



National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

TRANSCAAL ENGINEERS INDIA PVT LTD

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

#96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE,
BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

in the field of

CALIBRATION

Certificate Number: CC-2898

Issue Date: 01/10/2020

Valid Until:

02/12/2020*

* The validity is extended for one year up to 02.12.2021

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : MSME

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

1 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	EPAP in cmH2O	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	± 120 cmH2O	3%
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	FLOW	Using Gas flow analyzer, Comparison Method, Instrumentation & Technical Services University of Vermont	0 lpm to 15 lpm	3.6%
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	1 ml/hr to 100 ml/hr	1.2%
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow	Comparison method Using VT mobile IEC 62353:2014 / IEC 60601-1:2018	2.5 lpm to 25 lpm	3.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

2 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow	Comparison Method using Gas Flow Analyzer and Electrical Safety Analyzer	2.5 lpm to 25 lpm	3.7%
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow, 2 ml/hr - 100 ml/hr	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	< 10 ml/hr to > 200 (@ 10ml) ml/hr	2%
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow, 2 ml/hr - 100 ml/hr	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	10 ml/hr to 200 (@ 20 ml) ml/hr	1.2%
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow, 10 - 500 ml/hr	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	<10 ml/hr to > 200 (@ 10 ml) ml/hr	1.2%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE,
9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU,
BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

3 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow, 10 - 500 ml/hr	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	10 ml/hr to 200 (@ 20 ml/hr) ml/hr	1.2%
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Gauge Zero	Simulation method Using Vital sign simulator Instrumentation & Technical Services University of Vermont	± 1 mmHg	NA (Qualitative)
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Heart Rate accuracy	Simulation method Using Vital sign simulator Instrumentation & Technical Services University of Vermont	30 bpm to 320 bpm	1.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE,
9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU,
BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

4 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Hypoxic Guard Test	Using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	V.I R	NA (Qualitative)
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Inspiratory, Expiratory time	using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	0.25 s to 9.99 s	2.0%
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	IPAP in cmH2O	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	± 120 cm H2O	3%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

5 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Leak Test	Comparison method Using Vital sign simulator	Less than/Equal to 15 mmHg/min	NA (Qualitative)
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	0 psi to 45 psi	1.2%
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 & IEC 60601-1:2018	0 psi to 45 psi	1.2%
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Occlusion	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	0 psi to 45 psi	1.2%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

6 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Oxygen Percentage	Using Gas flow analyzer, Comparison Method, Instrumentation & Technical Services University of Vermont	0 % to 100 %	2.3%
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Oxygen Percentage	Using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	0 % to 100 %	2.3%
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	PEEP	Using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:201	-5 cmH2O to 40 cmH2O	3.5%
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Positive pressure	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	± 120 cmH2O	2.3%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

7 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure accuracy (Dynamic)	Simulation method Using Vital sign simulator Instrumentation & Technical Services University of Vermont	60/30 mmHg to 200/150 mmHg	1%
24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure Accuracy (Static)	Comparison method Using Vital sign simulator	0 mmHg to 300 mmHg	1%
25	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure Accuracy(PIP)	using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	± 120 cmH2O	3.5%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

8 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
26	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate	using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	2 bpm to 150 bpm	1.2%
27	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	RR in bpm	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	2 brpm to 150 brpm	2.0%
28	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Ti in sec	using VT mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0.25 s to 9.99 s	1.2%
29	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Vacuum	Comparison method Using VT Mobile & electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018	0 mmHg to 600 mmHg	2.5%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE,
9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU,
BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

9 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
30	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	1 ml to 999 ml	1.2%
31	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume Accuracy	using VT Mobile & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018, Instrumentation & Technical Services University of Vermont	0 ml to 1000 ml	3.6%
32	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume, 1 ml - 20 ml	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	< 10 & ml/hr to >200 (@ 10ml) ml/hr	1.3%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

10 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
33	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume, 1 ml - 20 ml	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	10 ml/hr to 200 (@ 20ml) ml/hr	1.2%
34	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume, 1 ml - 50 ml	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	<10 ml/hr to > 200 (@ 10 ml) ml/hr	1.2%
35	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume, 1 ml - 50 ml	Using Infusion Device Analyzer by Comparison method using IDA 1S & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	10 ml/hr to 200 (@ 20 ml) ml/hr	2.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

11 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
36	MEDICAL DEVICES-IMAGING/PLOTTERS	Amplitude accuracy	Simulation method Using Vital sign simulator & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0.05 mV to 5 mV	3.9%
37	MEDICAL DEVICES-IMAGING/PLOTTERS	Fetal Heart Rate	Using Fetal Simulator, Simulation method, Instrumentation & Technical Services University of Vermont	30 bpm to 240 bpm	0.39%
38	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart rate accuracy	Simulation method Using Vital sign simulator & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	30 bpm to 320 bpm	1.2%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

12 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
39	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety	Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	V, I & R	NA (Qualitative)
40	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety - Voltage	Using Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	Voltage, Current & Re	NA (Qualitative)
41	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety	Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	V, I & R	NA (Qualitative)
42	MEDICAL DEVICES-MONITORING UNIT	Fetal Heart Rate	Using PS320 & Electrical safety analyzer Simulation method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	30 bpm to 240 bpm	1.2%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

13 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
43	MEDICAL DEVICES-MONITORING UNIT	Heart rate	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	30 bpm to 240 bpm	1.3%
44	MEDICAL DEVICES-MONITORING UNIT	Heart rate accuracy	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	30 bpm to 320 bpm	2.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

14 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
45	MEDICAL DEVICES-MONITORING UNIT	Invasive Blood Pressure Accuracy	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	35/15 mmHg to 200/150 mmHg	1.9%
46	MEDICAL DEVICES-MONITORING UNIT	Maternal Heart Rate	Using PS320 & Electrical safety analyzer Simulation method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	60 bpm to 160 bpm	1%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

15 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
47	MEDICAL DEVICES-MONITORING UNIT	NIBP Leakage Test	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	< 330 mmHg	5%
48	MEDICAL DEVICES-MONITORING UNIT	NIBP Pressure Relief Test	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	< 15 mmHg	4.1%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

16 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
49	MEDICAL DEVICES-MONITORING UNIT	NIBP Test	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	35/15 mmHg to 200/150 mmHg	4%
50	MEDICAL DEVICES-MONITORING UNIT	Readability: 20 g	Comparison method	500 g to 15 kg	11.3g
51	MEDICAL DEVICES-MONITORING UNIT	Respiration rate	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 bpm to 100 bpm	5.8%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

17 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
52	MEDICAL DEVICES-MONITORING UNIT	SPO2 Accuracy Test	Simulation Method - Using Vital sign simulator, SPO2 functional tester & Electrical Safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	70 % to 100 %	3.6%
53	MEDICAL DEVICES-MONITORING UNIT	TOCO	Using PS320 & Electrical safety analyzer Simulation method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	20 IUP to 100 IUP	1.45%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

18 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
54	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Energy after 60 sec of full charge @ max energy	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	Greater than/ equal to 85 %	NA (Qualitative)
55	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Heart Rate Accuracy	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	10 bpm to 300 bpm	1%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

19 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
56	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Rate Accuracy	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	5 ppm to 800 ppm	2.4%
57	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Air Flow	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0.2 m/sec to 2 m/sec	5.8%
58	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Air Temperature	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0 °C to 50 °C	0.3%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

20 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
59	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Amplitude	Using Impulse 7000 DP & Electrical safety analyzer by Comparison method IEC 62353:2014 / IEC 60601-1:2018	0 mA to 25 mA	2.6%
60	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Charge time after 10 discharge cycles	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	Less than/Equal to 15 sec	NA (Qualitative)
61	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Controller Stability	Using VT Mobile, Stop watch & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	± 10 mmHg after 15 min	NA (Qualitative)



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

21 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
62	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Cuff Pressure Accuracy	Using VT Mobile, Stop watch & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 psi to 100 psi	2.3%
63	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Dialysate Conductivity Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	13 mS/cm to 15 mS/cm	0.21mS/cm
64	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety	Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	V, I & R	NA(Qualitative)



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

22 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
65	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Electrical Safety	Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018	V,I,R	NA (Qualitative)
66	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Flow Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	200 ml/min to 2000 ml/min	1.9%
67	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Inspiratory, Expiratory Time	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0.25 s to 9.99 s	2.0%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

23 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
68	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance	Using Comparison method, Flux meter, Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018	5 μ W/cm ² /nm to 70 μ W/cm ² /nm	6%
69	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Max Cuff Pressure	Using VT Mobile, Stop watch & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	Less than/Equal to 550 m mmHg to OEM spec	2.3%
70	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	NIBP Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	180/60 mmHg	3.2%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

24 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
71	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	NIBP Test	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	40/20 mmHg to 200/150 mmHg	4%
72	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Noise level	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	30 dB to 100 dB	5.8%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

25 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
73	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	O2 Saturation(Spo2), Heart Rate	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	30 bpm to 240 bpm	1.3%
74	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	O2 Saturation(Spo2), Heart Rate	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	70 % to 100 %	3.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

26 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
75	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Accuracy (Energy)	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	50 J to 270 J	1.3%
76	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Energy @ max setting for 10CHg cycle (at battery power)	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	50 J to 270 J	1.5%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

27 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
77	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Output Power	Comparison method using RF 303 & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 W to 400 W	5.8%
78	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Oxygen Percentage	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 % to 100 %	2.3%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

28 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
79	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Oxygen Percentage	Using Gas flow analyzer & Electrical safety analyzer, IEC 62353:2014 / IEC 60601-1:2018, Comparison Method, Instrumentation & Technical Services University of Vermont	0 % to 100 %	2.3%
80	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pacer Amplitude	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 mA to 25 mA	2.6%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

29 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
81	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Peep	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 cmH2O to 40 cmH2O	3.7%
82	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	pH Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	7 pH(water pH)	0.2pH



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

30 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
83	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Power Distribution Test	Comparison method using RF 303 & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 W to 400 W	6.0%
84	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	PPM	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	90 PPM	2.4%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

31 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
85	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure accuracy (PIP)	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 cmH2O to 120 cmH2O	3.6%
86	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Pressure Gauge	Comparison method Using Temperature sensor, logger, Pressure Calibrator & electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018, AMS 2750 DKD R6-1	0 bar to 2 bar	0.36%
87	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	PressureTest	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	± 3 mmHg (-700 to 1900 mm)	2.8%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

32 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
88	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Rate accuracy	Using Impulse 7000 DP & Electrical safety analyzer by Comparison method IEC 62353:2014 / IEC 60601-1:2018	5 ppm to 800 ppm	2.4%
89	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Relative Humidity	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	10 % RH to 95 % RH	4% RH
90	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	REM Test	Comparison method using RF 303 & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermon	Less than OEM specified R	NA (Qualitative)



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

33 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
91	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Respiration Rate	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	2 brpm to 150 brpm	1.2%
92	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Skin Temperature	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0 °C to 50 °C	5%
93	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Surface Temperature	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0 °C to 50 °C	0.7%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

34 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
94	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Synchronizer Operation	Method - Using Impulse 7000 DP, Vital sign simulator, SPO2 functional tester & Electrical safety analyzer IEC 62353:2014 /IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	Less than/Equal to 60 msec	NA (Qualitative)
95	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature	Comparison method Using Temperature sensor, logger, Pressure Calibrator & electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018, AMS 2750 DKD R6-1	110 °C to 135 °C	0.54°C
96	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature	Using Temperature sensor with logger & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	21 °C to 50 °C	0.7%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

35 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
97	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature	Using Temperature sensor with logger & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	32 °C to 42 °C	0.2°C
98	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature overshoot	Using Incubator Analyzer & electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018	0 °C to 50 °C	NA (Qualitative)
99	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Temperature Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 °C to 100 °C	1°C



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

36 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
100	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Timer Accuracy	Using VT Mobile, Stop watch & Electrical safety analyzer Comparison method IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	15 mins	1sec
101	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Timer Test	Using Dialysis meter & Electrical safety analyzer Comparison method IEC 62353:2014/ IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	15 min to 1 hr	1.2 sec to 2.2 sec



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :

TRANSCAAL ENGINEERS INDIA PVT LTD, #96/1, FIRST FLOOR, SUBHASHREE, 9TH CROSS, EAST PARK ROAD, MALLESWARAM, BANGALORE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

37 of 37

Validity

01/10/2020 to 02/12/2020*

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

*Transition to 2017 version completed w.e.f 01.10.2020 valid until 02.12.2021

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrum	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
102	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Volume Accuracy	Comparison method using VT Mobile & Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018 Instrumentation & Technical Services University of Vermont	0 ml to 1000 ml	3.6%

* CMCs represent expanded uncertainties expressed at approximately the 95% level of confidence, using a coverage factor of k = 2.