SAFETY TESTING LABORATORY : TEST REPORT

ISO 80601-2-69:2020

Medical electrical equipment

Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.

Test Report No.	:	SWEN/21-22/265-01
ULR No. & Discipline	:	TC633022000000177P / ELECTRONICS
Job No.	:	265-1
Date of Issue of Report	:	17th March 2022
Date of Sample Received	:	1st March 2022
Date of Testing	:	(2nd March 2022) to (10th March 2022)
Testing Location	:	LABORATORY / ~~ON-SITE~~
Name & Address of Testing Location	:	**SWEN KONFORMITY** Gokul RH-01, Survey no. 22, Near Chatrapati co-op bank, Vishal Nagar, Pimple Nilakh, Pune-411027, Maharashtra (India)
Trade mark of manufacturer	:	VENTURE CENTER
Name & Address of Customer	:	**Entrepreneurship Development Center** 100, NCL Innovation Park, Dr. Homi Bhabha Road Pune - 411008
Customer Representative	:	Mr. Anjan Kumar N
Sample Description	:	**Portable Oxygen Concentrator**
Condition Of Sample	:	OK
Reference standard	:	IEC 60601-1:2005+A1:2012+A2:2020
Model / ~~Type~~ / ~~Reference~~	:	K10WD
Serial No. / ~~I.D No~~	:	EDC21100901
Ratings	:	220-230 V a.c, 5 A
Test Method (Type/Routine/Verification)	:	Type test
Ambient Temperature & Humidity	:	27.3°C & 47% RH
Atmospheric pressure and Altitude	:	945hPa & 560m

Remarks: This report is governed by, and incorporates by reference, the condition of testing as posted as its date of issuance and is intended for your exclusive use. Any copying or replication of this report to or for any other person entity, or use of our name or trademark, is permitted only with our prior written permission. **This report sets forth solely our findings with respect to the test samples identified herein**. It includes all of the tests and all results thereof based upon the information that you provided us with. You have **10** calendar days from the date of issuance of this report to notify us of any material error or omission; provided, however, that such notice shall be written and shall specifically address the issue you wish to raise. A failure to raise such issue within the prescribed time shall constitute your unqualified acceptance of the completeness of this report, the tests conducted and the correctness of the report contents. The test report can also be received and checked for authenticity from website: www.swenlab.com. Annex-A of this test report is as per NABL accredited scope.

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Possible test case verdicts:

- Test does not apply to the test object……: N/A.
- Information not available……: N/AV
- Test object meets the requirement……: OK.
- Test object does not meet the requirement……: Fail/ NOT OK

General remarks:

- **"See form A. ##"** refers to additional information related to test conducted.
- **"See Table ##"** refers to a table appended to this report.
- **"See Fig. ##"** refers to a figure appended to this report.
- **"Appendix. ##"** refers to list of figures.

Units of Measurements:

- **V – Voltage.**
- **A – Ampere.**
- **Ω – Ohm.**
- **Hz – Frequency**
- **m – Meter**
- **°C – Degree Centigrade**
- **%RH – Relative Humidity**
- **hPa – Hectopascal**

Abbreviations:

- **R – Resistance.**
- **T – Temperature**
- **m – Meter**
- **Hrs. – Hours**
- **EUT – Equipment under test**
- **Annex A- Test under scope of NABL Accreditation.**
- **Annex B- Test under scope of Non NABL Accreditation**

Equipment's used for Testing:

Sr No.	Instrument Name	Make	Sr. No.	Range	L.C.	Calibration Due Date
1.	**Humidity cum temperature chamber**	Tech-Mark services	SK1011	(-10 - 130)°C (ambient-96)%RH	0.1°C 1%	01/03/2023
2.	**Thermo hygrometer**	HTC instruments	SWEN/EQ-03	(-50-70)°C (10-99)%RH	0.1°C 1%	09/08/2023
3.	**Digital Multimeter**	Fluke	25339389	(0-600) Va.c./Vd.c.	0.1Va.c./Vd.c.	09/08/2023
4.	**Altimeter/ Barometer**	HTC Instruments	AL- 7010	Altimeter- (-700 – 9000)m Barometer(300-1100)hPa	1 m 1 hPa	30/03/2022
5.	**Digital Clamp meter**	Rishabh	012805	(0 to 99.9)% THD	0.1%	19/01/2024
6.	**Leakage Current tester**	HIOKI	150215883	DC / AC :50µA/500 µA/5 mA/50 mA	0.01µA	09/07/2023
7.	**AC power Source**	GW - Instek	GER 200870	(0 to 310) V a.c.	0.1 V a.c.	23/01/2023
8.	**Flow Analyzer with oxygen sensor**	TSI	40882030027	Oxygen Concentration(21 to 100)% Volume(0.01 to300)L Pressure (-25 to 150.0)cm H_2O	Oxygen Concentration 0.1% Volume-0.01L Pressure –	30/03/2022

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					0.001 cm H_2O	

General Product Information: (Product information below are provided by the customer)

An oxygen concentrator is an electrically operated device intended to provide supplemental low flow oxygen therapy. The unit separates oxygen from ambient air, delivering high quality purified oxygen to patients.

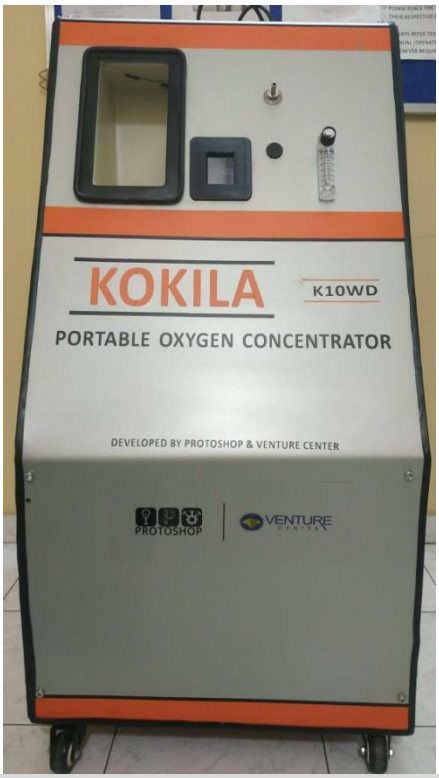

Fig 1: Front view of EUT

Fig 2: Back view of EUT

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Fig 3: RHS view of EUT

Fig 4: LHS view of EUT

Bill of Material (Marking Critical Components): (Product information below are provided by the customer)

Sr. no	List of Materials
Hardware materials	
1	Solenoid valves
2	Socket connector
3	Silencer
4	Push-in fitting
5	Push-in T-fitting
6	Pressure transmitter
7	Connecting cables
8	Non-return valves
9	Plastic tubing
10	Multi-tube holder
11	Push-in/threaded L-fitting
12	Push-in Y connector
13	Push-in T connector
14	Push-in L-connector
15	Low Pressure regulator
16	Canisters Aluminium - Set (two canisters + oxygen tank)
17	Orifice
14	Push-in L-connector
15	Low Pressure regulator
16	Canisters Aluminium - Set (two canisters + oxygen tank)
17	Orifice
18	Copper coil
19	Aluminium extrusions
20	Corner brackets
21	Hammer headed nuts and screws
22	Wheels + Locking
23	Springs - 2 for canisters
24	Rubber pads
25	PU Tubing
26	C Clamps
27	Sheet metal/aluminium composite
28	Flow meter + Humidifier bottle
29	Silicon tubing
30	Double hose connector

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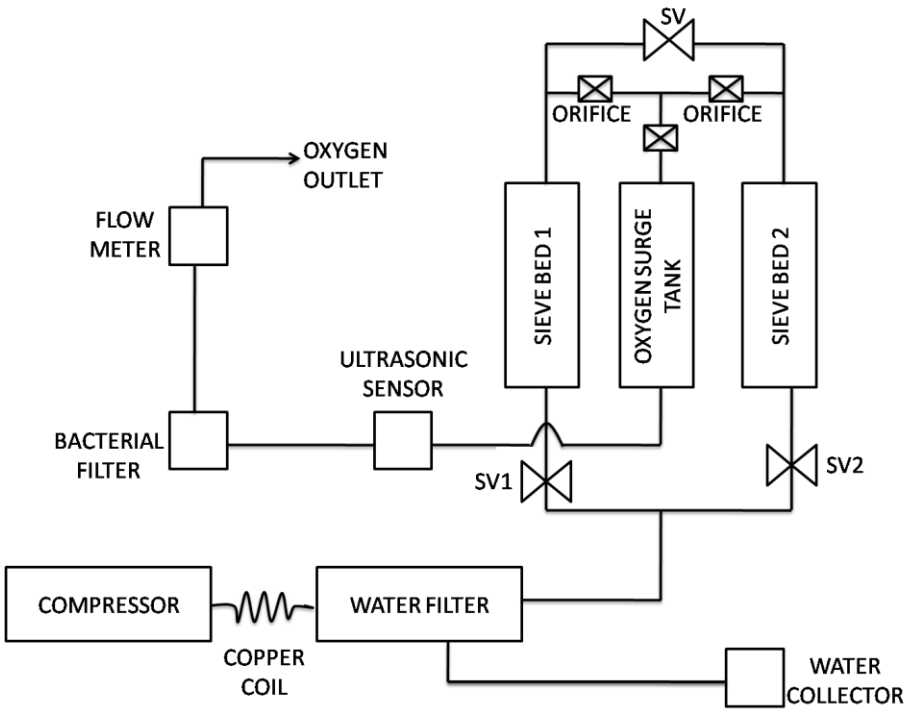
Filters	
Sr. no	List of Materials
1	Hepa filters (Compressor inlet)
2	Bacterial filter (oxygen outlet)

Electronics	
Sr. no	List of Materials
1	Mcbs
2	Fans
3	GSM Module
4	Wires
5	Controller
7	SMPS
8	Ultrasonic Sensor- Oxygen sensors
9	Compressor
10	STM controller

Circuit Diagram of EUT: (Product information below are provided by the customer)



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Annex - A

1. Humidity Preconditioning

Standard & Clause No	ISO 80601-2-69 (Clause 201.5) IEC 60601-1 (Clause 5.7)
Equipment Used & its Range	Temperature cum Humidity Chamber (-10 °C to 130) °C – Temperature (Ambient to 96)% - Humidity
Uncertainty	☐Included in Test Report ☒ N/A ☐Not Included in Test Report
Date of Performance	2nd March 2022 to 4th March 2022
Ambient Temperature (°C)	(26.8-27.5)
Ambient Humidity (%RH)	(38-50)

Clause No	Test Description	Verdict
201.5	Table: General requirements for testing of ME equipments	OK
5.7	Humidity Preconditioning	

Conditions for the preconditioning are :

Humidity Range	:	93 % ± 3 %	Set humidity	:	(93±3)%RH
Temperature Range	:	(20 to 30)°C	Set temperature	:	(28±2)°C
Total Time	:	48 Hr			

Supplementary Information:-

Fig 1A: Test Conditions

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2.1. Leakage Currents and Patient Auxiliary Currents

Standard & Clause No	ISO 80601-2-69 (Clause 201.8) IEC 60601-1 (Clause 8.7, 8.7.1, 8.7.3 & 8.7.4.5)
Equipment Used & its Range	HIOKI – Leakage Current Tester – ST 5540 AC :50 µA/500 µA/5 mA/50 mA DC : 50 µA/500 µA/5 mA/50 mA
Uncertainty	☐ Included in Test Report ☒ N/A ☐ Not Included in Test Report
Date of Performance	4th March 2022
Ambient Temperature (°C)	28.2
Ambient Humidity (%RH)	54

Clause No	Test Description	Verdict
201.8	**Table: Protection against electrical HAZARDS from ME EQUIPMENT**	**OK**
8.7	**Leakage Currents and Patient Auxiliary Currents**	
8.7.1	**General requirements**	
8.7.3	**Allowable values**	
8.7.4.5	**Measurement of the EARTH LEAKAGE CURRENT**	

	Comment
Input Voltage : 252.7V a.c Line – Ground Voltage : 251.3V a.c Neutral – Ground Voltage : 2.2 V a.c Frequency : 50 Hz	Measured earth leakage currents are lesser than 5mA & 10mA in Normal & Single Fault conditions respectively.

Item/Location	Normal Condition		Single Fault Condition (Line) :	
	Polarity :Normal (mA)	Polarity : Reverse (mA)	Polarity : Normal (mA)	Polarity : Reverse(mA)
Earth leakage current	0.90	0.93	1.58	1.58

NOTE – *The measurement is done for 10 s.*

Supplementary information:

Fig 2.1 A:Test Setup

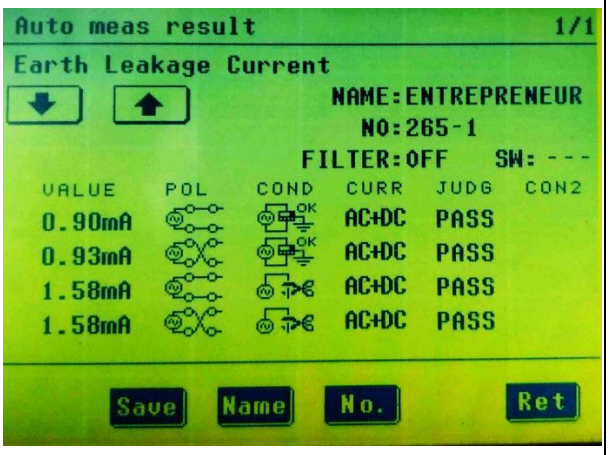

Fig 2.1 B:Test result

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2.2 Leakage Currents and Patient Auxiliary Currents

Standard & Clause No	ISO 80601-2-69 (Clause 201.8) IEC 60601-1 (Clause 8.7, 8.7.1, 8.7.3 & 8.7.4.6)
Equipment Used & its Range	HIOKI – Leakage Current Tester – ST 5540 AC :50 µA/500 µA/5 mA/50 mA DC : 50 µA/500 µA/5 mA/50 mA
Uncertainty	☐Included in Test Report ☒ N/A ☐Not Included in Test Report
Date of Performance	4th March 2022 & 10th March 2022
Ambient Temperature (°C)	28.2
Ambient Humidity (%RH)	54

Clause No	Test Description	Verdict
201.8	**Table: Protection against electrical HAZARDS from ME EQUIPMENT**	**OK**
8.7	**Leakage Currents and Patient Auxiliary Currents**	
8.7.1	**Genera requirements**	
8..7.3	**Allowable values**	
8.7.4.6	**Measurement of the TOUCH CURRENT**	

Input Voltage : 252.7V a.c Line – Ground Voltage : 251.3V a.c Neutral – Ground Voltage : 2.2V a.c Frequency : 50 Hz			**Comment** Measured values of touch current are lesser than 100 µA 500 µA in Normal & Single fault conditions respectively.				
Item/Location	**Normal Condition**		**Single Fault Condition (Earth) :**		**Single Fault Condition (Line) :**		
	Polarity : Normal (µA)	Polarity : Reverse (µA)	Polarity : Normal (µA)	Polarity : Reverse (µA)	Polarity : Normal (µA)	Polarity : Reverse (µA)	
Enclosure to Earth	9.4	9.6	269.5	302.0	9.5	9.3	
Enclosure to Enclosure	4.0	4.2	4.4	4.0	4.4	4.5	

NOTE – The measurement is done for 10 s.

Supplementary information:
Note: Enclosure to Earth Leakage current test values are of the retesting done on 10th March 2022 after some time essential modifications done by client.

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Fig 2.2 A: Test Setup 1

Fig 2.2 B: Test Setup 2

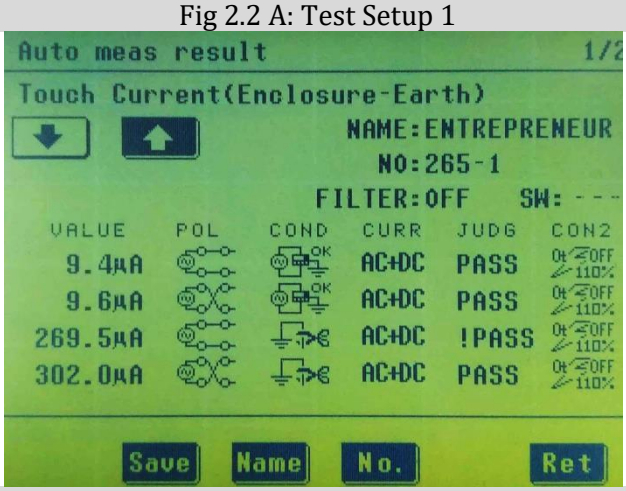

Fig 2.2 C: Test result 1

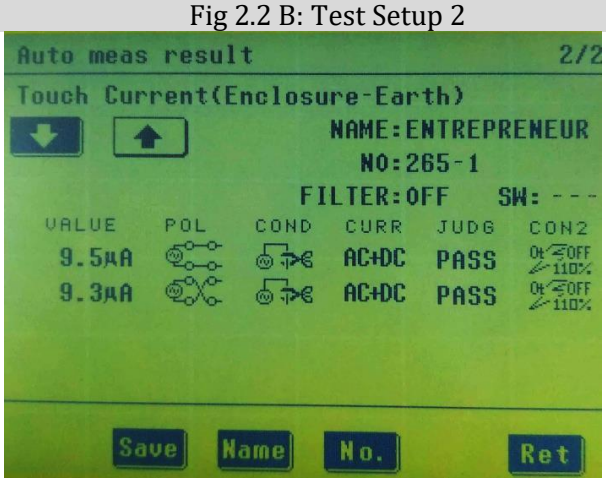

Fig 2.2 D: Test result 1

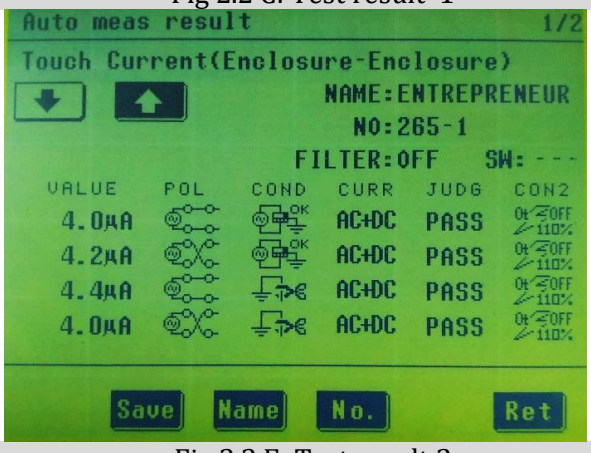

Fig 2.2 E: Test result 2

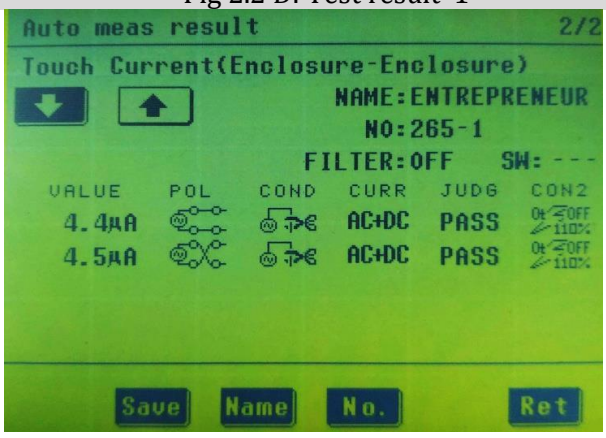

Fig 2.2 F: Test result 2

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Annex - B

3. Accuracy of continuous flow rate

Standard & Clause No	ISO 80601-2-69 (Clause 201.12.1.101)
Equipment Used & its Range	Flow analyzer Oxygen concentration (21to 100)% Volume (0.01 to 10)L Pressure(-25.0 to 150.0)cmH2O
Uncertainty	☐Included in Test Report ☒ N/A ☐Not Included in Test Report
Date of Performance	10th March 2022
Ambient Temperature (°C)	28.2
Ambient Humidity (%RH)	54

Clause No	Test Description	Verdict
201.12.1.101	**Table : Accuracy of continuous flow rate**	**OK**

			Comment
Input Voltage	:	230 V a.c.	Measured flow rate of delivered gas was within ±10% of indicated flow rate or ± 200ml/min whichever is greater
Maximum flow rate	:	7 LPM	

Equipment	Percentage flow rate (%)	Measured flow rate (Lpm)
EUT	**20%**	1.27
	50%	3.32
	100%	7.61

Supplementary information:
Note: Accuracy of continuous flow rate was retested on 10th March 2022 by considering digital display as the reference of flow indication. The test conducted after modification of resolution of flow from 1LPm to 0.1Lpm by client side.

Fig 3A: Set Condition 1 on Flow Meter

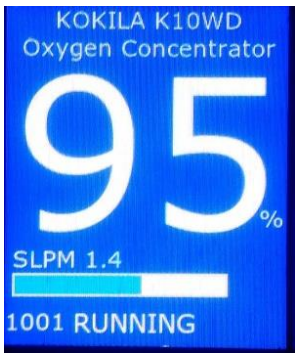

Fig 3B: Set Condition 1 on EUT

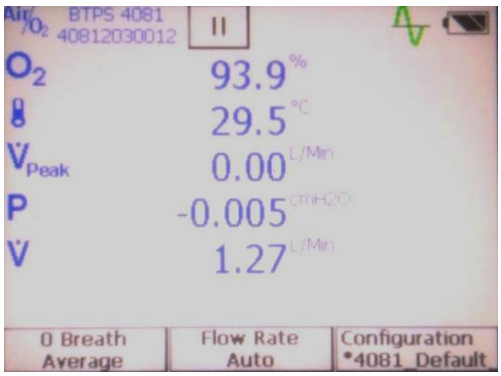

Fig 3C: Test result 1

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Fig 3D: Set Condition 2 on Flow Meter

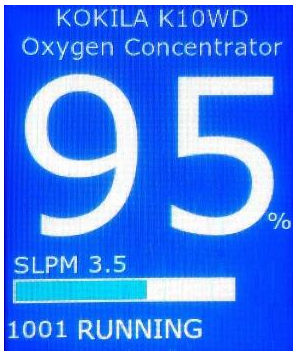

Fig 3E: Set Condition 2 on EUT

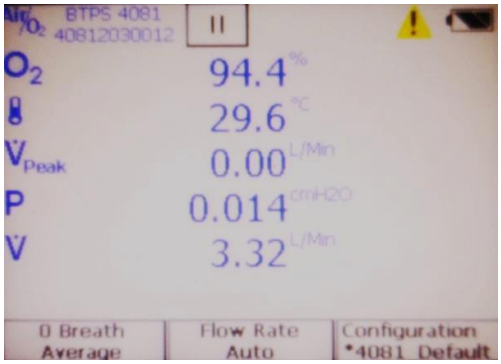

Fig 3F: Test result 2

Fig 3G: Set Condition 3 on Flow Meter

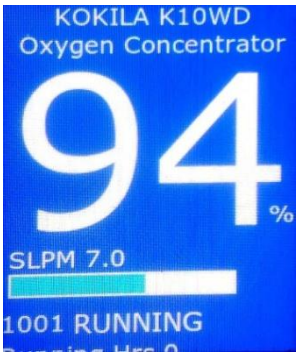

Fig 3H: Set Condition 3 on EUT

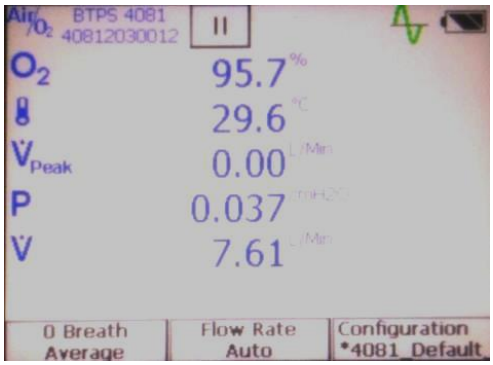

Fig 3I: Test result 3

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4. Accuracy of concentration

Standard & Clause No	ISO 80601-2-69 (Clause 201.12.1.103)
Equipment Used & its Range	Flow analyzer Oxygen concentration (21to 100)% Volume (0.01 to 10)L Pressure(-25.0 to 150.0)cmH2O
Uncertainty	☐Included in Test Report ☒ N/A ☐Not Included in Test Report
Date of Performance	4th March 2022
Ambient Temperature (°C)	28.4
Ambient Humidity (%RH)	52

Clause No	Test Description	Verdict
201.12.1.103	**Table : Accuracy of concentration**	**OK**

Nominal mains voltage	:	230V a.c.	Maximum flow rate	:	7 LPM
85 % Of Minimum Rated Voltage	:	187 V a.c.			
110% Of Maximum Rated Voltage	:	253 V a.c.			
Frequency	:	50Hz			

Testing condition	Measured flow rate (Lpm)	O_2 Concentration (%)	Declared O_2 Concentration (%)	Comment
85% of Minimum Rated Voltage	6.98	93.1	93% ± 3%	Measured oxygen concentration in the delivered gas is within limits as per stated by manufacturer in the IFU.
110% of Maximum Rated voltage	7.03	95.4		
Nominal mains voltage	1.18	93.6		
	2.07	92.9		
	3.08	93.9		
	4.05	94.4		
	4.98	95.1		
	6.03	95.0		
	7.08	95.2		

Supplementary information:

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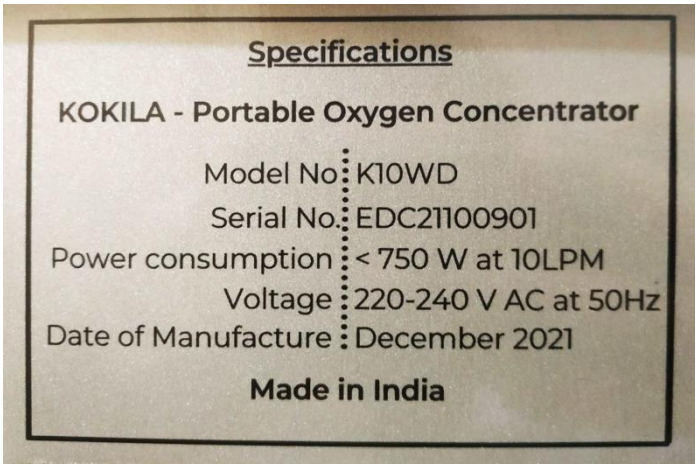
Copy of marking plate:



Tested By: Akash Chavan
(Testing Engineer)

Tested By : Vinay Kumar
(Assistant Testing Engineer)

Approved By: Amiya Sagar
(Technical Manager)

END OF TEST REPORT

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