National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 1 of 13

Validity 24/01/2025 to 23/01/2029 **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)(±)
Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Anesthesia Machine) PEEP Pressure	Using Gas Flow Analyzer by Direct Method	0 cmH2O to 30 cmH2O	0.60 cmH2O to 1.2 cmH2O
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Anesthesia Machine) Volume (VT & MV)	Gas Flow Analyzer (By Direct Method)	50 ml to 1000 ml	5 % to 10 %
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(BiPAP/CPAP) Breath Rate	Using Gas Flow Analyzer (By Direct Method)	15 brpm to 30 brpm	10 % to 5 %
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(BiPAP/CPAP) Pressure (IPAP & EPAP)	Using Gas Flow Analyzer (By Direct Method)	0 cmH2O to 25 cmH2O	4 %
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Flow Meter with Humidifier / Oxygen Concentrator) Flow Rate	Using Gas Flow Analyzer (By Direct Method)	1 LPM to 15 LPM	0.58 LPM to 1.2 LPM

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 2 of 13

Validity 24/01/2025 to 23/01/2029 **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)(±)
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Infusion Pump) Volume	Using Infusion Infusion Device Analyzer by Direct Method	1 mL to 500 mL	1.42 % to 1.19 %
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Infusion Pump/Syringe Pump) Flow Rate	Using Infusion Device Analyzer by Direct Method	1 ml/h to 1500 ml/h	1.42 % to 1.16 %
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	(Syringe Pump) Volume	Using Infusion Infusion Device Analyzer by Direct Method:	1 mL to 60 mL	1.42 % to 1.19 %
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	ECG/Digital BP Apparatus - Heart Rate Accuracy	Using Vital Sign Simulator by Comparison method	20 bpm to 300 bpm	3.6 %
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety (AC voltage 50Hz), Medical Devices Supply Voltage	Using Electrical Safety Analyser by Comparison Method	90 V to 265 V	2.5 %

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 3 of 13

Validity 24/01/2025 to 23/01/2029 **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)(±)
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow (Anesthesia Machine, PIF & PEF)	Using Gas Flow Analyzer by Direct Method	1 LPM to 15 LPM	6.8 % to 4.2 %
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump, Syringe pump - Occlusion	Using Infusion Device Analyzer by Comparison method	1 mmHg to 2500 mmHg	8.61 mmHg
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer (Flow)	Using Gas Flow analyzer by Direct Method	1 lpm to 15 lpm	4.2 % to 6.8 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Sphygmometer/Digital BP Apparatus - pressure accuracy	Using Vital Sign Simulator by Comparison method	30 mmHg to 300 mmHg	4.8 mmHg
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Sphygmometer/Digital BP Apparatus/Patient monitor (NIBP) - leakage test per minute	Using Vital Signs Simulator by Comparison method	0 mmHg/min to 15 mmHg/min	1.5 mmHg/min

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 4 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Pump - Vacuum	Using Pressure Indicator by Comparison method	100 mmHg to 675 mmHg	15.23 mmHg
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe pump/Infusion pump-Flow	Using infusion device analyzer by Direct/ comparison method	10 ml/h to 300 ml/h	1.47 %
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe pump/infusion pump-Volume	Using infusion device analyzer by Direct/ comparison method	1 mL to 500 mL	0.12 mL to 0.47 mL
19	MEDICAL DEVICES-IMAGING/PLOTTERS	(Trans illuminator light source / OT light) Lux Measurement	Digital Lux Meter (By Comparison Method)	100 lux to 100000 lux	6.3 %
20	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine (Amplitude)	Using Defibrillator Analyzer, Vital Sign Simulator (By Direct Method)	1 mV to 5 mV	6 %
21	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Unit (amplitude accuracy)	Using Vital Sign Simulator by Compariosn method	0.5 mV to 5 mV	0.06 mV

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 5 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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22	MEDICAL DEVICES-IMAGING/PLOTTERS	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices - Applied part leakage current (50Hz)	Using Electrical Safety Analyzer by Comparison Method	2 µA to 5000 µA	7.33 %
23	MEDICAL DEVICES-IMAGING/PLOTTERS	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety Medical Device-Equipment leakage current (50Hz)	Using Electrical Safety Analyser by Comparison Method	4 uA to 500 uA	5.87 % to 1.5 %
24	MEDICAL DEVICES-MONITORING UNIT	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Device-Earth Resistance	Using Electrical Safety Analyser by Comparison Method	0.2 ohm to 2 ohm	10.97 % to 3.2 %

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 6 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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25	MEDICAL DEVICES-MONITORING UNIT	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices - AC Current (50Hz)	Using Electrical Safety Analyzer	0.1 A to 20 A	7 %
26	MEDICAL DEVICES-MONITORING UNIT	Electronic Weighing Balance(Adult balance) (Class IV) readability: 100 g	Using F2 Class Standard Weights and procedure as per OIML R-76	5 kg to 150 kg	66.3 g
27	MEDICAL DEVICES-MONITORING UNIT	Electronic Weighing Balance(baby balance) (Class III) readability: 1 g	Using F2 Class Standard Weights >3 kg to 5 kg for calibration of class III Weighing Balances and Coarser as per OIML R-76	0.2 kg to 5 kg	20 g
28	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance (@500 V)-EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices	Using Electrical Safety Analyser by Comparison Method	0.5 Mohm to 20 Mohm	8.5 %

SCOPE OF ACCREDITATION

Laboratory Name :	ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA		
Accreditation Standard	ISO/IEC 17025:2017		
Certificate Number	CC-4240	**Page No**	7 of 13
Validity	24/01/2025 to 23/01/2029	**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)(±)
29	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance (@500V)-EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices	Using Electrical Safety Analyser	20 Mohm to 100 Mohm	8.9 %
30	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors (NIBP test)	Simulation Method - using Vital Sign Simulator	30 mmHg to 300 mmHg	2.1 mmHg to 4.8 mmHg
31	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors (Respiration Rate)	Simulation Method - using Vital Sign Simulator	15 brpm to 40 brpm	3.16 % to 0.97 %
32	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors/Pulse oximeter (Heart Rate Accuracy)	Simulation Method - Using Vital sign simulator and SPO2 Functional Tester	20 bpm to 300 bpm	3.6 % to 1.2 %
33	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors/Pulse oximeter (SPO2 accuracy test)	Simulation Method-using SPO2 functional tester	70 % to 100 %	3.6 %

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 8 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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34	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	(Ventilator) Flow/ PIF & PEF	Using Gas Flow Analyzer by Direct Method	1 LPM to 15 LPM	6.8 % to 4.22 %
35	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	(Ventilator) Inspiratory Time & Expiratory Time	Using Gas Flow Analyzer & by Direct Method	1 s to 5 s	0.1 s to 0.2 s
36	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	(Ventilator) O2 Concentration	Using Gas Flow Analyzer & by Direct Method	20 % to 100 %	2.5 % to 3.5 %
37	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	(Ventilator) Pressure/PEEP	Using Gas Flow Analyzer (By Direct Method)	0 cmH2O to 30 cmH2O	0.5 cmH2O to 1.5 cmH2O
38	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	(Ventilator) Volume (VT & MV)	Using Gas Flow Analyzer by Direct Method	50 ml to 1000 ml	6 % to 5 %

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 9 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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39	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Cuff pressure-Electrical Tourniquet	Using Vital Signs Simulator by Comparison method	1 psi to 6 psi	1.5 % to 3.5 %
40	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Charge Time After 1Discharge Cycle)	Using Defibrillator analyzer by Comparison method	1 s to 10 s	0.27 s
41	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (ECG Test - Heart Rate)	Using Defbrillator Analyzer (By Direct Method)	20 bpm to 300 bpm	3,6 % to 1.2 %
42	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator (Energy)	Using Defibrillator Analyzer (By Direct Method)	1 J to 360 J	3.1 % to 2 %

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 10 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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43	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices (Equipment AC Current 50Hz)	Using Electrical Safety Analyser by Comparison Method	0.1A to 20A	7%
44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices (Leakage Current 50Hz)	Using Electrical Safety Analyser by Comparison Method	23 µA to 10 mA	1.3 µA to 3.1 µA
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit/ Diathermy Machine/ Cautery Machine (Load Resistance)	Using Electrosurgery Analyzer (By Direct Method)	50 ohm to 5200 ohm	5 %
46	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit/ Diathermy Machine/ Cautery Machine (Output Power/ Power Distribution)	Using Electrical Surgery Analyzer by Comparison method	10 W to 400 W	6.5 % to 5.8 %

SCOPE OF ACCREDITATION

Laboratory Name : ELECTRO METER CORPORATION, PLOT NO-1294(P), CRP SQUARE, BHUBANESWAR, KHORDHA, ODISHA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 11 of 13

Validity 24/01/2025 to 23/01/2029 **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)(±)
47	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Infant incubator - air velocity	Comparison/Direct method using incubator analyzer	0.3 m/s to 7 m/s	2.8 %
48	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Infant incubator - relative humidity (25°C to 40°C)	Direct/comparison method using incubator analyzer	20 % to 90 %	4 %
49	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Infant incubator - skin/air temperature (40% to 60%RH)	Direct/comparison method using incubator analyzer	20 °C to 40 °C	1 %
50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Infant incubator - sound level (1kHz)	Direct/comparison method using incubator analyzer	30 dB to 130 dB	3 %

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 12 of 13

Validity 24/01/2025 to 23/01/2029 **Last Amended on** -

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51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Insulation Resistance (@500V)-EEG/Semi-auto analyser/Hematology analyser/OT table/Electronic bed/Mechanical bed/Electrical Safety for Medical Devices	Using Electrical Safety Analyser by Comparison Method	20 Mohm to 100 Mohm	8.9%
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Irradiance-Phototherapy Unit	Using Irradiance Meter by Comparison method	10 µW/cm2/nm to 100 µW/cm2/nm	6 %
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacer Current - External Pacemaker	Using defibrillator/pacemaker simulator by Comparison method	10 mA to 200 mA	2.5 %
54	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacer Rate - External Pacemaker	Using defibrillator/pacemaker simulator by Comparison method	40 ppm to 170 ppm	1.91 % to 0.90 %

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Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-4240 **Page No** 13 of 13

Validity 24/01/2025 to 23/01/2029 **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)(±)
55	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using Temperature Sensor & Data Logger by Comparison method	30 °C to 45 °C	2.35 %
56	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Radiant Warmer	Using temperature sensors with logger by Comparison method	21 °C to 50 °C	2.35 %
57	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Timer- Electrical Tourniquet	Using stop watch/timer	1 min to 60 min	0.7 s to 20.4 s

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