

CERTIFICATE OF ACCREDITATION

This is to attest

TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED.

NO.116, 3RD FLOOR, 11TH CROSS, MARGOSA ROAD (3RD MAIN), MALLESWARAM, BANGALORE, KA 560003, 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 January 21, 2025



International Accreditation Service Issued under the authority of IAS management

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED.

www.tepl.info

Contact Name Hidayat Rasool M Bijapur

Contact Phone +91-8095111996

Accredited to ISO/IEC 17025:2017

Effective Date January 21, 2025

CALIBRATION AND MEASUREMENT CAPABILITY (CMC)*

| MEASURED QUANTITY or DEVICE TYPE CALIBRATED ³ | RANGE | UNCERTAINTY ^{1,2} (±) | CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL) |
|--|--|-----------------------------------|---|
| | Biome | edical | |
| Electrical Safety Test ⁴ | | | |
| AC Voltage (50 Hz) | 90 V _{rms} to 264 V _{rms} | 2.4 % | Calibration procedure TEPL-CAL- |
| Earth Resistance | 0.01 Ω to 2 Ω | 3.2 % | ESA-01. |
| Equipment AC Current (50 Hz) | 0.01 A to 20 A | 7.0 % | Using Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 by direct |
| Leakage Current | 2 μA to 10 mA | 1.5 % | Method |
| 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 | 3.6 % | |
| | 20 MΩ to 100 MΩ | 9.2 % | |
| Anesthesia Machine | T | T | |
| Inspiratory, Expiratory Time | | 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 ₂ O to 40 cmH ₂ O | 3.5 % | |
| Pressure Accuracy (PIP) | 1 cmH ₂ O to 120 cmH ₂ O | 3.5 % | |
| Respiration Rate | 2 brpm to 150 brpm | 2.0 % | |
| Volume | 5 mL to 1000 mL | 3.6 % | |
| BiPAP | | | |
| EPAP in cmH ₂ O | 1 cmH ₂ O to 120 cmH ₂ O | 3.4 % | Calibration procedure TEPL-CAL-BiPAP-01. Using gas flow analyzer by direct method |
| IPAP in cmH ₂ O | 1 cmH ₂ O to 120 cmH ₂ O | 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.



International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

| MEASURED QUANTITY or DEVICE TYPE CALIBRATED ³ | RANGE | UNCERTAINTY ^{1,2} (±) | CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL) |
|--|--|-----------------------------------|---|
| Boyles Apparatus | | • | |
| Flow Rate Oxygen Percentage | 1 lpm to 15 lpm 21 % to 100 % | 2.5 % | Calibration procedure TEPL-CAL-BOYL-01. Using Gas Flow analyzer by direct method |
| Blood Pressure (BP) Appa | aratus (Sphygmomanomet | er / Digital BP Appara | tus) |
| Heart Rate accuracy | 30 bpm to 320 bpm | 2.2 % | Calibration procedure |
| Pressure (Dynamic) | 25 mmHg to 300 mmHg | 4.0 % | TEPL-CAL-BP-01 and TEPL-CAL-DBP-01. Using Vital sign simulator by Direct Method |
| Pressure (Static) | 25 mmHg to 300 mmHg | 1.0 % | |
| CPAP | | | · |
| Positive pressure | 1 cmH ₂ O to 150 cmH ₂ O | 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 |
| Pacer Rate | 5 ppm to 800 ppm | 2.7 % | TEPL-CAL-DEF-01. Using Defibrillator Ana- lyzer, Vital sign simulator by direct method |
| 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/ Diat | | | |
| Output Power | 1 W to 400 W | 7.3 % | Calibration procedure TEPL-CAL-ESU-01. |





International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

| MEASURED QUANTITY or DEVICE TYPE CALIBRATED ³ | RANGE | UNCERTAINTY ^{1,2} (±) | CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL) |
|--|--|-----------------------------------|--|
| | | | Using ESU Analyzer by Direct method |
| Electronic Tourniquet | | | |
| Cuff Pressure | 20 mm Hg to 600 mm Hg | 1.2 % | Calibration procedure |
| Timer | 5 min to 1 h 1 h to 2 h 2 h to 4 h | 4 s 8 s 17 s | TEPL-CAL-TOUR-01. Using Gas Flow analyzer, Stopwatch by direct Method |
| Enteral Feeding Pump | | | |
| Flow Rate | 1 mL/h to 600 mL/h | 2.3 % | Calibration procedure |
| Occlusion | 50 mmHg to 2300 mmHg | 1.6 % | TEPL-CAL-FP-01. |
| Volume | 1 mL to 999 mL | 2.3 % | Using Infusion Device Analyzer by direct method |
| External Pacemaker | | | |
| Pacer Rate | 5 bpm to 800 bpm | 2.7 % | Calibration procedure |
| Amplitude | 2 mA to 25 mA | 2.8 % | TEPL-CAL-PAC-01. Using Defibrillator Analyzer by direct method |
| 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 |
| Fetal Heart Rate | 30 bpm to 240 bpm | 0.4 % | TEPL-CAL-FM-01. Using Fetal simulator by direct Method |
| Oxygen 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 | 33 °C and 37 °C | 0.6 °C | Calibration procedure TEPL-CAL-HF-01 Using Temperature sensor with logger by Direct |

CL-267 TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED. Effective Date January 21, 2025 Page 4 of 7

IAS/CL/100-3



International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

| MEASURED QUANTITY or DEVICE TYPE CALIBRATED ³ | RANGE | UNCERTAINTY ^{1,2} (±) | CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL) |
|--|-------------------------------|-----------------------------------|--|
| | | | Method. |
| Incubator | • | • | • |
| Air Flow | 0.2 m/s to 2 m/s | 5.8 % | Calibration procedure |
| Air Temperature | 5 °C to 50 °C | 0.06 °C | TEPL-CAL-INCU-01. Using Incubator Analyzer by direct method |
| 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 | | <u> </u> | |
| Flow | 5 mL/h to 1000 mL/h | 2.3 % | Calibration procedure |
| Occlusion | 50 mmHg to 2300 mmHg | 1.6 % | TEPL-CAL-IP-01 |
| Volume | 1 mL to 1000 mL | 2.3 % | Using Infusion Device Analyzer by direct method |
| 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 | 1000 lx to 200000 lx | 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 | | <u> </u> | |
| Heart rate (Spo2 Pulse Rate) | 30 bpm to 240 bpm | 1.3 % | Calibration procedure TEPL-CAL-MPM-01. |
| Heart rate | 30 bpm to 320 bpm | 2.6 % | Using Vital sign simulator, SPO2 functional tester by direct method |
| 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 % | |

CL-267 TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED. Effective Date January 21, 2025 Page 5 of 7

IAS/CL/100-3



International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

| MEASURED QUANTITY or DEVICE TYPE CALIBRATED ³ | RANGE | UNCERTAINTY ^{1,2} (±) | CALIBRATION METHOD OR PROCEDURE, STANDARD EQUIPMENT (OPTIONAL) |
|--|--|-----------------------------------|--|
| SPO2 | 70 % to 100 % | 3.6 % | |
| Patient Warmer | | 1 | , |
| 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/cm²/nm to 100 μW/cm²/nm | 7.1 % | Calibration procedure TEPL-CAL-PT-01. Using Flux meter by Direct Method. |
| Pulse Oxymeter | | | |
| Pulse Oximeter Heart Rate | 30 bpm to 240 bpm | 2.2 % | Calibration procedure |
| SPO2 Accuracy (Pulse Oximeter) | 70 % to 100 % | 3.6 % | TEPL-CAL-POX-01. Using SPO2 functional tester by Direct Method |
| 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 | -10 mm Hg to -600 mm Hg | 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 | <u> </u> | I | 1.* |
| 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 ₂ O to 40 cmH ₂ O | 3.5 % | |
| Pressure (PIP) | 1 cmH ₂ O to 120 cmH ₂ O | 3.5 % | |
| Respiration Rate | 2 brpm to 150 brpm | 2.0 % | |
| Volume | 5 mL to 1000 mL | 3.6 % | |

CL-267
TRANSCAAL ENGINEERS INDIA PRIVATE LIMITED.
Effective Date January 21, 2025
Page 6 of 7
IAS/CL/100-3



International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

¹The 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.

²When 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.

³Capability is suitable for the calibration of measuring devices in the stated ranges.

⁴Capability is suitable for the calibration of devices intended to generate the indicated quantity in the stated ranges.

bpm = beats per minute brpm = breaths per minute ppm = pulse per minute

