



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

DESUN TEST AND CALIBRATION LABORATORY, P-23 KASBA INDUSTRIAL ESTATE, PH- I, GROUND FLOOR, KOLKATA, WEST BENGAL, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-4129

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Validity

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Last Amended on

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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)(±)
Permanent Facility					
1	MECHANICAL-ACCELERATION AND SPEED	Centrifuge / RPM Source	Using Digital Tachometer by Comparison Method:	> 100 rpm to 5000 rpm	8.425 rpm
2	MECHANICAL-ACCELERATION AND SPEED	Centrifuge / RPM Source	Using Digital Tachometer by Comparison Method:	> 5000 rpm to 10000 rpm	56.8 rpm
3	MECHANICAL-ACCELERATION AND SPEED	Centrifuge/RPM Source	Using Digital Tachometer by Comparison Method	100 rpm to	6.344 rpm
4	MECHANICAL-VOLUME	Beaker	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 4787:2021	1 ml to 100 ml	90 µl
5	MECHANICAL-VOLUME	Burette	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 4787:2021	1 ml to 10 ml	12 µl



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6	MECHANICAL-VOLUME	Measuring Cylinder	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 4787 :2021	1 ml to 100 ml	96 µl
7	MECHANICAL-VOLUME	Measuring Pipette	Using F1 Class Standard Weight with Digital Precision Balance (d: 0.01 mg) and Distilled Water of known density Based on IS/ISO 4787:2021	1 ml to 25 ml	22 µl
8	MECHANICAL-VOLUME	Micropipette	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 8655-6:2022	100 µl to 1000 µl	0.8 µl



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9	MECHANICAL-VOLUME	Micropipette	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 8655-6:2022	20 µl to 100 µl	0.3 µl
10	MECHANICAL-VOLUME	Volumetric Flask	Using F1 Class Standard Weight with Digital Precision Balance (d:0.01 mg) and Distilled Water of known density Based on IS/ISO 4787:2021	1 ml to 100 ml	75 µl
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	AC Voltage - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BiPAP (Breath Rate)	Using Gas Flow Analyzer by Direct Method	6 BPM to 30 BPM	1.0 BPM to 2.0 BPM
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BiPAP (Pressure - IPAP & EPAP)	Using Gas Flow Analyzer by Direct Method	5 cmH2O to 25 cmH2O	0.6 cmH2O to 3.0 cmH2O



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14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus (Pressure)	Using Vital Sign Simulator by Direct Method	50 mmHg to 300 mmHg	1.8 mmHg to 5.5 mmHg
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	CPAP (Pressure)	Using Gas Flow Analyzer by Direct Method	5 cmH2O to 30 cmH2O	2.0 cmH2O to 3.0 cmH2O
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Digital BP Apparatus (Non-Invasive Blood Pressure)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	3.72 % to 2.5 %
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 100 ml	0.29 ml to 0.5 ml



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20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter (Flow Rate)	Using Gas Flow Analyzer by Direct Method	5.0 LPM to 15.0 LPM	0.62 LPM to 2.0 LPM
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 50 ml	0.29 ml to 0.5 ml
24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Insulation Resistance - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %



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25	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Leakage Current - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	4 μ A to 10 mA	9.78% to 1.77 %
26	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Load Current - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %
27	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Nebulizer Machine (Flow Rate)	Using Gas Flow Analyzer by Direct Method	2 LPM to 15 LPM	0.62 LPM to 2.0 LPM
28	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Protective Earth Resistance - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71% to 3.41 %
29	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pulse Oxymeter (Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	80 % to 100 %	6.5 %



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30	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oxymeter (Pulse Rate)	Using Pulse Oxymeter Simulator by Direct Method	30 BPM to 240 BPM	11.1 % to 3.0 %
31	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Machine (Negative Pressure)	Using Reference Pressure Gauge with Hand Pump by Direct Method:	0 to (-)650 mmHg	17 mmHg
32	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr
33	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
34	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 50 ml	0.59 ml to 0.72 ml
35	MEDICAL DEVICES-IMAGING/PLOTTERS	AC Voltage - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %



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36	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine (Heart Rate)	Using Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	2.76 % to 4.0 %
37	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine (Millivolt - Amplitude)	Using Vital Sign Simulator by Direct Method	1.0 mV to 3.0 mV	6.5 %
38	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
39	MEDICAL DEVICES-IMAGING/PLOTTERS	Leakage Current - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	4 µA to 10 mA	9.78% to 1.77 %
40	MEDICAL DEVICES-IMAGING/PLOTTERS	Load Current - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %
41	MEDICAL DEVICES-IMAGING/PLOTTERS	Protective Earth Resistance - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71% to 3.41 %
42	MEDICAL DEVICES-MONITORING UNIT	AC Voltage - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %



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43	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
44	MEDICAL DEVICES-MONITORING UNIT	Leakage Current - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	4 µA to 10 mA	9.78% to 1.77 %
45	MEDICAL DEVICES-MONITORING UNIT	Load Current - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8 % to 6.29 %
46	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Heart Rate)	Using Vital Sign Simulator by Direct Method	30 BPM to 210 BPM	3.0 % to 1.7 %
47	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (IBP)	Using Vital Sign Simulator by Direct Method	20 mmHg to 250 mmHg	9.95 % to 3.0 %
48	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (NIBP)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	3.72 % to 2.5 %
49	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	80 % to 100 %	6.5 %



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50	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Pulse Rate - Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	30 BPM to 240 BPM	11.1 % to 2.28 %
51	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Respiration Rate)	Using Vital Sign Simulator by Direct Method	15 BPM to 100 BPM	6.1 %
52	MEDICAL DEVICES-MONITORING UNIT	Protective Earth Resistance - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71 % to 3.41%
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	AC Voltage - Defibrillator, Diathermy Machine, OT Table, Electronic Bed , Dialysis Machine & Patient Conditioning/Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
54	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Energy)	Using Defibrillator Analyzer by Direct Method	2 Joule to 360 Joule	7.95% to 2.73 %



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55	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Heart Rate)	Using Defibrillator Analyzer by Direct Method	30 BPM to 240 BPM	2.0 % to 3.0 %
56	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
57	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Leakage Current - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	4 μ A to 10 mA	9.78% to 1.77 %



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58	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Load Current - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %
59	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Protective Earth Resistance - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71 % to 3.41 %



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Site Facility					
1	MECHANICAL-ACCELERATION AND SPEED	Centrifuge / RPM Source	Using Digital Tachometer by Comparison Method:	> 100 rpm to 5000 rpm	8.425 rpm
2	MECHANICAL-ACCELERATION AND SPEED	Centrifuge / RPM Source	Using Digital Tachometer by Comparison Method:	> 5000 rpm to 10000 rpm	56.8 rpm
3	MECHANICAL-ACCELERATION AND SPEED	Centrifuge/RPM Source	Using Digital Tachometer by Comparison Method	100 rpm to	6.344 rpm
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	AC Voltage - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Anesthesia Machine (Tidal Volume)	Using Gas Flow Analyzer by Direct Method	10 ml to 800 ml	6 %
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Anesthesia Machine (Breath Rate)	Using Gas Flow Analyzer by Direct Method	6 BPM to 30 BPM	1.0 BPM to 2.0 BPM



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7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Anesthesia Machine (Pressure - PIP & PEEP)	Using Gas Flow Analyzer by Direct Method	1 cmH2O to 50 cmH2O	0.6 cmH2O to 3.0 cmH2O
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BiPAP (Breath Rate)	Using Gas Flow Analyzer by Direct Method	6 BPM to 30 BPM	1.0 BPM to 2.0 BPM
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BiPAP (Pressure - IPAP & EPAP)	Using Gas Flow Analyzer by Direct Method	5 cmH2O to 25 cmH2O	0.6 cmH2O to 3.0 cmH2O
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Boyles Apparatus (Flow Rate)	Using Gas Flow Analyzer by Direct Method	5 LPM to 15 LPM	0.62 LPM to 2.0 LPM
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus (Pressure)	Using Vital Sign Simulator by Direct Method	50 mmHg to 300 mmHg	1.8 mmHg to 5.5 mmHg
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	CPAP (Pressure)	Using Gas Flow Analyzer by Direct Method	5 cmH2O to 30 cmH2O	2.0 cmH2O to 3.0 cmH2O



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13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Digital BP Apparatus (Non-Invasive Blood Pressure)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	3.72 % to 2.5 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Feeding Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 100 ml	0.29 ml to 0.5 ml
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter (Flow Rate)	Using Gas Flow Analyzer by Direct Method	5.0 LPM to 15.0 LPM	0.62 LPM to 2.0 LPM
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr



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19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 50 ml	0.29 ml to 0.5 ml
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Insulation Resistance - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Leakage Current - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	4 µA to 10 mA	9.78% to 1.77 %
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Load Current - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %



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24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer Machine (Flow Rate)	Using Gas Flow Analyzer by Direct Method	2 LPM to 15 LPM	0.62 LPM to 2.0 LPM
25	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Protective Earth Resistance - Anesthesia Machine, Syringe Pump & Discharge Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71% to 3.41 %
26	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oxymeter (Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	80 % to 100 %	6.5 %
27	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oxymeter (Pulse Rate)	Using Pulse Oxymeter Simulator by Direct Method	30 BPM to 240 BPM	11.1 % to 3.0 %
28	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Machine (Negative Pressure)	Using Reference Pressure Gauge with Hand Pump by Direct Method:	0 to (-)650 mmHg	17 mmHg



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29	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Flow Rate)	Using Infusion Device Analyzer by Direct Method	2 ml/hr to 100 ml/hr	0.2 ml/hr to 1.46 ml/hr
30	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Occlusion Pressure)	Using Infusion Device Analyzer by Direct Method	1 psi to 30 psi	0.7 psi
31	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Syringe Pump (Volume)	Using Infusion Device Analyzer by Direct Method	2 ml to 50 ml	0.59 ml to 0.72 ml
32	MEDICAL DEVICES- IMAGING/PLOTTERS	AC Voltage - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
33	MEDICAL DEVICES- IMAGING/PLOTTERS	ECG Machine (Heart Rate)	Using Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	2.76 % to 4.0 %
34	MEDICAL DEVICES- IMAGING/PLOTTERS	ECG Machine (Millivolt - Amplitude)	Using Vital Sign Simulator by Direct Method	1.0 mV to 3.0 mV	6.5 %



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35	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
36	MEDICAL DEVICES-IMAGING/PLOTTERS	Leakage Current - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	4 μ A to 10 mA	9.78% to 1.77 %
37	MEDICAL DEVICES-IMAGING/PLOTTERS	Load Current - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %
38	MEDICAL DEVICES-IMAGING/PLOTTERS	OT Light, Light Source, Spot Light etc.	Using Lux Meter by Comparison Method	100 Lux to 9990 Lux	7.41 %
39	MEDICAL DEVICES-IMAGING/PLOTTERS	Protective Earth Resistance - ECG Machine & Imaging/Plotters Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71% to 3.41 %
40	MEDICAL DEVICES-MONITORING UNIT	AC Voltage - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
41	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %



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42	MEDICAL DEVICES-MONITORING UNIT	Leakage Current - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	4 μ A to 10 mA	9.78% to 1.77 %
43	MEDICAL DEVICES-MONITORING UNIT	Load Current - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8 % to 6.29 %
44	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Heart Rate)	Using Vital Sign Simulator by Direct Method	30 BPM to 210 BPM	3.0 % to 1.7 %
45	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (IBP)	Using Vital Sign Simulator by Direct Method	20 mmHg to 250 mmHg	9.95 % to 3.0 %
46	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (NIBP)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	3.72 % to 2.5 %
47	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	80 % to 100 %	6.5 %
48	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Pulse Rate - Oxygen Saturation)	Using Pulse Oxymeter Simulator by Direct Method	30 BPM to 240 BPM	11.1 % to 2.28 %



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49	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor (Respiration Rate)	Using Vital Sign Simulator by Direct Method	15 BPM to 100 BPM	6.1 %
50	MEDICAL DEVICES-MONITORING UNIT	Protective Earth Resistance - Patient Monitor & Monitoring Unit	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71 % to 3.41%
51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	AC Voltage - Defibrillator, Diathermy Machine, OT Table, Electronic Bed , Dialysis Machine & Patient Conditioning/Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	90 V to 230 V	5.67% to 3.0 %
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Energy)	Using Defibrillator Analyzer by Direct Method	2 Joule to 360 Joule	7.95% to 2.73 %
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Heart Rate)	Using Defibrillator Analyzer by Direct Method	30 BPM to 240 BPM	2.0 % to 3.0 %



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54	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit/Diathermy Machine/Cauty Machine (Power)	Using Electro Surgery Analyzer by Direct Method	10 Watt to 300 Watt	9.1 % to 6.02 %
55	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electronic Tourniquet (Pressure)	Using Reference Pressure Gauge by Direct Method	50 mmHg to 450 mmHg	15 mmHg
56	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	10 Mohm to >100 Mohm	11.34% to 8.81 %
57	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Leakage Current - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	4 μ A to 10 mA	9.78% to 1.77 %



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58	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Load Current - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	1 A to 10 A	9.8% to 6.29 %
59	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Phototherapy Unit (Irradiance)	Using Irradiance Meter by Comparison Method	10 μ W/cm ² /nm to 100 μ W/cm ² /nm	12.3 %
60	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Protective Earth Resistance - Defibrillator, Diathermy Machine, Dialysis Machine, OT Table, Electronic Bed & Patient Conditioning/ Maintenance Equipment	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	8.71 % to 3.41 %
61	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Ventilator (Breath Rate)	Using Gas Flow Analyzer by Direct Method	6 BPM to 40 BPM	1.0 BPM to 2.0 BPM



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62	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Ventilator (Inspiratory & Expiratory Time)	Using Gas Flow Analyzer by Direct Method	0.2 s to 5 s	0.024s to 0.033s
63	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Ventilator (Pressure- PEEP, PIP & MAP)	Using Gas Flow Analyzer by Direct Method	1 cmH2O to 50 cmH2O	0.6 cmH2O to 3.0 cmH2O
64	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Ventilator (Tidal Volume)	Using Gas Flow Analyzer by Direct Method	2 ml to 700 ml	6 %

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