



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

MEDICAL DEVICES TESTING AND CALIBRATION FACILITY, NIPER GUWAHATI, NIPERG MAIN BUILDING B-BLOCK, GROUND FLOOR, SILA KATAMUR, CHANGSARI(P), GUWAHATI, KAMRUP, ASSAM, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-3932

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Validity

22/05/2024 to 21/05/2026

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	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Chassis or Cabinet or Enclosure leakage	Using Electrical Safety Analyzer by Direct Method	10 microA to 2 microA	2 %
2	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Differential Leakage or Earth or Ground leakage	Using Electrical Safety Analyzer by Direct Method	75 μ A to 2 mA	2.5 %
3	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Ground wire resistance or Earth Resistance or Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 2 ohm	2 %
4	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Heart rate	Using Defibrillator Analyzer by ECG Simulation Method	30 bpm to 300 bpm	1.63 bpm to 12.74 bpm
5	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Insulation Resistance	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.96 ohm
6	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG - Patient Leakage Current at Applied parts	Using Electrical Safety Analyzer by Direct Method	10 μ A to 2 mA	2.6 % to 10.5 %



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7	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Amplitude	Using Defibrillator Analyzer by ECG Simulation Method	1 mV to 5 mV	0.3 mV to 0.72 mV
8	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG-Mains Voltage	Using Electrical Safety Analyzer by Direct Method	180 V to 264 V	5.2 V to 5.4 V
9	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Charging Time	Using Defibrillator Analyzer by Direct Method	1 s to 20 s	0.19 s
10	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Patient Leakage Current at Applied parts	Using Electrical Safety Analyzer by Direct Method	10 μ A to 2 mA	2.6 % to 10.5 %
11	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Chassis or Cabinet or Enclosure leakage	Using Electrical Safety Analyzer by Direct Method	10 μ A to 2 mA	2 %



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12	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Differential Leakage or Earth or Ground leakage	Using Electrical Safety Analyzer by Direct Method	75 μ A to 2 mA	2.5 %
13	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-ECG Amplitude	Using Defibrillator Analyzer by ECG Simulation Method	1 mV to 5 mV	0.3 mV to 0.75 mV
14	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Energy	Using Defibrillator Analyzer by Direct Method	10 J to 360 J	0.41 J to 15.5 J
15	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Ground wire resistance or Earth Resistance or Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 2 ohm	2 %
16	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Heart Rate	Using Defibrillator Analyzer by ECG Simulation Method	30 bpm to 300 bpm	1.63 bpm to 12.74 bpm



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17	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Insulation Resistance	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.96 ohm
18	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Mains Voltage	Using Electrical Safety Analyzer by Direct Method	180 V to 264 V	5.2 V to 5.4 V
19	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pace Maker - Amplitude or Output Accuracy	Using Defibrillator/ Pacemaker Analyzer by Direct Method	8 mA to 28 mA	0.73 mA to 1.74 mA
20	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pace Maker - Pulse Rate or Pacer Rate Accuracy	Using Defibrillator/ Pacemaker Analyzer by Direct Method	60 PPM to 180 PPM	2.57 PPM to 8.32 PPM



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3	MEDICAL DEVICES-IMAGING/PLOT TERS	ECG - Ground wire resistance or Earth Resistance or Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 2 ohm	2 %
4	MEDICAL DEVICES-IMAGING/PLOT TERS	ECG - Heart rate	Using Defibrillator Analyzer by ECG Simulation Method	30 bpm to 300 bpm	1.63 bpm to 12.74 bpm
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15	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Defibrillator-Heart Rate	Using Defibrillator Analyzer by ECG Simulation Method	30 bpm to 300 bpm	1.63 bpm to 12.74 bpm
16	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Defibrillator- Insulation Resistance	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.96 ohm



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