CERTIFICATE OF ACCREDITATION

This is to attest that

TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED.

NO.116, 3RD FLOOR, 11TH CROSS, MARGOSA ROAD (3RD MAIN), MALLESWARAM,
BANGALORE 560003, REPUBLIC OF INDIA

Calibration Laboratory CL-267

has met the requirements of AC204, *IAS Accreditation Criteria for Calibration Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories.* This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date May 24, 2023

Expiration Date May 1, 2025

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED.

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Accredited to ISO/IEC 17025:2017 *Effective Date May 24, 2023*

CALIBRATION AND MEASUREMENT CAPABILITY (CMC)*

MEASURED QUANTITY or DEVICE TYPE CALIBRATED[3]	RANGE	UNCERTAINTY[1,2] (±)	CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL)
Biomedical			
Electrical Safety Test[4]			
AC Voltage (50 Hz)	90 V_{rms} to 264 V_{rms}	2.4 %	Calibration procedure TEPL-CAL-ESA-01. Using Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 by direct Method
Earth Resistance	0.01 Ω to 2 Ω	3.2 %	
Equipment AC Current (50 Hz)	0.01 A to 20 A	7.0 %	
Leakage Current	2 µA to 10 mA	1.5 %	
Equipment Leakage Current	2 µA to 500 µA	1.5 %	
Applied Part Leakage Current	2 µA to 5000 µA	1.5 %	
Insulation Resistance	0.5 MΩ to 20 MΩ 20 MΩ to 100 MΩ	3.6 % 9.2 %	
Anesthesia Machine			
Inspiratory, Expiratory Time	0.25 s to 9.99 s	3.2 %	Calibration procedure TEPL-CAL-ANS-01. Using gas flow analyzer by direct method
Oxygen Percentage	21 % to 100 %	2.3 %	
PEEP	1 cmH_2O to 40 cmH_2O	3.5 %	
Pressure Accuracy (PIP)	1 cmH_2O to 120 cmH_2O	3.5 %	
Respiration Rate	2 brpm to 150 brpm	2.0 %	
Volume	5 mL to 1000 mL	3.6 %	
BiPAP			
EPAP in cmH_2O	1 cmH_2O to 120 cmH_2O	3.4 %	Calibration procedure TEPL-CAL-BiPAP-01. Using gas flow analyzer by direct method
IPAP in cmH_2O	1 cmH_2O to 120 cmH_2O	3.4 %	
Respiration Rate	2 brpm to 150 brpm	2.0 %	
Inspiratory Time (Ti)	0.25 s to 9.99 s	3.2 %	

** If information in this CMC is presented in non-SI units, the conversion factors stated in NIST Special Publication 811 "Guide for the Use of the International System of Units (SI)" apply.*

MEASURED QUANTITY or DEVICE TYPE CALIBRATED[3]	RANGE	UNCERTAINTY[1,2] (±)	CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL)
Boyles Apparatus			
Flow Rate	1 lpm to 15 lpm	2.5 %	Calibration procedure TEPL-CAL-BOYL-01. Using Gas Flow analyzer by direct method
Oxygen Percentage	21 % to 100 %	2.3 %	
Blood Pressure (BP) Apparatus (Sphygmomanometer / Digital BP Apparatus)			
Heart Rate accuracy	30 bpm to 320 bpm	2.2 %	Calibration procedure TEPL-CAL-BP-01 and TEPL-CAL-DBP-01. Using Vital sign simulator by Direct Method
Pressure (Dynamic)	25 mmHg to 300 mmHg	4.0 %	
Pressure (Static)	25 mmHg to 300 mmHg	1.0 %	
CPAP			
Positive pressure	1 cmH_2O to 150 cmH_2O	3.4 %	Calibration procedure TEPL-CAL-CPAP-01. Using gas flow analyzer by direct method
Defibrillator			
Heart Rate	10 bpm to 300 bpm	2.2 %	Calibration procedure TEPL-CAL-DEF-01. Using Defibrillator Analyzer, Vital sign simulator by direct method
Pacer Rate	5 ppm to 800 ppm	2.7 %	
NIBP	25 mmHg to 300 mmHg	4.0 %	
O_2 Saturation (Spo2)	70 % to 100 %	3.6 %	
O_2 Saturation (Spo2), Heart	30 bpm to 240 bpm	2.2 %	
Output Accuracy (Energy)	1 J to 360 J	3.0 %	
Pacer Amplitude	2 mA to 25 mA	2.8 %	
Dialysis Machine			
Dialysate Conductivity	13 mS/cm to 15 mS/cm	0.21 mS/cm	Calibration procedure TEPL-CAL-DIA-01. Using Dialysis Meter by direct method
Flow Rate	10 mL/min to 800 mL/min	3.5 %	
NIBP	25 mmHg to 300 mmHg	4.0 %	
pH Value	6.5 pH to 7.5 pH	0.2 pH	
Temperature	1 °C to 100 °C	0.06 °C	
ECG			
Amplitude	0.5 mV to 5 mV	2.6 %	Calibration procedure TEPL-CAL-ECG-01. Using Vital sign simulator & Defibrillator Analyzer by direct method
Heart rate	30 bpm to 320 bpm	2.2 %	
Electro Surgical Unit/ Diathermy Machine/ Cautery Machine			
Output Power	1 W to 400 W	7.3 %	Calibration procedure TEPL-CAL-ESU-01. Using ESU Analyzer by Direct method

MEASURED QUANTITY or DEVICE TYPE CALIBRATED[3]	RANGE	UNCERTAINTY[1,2] (±)	CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL)
Electronic Tourniquet			
Cuff Pressure	1 psi to 100 psi	1.2 %	Calibration procedure TEPL-CAL-TOUR-01. Using Gas Flow analyzer, Stopwatch by direct Method
Timer	1 min to 1 h	10 s	
Enteral Feeding Pump			
Flow Rate	1 mL/h to 600 mL/h	2.3 %	Calibration procedure TEPL-CAL-FP-01. Using Infusion Device Analyzer by direct method
Occlusion	50 mmHg to 2300 mmHg	1.6 %	
Volume	1 mL to 999 mL	2.3 %	
External Pacemaker			
Pacer Rate	5 bpm to 800 bpm	2.7 %	Calibration procedure TEPL-CAL-PAC-01. Using Defibrillator Analyzer by direct method
Amplitude	2 mA to 25 mA	2.8 %	
Fetal Doppler			
Fetal Heart Rate	30 bpm to 240 bpm	0.4 %	Calibration procedure TEPL-CAL-FD-01 Using Fetal Simulator by direct method
Fetal Monitor			
Maternal Heart Rate	60 bpm to 160 bpm	0.4 %	Calibration procedure TEPL-CAL-FM-01. Using Fetal simulator by direct Method
Fetal Heart Rate	30 bpm to 240 bpm	0.4 %	
Flow Meter			
Flow Rate	2.5 L/min to 25 L/min	2.5 %	Calibration procedure TEPL-CAL-FLM-01. Using Gas Flow analyzer by Direct Method
Heart Lung Machine			
Oxygen Percentage	21 % to 100 %	2.3 %	Calibration procedure TEPL-CAL-HLM-01 Using Gas flow analyzer by direct Method.
Humidifier			
Temperature	5 °C to 50 °C	0.6 °C	Calibration procedure TEPL-CAL-HF-01 Using Temperature sensor with logger by Direct Method.

MEASURED QUANTITY or DEVICE TYPE CALIBRATED[3]	RANGE	UNCERTAINTY[1,2] (±)	CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL)
Incubator			
Air Flow	0.2 m/s to 2 m/s	5.8 %	Calibration procedure TEPL-CAL-INCU-01. Using Incubator Analyzer by direct method
Air Temperature	5 °C to 50 °C	0.06 °C	
Noise level	30 dB to 100 dB	5.8 %	
Relative Humidity	10 %RH to 95 %RH	4 %RH	
Skin Temperature	5 °C to 50 °C	0.06 °C	
Surface Temperature	5 °C to 50 °C	0.06 °C	
Infusion Pump			
Flow	5 mL/h to 1000 mL/h	2.3 %	Calibration procedure TEPL-CAL-IP-01 Using Infusion Device Analyzer by direct method
Occlusion	50 mmHg to 2300 mmHg	1.6 %	
Volume	1 mL to 1000 mL	2.3 %	
Nebulizer			
Flow	2.5 L/min to 25 L/min	2.5 %	Calibration procedure TEPL-CAL-NEB-01. Using Gas Flow Analyzer by direct method
OT Light			
Light Intensity measurement	1 lux to 200,000 lux	4.9 %	Calibration procedure TEPL-CAL-LUX-01. Using Illuminance Meter by direct Method.
Oxygen Concentrator			
Flow	1 L/min to 15 L/min	2.5 %	Calibration procedure TEPL-CAL-OXCO-01. Using Gas Flow Analyzer by direct Method
Oxygen Percentage	21 % to 100 %	2.3 %	
Patient Monitors			
Heart rate (Spo2 Pulse Rate)	30 bpm to 240 bpm	1.3 %	Calibration procedure TEPL-CAL-MPM-01. Using Vital sign simulator, SPO2 functional tester by direct method
Heart rate	30 bpm to 320 bpm	2.6 %	
Invasive Blood Pressure Accuracy	35/15 mmHg to 200/150 mmHg	1.9 %	
NIBP Leakage Check	1 mmHg/min to 15 mmHg/min	5 %	
NIBP Pressure Relief Check	1 mmHg to 330 mmHg	4.1 %	
NIBP	1 mmHg to 300 mmHg	4 %	
Respiration rate	15 bpm to 150 bpm	5.8 %	
SPO2	70 % to 100 %	3.6 %	

MEASURED QUANTITY or DEVICE TYPE CALIBRATED[3]	RANGE	UNCERTAINTY[1,2] (±)	CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL)
Patient Warmer			
Temperature	32 °C to 43 °C	0.6 °C	Calibration procedure TEPL-CAL-PW-01. Using Temperature sensor with logger by Direct method
Phototherapy Unit			
Irradiance	5 µW/cm^2/nm to 100 µW/cm^2/nm	7.1 %	Calibration procedure TEPL-CAL-PT-01. Using Flux meter by Direct Method.
Pulse Oxymeter			
Pulse Oxymeter Heart Rate	30 bpm to 240 bpm	2.2 %	Calibration procedure TEPL-CAL-POX-01. Using SPO2 functional tester by Direct Method
SPO2 Accuracy (Pulse Oxymeter)	70 % to 100 %	3.6 %	
Radiant Warmer			
Temperature	21 °C to 50 °C	0.6 °C	Calibration procedure TEPL-CAL-RW-01. Using Temperature sensor with logger by direct method.
Suction Pump			
Vacuum Pressure	10 mmHg to 760 mmHg	2.5 %	Calibration procedure TEPL-CAL-SUM-01. Using Gas Flow analyzer by direct method.
Syringe Pump			
Flow Rate	5 mL/h to 1000 mL/h	2.3 %	Calibration procedure TEPL-CAL-SP-01. Using Infusion Device Analyzer by direct method
Occlusion	50 mmHg to 2300 mmHg	1.6 %	
Volume	1 mL to 60 mL	2.3 %	
Ventilator			
Inspiratory, Expiratory Time	0.25 s to 9.99 s	3.2 %	Calibration procedure TEPL-CAL-VENT-01. Using Gas Flow analyzer by Direct Method
Oxygen Percentage	21 % to 100 %	2.3 %	
Peep	1 cmH_2O to 40 cmH_2O	3.5 %	
Pressure (PIP)	1 cmH_2O to 120 cmH_2O	3.5 %	
Respiration Rate	2 brpm to 150 brpm	2.0 %	
Volume	5 mL to 1000 mL	3.6 %	

[1]The uncertainty covered by the Calibration and Measurement Capability (CMC) is expressed as the expanded uncertainty having a coverage probability of approximately 95 %. It is the smallest measurement uncertainty that a

laboratory can achieve within its scope of accreditation when performing calibrations of a best existing device. The measurement uncertainty reported on a calibration certificate may be greater than that provided in the CMC due to the behavior of the calibration item and other factors that may contribute to the uncertainty of a specific calibration.

[2]When uncertainty is stated in relative terms (such as percent, a multiplier expressed as a decimal fraction or in scientific notation), it is in relation to instrument reading or instrument output, as appropriate, unless otherwise indicated.

[3]All calibrations are performed at customer's facility.

[4]Electrical safety tests are applied to all medical devices where applicable.

bpm = beats per minute
brpm = breaths per minute