Laboratory	**Transcaal Engineers India Pvt. Limited, #96/1-1,1st Floor, East Park Road, 9th Cross, Malleswaram, Bangalore, Karnataka**
Accreditation Standard	**ISO/IEC 17025: 2005**
Certificate Number	**CC-2898** **Page** **1 of 9**
Validity	**03.12.2018 to 02.12.2020** **Last Amended on**

"In view of the transition for ISO/IEC 17025:2017, the validity of this accreditation certificate will cease on 30.11.2020"

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
	MEDICAL DEVICE C ALIBRATION			
1.	Electrical Safety#			
	A) Voltage	90-132 V ac rms 180-264 V ac rms	2.4%	Electrical safety test, using Electrical safety analyzer
	B) Earth Resistance	0 – 2 Ω	3.2%	IEC 62353:2014
	C)Equipment Current	0- 20 A AC	6.9%	
	D)Leakage Current	0 µA – 10 mA	1.2%	
	E)Insulation Resistance	0.5 – 20 MOhm 20-100 MΩ	3.5% 8.9%	
2.	Patient Monitor #			
	A) Heart rate accuracy	30 - 320 bpm	2.6%	Simulation Method – Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	B) Respiration rate	0 - 100 bpm	8.9%	
	C) NIBP leakage test	<330 mmHg	5%	
	D) NIBP test	35/15 to 200/150 mmHg	4 %	
	E) NIBP Pressure relief test	< 15 mmHg	4.1%	
	F) Invasive blood pressure accuracy	35/15 to 200/150 mmHg	10.2 %	
	G) SPO2 accuracy test Heart rate	70 % - 100 % 30 - 240 BPM	3.6% 1.3 %	

Vishal Shukla
Convenor

Avijit Das
Program Manager

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
3.	Syringe Pump #			Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014
	A)Flow	**2 ml/hr - 100 ml/hr**		
		16 – 200 ml/hr (20ml)	4.2%	
		< 10 & >200ml/Hr (10ml)	2%	
		1 ml - 20 ml		
	B) Volume	16 - 200ml/hr (20ml).	4.5%	
		< 10 & >200ml/Hr (10ml)	1.3%	
	C) Occlusion	0 - 45 psi	1.2%	
4.	Infusion Pump #			Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer IEC 62353:2014
	A)Flow	**10 - 500 ml/hr**	2.5%	
		16 – 200 ml/hr (20ml)	1.2%	
		< 10 & >200ml/Hr (10ml)		
	B) Volume	**1 ml to 50 ml**	2.6%	
		16 – 200 ml/hr (20 ml)	1.2%	
		< 10 & >200ml/Hr (10ml)		
	C) Occlusion	0 - 45 psi	2.5%	
5.	Autoclave #			Comparison method Using Temperature sensor, logger, Pressure Calibrator & electrical safety analyzer IEC 62353:2014, AMS 2750 DKD R6-1
	A)Temperature	110°C - 135°C	0.54°C	
	B) Pressure gauge	0 - 2 bar	0.36%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
6.	Defibrillator #			Simulation & Comparison Method – Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	A) Heart rate accuracy	10 to 300 bpm	1%	
	B) Output accuracy (Energy)	50 to 270 J	1.3%	
	C) Output energy @ max setting for 10CHg cycle (at battery power)	50 to 270 J	1.5 %	
	D) Charge time after 10 discharge cycles	≤ 15 sec	NA	
	E) Energy after 60 sec of full charge @ max energy	≥ 85%	NA	
	F)Synchronizer Operation	≤ 60 msec	NA	
	G) NIBP test	40/20 to 200/150 mmHg	4%	
	H) O2 saturation(Spo2) Heart rate	70 % to 100 % 30 to 240 BPM	3.6% 1.3%	
	I) Pacer Amplitude	0 to 25 mA	2.6%	
	J) Pacer Rate accuracy	5 to 800 ppm	2.4%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
7.	Suction Pump# (Vacuum)	0 to 600 mmHg	2.5%	Comparison method Using VT Mobile & electrical safety analyzer IEC 62353:2014
8.	Flow Meter#	2.5 to 25 lpm	3.6%	Comparison method Using VT mobile IEC 62353:2014
9.	BP Apparatus / Sphygmomanometer#			Comparison method Using Vital sign simulator
	A)Leak test	≤ 15 mmHg/min	NA	
	B)Gauge Zero	± 1 mmHg	NA	
	C) Pressure accuracy	0 - 300 mmHg	5%	
10.	Digital BP Apparatus#			Simulation method Using Vital sign simulator Instrumentation & Technical Services University of Vermont
	A) Leak test	≤ 15 mmHg/min	NA	
	B) Pressure accuracy	60/30 to 200/150 mmHg	4.9%	
	C) Heart Rate accuracy	30 to 320 bpm	1.6%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
11.	ECG Unit #			Simulation method Using Vital sign simulator & Electrical safety analyzer
	A) Heart rate accuracy	30 to 320 BPM	1.2 %	
	B) Amplitude accuracy	0.05 to 5 mV	3.9 %	IEC 62353:2014 Instrumentation & Technical Services University of Vermont
12.	Ventilator #			
	A)Volume Accuracy	0 to 1000 ml	3.6%	Comparison method using VT Mobile & Electrical safety analyzer
	B) Respiration rate	2 to 150 brpm	1.2%	
	C) Inspiratory, Expiratory Time	0.25 to 9.99 s	2.0%	IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	D) Pressure accuracy (PIP)	0 to 120 cm H2O	3.6%	
	E)Peep	0 to 40 cm H2O	3.7%	
	D) Oxygen percentage	0 to 100 %	2.3%	
13.	Nebulizer (Flow) #	2.5 to 25lpm	3.7%	Comparison Method using Gas Flow Analyzer and Electrical Safety Analyzer

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
14.	Radiant Warmer# (Temperature)	21- 50°C	0.7°C	Comparison method Using temperature sensors, logger & Electrical safety analyzer IEC 62353:2014
15.	Electro Surgery Unit#			
	A) Output Power	0 - 400 W	5.8%	Comparison method using RF 303 & Electrical safety analyzer IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	B)REM Test	< manufacturer specified resistance	NA	
	C) Power Distribution test	0 - 400 W	6.0%	
16.	Baby Weighing Scale#	500g to 15 kg Readability: 20 g	11.3g	Comparison method
17.	External Pace Maker #			
	A) Rate accuracy	5 to 800 ppm	2.4%	Using Impulse 7000 DP & Electrical safety analyzer by Comparison method IEC 62353:2014
	B) Amplitude	0 - 25mA	2.6%	
18.	Fetal Monitor #			Using PS320 & Electrical safety analyzer Simulation method IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	A) Fetal Heart Rate	30 to 240 bpm	1.2%	
	B)Maternal Heart Rate	60 to160 bpm	1%	
	C)TOCO	20 to 100 IUP	1.45%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
19.	Anesthesia Machine#			using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	A)Volume Accuracy	0 to 1000 ml	3.6%	
	B)Respiration Rate	2 to150 bpm	1.2%	
	C)Inspiratory, Expiratory time	0.25 to 9.99 s	2.0%	
	D)Pressure Accuracy(PIP)	±120 cm H_2O	3.5%	
	E)PEEP	(-)5 to 40 cm H_2O	3.5%	
	F)Oxygen Percentage	0 to 100%	2.3%	
	G)Hypoxic guard test	Safety Functional Check	NA	
20.	Dialysis Machine #			using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014 Instrumentation & Technical Services University of Vermont
	A) Dialysate Conductivity Test	13 to15 mS/cm	0.21mS/cm	
	B)Temperature Test	0-100°C(37°C)	1°C	
	C)Flow Test	200-2000 ml/min	1.9%	
	D)pH Test	7pH(water pH)	0.2 pH	
	E)Timer Test	15min to 1 Hr	1.2 -2.2 Sec	
	F)Pressure Test	±3 mmHg(-700 to 1900 mmHg)	2.8%	
	G) NIBP test	180/60 mmHg	3.2%	
	H) PPM	90 PPM	2.4%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
21.	Electronic Tourniquet #			
	A)Cuff pressure accuracy	0-100 psi	2.3%	using VT Mobile, Stop watch & Electrical safety analyzer Comparison method
	B)Timer Accuracy	15 mins	1 Sec	
	C)Max Cuff Pressure	≤550 mmHg / manufacturers Specification	2.3%	IEC 62353:2014 Instrumentation & Technical Services
	D)Controller Stability	±10 mmHg after 15 min	NA	University of Vermont
22.	CPAP (positive pressure) #	± 120 cmH20	2.3%	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014
23.	BiPAP #			using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014
	A)IPAP in cmH_2O	±120 cm H_2O	3%	
	B)EPAP in cmH_2O	±120 cm H_2O	3%	
	C)RR in bpm	2-150 brpm	2.0%	
	D)Ti in sec	0.25-9.99s	1.2%	

Sl.	Quantity Measured / Instrument	Range/Frequency	*Calibration Measurement Capability (±)	Remarks
24.	Patient Warmer (Temperature) #	32°C – 42°C	0.2°C	using Temperature sensor with logger & electrical safety analyzer Comparison method IEC 62353:2014
25.	Lab Incubator (Temperature) #	37°C	0.3°C	using Temperature sensor with logger & electrical safety analyzer Comparison method IEC 62353:2014
26.	Hot Air Oven# (Temperature)	50°C to 250°C	1°C	using Temperature sensor with logger & electrical safety analyzer Comparison method IEC 62353:2014

 # The laboratory is also capable for site calibration however, the uncertainty at site depends on the prevailing actual environmental conditions and master equipment used.