



IEC60601-1 Product Certification



Reports Summary:

1. IEC60601-1
2. ISO80601-2-12
3. IEC60601-1-8
4. IEC60601-1-2



contact@volvinnovations.com
www.volvinnovations.com

ISO9001:2015, ISO13485:2016

Test Report issued under the responsibility of:



<p>IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance</p>	
Report Reference No.:	ULR-TC56622100000018F
Date of issue.....:	2021-November-30
Total number of pages	126
Testing Laboratory	Intertek India Pvt Ltd
Address	17/F, 2nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India
Applicant's name	SFO Technologies Pvt Ltd
Address	Plot#36/37,CSEZ,Cochin – 682037 India
Discipline / Product Group.....:	Electronics / Medical Electrical Equipment
Test specification:	
Standard	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure	Test report
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1P_modified
Test Report Form Originator	UL(US)
Master TRF	2019-10-11
An independent organization testing for safety, performance, and certification.	
General disclaimer:	
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Registered office: Intertek India Private Limited,
 E-20,Block B1,Mohan Co-operative Industrial Area, Mathura Road, New Delhi-110 044,India
 Tel: +91-11-41595460,Facsimile: +91-11-4159 5475 © 2020 Intertek




General Remarks:

The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.


"(See Enclosure #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

Test item description	Pediatric & Adult Ventilator	
Trade-Mark		
Original Product/Equipment Manufacturer	Envolv Innovations Pvt Ltd	
Branding Manufacturer(s).....	Same as manufacturer	
Model/Type reference.....	Aperta P1	
Ratings.....	100 – 240~, 50 / 60 Hz, 1.5 A	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> Testing Laboratory:	Intertek India Private Limited	
Testing location/ address.....	17/F, 2nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India	
Tested by (name, function, signature).....	Neha Karnwal Project Engineer	
Approved by (name, function, signature)	Gnanaprakasam C, Senior Manager- Business & Operations	

List of Attachments (including a total number of pages in each attachment):	
1. Attachment-1: Photo Document - Pages - 123 to 126	
Summary of testing	
<p>Tests performed (name of test and test clause):</p> <ol style="list-style-type: none"> 1. Power input, clause 4.11 2. Humidity preconditioning treatment, clause 5.7 3. Determination of ACCESSIBLE PARTS, CLAUSE 5.9.2 4. Legibility of markings, clause 7.1.2 5. Durability of markings, clause 7.1.3 6. Residual voltage and stored charge in attachment plug, clause 8.4.3 7. Protective earthing—impedance and current-carrying capability, clause 8.6.4 8. Leakage currents and patient auxiliary current clause 8.7 9. Dielectric strength, clause 8.8.3 10. Mechanical strength and resistance to heat, clause 8.8.4.1 11. Measurement of creepage distances and air clearances, clause 8.9.4 12. Cord anchorage clause 8.11.3.5 13. Instability - in transport position clause 9.4.2.1 14. Instability – excluding transport position clause 9.4.2.2 15. Instability from horizontal and vertical forces clause 9.4.2.3 16. Castors and wheels clause 9.4.2.4 17. Movement over a threshold clause 9.4.2.4.3 18. Instability from unwanted lateral movement clause 9.4.3 19. Excessive temperatures in ME EQUIPMENT clause 11.1 21.mechanical strength clause 15.3 	<p>Testing location:</p> <p>Intertek India Private Limited 17/F, Industrial Suburb, II stage, Industrial Area, Yeshwanthpur, Bangalore – 560022, India</p>
Summary of compliance with National Differences	
List of countries addressed: N/A	
<input checked="" type="checkbox"/> The product fulfils the requirements IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012	

TEST REPORT ISO 80601-2-12 Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	
Report Number.....	CE-JOB-BAN-20-000902-002
Date of issue.....	2021-November-29
Total number of pages	55
Testing Laboratory	Intertek India private limited
Address	17/F, 2 nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India
Applicant's name	SFO Technologies Pvt Ltd
Address	Plot#36/37,CSEZ,Cochin – 682037 India
Discipline / Product Group.....	Electronics / Medical Electrical Equipment
Test specification:	
Standard	ISO 80601-2-12: 2020 (Edition 2.0)
Test procedure	Test Report
Non-standard test method.....	N/A
Test Report Form No.....	ISO80601_2_12B_Modified
Test Report Form(s) Originator	Intertek Semko AB
Master TRF.....	Dated 2020-05
Test item description	Paediatric & Adult Ventilator
Trademark	
Manufacturer	Envolv Innovations Pvt Ltd
Model/Type reference	Aperta P1
Ratings	100-240 ~ , 50/60 Hz, 1.5 A
An independent organization testing for safety, performance, and certification.	
General disclaimer:	
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General Remarks:

The test results presented in this report relate only to the object tested.
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 "(See Enclosure #)" refers to additional information appended to the report.
 "(See appended table)" refers to a table appended to the report.
 Throughout this report a comma (point) is used as the decimal separator.

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

Test item description: Paediatric & Adult Ventilator





Trademark:

Manufacturer : Envolv Innovations Pvt Ltd

Model/Type reference: Aperta P1

Ratings: 100 – 240~, 50/60 Hz, 1.5A

Gas Supply: 3 – 6 bar (O2 and Air)

<input checked="" type="checkbox"/>	Testing Laboratory:	
Testing location/ address		Intertek India private limited, 17/F, 2 nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India
Tested by (name, function, signature)		Neha Karnwal Project Engineer 
Approved by (name, function, signature)		Gnanaprakasam C, Senior Manager- Business & Operations 

List of Attachments (including a total number of pages in each attachment): N/A

Summary of testing:

<p>Tests performed (name of test and test clause):</p> <ol style="list-style-type: none">1. Overpressure requirement 201.4.11.101.12. Compatibility requirement 201.4.11.101.23. Additional requirements for audible acoustic energy 201.9.6.2.1.101.4. Additional requirements for interruption of the power supply/supply mains to ME equipment 201.11.8.1015. Volume-control inflation-type 201.12.1.1016. Pressure-control inflation-type 201.12.1.102	<p>Testing location:</p> <p>Intertek India private limited 17/F, 2nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India</p>
<p>Summary of compliance with National Differences</p> <p>List of countries addressed: N/A</p> <p><input checked="" type="checkbox"/> The product fulfils the requirements of ISO 80601-2-12:2020</p>	

<p>Copy of marking plate</p> <p>See IEC 60601-1 Test Report</p>

Test item particulars	
Classification of installation and use	Refer to IEC 60601-1 test report
Ventilatory modes	PCV, PSV, P SIMV, V SIMV, VCV, BiPAP
Tested VBS	Category – BCC Tube material- smooth bore silicon, Inspiratory limb length – 1.2-meter, Expiratory limb length – 1.2 meters, Humidifier limb length – 30 cm, Conical connectors – 22M/F
Gas supply options	O ₂ , Air
Pneumatic power (if applicable)	N/A
Integrated monitoring	O ₂ , Tidal Volume, PEEP, Pressure, RR
Possible test case verdicts:	
- test case does not apply to the test object : N/A	
- test object does meet the requirement : P (Pass)	
- test object does not meet the requirement : F (Fail)	
Testing..... :	
Date of receipt of test item.....	: 01 April 2021
Date (s) of performance of tests.....	: 21 June 2021 to 30 July 2021
Condition of Sample on receipt.....	: Good
General remarks:	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. “(see Enclosure #)” refers to additional information appended to the report. “(see appended table)” refers to a table appended to the report.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer’s Declaration per sub-clause 4.2.5 of IEC 60601-1:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not applicable
When differences exist; they shall be identified in the General product information section.	






Total Quality. Assured.

Test Report issued under the responsibility of:

17/F, II Stage, Industrial Suburb,
Yeshwanthpura Industrial Area,
Bangalore - 560022, INDIA
Telephone: +91-80-4021 3911
Facsimile : +91-80-4021 3915
www.intertek.com

TEST REPORT IEC 60601-1-8 Medical electrical equipment General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems	
Report Number.....	CE-JOB-BAN-20-000902-002
Date of issue	2021-November-29
Total number of pages	21
Name of Testing Laboratory preparing the Report.....	Intertek India Pvt Ltd 17/F, Industrial Suburb, II stage, Industrial Area, Yeshwanthpur, Bangalore – 560022, India
Applicant's name	SFO Technologies Pvt Ltd
Address	Plot#36/37,CSEZ,Cochin – 682037 India
Discipline / Product Group.....	Electronics / Medical Electrical Equipment
Test specification:	
Standard	IEC 60601-1- 8:2006, AMD1:2012 for use in conjunction with IEC 60601-1:2005, AMD1:2012
Test procedure	Test report
Non-standard test method.....	N/A
Test Report Form No.	IEC60601_1_8F_modified
Test Report Form(s) Originator	UL (US)
Master TRF	Dated 2020-07-10
General disclaimer:	
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Test item description	Paediatric & Adult Ventilator	
Trade Mark(s).....		
Manufacturer	Envolv Innovations Pvt Ltd	
Model/Type reference	Aperta P1	
Ratings	100 – 240 \sim , 50/60 Hz, 1.5A Gas Supply: 3 – 6 bar (O2 and Air)	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	Testing Laboratory:	Intertek India Private Limited
Testing location/ address		17/F, 2nd Stage, Industrial suburb Yeshwanthpur Industrial Area, Bangalore – 560 022, India
Tested by (name, function, signature)		Neha Karnwal Project Engineer 
Approved by (name, function, signature).....		Gnanaprakasam C, Senior Manager- Business & Operations 

List of Attachments (including a total number of pages in each attachment):	
Summary of testing:	
Tests performed (name of test and test clause):	Testing location:
Characteristics of auditory alarm signals clause 6.3.3.1 Characteristic of auditory alarm signal clause 6.3.3.2 Volume of auditory alarm signals and information signals clause 6.3.3.2 Alarm system delay clause 6.4.1 Delays to or from a DISTRIBUTED ALARM SYSTEM clause 6.4.2 Alarm Pre-set clause 6.5	Intertek India Private Limited 17/F, Industrial Suburb, II stage, Industrial Area, Yeshwanthpur, Bangalore – 560022, India
Summary of compliance with National Differences (List of countries addressed):	
<input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-1- 8:2006, AMD1:2012 for use in conjunction with IEC 60601-1:2005, AMD1:2012	

Statement concerning the uncertainty of the measurement systems used for the tests
 (May be required by the product standard or client)

Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:

Procedure number, issue date and title: LMS-APAC-IN-QC-12, issued on 01-April-2014 revised on 02-Feb-2021: Estimation of Measurement Uncertainty.

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

Statement not required by the standard used for type testing

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

Copy of marking plate:
 Refer IEC 60601-1 test report.

Test item particulars	Refer IEC 60601-1 test report
Classification of installation and use	Mobile
Supply Connection.....	Internally powered /Appliance coupler
Equipment Type.....	ME Equipment
Accessory and detachable parts included.....	
Options included.....	Breathing circuit accessories (Inhalation Tube, Exhalation Tube, Air Filter, Moisture Trap, Patient Mask, Y-arm) Air and Oxygen hoses, carrying cart with accessory holders, Air Compressor Kit, Test Lung, Disinfecting filter cartridge, Arm holder, AC Power cord.

Possible test case verdicts:

- test case does not apply to the test object : N/A
- test object does meet the requirement : P (Pass)
- test object does not meet the requirement : F (Fail)

Testing..... :

Date of receipt of test item..... : 20 July 2021

Date (s) of performance of tests..... : 20 July 2021 to 30 July 2021

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
 "(See appended table)" refers to a table appended to the report.

This Test Report Form is intended for the evaluation of alarm systems in medical electrical equipment and medical electrical systems in accordance with IEC 60601-1-8.
 This Test Report Form can be used to complement the IEC 60601-1 Test Report.
 The collateral standard does not specify: whether any particular medical electrical equipment or medical electrical system is required to be provided with ALARM SYSTEMS; the particular circumstances which initiate an ALARM CONDITION; the allocation of priorities to a particular ALARM CONDITION; or the means of generating ALARM SIGNALS.

Throughout this report a comma / point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:

Date: 01 December 2021

To

SFO TECHNOLOGIES PVT LTD R&D Division - Cochin
#36/37, Cochin Special Economic Zone,
Kakkanad P.O. , Cochin - 682037
Kerala, INDIA

Subject: EMC test reports in conformity with IEC 60601-1-2 :2014 Ed.4.0

Dear Sir,

Please find EMC test reports of product ICU Ventilator enclosed for your reference. This reports is issued under Project No: CE-JOB-BAN-20-000902 executed by Intertek 'India Private Limited, Bangalore laboratory.

1. **Report No: TASL/17025/EMC/TRP/COM/2122/167, Total pages: 21**
2. **Report No: JOU 2132MED156, Total pages: 73**

Should you require any further details, please do let us know.

Thanking you and assuring you of our best services.

Yours Faithfully,
For **Intertek India Private Limited.**

Gnanaprakasam. C
Senior Manager - Business & Operations (South)





Certificate No: TC-5992



TEST REPORT	
ULR NUMBER	ULR-TC599221000000055F
ELECTRONICS TESTING EMC TEST FACILITY	
TEST REPORT NUMBER	JOU 2132MED156
TEST REPORT ISSUE DATE	30 November 2021
TEST REPORT VERSION	1.0
MANUFACTURER	Envolv Innovations Pvt. Ltd, #V1/809, Kakkanad, Cochin. INDIA - 682021
EUT NAME	ICU Ventilator
EUT MODEL	APERTA P1
CONDITION OF EUT WHEN RECEIVED	Good
ISSUED TO : NAME AND CONTACT INFORMATION OF CUSTOMER	Intertek India Pvt. Ltd, 7/F, II Stage, Industrial Suburb, Yeshwanthpur Indl. Area, Bangalore. Karnataka. India - 560022
ISSUED BY : NAME AND ADDRESS OF TEST LABORATORY	Tarang Labs, Wipro Limited Sy. No.69P,71/4P,78/8AP,134P,76P,77P,80P,70P, 79/1P, Unit 1, Sarjapur Road, Doddakannelli Village, Varthur Hobli, Bengaluru (Bangalore) Rural, Karnataka, 560035 Tel: +91-80-30292929 Fax: +91-80-30298200 Email: tarang-planet@wipro.com Web: www.wipro.com

Template Number: TARANG/T/051

Template Version:1.03

Template Date: 20 Aug 2021

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1 TEST REPORT SUMMARY

Applicant	Intertek India Pvt. Ltd,
Manufacturer	Envolv Innovations Pvt. Ltd,
EUT Name	ICU Ventilator
EUT Model	APERTA P1
EUT Serial Number	AP-21-0026
Date of receipt of test item	4 August 2021
EUT Category / Type of Equipment	Medical/Floor standing
EUT Operating Voltage range	100 to 240V AC
EUT Operating Frequency range	50/60 Hz
EUT Power Rating	345 Watts
EUT Operating Current(max)	1.5 Ampere (Maximum)
Date of Test	4 August 2021 to 14 August 2021
Venue of Test	Tarang Labs-EMC

Applicable Standard	Applicable Test	Frequency range/ Class/ Test level	Applicable port	Results-Criterion
IEC 60601-1-2 (Edition 4.0):2014/ CISPR 11 (Edition 6.1) 2015+AMD1 CSV:2016*	Radiated Emission	Frequency Range: 30MHz to 1GHz	Enclosure	PASS
IEC 60601-1-2 (Edition 4.0):2014/ CISPR 11 (Edition 6.1) 2015+AMD1 CSV:2016*	Conducted Emission on Power line	Frequency Range: 150kHz to 30MHz	Power port	PASS
IEC 60601-1-2 (Edition 4.0):2014/ IEC 61000-3-2 (Edition 5.0):2018*	Harmonic Emission	Class A	Power port	PASS
IEC 60601-1-2 (Edition 4.0):2014/ IEC 61000-3-3 (Edition 3.1): 2013+AMD1:2017*	Flicker Emission	As per clause 5 of IEC 61000-3-3 (Edition 3.1) 2013+AMD1:2017	Power port	PASS
IEC 60601-1-2 (Edition 4.0):2014/ IEC 61000-4-2 (Edition 2.0):2008	Electrostatic discharge (Before Modification)	Direct Method: CD:2: ± 4kV AD:3: ± 8kV Indirect Method: CD:2: ± 4kV	Enclosure	Refer Section 5.3.5.10
IEC 60601-1-2 (Edition 4.0):2014/ IEC 61000-4-2 (Edition 2.0):2008	Electrostatic discharge (After Modification)	Direct Method: CD:4: ±8kV AD:4: ±15kV Indirect Method: CD:4: ±8kV	Enclosure	Refer Section Annexure II
IEC 60601-1-2 (Edition 4.0):2014/ IEC 61000-4-4 (Edition 3.0):2012	Electric Fast Transient (Power line)	Power Port:2: ±1kV	Power port	Refer Section 5.3.6.10

Report Number: JOU 2132MED156 ULR NO: TC59922100000055F	EMC TEST REPORT	Page 6 of 73
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**EMC Test Report
for
ICU Ventilator**

ULR - TC52282100000238F

Test Report No.: TASL/17025/EMC/TRP/COM/2122/167



TC- 5228

This report shall not be reproduced without the written approval of EMC Centre Tata Advanced Systems. The test results stated in this report are valid only for the specific item tested under specific conditions and applied to the sample as received limited to the parameters monitored during the conduction of the test.

For any Complaints / Suggestions please email to:

gmlabs@tataadvancedsystems.com

Submitted by




**Tata Advanced Systems Limited
42 - 43 Electronics City
Hosur Road, Bengaluru – 560 100.
Tel: 080 - 6785 9900 Fax: 080 – 6785 9903**

EMC Centre Test Report	Report No: TASL/17025/EMC/TRP/COM/2122/167	Model No: Aperta P1	Page 4 of 20
	<u>ULR - TC52282100000238F</u>	Serial No: AP-21-0026	

1. General Information

Name of the Applicant	M/s.Intertek India Pvt Ltd.
Contact Name	Mr.Rachan.S
Contact No	+918749008850
Email id	Rachan.s@intertek.com
EUT Manufacturer Name and Address	M/s.Envolv Innovations Pvt. Ltd., VI/809, Kakkanad, Cochin - 682021, India
EUT Name	ICU Ventilator
Model Number	Aperta P1
Serial Number	AP-21-0026
Supply Voltage & power	AC Mode: 100 - 240V AC,1.5A; Battery Mode
Test Location	M/s. Tata Advanced Systems Limited,42 - 43 Electronics City Hosur Road, Bengaluru - 560 100.
Test Standard	IEC 60601-1-2(edition.4.0) IEC 61000-4-3, IEC 61000-4-8, IEC 61000-4-11
Status of EUT on receipt	EUT was received in Good Condition
EUT Received on	23/08/2021
Dates of Test	26/08/2021 to 28/08/2021
Test Report Issued on	30/11/2021
Test Witnessed by	Mr.Rachan S (M/s.Intertek India Pvt Ltd.)
Test Result	Pass
Statement of conformity	Declaration of conformity of the results is based as per the standard limits/ based on decision rule considering MU
Test Report Prepared By	Mr. Akhilesh Sidapara

Test Engineer and Reviewer Details

 <small>Digitally signed by: ak2021 DN: CN = ak2021 C = IN O = ak2021 OU = ak2021 Date: 2021.11.30 18:54:43 +05'30'</small> (Akhilesh Sidapara) Test Engineer	 <small>Digitally signed by: R Munusamy DN: CN = R Munusamy C = IN O = TATA POWER SED OU = EMC Date: 2021.11.30 18:55:17 +05'30'</small> (R. Munusamy) Lab in Charge	 <small>Digitally signed by: J Gopinathan DN: CN = J Gopinathan C = IN O = TATA POWER SED OU = EMC Date: 2021.11.30 18:55:49 +05'30'</small> (J. Gopinathan) Technical Manager
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Note: This report is digitally signed by the approving authority through a secured workflow

EMC Centre Test Report	Report No: TASL/17025/EMC/TRP/COM/2122/167	Model No: Aperta P1	Page 5 of 20
	<u>ULR - TC52282100000238F</u>	Serial No: AP-21-0026	

2. Test Summary

I. ELECTRONICS TESTING

1. EMC TESTING

Sl. No	Name of the Test	Test Standard	Test Result
1.	Radiated Immunity	IEC 61000-4-3_Edition 4.0_2020	Pass Refer Annex 1
2.	Power Frequency Magnetic field	IEC 61000-4-8_Edition 2.0_2009	Pass Refer Annex 2
3.	Voltage Dips & short interruptions	IEC 61000-4-11_Edition 2.1_2017	Pass Refer Annex 3

2.1 OPINIONS& INTERPRETATIONS

Not Applicable

2.2 DEVIATION FROM STANDARD

No deviation from standard.