



National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

**PSG CENTRE FOR INDUSTRIAL RESEARCH AND
DEVELOPMENT**

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

A115, PSG COLLEGE OF TECHNOLOGY, AVINASHI ROAD, PEELAMEDU, COIMBATORE, TAMIL NADU,
INDIA

in the field of

CALIBRATION

Certificate Number: CC-3769

Issue Date: 05/12/2023

Valid Until:

04/12/2025

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: P.S. GOVINDASWAMY NAIDU SONS & CHARITIES

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : PSG CENTRE FOR INDUSTRIAL RESEARCH AND DEVELOPMENT, A115, PSG COLLEGE OF TECHNOLOGY, AVINASHI ROAD, PEELAMEDU, COIMBATORE, TAMIL NADU, INDIA

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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	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Earth Leakage Current (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Insulation Resistance Test (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	3.0%



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4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Patient Leakage Current (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Protective Earth Resistance (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.90 ohm	0.022 ohm to 0.055 ohm
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Flow meter with Humidifier / Flow meter / Oxygen Concentrator	Using Gas Flow Analyzer by Comparison method	1 lpm to 15 lpm	2.53%
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Infusion pump / Feeding pump	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	4.28%



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8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Nebulizer (Electric)	Using Gas Flow Analyzer by comparison method	7 lpm to 10 lpm	3.8%
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Suction Pump	Using Gas flow Analyzer by Comparison method	1 lpm to 15 lpm	2.41%
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Syringe Pump	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	3.08%
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Heart Rate - Pulse Oxymeter	Using SpO2 Functional Tester by Direct method	30 bpm to 150 bpm	1.28%
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure - Infusion Pump / Feeding pump	Using Infusion Device Analyzer by Direct method	0 to 1300 mmHg	2.07%
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure - Syringe Pump	Using Infusion Device Analyzer by Direct method	0 to 900 mmHg	3.04%



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14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (Leak Test) - BP Apparatus / Sphygmomanometer	Using Vital Sign Simulator by Direct Method	0 to 40 mmHg	5.80mmHg
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure (NIBP) - BP Apparatus / Sphygmomanometer	Using Vital Sign Simulator and SpO2 Functional Tester by Direct Method	0 to 200 mmHg	5.80mmHg
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - Flow meter with Humidifier	Using Digital Pressure Gauge by comparison method	0 to 60 psi	1.95%
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - Nebulizer (Electric)	Using Gas Flow Analyzer by Comparison method	0 to 50 psi	4.97%
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - BP Apparatus	Using Vital Sign Simulator and SpO2 Functional Tester by Direct Method	30 bpm to 150 bpm	1.30%
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	SPO2 - Pulse Oxymeter	Using SpO2 Functional Tester and by Direct method	80 % to 100 %	2.30%



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20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Temperature - Flow meter with Humidifier	Using RTD sensor with Documenting Process Calibrator by comparison method	20 °C to 50 °C	1.00°C
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Vacuum - Suction Pump	Using Digital Pressure Gauge by Comparison method	0 to 650 mmHg	13.8mmHg
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Infusion pump / Feeding pump	Using Infusion Device Analyzer by Direct method	1 ml to 400 ml	6.4%
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Syringe Pump	Using Infusion Device Analyzer by Direct method	1 ml to 50 ml	6.4%
24	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Output Amplitude - ECG Machine/Recorder	Using Vital Signs Simulator by Direct Method	0.5 mV to 2.5 mV	4.8%
25	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.60 µA to 223 µA



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26	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Earth Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
27	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Insulation Resistance Test (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	3.0%
28	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Patient Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
29	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Protective Earth Resistance (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.90 ohm	0.016 ohm to 0.055 ohm
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart Rate - ECG Machine/Recorder, Monitors	Using Vital Sign Simulator by Direct Method	30 bpm to 300 bpm	1.30%
31	MEDICAL DEVICES-MONITORING UNIT	ECG - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0.5 mV to 5 mV	6.26%



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32	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
33	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Earth Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
34	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Patient Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
35	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Protective Earth Resistance (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	0.05 Ohm to 1.9 Ohm	0.016 Ohm to 0.055 Ohm
36	MEDICAL DEVICES-MONITORING UNIT	Heart Rate - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	1.60%



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37	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance- (Common for Patient Monitor, Syringe/Infusion Pump, Defibrillator, Suction Pump, ECG Unit, Electro-Surgical Unit, Autoclave, Radiant Warmer, Patient Warmer, Infant Incubator)	Using Electrical Safety Analyser by Direct Method	1 Mohm to 100 Mohm	3.0%
38	MEDICAL DEVICES-MONITORING UNIT	Invasive blood pressure accuracy - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.33%
39	MEDICAL DEVICES-MONITORING UNIT	Non-Invasive Blood Pressure (Leak Test) - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	10 mmHg to 200 mmHg	1.3mmHg
40	MEDICAL DEVICES-MONITORING UNIT	Non-Invasive Blood Pressure Accuracy - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.80mmHg
41	MEDICAL DEVICES-MONITORING UNIT	Respiration Rate - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	10 brpm to 100 brpm	5.8%



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42	MEDICAL DEVICES-MONITORING UNIT	SPO2 - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	80 % to 100 %	2%
43	MEDICAL DEVICES-MONITORING UNIT	Temperature - Patient Monitors / Multipara Monitors	Using process calibrator by Direct Method	20 °C to 50 °C	0.58°C
44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Discharge Time - Defibrillator	Using Defibrillator Analyzer by Direct Method	1.5 sec to 10 sec	0.12sec
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	ECG - Defibrillator	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	6.26%



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46	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant War	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
47	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Earth Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A



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48	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Insulation Resistance Test (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyser by Direct Method	1 Mohm to 100 Mohm	3.0%
49	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Patient Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A



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50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Protective Earth Resistance (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyser by Direct Method	0.05 ohm to 1.90 ohm	0.016 ohm to 0.055 ohm
51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator	Using Defibrillator analyzer by Direct Method	20 J to 300 J	7.50J
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Heart Rate-Defibrillator	Using Defibrillator Analyser, Spotlight pulse oximeter analyser by Direct Method.	30 bpm to 300 bpm	1.60%
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	HF Leakage - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electro Surgery Analyser and Electrical Safety Analyser by Direct Method	10 mA to 150 mA	6.81%



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54	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	NIBP-Defibrillator	Using Defibrillator Analyser, by Direct Method	0 to 200 mmHg	5.80mmHg
55	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output - Defibrillator	Using Defibrillator analyzer by Direct Method	1 mA to 20 mA	3.80%
56	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defibrillator analyzer by Direct Method	30 ppm to 180 ppm	1.92%
57	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Power - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electro Surgery Analyser by Direct Method	10 W to 300 W	8.48%
58	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - Autoclave	Using Digital Pressure Gauge by Comparison method	0 to 2 bar	0.1bar



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59	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	REM - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electrical Safety Analyser by Direct Method	50 ohm to 500 ohm	3.08%
60	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	SPO2-Defibrillator	Using Defibrillator Analyser & Spotlight pulse oximeter analyser by Direct Method	80 % to 100 %	2%
61	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Autoclave	Using Temperature sensor with logger Comparison method	50 °C to 125 °C	1.3°C
62	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using RTD sensor Process Calibrator Comparison method	30 °C to 45 °C	1.00°C
63	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Radiant Warmer	Using using RTD sensor with Process Calibrator Comparison method	30 °C to 40 °C	1.2°C



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64	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Time - Autoclave	Using Digital Timer Comparison method	1 sec to 45 Min	0.1 sec to 10 sec



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Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
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4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Patient Leakage Current (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Test - Protective Earth Resistance (Common for Syringe Pump, Infusion Pump, Nebulizer, Pulse Oxymeter, BP Apparatus, Suction Pump)	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.90 ohm	0.022 ohm to 0.055 ohm
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Flow meter with Humidifier / Flow meter / Oxygen Concentrator	Using Gas Flow Analyzer by Comparison method	1 lpm to 15 lpm	2.53%
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Infusion pump / Feeding pump	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	4.28%



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8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Nebulizer (Electric)	Using Gas Flow Analyzer by comparison method	7 lpm to 10 lpm	3.8%
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Suction Pump	Using Gas flow Analyzer by Comparison method	1 lpm to 15 lpm	2.41%
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Syringe Pump	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	3.08%
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Heart Rate - Pulse Oxymeter	Using SpO2 Functional Tester by Direct method	30 bpm to 150 bpm	1.28%
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure - Infusion Pump / Feeding pump	Using Infusion Device Analyzer by Direct method	0 to 1300 mmHg	2.07%
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion Pressure - Syringe Pump	Using Infusion Device Analyzer by Direct method	0 to 900 mmHg	3.04%



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14	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pressure (Leak Test) - BP Apparatus / Sphygmomanometer	Using Vital Sign Simulator by Direct Method	0 to 40 mmHg	5.80mmHg
15	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pressure (NIBP) - BP Apparatus / Sphygmomanometer	Using Vital Sign Simulator and SpO2 Functional Tester by Direct Method	0 to 200 mmHg	5.80mmHg
16	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pressure - Flow meter with Humidifier	Using Digital Pressure Gauge by comparison method	0 to 60 psi	1.95%
17	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pressure - Nebulizer (Electric)	Using Gas Flow Analyzer by Comparison method	0 to 50 psi	4.97%
18	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - BP Apparatus	Using Vital Sign Simulator and SpO2 Functional Tester by Direct Method	30 bpm to 150 bpm	1.30%
19	MEDICAL DEVICES- DISCHARGE EQUIPMENT/DEVICES	SPO2 - Pulse Oxymeter	Using SpO2 Functional Tester and by Direct method	80 % to 100 %	2.30%



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20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Temperature - Flow meter with Humidifier	Using RTD sensor with Documenting Process Calibrator by comparison method	20 °C to 50 °C	1.00°C
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Vacuum - Suction Pump	Using Digital Pressure Gauge by Comparison method	0 to 650 mmHg	13.8mmHg
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Infusion pump / Feeding pump	Using Infusion Device Analyzer by Direct method	1 ml to 400 ml	6.4%
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Syringe Pump	Using Infusion Device Analyzer by Direct method	1 ml to 50 ml	6.4%
24	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Output Amplitude - ECG Machine/Recorder	Using Vital Signs Simulator by Direct Method	0.5 mV to 2.5 mV	4.8%
25	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.60 µA to 223 µA



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26	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Earth Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
27	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Insulation Resistance Test (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	3.0%
28	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Patient Leakage Current (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
29	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Test - Protective Earth Resistance (Common for ECG Machine)	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.90 ohm	0.016 ohm to 0.055 ohm
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart Rate - ECG Machine/Recorder, Monitors	Using Vital Sign Simulator by Direct Method	30 bpm to 300 bpm	1.30%
31	MEDICAL DEVICES-MONITORING UNIT	ECG - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0.5 mV to 5 mV	6.26%



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32	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
33	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Earth Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
34	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Patient Leakage Current (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A
35	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety Test - Protective Earth Resistance (Common for Patient Monitor / Multipara Monitor)	Using Electrical Safety Analyser by Direct Method	0.05 Ohm to 1.9 Ohm	0.016 Ohm to 0.055 Ohm
36	MEDICAL DEVICES-MONITORING UNIT	Heart Rate - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	1.60%



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37	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance- (Common for Patient Monitor, Syringe/Infusion Pump, Defibrillator, Suction Pump, ECG Unit, Electro-Surgical Unit, Autoclave, Radiant Warmer, Patient Warmer, Infant Incubator)	Using Electrical Safety Analyser by Direct Method	1 Mohm to 100 Mohm	3.0%
38	MEDICAL DEVICES-MONITORING UNIT	Invasive blood pressure accuracy - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.33%
39	MEDICAL DEVICES-MONITORING UNIT	Non-Invasive Blood Pressure (Leak Test) - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	10 mmHg to 200 mmHg	1.3mmHg
40	MEDICAL DEVICES-MONITORING UNIT	Non-Invasive Blood Pressure Accuracy - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.80mmHg
41	MEDICAL DEVICES-MONITORING UNIT	Respiration Rate - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	10 brpm to 100 brpm	5.8%



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42	MEDICAL DEVICES-MONITORING UNIT	SPO2 - Patient Monitors / Multipara Monitors	Using SPO2 Simulator, Vital Sign Simulator by Direct Method	80 % to 100 %	2%
43	MEDICAL DEVICES-MONITORING UNIT	Temperature - Patient Monitors / Multipara Monitors	Using process calibrator by Direct Method	20 °C to 50 °C	0.58°C
44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Discharge Time - Defibrillator	Using Defibrillator Analyzer by Direct Method	1.5 sec to 10 sec	0.12sec
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	ECG - Defibrillator	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	6.26%



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46	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Chassis/Enclosure Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant War	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A
47	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Earth Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 9000 μ A	3.60 μ A to 223 μ A



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48	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Insulation Resistance Test (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyser by Direct Method	1 Mohm to 100 Mohm	3.0%
49	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Patient Leakage Current (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	10 μ A to 1000 μ A	3.60 μ A to 24.5 μ A



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50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Test - Protective Earth Resistance (Common for Defibrillator, Infant Incubator, Electro Surgical Unit/ Diathermy Machine/ Cauty Machine, Autoclave, Patient Warmer, Radiant Warmer)	Using Electrical Safety Analyser by Direct Method	0.05 ohm to 1.90 ohm	0.016 ohm to 0.055 ohm
51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Energy - Defibrillator	Using Defibrillator analyzer by Direct Method	20 J to 300 J	7.50J
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Heart Rate-Defibrillator	Using Defibrillator Analyser, Spotlight pulse oximeter analyser by Direct Method.	30 bpm to 300 bpm	1.60%
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	HF Leakage - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electro Surgery Analyser and Electrical Safety Analyser by Direct Method	10 mA to 150 mA	6.81%



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54	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	NIBP-Defibrillator	Using Defibrillator Analyser, by Direct Method	0 to 200 mmHg	5.80mmHg
55	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Output - Defibrillator	Using Defibrillator analyzer by Direct Method	1 mA to 20 mA	3.80%
56	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - Defibrillator	Using Defibrillator analyzer by Direct Method	30 ppm to 180 ppm	1.92%
57	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Power - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electro Surgery Analyser by Direct Method	10 W to 300 W	8.48%
58	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure - Autoclave	Using Digital Pressure Gauge by Comparison method	0 to 2 bar	0.1bar



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59	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	REM - Electro Surgical Unit/ Diathermy Machine/ Cauty Machine	Using Electrical Safety Analyser by Direct Method	50 ohm to 500 ohm	3.08%
60	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	SPO2-Defibrillator	Using Defibrillator Analyser & Spotlight pulse oximeter analyser by Direct Method	80 % to 100 %	2%
61	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Autoclave	Using Temperature sensor with logger Comparison method	50 °C to 125 °C	1.3°C
62	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using RTD sensor Process Calibrator Comparison method	30 °C to 45 °C	1.00°C
63	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature - Radiant Warmer	Using using RTD sensor with Process Calibrator Comparison method	30 °C to 40 °C	1.2°C



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64	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Time - Autoclave	Using Digital Timer Comparison method	1 sec to 45 Min	0.1 sec to 10 sec

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