Laboratory	**Apex Quality Certification Services Pvt. Ltd., 161, Kasturba Nagar, Nirman Nagar, Jaipur, Rajasthan**
Accreditation Standard	**ISO/IEC 17025: 2017**
Certificate Number	**CC-2298** **Page 1 of 8**
Validity	**01.08.2019 to 31.07.2021** **Last Amended on 14.08.2019**

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
	MEDICAL DEVICES CALIBRATION			
1.	**PATIENT MONITOR**			
	Heart Rate	30 bpm to 300 bpm	2.3%	Using Patient Monitor Simulator by Direct Method
	Respiration rate	10 Brpm to 100 Brpm	3.9%	
	NIBP	35/15 mmHg to 200/150 mmHg	1.8 % to 9.7%	
	SpO_2	80% to100%	2%	
	Invasive Pressure	0 to 200 mmHg	1.8% to 9.7%	
2.	**Infusion / Syringe Pump**			
	Flow Rate	300 ml/hr to 1000 ml/hr	1.8% to1.3%	Using Infusion Device Analyzer by Direct Method
	Volume	50 ml to 190 ml	1.7%	
	Occlusion Pressure	0 to 45 psi	1.1 psi	
3.	**Defibrillator**			
	Heart Rate	30 bpm to 360 bpm	2.3%	Using Defibrillator Analyzer by Direct Method
	Output Energy	50 J to 270 J	1.9%	
	Discharge Time	0.1 sec to 100 sec.	0.07sec	
	Synchronizer Operation	-120 msec to 380 msec.	1.3 msec.	
4.	**Suction Pump/ Aspirator**			
	Vacuum (Pressure)	0 to (-)0.8 bar	0.02 bar	Using Pressure Calibrator By Direct Method
5.	**BP Apparatus (Sphygmomanometer)**			
	Leak Test	0 to 10 mmHg/min.	2.23 mmHg/min	Using Vital Sign Simulator by Direct Method
	NIBP (Static Pressure)	0 to 300 mmHg	1.89 mmHg to 4.79 mmHg	

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Program Manager

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6.	**ECG MACHINE**			
	Heart Rate	30 bpm to 360 bpm	2.3 %	Using ECG Analyzer/Vital Sign Simulator by Direct Method
	Amplitude	0.05 mV to 5.0 mV	0.04 mV to 0.29 mV	
7.	**Ventilator** ♣			
	Tidal volume	0.33 L to 60 L	3.5 %	Using Gas Flow Analyzer & Vital Sign Simulator by Direct Method
	Respiration Rate	2 Brpm to 150 Brpm	3.9 %	
	Mean Airway Pressure	80 cmH_2O	4.5 %	
	Positive End Expiratory Pressure (Peep)	(-)5 cmH_2O to 40 cmH_2O	4.5 %	
	Oxygen Concentration	0 to 100%	2.4 %	
8.	**NEBULIZER**			
	Flow	50 lpm to 190 lpm	3.5%	Using Gas Flow Analyzer by Direct Method
9.	**Anasthesia Machine**♣			
	Flow	50 lpm to 190lpm	3.5 %	Using Gas Flow Analyzer by Direct Method
	Volume	0.33 L to 10 L	3.5 %	
	Respiration Rate	2 Brpm to 150 Brpm	3.9 %	
	Mean Airway Pressure	80 cmH2O	4.5 %	
	Positive End Expiratory Pressure (PEEP)	(-)5 cmH_2O to 40 cmH_2O	4.5 %	
	Oxygen Percentage	0 to 100%	2.4 %	
10.	**Radiant Warmer And Infant Incubator**			
	Temperature Of Warmer	25 to 40°C	0.16 °C	Using Temperature sensor with Indicator, Thermo-anemometer, Thermohygrometer, Sound level meter by Direct Method
	Humidity In Warmer	30% to 70% RH	1.8% RH	
	Air Flow	0.4 m/s to 21 m/s	0.17 m/s	
	Sound Level	74 & 114 dB	0.52dB	

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11.	**Pulse oxymeter**			
	1. Heart rate	30 bpm to 240 bpm	2.3 %	Using SpO2 Analyzer Direct Method
	2. SpO2	80% to 100%	1.4 %	
12.	**Tourniquet**			
	1 cuff pressure	30 mmHg to 400 mmHg	6% to1.5%	Using Vital Sign Simulator by Direct Method
	2. Time Interval	10 sec. to 59 mins.	1.2 sec to 35 sec.	
13.	**Blood Gas Analyzer, Semi Auto Analyser, EEG Machine, Hematology Analyzer, O.T. Table, Electronic/ Mechanical Bed** Ground Wire Resistance	< 2 Ω	8.47%	Using Electrical Safety Analyzer by Direct Method
	Chasis Leakage Current	< 100 µA NC <500 µA SFC	5%	
	Patient leakage current	<100 µA for AB, BF < 10 µA CF	5%	
	Patient Lead Leakage Current, Isolation Test (Mains On Applied Parts)	<100 µA for BF <10 µA for CF	10.9%	
	Insulation test (Optional 500v)	< 2 MΩ	14.3%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
	MECHANICAL CALIBRATION			
I.	**DIMENSION (BASIC MEASURING INSTRUMENT, GAUGE ETC.)**			
1.	Vernier Caliper[$] L.C.:0.01mm	0 to 600mm	14.1 µm	Using Caliper Checker by Comparison Method
2.	External Micrometer[$] L.C.: 0.001mm [Φ]	0 to 25 mm	1.5 µm	Using Micrometer Checker & Slip Gauges and Optical Flats By Comparison Method as per IS:2967
3.	Plunger Type Dial Gauge[$] L.C.: 0.001mm L.C.: 0.01mm	 Upto10 mm 0 to 50 mm	 2.3 µm 8.0 µm	Using Slip Gauges & Dial Comparator Stand By Comparison Method
4.	Depth Gauge[$] (Vernier/Digital/Dial) L.C.: 0.01 mm	0 to 300 mm	10.0 µm	Using Slip Gauge set& surface plate by Comparison Method
5.	Height Gauge[$] L.C.: 0.01mm	0 to 600 mm	10.0 µm	Using Caliper Checker and Slip Gauge by Comparison Method
6.	Feeler Gauge[$]	Upto 3 mm	2.0 µm	Using Digital Micrometer
7.	Plain Plug Gauge[$]	1mm to 50 mm	4.7 µm	Using Comparator Stand, Digital Plunger Gauge, Slip Gauge Set by Comparison Method

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
8.	Snap Gauge[$]	3mm to 100 mm	4 µm	Using Slip Gauge Set by Comparison Method
9.	Measuring Pin[$]	Upto 25 mm	2.6 µm	Using Comparator Stand, Digital Plunger Gauge, Slip Gauge Set by Comparison Method
10.	Dial/ Digital Thickness Gauges[$] L.C.: 0.001 mm L.C.: 0.01mm	 Upto 10 mm Upto 25 mm	 1.3 µm 6.0 µm	 Using Slip Gauges Set by Comparison Method
11.	Coating Thickness Gauges[$]	10µm to 1000µm	3 µm	Using Standard Coating Foils by Comparison Method
II.	**ACCELERATION AND SPEED**			
1.	Tachometer /Centrifuge/RPM Meter[#] (Non contact Type)	 100 rpm to 30,000 rpm	 5 % rdg to 0.11 % rdg	 Using Digital Tachometer & RPM Calibrator
III.	**WEIGHING SCALE & BALANCE**			
1.	Weighing Scale & Balance[*] Readability= 0.01mg Readability =0.1mg Readability =1g Readability=20g	 0 to 200g 0 to 200g 0 to 30 kg 0 to 135 kg	 0.1mg 0.2mg 2g 40g	 Using Standard Weights of E2 Class as per OIML R-76-1 & OIML R-76-2 Using Standard Weights of FI Class as per OIML R-76-1 & OIML R-76-2

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
IV.	**PRESSURE INDICATING DEVICES**			
1.	Pressure- Pneumatic# (Pressure Gauges, Pressure Indicator, Pressure Transducers, Transmitters,	0 to 30 bar	0.06 bar	Using Digital Pressure Gauges as per DKD R 6-1 by Comparison Method
2	Pressure- Hydraulic# (Pressure Gauges, Pressure Indicator, Pressure Transducers, Transmitters	0 to 30 bar 30 bar to 600 bar	0.06 bar 2.5 bar	Using Digital Pressure Gauges as per DKD R 6-1 by Comparison Method
3.	Vacuum-Pneumatic# (Vacuum Gauges, Vacuum Transmitters, Switches)	(-) 0.8 bar to 0 bar	0.018 bar	Using Digital Vacuum Gauge as per DKD R 6-1 by Comparison Method
V.	**VOLUME**			
1.	Micro Pipette, Piston Pipette♣	10 µl to 100 µl >100 µl to 1000 µl	0.66 µl 0.47 µl	Using Weighing Balance with d:0.01mg/0.1mg Cap.82g/220g and distilled water of known density as per ISO 8655-6:2002 Gravimetric Method

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
		THERMAL CALIBRATION		
I.	**TEMPERATURE**			
1.	RTD /Thermocouple / Temperature Sensor With & Without Indicator / Temperature Transmitter[#]	(-) 30 ºC to 200 ºC	0.23 ºC	Using RTD Sensor with Indicator and Liquid Bath By Comparison Method
		200 ºC to 1200 ºC	3.0 ºC	Using R type T/C with Indicator and Dry Well Bath by Comparison Method
2.	Liquid In Glass Thermometer[$]	(-)10 ºC to 200 ºC	1.0 ºC	Using RTD Sensor with Indicator and Liquid Bath By Comparison Method
3.	Temperature Indicator With Sensor of Deep Freezers/Bath[♣]	(-) 80 ºC to 10 ºC	2.5 ºC	Using RTD Sensor with Indicator (Single Position Calibration)
4.	Temperature Indicator with Sensors of Oven/ Incubator/ BOD Incubator (For Non Medical Devices)/ Autoclave(For Non Medical Devices)/ Bath[♣]	10 ºC to 250 ºC	1.25 ºC	Using RTD Sensor with Indicator (Single Position Calibration)

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Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
5.	Temperature Indicator with sensors of Furnace / Oven / Muffle Furnace[♣]	250 ºC to 1200 ºC	3.0 ºC	Using R type T/C with Indicator and Dry Well Bath by Comparison Method

*** Measurement Capability is expressed as an uncertainty (±) at a confidence probability of 95%**
[$] Only in Permanent Laboratory
[♣] Only for Site Calibration
[#] The laboratory is also capable for site calibration however, the uncertainty at site depends on the prevailing actual environmental conditions and master equipment used.
[Φ] Laboratory can also calibrate instruments/devices of coarser resolution / least count within the accredited range using same reference standard/ master equipment under the scope of accreditation.

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