



National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)



SCOPE OF ACCREDITATION

Laboratory Name PRISM CALIBRATION CENTRE, GF-101,F/101,101 A,B, TF-85 TO101 RUDRAKSH COMPLEX-II,, AHMEDABAD, --SELECT DISTRICT--, GUJARAT , INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number CC-2480 Page No. : 25 / 60

Validity 26/11/2019 to 25/11/2021 Last Amended on 05/12/2019

S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(\pm)	Remarks
142	MECHANICAL-WEIGHTS	Weights	50 kg	4.1g	Using F1 Class Standard Weights and Precision Balance of Readability: 5g/10g up to 100 kg and ABBA Weighing Cycle Procedure based on OIML R 111
143	MECHANICAL-WEIGHTS	Weights	500 g	0.91mg	Using F1 Class Standard Weights and Precision Balance of Readability: 1 mg up to 1 kg and ABBA Weighing Cycle Procedure based on OIML R 111
144	MECHANICAL-WEIGHTS	Weights	500 mg	0.01mg	Using E2 Class Standard Weights and Precision Balance of Readability: 0.01 mg up to 100 g and Readability: 0.1 mg up to 220 g by substitution method of Weighing and ABBA Weighing Cycle Procedure based on OIML R 111
145	MEDICAL DEVICES-IMAGING/PLOTTERS	Amplitude	0.05 mV to 5.0 mV	4.30% to 4.30%	Using Vital Sign Simulator Prosim 4 By Direct Method
146	MEDICAL DEVICES-IMAGING/PLOTTERS	Chasis Leakage		5.0%	Using Electrical Safety Analyzer ESA 615 By Direct Method



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S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(±)	Remarks
147	MEDICAL DEVICES-IMAGING/PLOTTERS	Ground Wire Resistance	<0.3 OHM	2.60%	Using Electrical Safety Analyzer ESA 615 By Direct Method
148	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart Rate	30 bpm to 300 bpm	2.24% to 2.24%	Using Vital Sign Simulator Prosim 4 By Direct Method
149	MEDICAL DEVICES-IMAGING/PLOTTERS	Insulation Resistance (Optional 500V)	<2 MOHM	2%	Using Electrical Safety Analyzer ESA 615 By Direct Method
150	MEDICAL DEVICES-IMAGING/PLOTTERS	Patient Lead leakage Current (Mains On Patient Applied Part Isolation Test)	<100 BF <10 CF	5%	Using Electrical Safety Analyzer ESA 615 By Direct Method
151	MEDICAL DEVICES-IMAGING/PLOTTERS	Patient Leakage	<100 (AB & BF) <10 (CF)	5%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
152	MEDICAL DEVICES-MONITORING UNIT	Baby Weighing Scale	500 g to 15 kg	3.5g to 3.5g	Using Standard Weight By Comparison Method
153	MEDICAL DEVICES-MONITORING UNIT	Chasis Leakage	<100(NC) <500(SFC) µA	5.20%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
154	MEDICAL DEVICES-MONITORING UNIT	Ground Wire Resistance	<0.3 OHM	2.90%	Using Electrical Safety Analyzer ESA 615 By Direct Method
155	MEDICAL DEVICES-MONITORING UNIT	Heart Rate	30 bpm to 300 bpm	2.9% to 2.9%	Using Vital Sign Simulator Prosim 4 by Direct method
156	MEDICAL DEVICES-MONITORING UNIT	IABP	22 mmHg to 167 mmHg	1.5% to 1.5%	Using Vital Sign Simulator Prosim 4 By Direct Method



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157	MEDICAL DEVICES-MONITORING UNIT	Insulation Resistance (Optional 500V)	<2 MOHM	2.25%	Using Electrical Safety Analyzer ESA 615 By Direct Method
158	MEDICAL DEVICES-MONITORING UNIT	NIBP (Dynamic)	22 mmHg to 167 mmHg	5.8% to 5.8%	Using Vital Sign Simulator Prosim 4 By Direct Method
159	MEDICAL DEVICES-MONITORING UNIT	NIBP Leak Test	22 mmHg to 167 mmHg	0.5mmHg to 0.5mmHg	Using Vital Sign Simulator Prosim 4 By Direct Method
160	MEDICAL DEVICES-MONITORING UNIT	Patient Lead leakage Current (Mains On Patient Applied Part Isolation Test)	<100 BF <10 CF µA	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method
161	MEDICAL DEVICES-MONITORING UNIT	Patient Leakage	<100 (AB & BF) <100 (CF) µA	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method
162	MEDICAL DEVICES-MONITORING UNIT	Patient Weighing Scale	15 kg to 150 kg	7.0g to 7.0g	Using Standard Weight By Comparison Method
163	MEDICAL DEVICES-MONITORING UNIT	Pulse OxymeterHeart Rate	30 bpm to 300 bpm	3.00% to 3.00%	Using SpO2 SPOT Light Meter
164	MEDICAL DEVICES-MONITORING UNIT	Pulse OxymeterSpO2	70 % to 100 %	4.00% to 4.00%	Using SpO2 SPOT Light Meter
165	MEDICAL DEVICES-MONITORING UNIT	Respiration Rate	10 bpm to 150 bpm	6.0% to 6.0 %	Using Vital Sign Simulator Prosim 4 By Direct Method
166	MEDICAL DEVICES-MONITORING UNIT	SpO2	70 % to 100 %	4.5% to 4.5%	Using Vital Sign Simulator Prosim 4 & SPOT Light Meter by Direct method



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S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(±)	Remarks
167	MEDICAL DEVICES-MONITORING UNIT	Temperature	30 °C to 42 °C	1.40°C to 1.40°C	Using Temperature bath and Master Sensor with Indicator by Comparison Method
168	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Chasis Leakage	<100 NC <500 SFC µA	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method
169	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Current	1.00 mA to 100.0 mA	1.4% to 1.4%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
170	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Discharge Time	0.1 Sec to 100.0 Sec	0.10Sec to 0.10Sec	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
171	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Electronic/Mechanical BedChasis Leakage	< 100 (NC) <500 (SFC)	5.20%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
172	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Electronic/Mechanical BedGround Wire Resistance	<0.3 OHM to	2.90%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
173	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Electronic/Mechanical BedInsulation Resistance (Optional 500V)	<2 MOHM	2.25%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
174	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Electronic/Mechanical BedPatient Leakage	<100 (AB & BF) <10 (CF)	5.20%%	Using Electrical Safety Analyzer ESA 615 By Direct Method



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S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(±)	Remarks
175	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Ground Wire Resistance	<0.3 OHM	2.90%	Using Electrical Safety Analyzer ESA 615 By Direct Method
176	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Heart Rate	10 bpm to 200 bpm	7.9% to 1.8%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
177	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Insulation Resistance (Optional 500V)	<2 MOHM	2.25%	Using Electrical Safety Analyzer ESA 615 By Direct Method
178	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Output Energy	2 J to 400 J	3.4% to 4.9%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
179	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pacer Output	10 mA to 100 mA	0.15% to 1.20%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
180	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pacer Rate	5 ppm to 800 ppm	1.40% to 1.40%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
181	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Patient Lead leakage Current (Mains On Patient Applied Part Isolation Test)	<100 BF <10 CF µA	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method
182	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Patient Lead leakage Current(Mains On Patient Applied Part Isolation Test)	<100 (BF) <10 (CF)	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method



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S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(±)	Remarks
183	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Patient Leakage	<100 Ab & BF <10 CF µA	5.20%%	Using Electrical Safety Analyzer ESA 615 By Direct Method
184	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Patient Leakage	<100 (AB & BF) <100 (CF) µA	5.20%	Using Electrical Safety Analyzer ESA 615 By Direct Method
185	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pressure	0 bar to 2 bar	0.40% to 0.40%	Pressure Calibrator & Electrical Safety Analyzer By Comparison Method
186	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pressure	10 mmHg to 390 mmHg	4.20% to 4.20%	Using Vital Sign Simulator Prosim 4 By Direct Method & Digital Stop Watch By Direct Method
187	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pulse Rate	30 ppm to 800 ppm	0.20% to 1.20%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
188	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Pulse Width	5.00 ms to 100.0 ms	0.035% to 0.035%	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method
189	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Synchronization Test	120 msec to 380 msec	1.35 msec to 1.35msec	Using Defibrillator or Analyzer Impulse 7000 DP By Direct Method



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S.No	Discipline / Group	Quantity Measured/ Instrument	Range / Frequency	* Calibration Measurement Capability(±)	Remarks
190	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Temperature	0 °C to 100 °C	0.75°C to 0.75°C	Using Temperature Sensor,Data Logger & Safety Analyzer ESA615 By Comparison Method
191	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Temperature	110 °C to 135 °C	0.60°C to 0.60°C	Using Temperature Sensor,Logger & electrical Safety Analyzer By Comparison Method
192	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Temperature	2 °C to 37 °C	0.3°C to 0.3°C	Using Temperature Sensor With Logger & electrical Safety Analyzer Comparison Method
193	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Temperature	32 °C to 42 °C	0.3°C to 0.3°C	Using Temperature Sensor with Logger & Electrical Safety Analyzer Comparison Method
194	MEDICAL DEVICES-PATIENT CONDITIONING/ MAINTENANCE	Time Interval	1 Min to 60 Min	0.75Min to 0.75Min	Using Vital Sign Simulator Prosim 4 By Direct Method & Digital Stop Watch By Direct Method
195	THERMAL- SPECIFIC HEAT & HUMIDITY	Environment Chambers/Humidity Chamber/Generator/RH & Temp. Devices (Single Position)	15 °C to 50 °C@ 50% RH	0.42°C to 0.42°C@50% RH	Usind Digital Hygrometer & Portable Data Logger As Per DKD R5-7