safety analyser by Direct Method	10 μ A to 0.8 mA	2.91 μ A to 9.75 μ A
23	MEDICAL DEVICES-MONITORING UNIT	Earth Resistance of Patient Monitors, Apnea Monitors, Fetal Monitor, Therapeutic Stimulator, Weighing Scale, Hematology Analyser	Using Electrical Safety analyser by Direct Method	0.098 ohm to 1.8 ohm	0.032 ohm
24	MEDICAL DEVICES-MONITORING UNIT	ECG Rate - Fetal Monitor	Using Vital Sign Simulator by Direct Method	30 BPM to 240 BPM	3.21 % to 1.75 %
25	MEDICAL DEVICES-MONITORING UNIT	ECG Rate - Patient Monitor	Using Vital Sign Simulator by Direct method	30 BPM to 300 BPM	3.21 % to 1.75 %
26	MEDICAL DEVICES-MONITORING UNIT	IBP - Patient Monitor	Using Vital Sign Simulator by Direct Method	0 mmHg to 120 mmHg	6.4 %



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27	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance - 500 V DC - Patient Monitors, Apnea Monitors, Fetal Monitor, Therapeutic Stimulator, Weighing Scale, Hematology Analyser	Using Electrical Safety analyser by Direct Method 500 V DC	10 M ohm to 100 M Ohm	8.97 % to 12.87 %
28	MEDICAL DEVICES-MONITORING UNIT	Load Current of Patient Monitors, Apnea Monitors, Fetal Monitor, Therapeutic Stimulator, Weighing Scale, Hematology Analyser	Using Electrical Safety analyser by Direct Method	0.2 A to 15 A	29.7 %
29	MEDICAL DEVICES-MONITORING UNIT	NIBP - Patient Monitor	Using Vital Sign Simulator by Direct Method	15 mmHg to 200 mmHg	6.78 % to 1.16 %
30	MEDICAL DEVICES-MONITORING UNIT	Patient Leakage current of Patient Monitors, Apnea Monitors, Fetal Monitor, Therapeutic Stimulator, Weighing Scale, Hematology Analyser	Using Electrical Safety analyser by Direct Method	10 μ A to 8 mA	2.91 μ A to 2.99 μ A
31	MEDICAL DEVICES-MONITORING UNIT	Pulse Rate - Patient Monitor	Using Vital Sign Simulator by Direct Method	30 brpm to 240 brpm	12.54 % to 3.97 %
32	MEDICAL DEVICES-MONITORING UNIT	Respiration Rate - Patient Monitor	Using Vital Sign Simulator by Direct Method	12 brpm to 100 brpm	9.07 % to 5.85 %



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33	MEDICAL DEVICES-MONITORING UNIT	SPO2 - Patient Monitor	Using Vital Sign Simulator by Direct Method	70 % to 100 %	11.27 % to 4.91 %
34	MEDICAL DEVICES-MONITORING UNIT	Temperature - Patient Monitor	Using Vital Sign Simulator by Direct Method	30 °C to 42 °C	1.82 % to 1.30 %
35	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Breath Rate - Anaesthesia Workstation	Using Gas Flow Analyzer by Direct Method	6 BPM to 40 BPM	3.36 % to 7.32 %
36	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Breath Rate - Ventilator	Using Gas Flow Analyzer by Direct Method	6 BPM to 40 BPM	3.35 % to 1.18 %
37	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Charging Time/ Sync Time - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	38 ms to 5 s	5.18 % to 2.65 %
38	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Earth / Enclosure Leakage of Defibrillator, Ventilator, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Heart Lung Machine, Patient Warmer, OT Table, Radiant Warmer, Phototherapy Unit	Using Electrical Safety analyser by Direct Method	10 µA to 0.8 mA	2.91 µA to 9.75 µA

This is annexure to 'Certificate of Accreditation' and does not require any signature.



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39	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Earth Resistance of Autoclave, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine/ Cautery Machine, External Pace Maker, Electronic Tourniquet, Dialysis Machine, Heart Lung Machine, Pat	Using Electrical Safety analyser by Direct Method	0.098 Ohm to 1.8 ohm	0.032 ohm
40	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	ECG Rate - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method:	15 BPM to 300 BPM	6.16 % to 1.77 %
41	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	2 J to 270 J	9.86 % to 5.03 %
42	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	High Frequency Leakage Current - Electrosurgical Unit @ 448 kHz	Using Electrosurgical Analyzer by Direct Method	10 mA to 100 mA	4.27 mA to 5.55 mA
43	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Inspiratory Oxygen Concentrator - Ventilator	Using Gas Flow Analyzer by Direct Method	21 % to 100 %	3.40 % to 2.32 %



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44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance - 500 V DC, Defibrillator,Ventilat or, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Heart Lung Machine, Patient Warmer, OT Table,Radiant Warmer, Phototherapy Un	Using Electrical Safety analyser by Direct Method 500 V DC	10 M Ohm to 100 M Ohm	8.97 % to 12.87 %
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Load Current of Defibrillator,Ventilat or, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Heart Lung Machine, Patient Warmer, OT Table,Radiant Warmer, Phototherapy Unit.	Using Electrical Safety analyser by Direct Method	0.2 A to 15 A	29.7 %
46	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Output Power - Electrosurgical Unit	Using Electrosurgical Analyzer by Direct Method	1 W to 300 W	1.38 W to 22.61 W
47	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	OXYGEN CONCENTRATION - Anesthesia Workstation	Using Gas Flow Analyzer by Direct Method	21 % to 100 %	2.77 %



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48	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Current - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	10 mA to 140 mA	5.76 % to 2.79 %
49	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defibrillator/ Pacemaker Analyzer by Direct Method	30 PPM to 180 PPM	2.23 % to 1.53 %
50	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Patient Leakage Current of Defibrillator,Ventilat or, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Heart Lung Machine, Patient Warmer, OT Table,Radiant Warmer, Phototherapy Unit	Using Electrical Safety analyser by Direct Method	10 μ A to 8 mA	2.91 μ A to 2.99 μ A
51	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Positive End Expiratory Pressure - Ventilator	Using Gas Flow Analyzer by Direct Method	0 CMH2O to 35 CMH2O	0.59 cmH2O to 0.35 cmH2O
52	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Positive End Expiratory Pressure - Anaesthesia Workstation	Using Gas Flow Analyzer by Direct Method	0 cmH2O to 30 cmH2O	0.26 cmH2O to 0.27 cmH2O



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53	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Tidal Volume - Anaesthesia Workstation	Using Gas Flow Analyzer by Direct Method	50 ml to 1000 ml	3.42 % to 2.12 %
54	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Tidal Volume - Ventilator	Using Gas Flow Analyzer by Direct Method	50 ml to 1000 ml	3.42 % to 2.12 %
55	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 +130 °C	1.18 °C

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