



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

BIO VISION MEDICAL SYSTEMS, NO 49&50, SECOND FLOOR, SAMUVEL NAGAR, CHENNAI, CHENNAI, TAMIL NADU, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-3182

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Validity

12/11/2024 to 11/11/2028

Last Amended on -

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)(±)
Permanent Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	FiO2 (Anesthesia, Ventilator, Oxygen Concentrator)	Using Gas Flow Analyser by Direct Method	21 % to 100 %	0.5 % to 2.3 %
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Flowmeters, Oxygen Concentrator)	Using Gas Flow Analyser by Direct Method	1 lpm to 15 lpm	0.09 lpm to 0.46 lpm
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Nebulisers)	Using Gas Flow Analyser by Direct Method	1 lpm to 15 lpm	0.09 lpm to 0.46 lpm
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Syringe Pump)	Using Infusion Analyser by Direct method	1 ml/hr to 1000 ml/hr	0.12 ml/hr to 22.63 ml/hr
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Boyles, Flowmeter	Using Gas Flow Analyser by Direct Method	1 lpm to 30 lpm	0.09 lpm to 0.87 lpm
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Infusion Pump, Feeding Pump	Using Infusion Analyser by Direct method	1 ml/hr to 1000 ml/hr	0.12 ml/hr to 28 ml/hr
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Gauge Pressure - Boyles, Anesthesia, Compressor	Using Gas Flow Analyser by Direct Method	0 psi to 150 psi	1.23 %



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8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Inspiratory Time (Ti), Expiratory Time (Te), Pause Time (Tp) for I:E Ratio - Anesthesia, Ventilator, BiPAP	Using Gas Flow Analyser by Direct Method	0.4 sec to 5.5 sec	0.02 sec to 0.14 sec
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Insulation Resistance - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Leakage Current (Enclosure, Earth, Patient) - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	10 µA to 1000 µA	7.5 % to 2.42 %
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure (Infusion Pump/Feeding Pump)	Using Infusion Analyser by Direct method	1 psi to 30 psi	3.15 %
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure (Syringe Pump)	Using Infusion Analyser by Direct method	1 psi to 30 psi	3.15 %



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13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (IPAP/EPAP, CPAP) - BiPAP, CPAP	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (Static, Dynamic, Relief) - BP Apparatus	Using BP Pump Pressure Analyser by Direct Method	10 mmHg to 400 mmHg	0.95 % to 0.6 %
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - CPAP	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - PEEP, PIP, Mean Airway Pressure (Anesthesia, Ventilator)	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure Gauge (Oxygen Cylinder, Autoclave, Central Line Pressure, Manifold)	Using Gas Flow Analyser by Direct Method	-10 psi to 150 psi	1.23 %
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Protective Earth Resistance - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49%



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19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - Pulse Oximeter	Using SpO2 Simulator by Simulation Method	30 bpm to 250 bpm	2.2 bpm to 5.3 bpm
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate (Anesthesia, Ventilator, BiPAP)	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	2.6 % to 4.15 %
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate - BiPAP/CPAP	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	2.6 % to 4.15 %
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	SpO2 - Pulse Oximeter	Using SpO2 Simulator by Simulation Method	60 % to 100 %	2.63 % to 3.62 %
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Vacuum Pressure - Suction/Wall Suction/Manifold	Using Gas Flow Analyser by Direct Method	-10 psi to 0 psi	0.14 psi
24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Voltage @50Hz - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.9 V



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25	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume (Syringe Pump)	Using Infusion Analyser by Direct method	1 ml to 60 ml	0.06 ml to 1.41 ml
26	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume (Tidal Volume, Minute Volume) - Anesthesia, Ventilator, BiPAP	Using Gas Flow Analyser by Direct Method	0.010 litres to 25 litres	0.001 litres to 1.2 litres
27	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Infusion Pump/Feeding Pump	Using Infusion Analyser by Direct method	1 ml to 500 ml	0.06 ml to 11.58 ml
28	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Heart Rate	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	4.84 % to 1.24 %
29	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Output Amplitude	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2 mV	0.17 mV to 0.21 mV
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Fetal Heart Rate - Fetal Doppler	Using Fetal Simulator by Direct Method	30 bpm to 240 bpm	3.99 % to 3.5 %
31	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %



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32	MEDICAL DEVICES-IMAGING/PLOTTERS	Leakage Current (Enclosure, Earth, Patient) - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	7.5 % to 2.42 %
33	MEDICAL DEVICES-IMAGING/PLOTTERS	Light Intensity - Light Source/Spot Light/Examination Light	Using Digital Luxmeter by Direct Method	100 lux to 25000 lux	20 lux to 2988 lux
34	MEDICAL DEVICES-IMAGING/PLOTTERS	Protective Earth Resistance - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %
35	MEDICAL DEVICES-IMAGING/PLOTTERS	Voltage - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V
36	MEDICAL DEVICES-MEDICAL DEVICE ANALYZER/SIMULATOR EQUIPMENT	Amplitude - fECG/mECG - Fetal Simulator	Using Amplifier and Oscilloscope by direct method	0.5 mV to 5.0 mV	5.37 % to 3.83 %
37	MEDICAL DEVICES-MEDICAL DEVICE ANALYZER/SIMULATOR EQUIPMENT	Current - ESU Analyser/Diathermy Analyser/Cautery Analyser	Using Oscilloscope by Comparative Method	50 mA to 1500 mA	3.51 %



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38	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	ECG Output Amplitude - ECG Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator, Defib/Pacer Analyser	Using Amplifier and Oscilloscope by direct method	0.5 mV to 5.0 mV	5.37 % to 3.83 %
39	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Energy - Defib/Pacer Analyser	Using Oscilloscope by Direct Method	2 J to 300 J	0.16 J to 9.86 J
40	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Fetal (fHR) and Maternal (mHR) Heart Rate/Frequency	Using Amplifier and Oscilloscope by direct method	30 bpm to 300 bpm	0.67 bpm to 3.51 bpm
41	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	FiO2 - Ventilator Analyser/Flow Analyser/FiO2 Analyser	Using Certified Oxygen Cylinder Direct Method	21 % to 100 %	1.15 % to 3.76 %
42	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Heart Rate - ECG Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator, Defib/Pacer Analyser	Using Amplifier and Oscilloscope by Direct Method	30 bpm to 300 bpm	0.67 bpm to 3.51 bpm



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43	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	IBP - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using 6.1/2 Digital Multimeter by Direct Method	10 mmHg to 300 mmHg	2 %
44	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Infusion Device Analyzer-Flow Rate	Using Weighing balance, Stopwatch by Gravimetric method	1 ml/hr to 1500 ml/hr	1.88 % to 1.23 %
45	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Infusion Device Analyzer - Occlusion Pressure	Using Pressure Calibrator, pressure source by Comparison method	2 psi to 50 psi	4.23 % to 1.3 %
46	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Infusion Device Analyzer - Volume	Using Weighing balance by Weighing method	1 ml to 500 ml	1.5 % to 0.5 %
47	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Inspiratory Time (Ti)/Expiratory Time (Te) - Ventilator Analyser/Flow Analyser	Using Oscilloscope by Direct Method	0.41 sec to 5.60 sec	0.01 sec to 0.07 sec



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48	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Irradiance - Irradiancemeter	Using Irradiancemeter by Comparison Method	0 μ W/cm ² /nm to 100 μ W/cm ² /nm	4.62 %
49	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Load - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using 6.1/2 Digital Multimeter by Direct Method	50 ohm to 1550 ohm	0.58 ohm to 0.69 ohm
50	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Load/Variable Load - Defib/Pacer Analyser	Using 6.1/2 Digital Multimeter by Direct Method	50 ohm to 1500 ohm	0.58 ohm to 0.69 ohm
51	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Output Power - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using ESU as source and Oscilloscope by Comparison Method	1 W to 500 W	0.15 W to 9.54 W
52	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pacer Output Amplitude - Defib/Pacer Analyser, Pacemaker Analyser	Using Source and 6.1/2 Digital Multimeter by Comparison Method	4 mA to 35 mA	0.01 mA to 0.05 mA



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53	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pacer Rate - Defibrillator/ Analyser, Pacemaker Analyser	Using Oscilloscope by Comparison Method	30 PPM to 200 PPM	0.35 PPM to 2.44 PPM
54	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pressure - Vital Sign Simulator/Monitor Simulator/ Pressure Analyser/ Multiparameter Simulator	Using Digital Manometer by Direct method	10 mmHg to 400 mmHg	1 % to 0.4 %
55	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pulse Rate - SpO2 Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using Amplifier and Oscilloscope by Direct Method	30 bpm to 300 bpm	0.90 bpm to 1.01 bpm
56	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	REM - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using 6.1/2 Digital Multimeter by Direct Method	3 ohm to 500 ohm	0.58 ohm to 0.7 ohm
57	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Respiration Rate (Impedance) - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using Digital Multimeter by Direct Method	100 ohms to 2000 ohms	1 %



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58	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Respiration Rate - Ventilator Analysers/Flow Analysers	Using Oscilloscope by Direct Method	8 brpm to 40 brpm	0.29 brpm to 0.48 brpm
59	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	SpO2 - SpO2 Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using SpO2 Analyser by Comparison Method	60 % to 100 %	2 % to 3.92 %
60	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Temperature - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using 6.1/2 Digital Multimeter by Direct Method	25 deg C to 42 deg C	0.05 %
61	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Voltage - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using ESU as source and DMM by Comparison Method	5 V to 1000 V	3.52 %
62	MEDICAL DEVICES- MONITORING UNIT	ECG Output Amplitude - Patient Monitors	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV
63	MEDICAL DEVICES- MONITORING UNIT	Fetal ECG (fECG) Amplitude - Fetal Monitor, CTG, NST	Using Fetal Simulator by Direct Method	0.5 mV to 2 mV	0.17 mV to 0.21 mV



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64	MEDICAL DEVICES-MONITORING UNIT	Fetal Heart Rate - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	30 bpm to 240 bpm	3.99 % to 3.5%
65	MEDICAL DEVICES-MONITORING UNIT	Heart Rate - Patient Monitors	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	4.85 % to 1.25%
66	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %
67	MEDICAL DEVICES-MONITORING UNIT	Leakage Current (Enclosure, Earth, Patient) - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	7.5 % to 2.42 %
68	MEDICAL DEVICES-MONITORING UNIT	Maternal ECG (mECG) Amplitude - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV



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69	MEDICAL DEVICES-MONITORING UNIT	Maternal Heart Rate - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	60 bpm to 160 bpm	2.18 bpm to 5.62 bpm
70	MEDICAL DEVICES-MONITORING UNIT	Pressure - Monitors (Dynamic/Leak/Relief)	Using BP Pump Pressure Analyser by Direct Method	30 mmHg to 300 mmHg	0.95 % to 0.55 %
71	MEDICAL DEVICES-MONITORING UNIT	Protective Earth - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %
72	MEDICAL DEVICES-MONITORING UNIT	Pulse Rate - Patient Monitors	Using SpO2 Simulator by Simulation Method	30 bpm to 250 bpm	2.2 bpm to 5.3 bpm
73	MEDICAL DEVICES-MONITORING UNIT	SpO2 - Patient Monitors	Using SpO2 Simulator by Simulation Method	60 % to 100 %	2.63 % to 3.62 %
74	MEDICAL DEVICES-MONITORING UNIT	Voltage - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V



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75	MEDICAL DEVICES-MONITORING UNIT	Weigh Scales (d:1g) Class III and coarser	Using Cylindrical Knob SS F1 Class Weights by Direct Method	0.5 kg to 10 kg	1 %
76	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Current - ESU, Surgical Diathermy, Cautery	Using ESU Analyser Direct Method	50 mA to 1500 mA	8 % to 6.4 %
77	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	ECG Output Amplitude - Defibrillator/ECG, TMT, Holter	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV
78	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator, AED	Using Defib/Pacer Analyser by Direct Method	2 J to 300 J	0.16 J to 12.75 J
79	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	FiO2 - Ventilators, Oxygen Concentrators	Using Gas Flow Analyser by Direct Method	21 % to 100 %	0.5 % to 2.3 %
80	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Flow - Ventilators, HFNC/HFOT	Using Gas Flow Analyser by Direct Method	2 lpm to 60 lpm	0.09 lpm to 1.72 lpm



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81	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Heart Rate - Defibrillator/ECG, TMT, Holter	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	1.45 bpm to 3.74 bpm
82	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Humidity - Infant Incubator	Using Thermohygrometer Comparison Method	30 %RH to 90 %RH (25°C to 40°C)	3.58 %RH
83	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Inspiratory Time (Ti), Expiratory Time(Te), Pause Time (Tp), for I:E - Ventilator	Using Gas Flow Analyser by Direct Method	0.4 sec to 5.5 sec	0.02 sec to 0.15 sec
84	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Tab	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %
85	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance - Irradiancemeter	Using Irradiancemeter by Comparison Method	0 μ W/cm ² /nm to 100 μ W/cm ² /nm	4.62 %



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86	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance - Phototherapy	Using Irradiancemeter Direct Method	0 μ W/cm ² /nm to 100 μ W/cm ² /nm	4.62 %
87	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Leakage Current (Enclosure, Earth, Patient) - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Hear	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	2.53 % to 2.36 %
88	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Power - ESU, Surgical Diathermy, Cautery	Using ESU Analyser Direct Method	1 W to 400 W	0.2 W to 19.23 W
89	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output Amplitude - Defibrillator	Using Defib/Pacer Analyser by Direct Method	4.5 mA to 35 mA	0.3 mA to 0.35 mA
90	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output Amplitude - Pacemaker	Using Defib/Pacer Analyser by Direct Method	4.5 mA to 35 mA	0.3 mA to 0.35 mA



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91	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defib/Pacer Analyser by Direct Method	30 PPM to 200 PPM	1.65 PPM to 2.72 PPM
92	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Pacemaker	Using Defib/Pacer Analyser by Direct Method	30 PPM to 200 PPM	1.65 PPM to 2.72 PPM
93	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - PEEP, PIP, Mean Airway Pressure) - Ventilator	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
94	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - Tourniquet	Using BP Pump Pressure Analyser by Direct Method	20 mmHg to 400 mmHg	0.67 mmHg to 2.37 mmHg
95	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Protective Earth - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Table, L	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %



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96	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Respiration Rate - Ventilator	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	4.15 % to 2.6 %
97	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Sound Level - Incubator (@ 1kHz)	Using Sound level meter - Direct Method	30 dB to 120 dB	1.75 dB
98	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Autoclave/Sterilisers /ETO	Using Digital Thermometer by Comparison Method	50 ° C to 150 ° C	1.4 ° C
99	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Infant Incubator	Using Digital Thermometer - Direct Method	25 ° C to 37 ° C	0.4 ° C
100	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using Digital Thermometer - Direct Method	30 ° C to 45 ° C	0.4 ° C
101	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Radiant Warmer	Using Digital Thermometer - Direct Method	25 ° C to 37 ° C	0.4 ° C



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102	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Voltage - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Table, Lab Equip	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V
103	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Volume (Tidal Volume, Minute Volume) - Ventilator	Using Gas Flow Analyser by Direct Method	0.010 Litres to 25 Litres	0.001 Litres to 1.2 Litres



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Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	FiO2 (Anesthesia, Ventilator, Oxygen Concentrator)	Using Gas Flow Analyser by Direct Method	21 % to 100 %	0.5 % to 2.3 %
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Flowmeters, Oxygen Concentrator)	Using Gas Flow Analyser by Direct Method	1 lpm to 15 lpm	0.09 lpm to 0.46 lpm
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Nebulisers)	Using Gas Flow Analyser by Direct Method	1 lpm to 15 lpm	0.09 lpm to 0.46 lpm
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Syringe Pump)	Using Infusion Analyser by Direct method	1 ml/hr to 1000 ml/hr	0.12 ml/hr to 22.63 ml/hr
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Boyles, Flowmeter	Using Gas Flow Analyser by Direct Method	1 lpm to 30 lpm	0.09 lpm to 0.87 lpm
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Infusion Pump, Feeding Pump	Using Infusion Analyser by Direct method	1 ml/hr to 1000 ml/hr	0.12 ml/hr to 28 ml/hr
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Gauge Pressure - Boyles, Anesthesia, Compressor	Using Gas Flow Analyser by Direct Method	0 psi to 150 psi	1.23 %



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8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Inspiratory Time (Ti), Expiratory Time (Te), Pause Time (Tp) for I:E Ratio - Anesthesia, Ventilator, BiPAP	Using Gas Flow Analyser by Direct Method	0.4 sec to 5.5 sec	0.02 sec to 0.14 sec
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Insulation Resistance - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Leakage Current (Enclosure, Earth, Patient) - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	10 µA to 1000 µA	7.5 % to 2.42 %
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure (Infusion Pump/Feeding Pump)	Using Infusion Analyser by Direct method	1 psi to 30 psi	3.15 %
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure (Syringe Pump)	Using Infusion Analyser by Direct method	1 psi to 30 psi	3.15 %



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13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (IPAP/EPAP, CPAP) - BiPAP, CPAP	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (Static, Dynamic, Relief) - BP Apparatus	Using BP Pump Pressure Analyser by Direct Method	10 mmHg to 400 mmHg	0.95 % to 0.6 %
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - CPAP	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - PEEP, PIP, Mean Airway Pressure (Anesthesia, Ventilator)	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure Gauge (Oxygen Cylinder, Autoclave, Central Line Pressure, Manifold)	Using Gas Flow Analyser by Direct Method	-10 psi to 150 psi	1.23 %
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Protective Earth Resistance - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49%



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19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - Pulse Oximeter	Using SpO2 Simulator by Simulation Method	30 bpm to 250 bpm	2.2 bpm to 5.3 bpm
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate (Anesthesia, Ventilator, BiPAP)	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	2.6 % to 4.15 %
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate - BiPAP/CPAP	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	2.6 % to 4.15 %
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	SpO2 - Pulse Oximeter	Using SpO2 Simulator by Simulation Method	60 % to 100 %	2.63 % to 3.62 %
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Vacuum Pressure - Suction/Wall Suction/Manifold	Using Gas Flow Analyser by Direct Method	-10 psi to 0 psi	0.14 psi
24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Voltage @50Hz - Discharge Equipment/Devices - Suction, BP Montior, Nebuliser, Syringe Pump, Infusion Pump, Feeding Pump, CPAP, BiPAP, Anesthesia Machine, Pulse Oximeter	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.9 V



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25	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume (Syringe Pump)	Using Infusion Analyser by Direct method	1 ml to 60 ml	0.06 ml to 1.41 ml
26	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume (Tidal Volume, Minute Volume) - Anesthesia, Ventilator, BiPAP	Using Gas Flow Analyser by Direct Method	0.010 litres to 25 litres	0.001 litres to 1.2 litres
27	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Infusion Pump/Feeding Pump	Using Infusion Analyser by Direct method	1 ml to 500 ml	0.06 ml to 11.58 ml
28	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Heart Rate	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	4.84 % to 1.24 %
29	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Output Amplitude	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2 mV	0.17 mV to 0.21 mV
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Fetal Heart Rate - Fetal Doppler	Using Fetal Simulator by Direct Method	30 bpm to 240 bpm	3.99 % to 3.5 %
31	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %



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32	MEDICAL DEVICES-IMAGING/PLOTTERS	Leakage Current (Enclosure, Earth, Patient) - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	7.5 % to 2.42 %
33	MEDICAL DEVICES-IMAGING/PLOTTERS	Light Intensity - Light Source/Spot Light/Examination Light	Using Digital Luxmeter by Direct Method	100 lux to 25000 lux	20 lux to 2988 lux
34	MEDICAL DEVICES-IMAGING/PLOTTERS	Protective Earth Resistance - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %
35	MEDICAL DEVICES-IMAGING/PLOTTERS	Voltage - Imaging/Plotters - Light Source, EEG, Fetal Monitors, ECG Machine	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V
36	MEDICAL DEVICES-MEDICAL DEVICE ANALYZER/SIMULATOR EQUIPMENT	Amplitude - fECG/mECG - Fetal Simulator	Using Amplifier and Oscilloscope by direct method	0.5 mV to 5.0 mV	5.37 % to 3.83 %
37	MEDICAL DEVICES-MEDICAL DEVICE ANALYZER/SIMULATOR EQUIPMENT	Current - ESU Analyser/Diathermy Analyser/Cautery Analyser	Using Oscilloscope by Comparative Method	50 mA to 1500 mA	3.51 %



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38	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	ECG Output Amplitude - ECG Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator, Defib/Pacer Analyser	Using Amplifier and Oscilloscope by direct method	0.5 mV to 5.0 mV	5.37 % to 3.83 %
39	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Energy - Defib/Pacer Analyser	Using Oscilloscope by Direct Method	2 J to 300 J	0.16 J to 9.86 J
40	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Fetal (fHR) and Maternal (mHR) Heart Rate/Frequency	Using Amplifier and Oscilloscope by direct method	30 bpm to 300 bpm	0.67 bpm to 3.51 bpm
41	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	FiO2 - Ventilator Analyser/Flow Analyser/FiO2 Analyser	Using Certified Oxygen Cylinder Direct Method	21 % to 100 %	1.15 % to 3.76 %
42	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Heart Rate - ECG Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator, Defib/Pacer Analyser	Using Amplifier and Oscilloscope by Direct Method	30 bpm to 300 bpm	0.67 bpm to 3.51 bpm



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43	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	IBP - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using 6.1/2 Digital Multimeter by Direct Method	10 mmHg to 300 mmHg	2 %
44	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Inspiratory Time (Ti)/Expiratory Time (Te) - Ventilator Analyser/Flow Analyser	Using Oscilloscope by Direct Method	0.41 sec to 5.60 sec	0.01 sec to 0.07 sec
45	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Irradiance - Irradiancemeter	Using Irradiancemeter by Comparison Method	0 μ W/cm ² /nm to 100 μ W/cm ² /nm	4.62 %
46	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Load - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using 6.1/2 Digital Multimeter by Direct Method	50 ohm to 1550 ohm	0.58 ohm to 0.69 ohm
47	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Load/Variable Load - Defib/Pacer Analyser	Using 6.1/2 Digital Multimeter by Direct Method	50 ohm to 1500 ohm	0.58 ohm to 0.69 ohm



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48	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Output Power - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using ESU as source and Oscilloscope by Comparison Method	1 W to 500 W	0.15 W to 9.54 W
49	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pacer Output Amplitude - Defib/Pacer Analyser, Pacemaker Analyser	Using Source and 6.1/2 Digital Multimeter by Comparison Method	4 mA to 35 mA	0.01 mA to 0.05 mA
50	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pacer Rate - Defib/Pacer Analyser, Pacemaker Analyser	Using Oscilloscope by Comparison Method	30 PPM to 200 PPM	0.35 PPM to 2.44 PPM
51	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pressure - Vital Sign Simulator/Monitor Simulator/ Pressure Analyser/ Multiparameter Simulator	Using Digital Manometer by Direct method	10 mmHg to 400 mmHg	1 % to 0.4 %
52	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Pulse Rate - SpO2 Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using Amplifier and Oscilloscope by Direct Method	30 bpm to 300 bpm	0.90 bpm to 1.01 bpm



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53	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	REM - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using 6.1/2 Digital Multimeter by Direct Method	3 ohm to 500 ohm	0.58 ohm to 0.7 ohm
54	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Respiration Rate (Impedance) - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using Digital Multimeter by Direct Method	100 ohms to 2000 ohms	1 %
55	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Respiration Rate - Ventilator Analysers/Flow Analysers	Using Oscilloscope by Direct Method	8 brpm to 40 brpm	0.29 brpm to 0.48 brpm
56	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	SpO2 - SpO2 Simulator, Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using SpO2 Analyser by Comparison Method	60 % to 100 %	2 % to 3.92 %
57	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Temperature - Vital Signs Simulator, Patient Monitor Simulator, Multiparameter Simulator	Using 6.1/2 Digital Multimeter by Direct Method	25 deg C to 42 deg C	0.05 %



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58	MEDICAL DEVICES- MEDICAL DEVICE ANALYZER/ SIMULATOR EQUIPMENT	Voltage - ESU Analyser, Diathermy Analyser, Cautery Analyser	Using ESU as source and DMM by Comparison Method	5 V to 1000 V	3.52 %
59	MEDICAL DEVICES- MONITORING UNIT	ECG Output Amplitude - Patient Monitors	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV
60	MEDICAL DEVICES- MONITORING UNIT	Fetal ECG (fECG) Amplitude - Fetal Monitor, CTG, NST	Using Fetal Simulator by Direct Method	0.5 mV to 2 mV	0.17 mV to 0.21 mV
61	MEDICAL DEVICES- MONITORING UNIT	Fetal Heart Rate - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	30 bpm to 240 bpm	3.99 % to 3.5%
62	MEDICAL DEVICES- MONITORING UNIT	Heart Rate - Patient Monitors	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	4.85 % to 1.25%
63	MEDICAL DEVICES- MONITORING UNIT	Insulation Resistance - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %



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64	MEDICAL DEVICES-MONITORING UNIT	Leakage Current (Enclosure, Earth, Patient) - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	7.5 % to 2.42 %
65	MEDICAL DEVICES-MONITORING UNIT	Maternal ECG (mECG) Amplitude - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV
66	MEDICAL DEVICES-MONITORING UNIT	Maternal Heart Rate - CTG, Fetal Monitors, NST	Using Fetal Simulator by Direct Method	60 bpm to 160 bpm	2.18 bpm to 5.62 bpm
67	MEDICAL DEVICES-MONITORING UNIT	Pressure - Monitors (Dynamic/Leak/Relief)	Using BP Pump Pressure Analyser by Direct Method	30 mmHg to 300 mmHg	0.95 % to 0.55 %
68	MEDICAL DEVICES-MONITORING UNIT	Protective Earth - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %
69	MEDICAL DEVICES-MONITORING UNIT	Pulse Rate - Patient Monitors	Using SpO2 Simulator by Simulation Method	30 bpm to 250 bpm	2.2 bpm to 5.3 bpm



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70	MEDICAL DEVICES-MONITORING UNIT	SpO2 - Patient Monitors	Using SpO2 Simulator by Simulation Method	60 % to 100 %	2.63 % to 3.62 %
71	MEDICAL DEVICES-MONITORING UNIT	Voltage - Monitoring Unit - Patient Monitor, Apnea Monitor, Fetal Monitor, Physiotherapy Devices/Stimulators, Hematology Analysers, Baby Weigh Scale	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V
72	MEDICAL DEVICES-MONITORING UNIT	Weigh Scales (d:1g) Class III and coarser	Using Cylindrical Knob SS F1 Class Weights by Direct Method	0.5 kg to 10 kg	1 %
73	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Current - ESU, Surgical Diathermy, Cautery	Using ESU Analyser Direct Method	50 mA to 1500 mA	8 % to 6.4 %
74	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	ECG Output Amplitude - Defibrillator/ECG, TMT, Holter	Using Defib/Pacer Analyser by Direct Method	0.5 mV to 2.0 mV	0.17 mV to 0.21 mV
75	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator, AED	Using Defib/Pacer Analyser by Direct Method	2 J to 300 J	0.16 J to 12.75 J



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76	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	FiO ₂ - Ventilators, Oxygen Concentrators	Using Gas Flow Analyser by Direct Method	21 % to 100 %	0.5 % to 2.3 %
77	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Flow - Ventilators, HFNC/HFOT	Using Gas Flow Analyser by Direct Method	2 lpm to 60 lpm	0.09 lpm to 1.72 lpm
78	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Heart Rate - Defibrillator/ECG, TMT, Holter	Using Defib/Pacer Analyser by Direct Method	30 bpm to 300 bpm	1.45 bpm to 3.74 bpm
79	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Humidity - Infant Incubator	Using Thermohygrometer Comparison Method	30 %RH to 90 %RH (25°C to 40°C)	3.58 %RH
80	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Inspiratory Time (Ti), Expiratory Time(Te), Pause Time (Tp), for I:E - Ventilator	Using Gas Flow Analyser by Direct Method	0.4 sec to 5.5 sec	0.02 sec to 0.15 sec



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81	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Tab	Using Electrical Safety Analyser by Direct Method	10 Mohm to 200 Mohm	11.8 % to 3.06 %
82	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance - Irradiancemeter	Using Irradiancemeter by Comparison Method	0 $\mu\text{W}/\text{cm}^2/\text{nm}$ to 100 $\mu\text{W}/\text{cm}^2/\text{nm}$	4.62 %
83	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance - Phototherapy	Using Irradiancemeter Direct Method	0 $\mu\text{W}/\text{cm}^2/\text{nm}$ to 100 $\mu\text{W}/\text{cm}^2/\text{nm}$	4.62 %
84	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Leakage Current (Enclosure, Earth, Patient) - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Hear	Using Electrical Safety Analyser by Direct Method	10 μA to 1000 μA	2.53 % to 2.36 %



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85	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Power - ESU, Surgical Diathermy, Cautery	Using ESU Analyser Direct Method	1 W to 400 W	0.2 W to 19.23 W
86	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output Amplitude - Defibrillator	Using Defib/Pacer Analyser by Direct Method	4.5 mA to 35 mA	0.3 mA to 0.35 mA
87	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output Amplitude - Pacemaker	Using Defib/Pacer Analyser by Direct Method	4.5 mA to 35 mA	0.3 mA to 0.35 mA
88	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defib/Pacer Analyser by Direct Method	30 PPM to 200 PPM	1.65 PPM to 2.72 PPM
89	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Pacemaker	Using Defib/Pacer Analyser by Direct Method	30 PPM to 200 PPM	1.65 PPM to 2.72 PPM
90	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - PEEP, PIP, Mean Airway Pressure) - Ventilator	Using Gas Flow Analyser by Direct Method	0 cmH2O to 150 cmH2O	4.94 % to 0.7 %



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91	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - Tourniquet	Using BP Pump Pressure Analyser by Direct Method	20 mmHg to 400 mmHg	0.67 mmHg to 2.37 mmHg
92	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Protective Earth - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Table, L	Using Electrical Safety Analyser by Direct Method	50 mohm to 1000 mohm	5.12 % to 2.49 %
93	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Respiration Rate - Ventilator	Using Gas Flow Analyser by Direct Method	5 bpm to 75 bpm	4.15 % to 2.6 %
94	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Sound Level - Incubator (@ 1kHz)	Using Sound level meter - Direct Method	30 dB to 120 dB	1.75 dB
95	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Autoclave/Sterilisers /ETO	Using Digital Thermometer by Comparison Method	50 ° C to 150 ° C	1.4 ° C



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96	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Infant Incubator	Using Digital Thermometer - Direct Method	25 ° C to 37 ° C	0.4 ° C
97	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using Digital Thermometer - Direct Method	30 ° C to 45 ° C	0.4 ° C
98	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Radiant Warmer	Using Digital Thermometer - Direct Method	25 ° C to 37 ° C	0.4 ° C
99	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Voltage - Patient Conditioning Maintenance - Incubator, Autoclave/Steriliser, Defibrillator, Ventilator, Electrosurgical Unit, Diathermy, Tourniquet, Dialysis, Heart Lung Machine, OT Table, Lab Equip	Using Electrical Safety Analyser by Direct Method	1 V to 400 V	0.16 V to 2.89 V
100	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Volume (Tidal Volume, Minute Volume) - Ventilator	Using Gas Flow Analyser by Direct Method	0.010 Litres to 25 Litres	0.001 Litres to 1.2 Litres

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