



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 32

Validity

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

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-

* The validity is extended for one year up to 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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

2 of 32

Validity

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

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-

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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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

3 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

4 of 32

Validity

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

Last Amended on

-

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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	200 (@ 10ml) ml/hr	1.3%
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%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

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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 32

Validity

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

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-

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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%
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%



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SCOPE OF ACCREDITATION

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

6 of 32

Validity

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

Last Amended on

-

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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%
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)



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 32

Validity

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

Last Amended on

-

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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%
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%



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

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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 32

Validity

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

Last Amended on

-

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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%
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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

9 of 32

Validity

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

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-

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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%
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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

10 of 32

Validity

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

Last Amended on

-

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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%
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



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

11 of 32

Validity

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

Last Amended on

-

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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%
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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

12 of 32

Validity

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

Last Amended on

-

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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%
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)



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

13 of 32

Validity

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

Last Amended on

-

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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%
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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

14 of 32

Validity

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

Last Amended on

-

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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%
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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

15 of 32

Validity

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

Last Amended on

-

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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)



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

16 of 32

Validity

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

Last Amended on

-

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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)



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

17 of 32

Validity

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

Last Amended on

-

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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%



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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

18 of 32

Validity

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

Last Amended on

-

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68	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Irradiance	Using Comparison method, Flux meter, Electrical safety analyzer IEC 62353:2014 / IEC 60601-1:2018	5 $\mu\text{W}/\text{cm}^2/\text{nm}$ to 70 $\mu\text{W}/\text{cm}^2/\text{nm}$	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

19 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 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 :

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

20 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

21 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

22 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

23 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

24 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 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 cm H ₂ O to 40 cm H ₂ O	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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

25 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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 :

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

26 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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 cmH ₂ O to 120 cmH ₂ O	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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

27 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

28 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

29 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

30 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

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Accreditation Standard

ISO/IEC 17025:2017

Certificate Number

CC-2898

Page No

31 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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

32 of 32

Validity

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

Last Amended on

-

* The validity is extended for one year up to 02.12.2021

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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.