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..... :	S239804.01
Date of issue ..... :	18 September 2022
Total number of pages ..... :	68
Name of Testing Laboratory preparing the Report ..... :	ITL (Product Testing) Ltd.
Applicant's name ..... :	Flight Medical Innovations Ltd.
Address..... :	7 Hatnufa St., Petach Tikva 4951025, Israel
Test specification:	
Standard ..... :	ISO 80601-2-12:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012
Test procedure..... :	PM120
Non-standard test method..... :	N/A
TRF template used..... :	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ..... :	ISO80601_2_12C
Test Report Form(s) Originator.... :	Intertek Semko AB
Master TRF ..... :	Dated 2021-01-21

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Test item description ..... :	Critical Care Lung Ventilator		
Trade Mark(s)..... :	Flight Medical		
Manufacturer ..... :	Same as applicant		
Model/Type reference ..... :	Ventoux 8", Ventoux 12"		
Ratings ..... :	100-240Vac, 50-60Hz, 6A Max.; DC input: 11-30Vdc, 4.8A Max.; 21.6Vdc, 3400 mAh (from Li-Ion rechargeable batteries x2); Input O2 pressure: 2.4-6.2 bar, 35-90 PSI		
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**Testing Laboratory:**	ITL (Product Testing) Ltd.	
Testing location/ address.....:		1 Bat Sheva St., Lod 7110603, Israel	
Tested by (name, function, signature).....:		Slava Shapira, Safety Department Engineer	
Approved by (name, function, signature)...:		Slava Pilyagin, Safety Department Team Leader	
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments:

Attachement #	Description
1	Environmental test results
2	Photographs

Appendix #	Description
1	Accuracy Testing
2	DOC-0428-A03 Ventoux Risk Analysis
3	DOC-0486 Rev. A02 Operating manual Ventoux
4	DOC-0548 A00 Essential Performance criteria
5	DOC-0820 A00 VX-Regulator at 12 bar Pressure Test Report
6	DOC-0819 A00 Maximum Input Flow Rate
7	DOC-0812 VENTOUX patient air temperature test

- IEC 60601-1 evaluated in Test Report S239800.01
- IEC 60601-1-6 evaluated in Test Report S239801.01
- IEC 60601-1-8 evaluated in Test Report S239802.01

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
201.4.11.101.2 Input Flow 201.9.6.2.1.101 Acoustic Energy 201.9.101 Suction procedures 201.12.1.101 Accuracy of volume – controlled ventilation 201.12.1.102 Accuracy of pressure – controlled ventilation 201.15.3.5.101.1 d Shock test 201.15.3.5.101.1 e Broad-band random vibration test	ITL (Product Testing) Ltd. 1 Bat Sheva St., Lod 7110603, Israel

Summary of compliance with National Differences (List of countries addressed): N/A

Statement concerning the uncertainty of the measurement systems used for the tests:

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

Procedure number, issue date and title:
PM 196, Version: V4, dated: 4 June 2019, 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

Statement concerning the ASCA program specifications:

* We hereby declare that current test report meets ASCA program specifications.

** More details regarding that matter can be observed in ASCA Summary Test Report

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See IEC 60601-1 test report

Test item particulars:	
Classification of installation and use .....:	See IEC 60601-1 test report
Supply Connection.....:	See IEC 60601-1 test report
Ventilatory modes.....:	AC: PC/VC/PRVC, SIMV: PC/VC/PRVC CPAP/PSV, VG, APRV, NIV, HFOT
Tested VBS .....:	---
Gas supply options .....:	Available
Pneumatic power (if applicable) .....:	N/A
Integrated monitoring .....:	Available
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A (Not Applicable)
- test object does meet the requirement.....:	P (Pass)
- test object was not evaluated for the requirement.....:	N/E (Not Evaluated)
- test object does not meet the requirement.....:	F (Fail)
Testing:	
Date of receipt of test item .....:	14.11.2021
Date (s) of performance of tests.....:	14.11.2021 – 06.03.2022
General remarks:	
"(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.**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
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 ..... :	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies).....:	See IEC 60601-1 test report
General product information and other remarks: See IEC 60601-1 test report	

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Clause	Requirement + Test	Result - Remark	Verdict
201.4	**GENERAL REQUIREMENTS**		**P**
201.4.3. 101	**Essential performance**		**P**
	Additional essential performance requirements are found in the subclauses listed in Table 201.101	Considered	**P**
201.4.4	**Additional requirements for expected service life**		**P**
	In the risk management file, the manufacturer shall:	See Risk Management File DOC0428, as per section	**P**
	aa) state the probability of component failure that results in the ventilator needing to be taken out of service during the expected service life assuming that the preventative inspection, maintenance and calibration are performed according to the accompanying documents; and…:	See Risk Management File DOC0428, 4.8 Hazards arising from maintenance, aging and contributory affects	**P**
	bb) summarize the methodology used to determine this probability……:	See Risk Management File DOC0428, 4.8 Hazards arising from maintenance, aging and contributory affects	**P**
201.4.6	**ME equipment or ME system parts that contact the patient**		**P**
	aa) The VBS or its parts or accessories that can come into contact with the patient shall be subject to the requirements for applied parts	Considered	**P**
201.4.11. 101	**Additional requirements for pressurized gas input**		**P**
201.4.11. 101.1	**Overpressure requirement**		**P**
	a) A ventilator with a pressurized gas input shall:		**P**
	1) operate and meet the requirements of this document throughout its rated range of input pressure; and	See RM File DOC-0428, Part 4.2 Mechanical /Electronic Components Hazards Item 26 See Attachment 5	**P**
	2) not cause an unacceptable risk under the single fault condition of 1 000 kPa……: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Management File DOC0428, High Pressure Alarm	**P**
	b) A ventilator with a maximum rated input pressure in excess of 600 kPa shall not cause an unacceptable risk under the single fault condition of twice the maximum rated input pressure……: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Management File DOC0428, Mechanical / Electronic Components	**P**
201.4.11. 101.2	**Compatibility requirement**		**P**
	If the ventilator is intended to be connected to a medical gas pipeline system conforming with ISO 7396-1:2016 then:		**P**
	a) the rated range of input pressure shall cover the range specified in ISO 7396-1:2016; and	35-90 psig/ 240-620 kPa See attachment 6	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) under normal condition,	See appended Table 201.4.11.101.2	**P**
	1) the maximum input flowrate required by the ventilator for each gas shall not exceed 60 l/min averaged over 10 s at a pressure of 280 kPa, measured at the gas intake port; and	See appended Table 201.4.11.101.2	**P**
	2) any transient input flowrate shall not exceed 200 l/min averaged over 3 s, or:	See appended Table 201.4.11.101.2	**P**
	3) the accompanying documents shall disclose:		**N/A**
	i) the maximum input flowrate required by the ventilator for each gas at a pressure of 280 kPa averaged over 10 s, measured at the gas intake port; and	Not specified	**N/A**
	ii) the maximum transient input flowrate averaged for 3 s required by the ventilator for each gas at a pressure of 280 kPa, measured at the gas intake port; and	Not specified	**N/A**
	iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the risk that the ventilator interferes with the operation of adjacent equipment.	Not specified	**N/A**
201.5	**GENERAL REQUIREMENTS FOR TESTING OF ME EQUIPMENT**		**P**
201.5.101	**ADDITIONAL REQUIREMENTS FOR GENERAL REQUIREMENTS FOR TESTING OF ME EQUIPMENT**		**P**
201.5.101.1	**Ventilator test conditions**		**P**
	a) For testing, the ventilator		**P**
	1) shall be connected to gas supplies as specified for normal use	Complied	**P**
	2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.	No other gases except industrial grade oxygen and air used	**N/A**
	b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.	Same as above	**N/A**
201.5.101.2	**Gas flowrate and leakage specifications**		**P**
	All requirements for gas flowrate, volume and leakage in this document		**P**
	a) are expressed at STPD,	Complied	**P**
	b) except for those associated with the VBS, which are expressed at BTPS.	Considered	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

201.5.101.3	**Ventilator testing errors**		**P**
	a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty		**P**
	b) The manufacturer shall disclose the measurement uncertainty for each disclosed tolerance in the technical description	See DOC-0486 Operating manual Ventoux 6.4 Alarm Controllers, 6.5 Setting Controllers	**P**

201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		**P**
201.7.2.3	**Consult accompanying documents**		**N/A**
	The ventilator shall be marked with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002	Marked with 	**N/A**
201.7.2.4.101	**Additional requirements for accessories**		**P**
	a) Accessories supplied separately shall:		**P**
	1) fulfil the requirements of 201.102.1; and	Considered	**P**
	2) be marked with an indication of any limitations or adverse effects of the accessory on the basic safety or essential performance of the ventilator, if applicable	No such limitation detected	**N/A**
	b) If marking the accessory is not practicable, this information may be placed in the instructions for use	Considered	**P**
201.7.2.13.101	**Additional requirements for physiological effects**		**N/A**
	a) All natural rubber latex-containing components in the gas pathways or accessories shall be marked as containing latex	No such parts	**N/A**
	b) Such marking shall be clearly legible	No such parts	**N/A**
	c) Symbol 5.4.5 from ISO 15223-1:2016, may be used.	No such parts	**N/A**
	d) The instructions for use shall disclose all-natural rubber latex-containing components	No such parts	**N/A**
201.7.2.17.101	**Additional requirements for protective packaging**		**P**
	a) Packages containing breathing attachments intended for single use or for reuse shall have clearly legible markings of the following:		**P**
	1) a description of the contents	Complied	**P**
	2) an identification reference to the batch, type or serial number or symbols 5.1.5, 5.1.6 or 5.1.7 from ISO 15223-1:2016	Complied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) the word “LATEX”, or symbol 5.4.5 from ISO 15223-1:2016 if containing natural rubber latex		**P**
	b) For a specific model or type reference, the indication of single use shall be consistent for the model or type reference	Considered	**P**
201.7.2.18	**External gas source**		**P**
	aa) the gas name or chemical symbol in accordance with ISO 5359:2014	FiO2	**P**
	bb) the rated range of gas pressure	35-90 psig	**P**
	cc) for oxygen gas inputs, the rated range of oxygen concentration	Not mentioned	**N/A**
	dd) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used	Not used	**N/A**
201.7.2.101	**Additional requirements for marking on the outside of ME equipment or ME equipment parts**		**P**
	a) The ME equipment**,** parts or accessories shall have clearly legible markings including		**P**
	1) any special storage, handling or operating instructions.	Provided	**P**
	2) any warnings or precautions relevant to the immediate operation of the ventilator.	No such warnings	**N/A**
	3) an arrow indicating the intended direction of gas flow i) for the gas output port; and ii) for the gas return port	No such indications	**N/A**
	4) Symbol 0794 of ISO 7000 or Symbol 0795 of ISO 7000 may be used.	Not used	**N/A**
	b) If applicable, operator-accessible ME equipment, parts or accessories shall have clearly legible markings of the following:		**N/A**
	1) for a ventilator intended to be used in the magnetic resonance (MR) environment	Not used	**N/A**
	i) Symbol 7.3.1-1 or Symbol 7.3.1-2 of IEC 62570 for an ‘MR Safe’ ventilator, or	Not used	**N/A**
	ii) Symbol 7.3.2 of IEC 62570 for an ‘MR Conditional’ventilator, in accordance with IEC 62570:2014	Not used	**N/A**
	2) an arrow indicating the direction of the flow for flow-direction-sensitive components that are operator-removable without the use of a tool	No such indications	**N/A**
	3) an indication of the date after which ME equipment, part or accessory should not be used, expressed as the year and month. i) Symbol 5.1.4 of ISO 15223-1:2016 (Table 201.D.2.101, symbol 1) may be used	No such indications	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	4) a warning not to obstruct the gas intake port i) A symbol evaluated according to IEC 62366-1 as information for safety may be utilized	No such warnings	**N/A**
201.7.4.3	**Units of measurement**		**P**
	All gas volume, flowrate and leakage specifications:		**P**
	aa) shall be expressed at STPD; except	Complied	**P**
	bb) for those associated with the VBS which shall be expressed at BTPS	Considered	**P**
201.7.9.1	**Additional general requirements**		**P**
	Name or trade name and address of the manufacturer, and	See DOC-0468 Rev. A02 Operating manual Ventoux, Clause 13.5	**P**
	where the manufacturer does not have an address within the locale, an authorized representative within the locale	Not such case	**N/A**
201.7.9.2.1 .101	The instructions for use shall disclose the following:		**P**
	a) if the ventilator, its parts or accessories are intended for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the ventilator, its parts or accessories would be reused; and……: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See RM File DOC-0428 4.13 Patient Circuit Hazards and Contributory Factors	**P**
	b) the intended range of tidal volume.	PIF: 1 to 120 L/min VTi: 0 to 7500 ml MVi: 0 to 99.9 L	**P**
201.7.9.2.2 .101	**Additional requirements for warnings and safety notices**		**P**
	The instructions for use shall include:		**P**
	a) a warning statement to the effect of “Warning: Do not cover the ventilator or place in a position that affects proper operation”	See DOC-0486 Rev. A02 Operating manual Ventoux 2.2 Cautions	**P**
	b) a warning statement to the effect of “Warning: Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.”	See DOC-0486 Rev. A02 Operating manual Ventoux 2.1 General warnings	**P**
	c) a warning statement to the effect of “WARNING: Do not add any attachments or accessories of the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.”	See DOC-0486 Rev. A02 Operating manual Ventoux 2.2 Cautions	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	d) a warning statement to the effect of "Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."	See DOC-0486 Rev. A02 Operating manual Ventoux 2.2 Cautions	**P**
	e) a warning statement to the effect of "Warning: The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."	See DOC-0486 Rev. A02 Operating manual Ventoux, 2.1 General warnings	**P**
	f) a warning statement to the effect of "Warning: The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."	See DOC-0486 Rev. A02 Operating manual Ventoux, 2.1 General warnings	**P**
	g) a warning statement to the effect of "Warning: The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebuliser	See DOC-0486 Rev. A02 Operating manual Ventoux, 2.1 General warnings	**P**
	h) a warning statement to the effect of "Warning: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health."	See DOC-0486 Rev. A02 Operating manual Ventoux, 4.7.2 Low-Flow Oxygen Port	**P**
	i) a warning statement to the effect of "Warning: When using nebulisation or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.	See DOC-0486 Rev. A02 Operating manual Ventoux, 2.1 General warnings	**P**
201.7.9.2.8 .101	**Additional requirements for start-up procedure**		**P**
	a) The instructions for use shall disclose a method by which the following can be functionally tested by the healthcare professional operator to determine if they are operating correctly;		**P**
	1) the assembled VBS	See DOC-0486 Rev. A02 Operating manual Ventoux, 5.1 Powering on the Ventilator	**P**
	2) switchover to and operation from the internal electrical power source; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 4.5 Connecting the Power Cord (for AC)	**P**
	3) all of the alarm signals, including the alarm signals from any distributed alarm systems.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.13 Alarm Signal Validation	**P**
	b) Portions of this test method may		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	1) be automatically performed by the ventilator; or	See DOC-0486 Rev. A02 Operating manual Ventoux, 5.1 Powering on the Ventilator	**P**
	2) require healthcare professional operator action.	Not specified	**N/A**
201.7.9.2.9 .101	**Additional requirements for operating instructions**		**P**
	The instructions for use shall disclose:		**P**
	a) a listing of the following pressures:	Inspected and complied	**P**
	1) maximum limited pressure (PLIM max);	See DOC-0486 Rev. A02 Operating manual Ventoux, 4.7.1 Internal O2 Mixer, 14 Technical Specifications	**P**
	2) if provided, the rated range to which the maximum working pressure (PW max) can be set, if adjustable;	Maximum pressure not adjustable	**N/A**
	3) the means by which the maximum working pressure is accomplished	See DOC-0486 Rev. A02 Operating manual Ventoux, 14 Technical Specifications	**P**
	4) a statement that airway pressure can be sub atmospheric during the expiratory phase for a ventilator that can generate sub atmospheric pressure in the expiratory phase, if applicable	Not such case	**N/A**
	5) the minimum limited pressure at the patient-connection port, for ventilators that can generate sub atmospheric pressure in the expiratory phase.	Same as above	**N/A**
	b) the rated range of the following characteristics of the assembled operator-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained:		**P**
	1) inspiratory gas pathway resistance,	See DOC-0486 Rev. A02 Operating manual Ventoux, 1 Introduction	**P**
	2) expiratory gas pathway resistance, and	See DOC-0486 Rev. A02 Operating manual Ventoux, 1 Introduction	**P**
	3) VBS compliance	See DOC-0486 Rev. A02 Operating manual Ventoux, 1 Introduction	**P**
	c) the conditions under which the ventilator maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.8 Environmental Specifications	**P**
	d) an explanation of the meaning of the IP classification marked on the ME equipment	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.8 Environmental Specifications	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	e) an indication as to whether the ventilator is intended for non-invasive ventilation	See DOC-0486 Rev. A02 Operating manual Ventoux, 9.6 NIV (Non-Invasive Ventilation) Sub Mode	**P**
	f) any special storage, handling or operating instructions	Not specified	**N/A**
	g) a cross reference between the manufacturer-specific naming of the ventilator's ventilation modes and the ventilation-mode systematic coding scheme in Annex E of ISO 19223:2019	Complied	**P**
201.7.9.2.12	**Cleaning, disinfection, and sterilization**		**P**
	aa) The instructions for use shall identify which portions of the gas pathways through the ventilator can become contaminated with body fluids or by contaminates carried by expired breathing gases during both normal condition and single fault condition	See DOC-0486 Rev. A02 Operating manual Ventoux, 12 Cleaning and Maintenance	**P**
201.7.9.2.14.101	**Additional requirements for accessories, supplementary equipment, used material**		**P**
	a) The instructions for use of the ventilator shall include a statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the ventilator breathing system	See DOC-0486 Rev. A02 Operating manual Ventoux, 2.1 General Warning	**P**
	b) If applicable, the instructions for use of the ventilator shall disclose:		**P**
	1) any restrictions on the positioning of components within the ventilator breathing system; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 1 Introduction	**P**
	2) any adverse effect of any recommended accessory on the essential performance or basic safety of the ventilator (additional requirements are found in 201.16) ……:	See RM File - DOC-0428-A03 Ventoux Risk Analysis	**P**
201.7.9.2.16.101	**Additional requirements for reference to the technical description**		**P**
	Where the technical description is supplied as a separate document from the instructions for use, then the instructions for use shall:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.12 Technical Description	**P**
	a) list the contents of the technical description; and	Same as above	**P**
	b) wherever appropriate, provide a cross reference to the additional information available in the technical description	Same as above	**P**
201.7.9.3.1.101	**Additional general requirements**		**P**
	The technical description shall disclose:		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) a summary description of the filtering or smoothing techniques for measured or computed variables that are displayed or used for control necessary for the operator to form a mental model of the operation of the ventilator	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.12 Technical Description	**P**
	b) a pneumatic diagram of the ventilator, including a diagram for operator-detachable parts of the ventilator breathing system either supplied or recommended in the instructions for use; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.12 Technical Description	**P**
	c) a summary description of the means of initiating and terminating the inflation phase in each ventilation-mode of the ventilator	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.12 Technical Description	**P**
	d) the essential technical characteristics of each recommended breathing system filter	Same as above	**P**
201.7.9.3.101	**Additional requirements for the technical description**		**P**
	The technical description shall disclose:		**P**
	a) a description of a procedure for checking the function of the alarm system for each of the alarm conditions specified in this document, if not performed automatically during start-up; and	See DOC-0761 Ventoux	**P**
	b) which checks are performed automatically	Same as above	**P**

201.9	**Protection against mechanical hazards of ME equipment and ME systems**		**P**
201.9.6.2.1.101	**Additional requirements for audible acoustic energy**		**P**
	a) The A-weighted sound pressure level emitted by the ventilator shall be:		**P**
	1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and	See appended Table 201.9.6.2.1.101	**P**
	2) disclosed in the instructions for use	See DOC-0486 Rev. A02 Operating manual Ventoux, 6.5 Setting controllers	**P**
	b) The A-weighted sound power level shall be:		**P**
	1) calculated according to 8.2.5 and 8.6 of ISO 3744:2010; and	See appended Table 201.9.6.2.1.101	**P**
	2) disclosed in the instructions for use	See DOC-0486 Rev. A02 Operating manual Ventoux, 6.5 Setting controllers	**P**
201.9.101	**Additional requirements for suction procedures**		**P**
	a) The instructions for use shall disclose recommended ventilation settings for use with a closed suction catheter.	See DOC-0486 Rev. A02 Operating manual Ventoux, 6 Ventilator Settings	**P**
	b) A ventilator shall continue to function as intended after the use of a closed suction catheter		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	1) for each ventilation-mode with the lowest tidal volume of each intended tidal volume range indicated in the instructions for use; and	See appended Table 201.9.101	**P**
	2) using the VBS configuration with the lowest compliance of those indicated in the instructions for use	See DOC-0486 Rev. A02 Operating manual Ventoux, 6 Ventilator Settings	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
201.11	**Protection against excessive temperatures and other hazards**		**P**
201.11.1.2.2	**Applied parts not intended to supply heat to a patient**		**N/A**
	Over the rated flowrate range and at the maximum rated operating temperature, the temperature of the gas delivered by the ventilator at the patient-connection port, both with and without each humidifier specified for use in the instructions for use, when averaged over 120 s shall neither exceed:		**N/A**
	aa) 70 °C; nor		**N/A**
	bb) an energy equivalent to 43 °C and 100 % relative humidity (specific enthalpy not to exceed 197 kJ/m3 dry air).		**N/A**
201.11.6.5.101	**Additional requirements for ingress of water or particulate matter into ME equipment or ME system**		**P**
	a) Enclosures of ventilators shall provide at least an IP21 degree of protection to the harmful ingress of water	See corresponded table in IEC 60601-1 test report, IP34	**P**
	b) Enclosures of ventilators should provide an IP22 degree of protection to the harmful ingress of water	Same as above	**P**
	After these procedures, confirm that basic safety and essential performance are maintained.	Inspected and complied	**P**
201.11.6.6	**Cleaning and disinfection of ME equipment or ME system**		**P**
	aa) Gas pathways through the ventilator and its accessories that can become contaminated with body fluids or by contaminants carried by expired gases during normal condition or single fault condition shall be designed to allow dismantling:		**P**
	1) for cleaning and disinfection; or	See corresponded table in IEC 60601-1 test report	**P**
	2) cleaning and sterilization.		**N/A**
	bb) Ventilator enclosures shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the risk of cross infection of the next patient……..: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A03), section 4.6	**P**
	cc) Processing instructions for the ventilator and its accessories shall		**P**
	1) conform with ISO 17664:2017 and ISO 14937:2009; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 12.1 Cleaning and Disinfecting, 12.1.2 VENTOUX Ventilator Accessories	**P**
	2) be disclosed in the instructions for use.	Same as above	**P**
	After these procedures, ensure that basic safety and essential performance are maintained.	Same as above	**P**
201.11.7	**Biocompatibility of ME equipment and ME systems**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	aa) The manufacturer of a ventilator, VBS, its parts or accessories shall address in the risk management process the risks associated with the leaching or leaking of substances into the gas pathway.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A03), section 4.6	**P**
	bb) The gas pathways shall be evaluated for biocompatibility according to ISO 18562-1:2017.	See Appendix 1 in IEC 60601-1 Test Report	**P**
	cc) A VBS, its parts or accessories that contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, in a concentration that is above 0,1 % weight by weight of any article, shall be marked as containing such substances:	No such substances	**N/A**
	1) on the VBS, its parts or accessories itself; or	No such substances	**N/A**
	2) on the packaging.	No such substances	**N/A**
	3) The symbol of:		**N/A**
	i) EN 15986:2011[25] may be used for phthalates.	No such substances	**N/A**
	ii) ISO 7000-2725 may be used for other substances	No such substances	**N/A**
	4) If the intended use of a VBS, its parts or accessories includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these substances shall be included in the risk management file (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)……..:	No such substances	**N/A**
	5) The instructions for use shall contain information:		**N/A**
	i) on residual risks for these patient groups; and	No such substances	**N/A**
	ii) if applicable, on appropriate precautionary measures……..:	No such substances	**N/A**
201.11.8. 101	**Additional requirements for interruption of the power supply/supply mains to ME equipment**		**P**
	The ventilator shall be equipped with:		**P**
	a) an internal electrical power source capable of powering the ventilator for at least 30 min when the supply mains fall outside the values necessary to maintain normal operation	Complied	**P**
	b) a means of determining the remaining capacity or operation time provided by the internal electrical power source.	Indicated by display and by audio alarm	**P**
	1) This indication may be qualitative		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	c) a means to determine the power source that is currently powering the ventilator	 See DOC-0486 Rev. A02 Operating manual Ventoux, 4.4 - 4.5	**P**
	d) be equipped with an alarm system that detects a technical alarm condition or the alarm condition for switchover to an internal electrical power source shall be at least a low priority	Considered as Info (low) priority See DOC-0486 Rev. A02 Operating manual Ventoux, 7.4.1 Power alarms	**P**
	e) generate an information signal to indicate a switchover to an internal electrical power source	Shown on Display	**P**
	f) be equipped with an alarm system that detects a technical alarm condition to indicate when the internal electrical power source nears depletion, at least 10 min prior to the loss of ventilation……:	Low batteries – Medium priority See DOC-0486 Rev. A02 Operating manual Ventoux, 7.4.1 Power alarms	**P**
	1) The internal electrical power source nears depletion alarm condition shall be at least a medium priority	Low batteries – Medium priority alarm See DOC-0486 Rev. A02 Operating manual Ventoux, 7.4.1 Power alarms	**P**
	2) As the internal electrical power source depletes further, at least 5 min prior to the loss of ventilation, the depletion internal electrical power source technical alarm condition shall escalate to high priority……:	Batteries empty – High priority alarm See DOC-0486 Rev. A02 Operating manual Ventoux, 7.4.1 Power alarms	**P**
	The instructions for use shall disclose:		**P**
	g) for each intended tidal volume under the conditions of Table 201.102, the operational time of the ventilator when powered from:		**P**
	1) an aged (see k), fully charged internal electrical power source……..:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.6 Internal Battery Specifications	**P**
	2) an external reserve electrical power source, if provided……..:	Not specified	**N/A**
	h) the means by which the secondary supply mains, if provided, can be tested.	No secondary supply mains used	**N/A**
	i) the behaviour of the ventilator after a switchover:		**P**
	1) to the internal electrical power source; or	See DOC-0486 Rev. A02 Operating manual Ventoux, 5.1 Powering on the Ventilator	**P**
	2) to the external reserve electrical power source, if provided.	Not specified	**N/A**
	j) the behaviour of the ventilator while:		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	1) the internal electrical power source is recharging; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 5.1 Powering on the Ventilator	**P**
	2) the external reserve electrical power source is recharging, if provided	No external electrical power source	**N/A**
	k) Age a new internal electrical power source by operating the ventilator from the internal electrical power source using the worst-case intended tidal volume and inflation-type under the conditions of Table 201.102 or by discharging and charging circuits	Inspected	**P**
	Non-transit-operable ventilator repeat age test 10 times; and	Transit-operable	**N/A**
	Transit-operable ventilator, repeat age test 50 times	Inspected	**P**
	Operate the ventilator using an intended tidal volume and inflation-type under the conditions of Table 201.102	Considered	**P**
	Confirm that the medium priority alarm condition occurs at least 10 min prior to the loss of ventilation……:	Inspected and complied	**P**
	Confirm that the high priority alarm condition occurs at least 5 min prior to the loss of ventilation……...:	Inspected and complied	**P**
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**		**P**
201.12.1	**Accuracy of controls and instruments**		**P**
	aa) The controls of a ventilator shall be clearly legible under the conditions specified in 7.1.2 of IEC 60601-1:2005+AMD1:2012	Complied	**P**
201.12.1.101	**Volume-control inflation-type**		**P**
	a) With a volume-control inflation-type selected and the ventilator operating in normal condition, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error	See Appended Table 201.12.1.101	**P**
	b) This disclosure shall include at least:		**P**
	1) the maximum error of the inspiratory volume in relation to the set tidal volume……..:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	2) the maximum error of the PEEP in relation to the set value of BAP……..:	Same as above	**P**
	3) the maximum error of the inspiratory oxygen (O2) concentration at the patient connection port in relation to the set value……:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	4) the disclosed accuracies shall include the effects of the range of the rated input oxygen concentration	Same as above	**P**
	c) All of the errors may be reported separately for the following ranges of intended tidal volume:		**P**
	1) Vtidal ≥ 300 ml;	No such volume	**N/A**
	2) 300 ml ≥ Vtidal ≥ 50 ml; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	3) Vtidal ≤ 50 ml	Same as above	**P**
	d) The accuracy of the performance of the ventilator shall either be:		**P**
	1) determined for each VBS configuration indicated in the instructions for use; or	Not such case	**N/A**
	2) determined for the worst-case VBS configurations indicated in the instructions for use	Determined the worst case, See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	e) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the risk management file……:	RM File Reference: See RM File - DOC-0428-A03 Ventoux Risk Analysis	**P**
201.12.1.102	**Pressure-control inflation-type**		**P**
	a) With a pressure-control inflation-type selected and the ventilator operating in normal condition, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.	See Appended Table 201.12.1.102	**P**
	b) This disclosure shall include at least:		**P**
	1) the maximum error of the airway pressure (Paw) at the end of the inflation phase in relation to the set value……..:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	2) the maximum error of PEEP in relation to the set value BAP……..:	Same as above	**P**
	3) the maximum error of the inspiratory oxygen (O2) concentration at the patient connection port in relation to the set value……:	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	4) the disclosed accuracies shall include the effects of the range of the rated input oxygen concentration	Same as above	**P**
	c) All of the errors may be reported separately for the following ranges of intended tidal volume:		**P**
	1) Vtidal ≥ 300 ml;	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	2) 300 ml ≥ Vtidal ≥ 50 ml; and	Same as above	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) Vtidal ≤ 50 ml	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	d) The accuracy of the performance of the ventilator shall either be:	Inspected and complied	**P**
	1) determined for each VBS configuration indicated in the instructions for use; or	Not such case	**N/A**
	2) determined for the worst-case VBS configuration indicated in the instructions for use	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	e) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the risk management file:	RM File Reference: See RM File - DOC-0428-A03 Ventoux Risk Analysis	**P**
201.12.1. 103	**Other inflation-types**		**N/A**
	a) If other inflation-types are provided, then with each other inflation-type selected and the ventilator operating in normal condition		**N/A**
	1) the performance at the patient-connection port; and	No other inflation types	**N/A**
	2) their acceptance criteria;	No other inflation types	**N/A**
	as determined by the manufacturer, shall be disclosed in the instructions for use	No other inflation types	**N/A**
	3) The disclosed performance and acceptance criteria shall include the effects of the range of the rated input oxygen concentration.	No other inflation types	**N/A**
	b) All of the performance and acceptance criteria may be reported separately for the following ranges of intended tidal volume:		**N/A**
	1) Vtidal ≥ 300 ml;	No other inflation types	**N/A**
	2) 300 ml ≥ Vtidal ≥ 50 ml; and.	No other inflation types	**N/A**
	3) Vtidal ≤ 50 ml	No other inflation types	**N/A**
	c) The acceptance criteria of the performance of the ventilator shall either be		**N/A**
	1) determined for each VBS configuration indicated in the instructions for use; or	Not such case	**N/A**
	2) determined for the worst-case VBS configuration indicated in the instructions for use.	No other inflation types	**N/A**
	In determining the worst-case configuration consider use with active and passive humidification	Same as above	**N/A**
	d) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the risk management file……..:	No such risks	**N/A**
	Tests specified by the manufacturer		**N/A**
201.12.1. 104	**Inspiratory volume monitoring**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) If the ventilator is equipped with inspiratory volume monitoring equipment, the accuracy of the inspiratory volume monitoring equipment shall be disclosed in the instructions for use.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	b) For actual tidal volumes greater than 50 ml, the accuracy of the inspiratory volume monitoring equipment shall be within ±(4,0 +(15 % of the actual inspiratory volume)) ml.	See Appended Table 201.12.1.101 and 201.12.1.102	**P**
201.12.1.105	**Response of the ventilator to an increase in set O2 concentration**		**P**
	a) The length of time required for the oxygen concentration in the tidal volume to change from a volume fraction of oxygen of 21 % to a volume fraction of 90 % of the maximum achievable volume fraction of oxygen shall be disclosed in the instructions for use	Can produce O2 between 21-100%	**P**
	b) The worst-case input oxygen concentration within the rated range shall be utilized for this test.		**P**
	c) The time shall be reported separately, as appropriate, at tidal volumes for each intended tidal volume under the conditions of Table 201.106, using:		**P**
	1) the worst-case VBS; or	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	2) the maximum internal volume VBS and	Same as above	**P**
	3) if base or continuous flow controls are provided, at:		**P**
	i) the minimum bias flow, or	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	ii) the minimum continuous flow	Same as above	**P**
	d) The time may be reported separately for:		**P**
	1) each VBS; or	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	2) as a maximum (for the worst-case VBS and minimum tidal volume).	Same as above	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
201.12.4.101	**Oxygen monitor**		**P**
	a) The ventilator shall either:		**P**
	1) be equipped with O2 monitoring equipment for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the patient-connection port) that is integral to the ventilator; or	Equipped with a monitor	**P**
	2) the instructions for use shall contain a statement to the effect that the ventilator is to be equipped with O2 monitoring equipment for measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the patient-connection port) before being put into service	Not specified	**N/A**
	b) Such O2 monitoring equipment shall conform with the following subclauses of ISO 80601-2-55:2018:	See ISO 80601-2-55 test report	**P**
	1) 201.7.4.3;	Complied	**P**
	2) 201.7.9.2.9.101 k);	Complied	**P**
	3) 201.12.1.101;	Complied	**P**
	4) 201.12.1.102;		**N/A**
	5) 201.12.1.103; and	Complied	**P**
	6) 208.6.1.2	Complied	**P**
	c) Where the O2 monitoring equipment is not an integral part of the ventilator, the instructions for use shall include the following:		**N/A**
	1) a statement to the effect that the ventilator is to be provided with O2 monitoring equipment that conforms with ISO 80601-2-55:2018 before being put into service; and	O2 monitor is integral part of the ventilator	**N/A**
	2) information on where to connect the O2 monitoring equipment	Same as above	**N/A**
	d) The O2 monitoring equipment shall, in addition, be equipped with an alarm system that includes a high oxygen level alarm condition	See DOC-0486 Rev. A02 Operating manual Ventoux, 7 Ventilator Alarms and Backup Ventilation	**P**
	e) The high oxygen level alarm condition		**P**
	1) shall be at least medium priority; unless	Medium priority	**P**
	2) an intelligent alarm system, based on additional information, determines that the high oxygen level alarm condition is suppressed or its priority is changed……..:	No such alarm system	**N/A**
201.12.4.102	**Measurement of airway pressure**		**P**
	a) The ventilator shall be equipped with monitoring equipment to measure the airway pressure	Equipped with pressure sensor that monitored on the display	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) The site of actual measurement may be anywhere in the ventilator breathing system; but	Measured on the patient circuit	**P**
	the indicated value shall be referenced to the patient-connection port.	Inspected and complied	**P**
	c) Under steady-state conditions, the indicated airway pressure shall be accurate to within ±(2 +(4 % of the actual reading)) hPa (±(2 +(4 % of the actual reading)) cmH2O).	See appended Table 201.12.1.102	**P**
201.12.4.103	**Measurement of expired volume and low volume alarm conditions**		**P**
201.12.4.103.1	**Ventilators intended to provide a tidal volume >50 ml**		**P**
	a) A ventilator intended to provide a tidal volume greater than 50 ml shall either:		**P**
	1) be equipped with monitoring equipment for indicating the volume expired through the patient-connection port; or	Equipped with monitoring equipment	**P**
	2) if not so equipped, the instructions for use shall include a statement to the effect that the ventilator is to be equipped with monitoring equipment that conforms with this document before being put into service	Not such case	**N/A**
	If equipped		**P**
	b) unless the expired volume monitoring equipment is an integral part of the ventilator, information on where to connect the expired volume monitoring equipment shall be disclosed in the instructions for use.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	c) the accuracy of measurement of expired volumes greater than 50 ml shall be within ±(4,0 +(15 % of the actual volume expired through the patient-connection port)) ml.	See appended Table 201.12.1.101 and 201.12.1.102	**P**
	d) the accuracy of expired volume monitoring equipment shall be disclosed in the instructions for use.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	e) The disclosed accuracies shall include the effects of the range of the rated input oxygen concentration.	Inspected and complied	**P**
	f) the expired volume monitoring equipment shall be equipped with an alarm system to indicate when:		**P**
	1) the low expired volume alarm limit is reached; and	Complied, See IEC 60601-1-8 report	**P**
	2) the high expired volume alarm limit is reached.	Complied, See IEC 60601-1-8 report	**P**
	g) the low expired volume and the high expired volume alarm conditions:		**P**
	1) shall be at least medium priority; unless	Medium priority	**P**
	2) an intelligent alarm system, based on additional information, determines that	No such alarm system	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	i) the low expired volume or	No such alarm system	**N/A**
	ii) the high expired volume alarm condition is suppressed or its priority is changed	No such alarm system	**N/A**
	h) the expired volume monitoring equipment may be equipped with an alarm system that:		**P**
	1) starts with low priority alarm conditions to indicate when the expired volume reaches either alarm limit; and	Inspected and complied	**P**
	2) if this state continues, escalates to medium priority alarm conditions	Medium priority	**P**
	i) the expired volume alarm limits may be:		**P**
	1) pre-adjusted;	Pre-adjusted	**P**
	2) responsible organization-adjustable;		**P**
	3) healthcare professional operator-adjustable;	Alarm limits adjustable only by service personnel	**N/A**
	4) ventilator-adjustable; or	Alarm limits adjustable only by service personnel	**N/A**
	5) a combination of healthcare professional operator-adjustable and ventilator-adjustable	Alarm limits adjustable only by service personnel	**N/A**
	j) if the alarm limits are adjustable by the ventilator, a summary description of the algorithm that determines the alarm limit values shall be disclosed in the instructions for use	Alarm limits adjustable only by service personnel	**N/A**
201.12.4. 103.2	**Ventilators intended to provide a tidal volume ≤50 ml**		**P**
	a) If a ventilator is intended to provide a tidal volume ≤50 ml, it may be equipped with expired volume monitoring equipment.	See appended Table 201.12.1.101 and 201.12.1.102	**P**
	b) The accuracy of the expired volume monitoring equipment at an expired volume ≤50 ml shall be disclosed in the instructions for use.	See DOC-0486 Rev. A02 Operating manual Ventoux, 14.3 Operating Specifications	**P**
	c) The disclosed accuracies shall include the effects of the range of the rated input oxygen concentration.	Inspected and complied	**P**
	d) The expired volume monitoring equipment may be equipped with an alarm system to indicate when the expired volume reaches the low expired volume alarm limit.	Equipped with alarm system	**P**
	e) The low expired volume alarm condition:		**P**
	1) shall be at least low priority; unless	Inspected and complied	**P**
	2) an intelligent alarm system, based on additional information, determines that	Not such alarm system	**N/A**
	i) the low expired volume alarm condition is suppressed; or		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	ii) its priority is changed	Alarm priority adjustable only by service personnel	**N/A**
	f) If provided, the expired volume alarm limit may be:		**P**
	1) pre-adjusted	Pre-adjusted	**P**
	2) responsible organization-adjustable		**P**
	3) healthcare professional operator-adjustable	Alarm limits adjustable only by service personnel	**N/A**
	4) ventilator-adjustable	Alarm limits adjustable only by service personnel	**N/A**
	5) a combination of healthcare professional operator-adjustable and ventilator-adjustable	Alarm limits adjustable only by service personnel	**N/A**
	g) If the alarm limit is adjustable by the ventilator, a summary description of the algorithm that determines the alarm limit values shall be disclosed in the instructions for use	Alarm limits adjustable only by service personnel	**N/A**
201.12.4.104	**Expiratory end-tidal CO2 monitoring equipment**		**P**
	a) If a ventilator intended to provide a tidal volume ≤50 ml is not equipped with expired volume monitoring equipment (see 201.12.4.103.2), the ventilator shall either		**P**
	1) be equipped with CO2 monitoring equipment for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the patient-connection port) that is integral to the ventilator; or	Ventilator can be equipped with Capnography See DOC-0486 Rev. A02 Operating manual Ventoux	**P**
	2) the instructions for use shall contain a statement to the effect that the ventilator is to be equipped with CO2 monitoring equipment for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the patient-connection port) before being put into service	Same as above	**N/A**
	b) Such CO2 monitoring equipment shall conform with the following subclauses of ISO 80601-2-55:2018:	See ISO 80601-2-55 test report	**P**
	1) 201.7.4.3;	Complied	**P**
	2) 201.7.9.2.9.101 k);	Complied	**P**
	3) 201.12.1.101;	Complied	**P**
	4) 201.12.1.102;		**N/A**
	5) 201.12.1.103; and	Complied	**P**
	6) for expired CO2 concentration, 208.6.1.2.	Complied	**P**
	c) Where the CO2 monitoring equipment is not an integral part of the ventilator, the instructions for use shall include the following:	Integral part of EUT	**N/A**
	1) a statement to the effect that the ventilator is to be provided with CO2 monitoring equipment	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	that conforms with ISO 80601-2-55:2018 before being put into service; and		
	2) information on where to connect the CO2 monitoring equipment.	Same as above	**N/A**
201.12.4. 105	**Maximum limited pressure protection device**		**P**
	a) A protection device shall be provided to prevent the airway pressure from exceeding the maximum limited pressure under both:		**P**
	1) normal condition; and	0 to 60 cmH2O, See DOC-0486 Rev. A02 Operating manual Ventoux 6.2 Main controllers	**P**
	2) single fault condition	Same as above	**P**
	b) The maximum limited pressure shall not exceed the lower of:		**P**
	1) 20 hPa (20 cmH2O) more than the high pressure alarm limit; or……:	0 to 60 cmH2O, See DOC-0486 Rev. A02 Operating manual Ventoux 6.2 Main controllers	**P**
	2) 125 hPa (125 cmH2O)……:	Not such case	**N/A**
201.12.4. 106	**High airway pressure alarm condition and protection device**		**P**
	a) The ventilator shall be equipped with monitoring equipment with an alarm system to indicate when the high-pressure limit for airway pressure is reached	Complied	**P**
	b) The high airway pressure alarm condition:		**P**
	1) shall be high priority; unless	Considered and complied	**P**
	2) an intelligent alarm system, based on additional information, determines that	No such alarm system	**N/A**
	i) the high airway pressure alarm condition is suppressed; or	Same as above	**N/A**
	ii) its priority is changed	Same as above	**N/A**
	c) The high airway pressure alarm limit may be		**P**
	1) independently adjustable; or	Limit can be adjusted only by service personnel	**N/A**
	2) related to the set pressure of the ventilator	Pre-set	**P**
	d) It shall not be possible to set the high-airway pressure alarm limit to a value greater than the maximum limited pressure limit.		**P**
	e) Means shall be provided to require the operator to perform a deliberate sequence of actions to confirm the setting of the high-pressure alarm limit to values exceeding the lower of	Limit can be adjusted only by service personnel	**N/A**
	1)20 hPa (20 cmH2O) more than the operator-set pressure; or	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	2)60 hPa (60 cmH2O).	Same as above	**N/A**
	f) Patient-generated transient pressure increases should not cause the high-pressure alarm condition.	Considered and complied	**P**
	g) The high airway pressure alarm condition delay shall not exceed 200 ms and the ventilator shall	Considered and complied	**P**
	1) act to attempt to cause the pressure to start to decline within that duration; and	Inspected and complied	**P**
	2) act to prevent the pressure from continuing to rise.	Inspected and complied	**P**
	h) Whenever the high-pressure alarm condition occurs, the ventilator shall, within no more than two respiratory cycles or 15 s, whichever is less, reduce the airway pressure to either……:		**N/A**
	1) the atmospheric pressure; or		**N/A**
	2) the set BAP level.		**N/A**
	i) During single fault condition, the airway pressure may fall below the set BAP level	Inspected and complied	**P**
201.12.4. 107	**PEEP alarm conditions**		**P**
	a) The ventilator shall be equipped with monitoring equipment with an alarm system that detects an alarm condition to indicate when the end-expiratory pressure is above the high PEEP alarm limit.	Equipped	**P**
	b) The ventilator may be equipped with monitoring equipment with an alarm system that detects an alarm condition to indicate when the end-expiratory pressure is below the low PEEP alarm limit.	Equipped with an alarm system	**P**
	c) Both the high and low PEEP alarm conditions:		**P**
	1) shall be of at least medium priority; unless	Complied	**P**
	2) an intelligent alarm system, based on additional information determines that the high or low PEEP alarm condition:		**N/A**
	i) is suppressed; or	No such alarm system	**N/A**
	ii) the priority is changed.	Same as above	**N/A**
	d) The alarm condition delay for high PEEP alarm condition shall not exceed the duration of three inflations……..:		**N/A**
201.12.4. 108	**Obstruction alarm condition**		**P**
	a) The ventilator shall be equipped with monitoring equipment with an alarm system that detects a technical alarm condition to indicate when the alarm limit for obstruction is reached	Complied	**P**
	b) The obstruction technical alarm condition:		**P**
	1) shall be high priority, unless		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	2) an intelligent alarm system, based on additional information, determines that the obstruction technical alarm condition	No such alarm system	**N/A**
	i) is suppressed; or	Same as above	**N/A**
	ii) its priority is changed	Same as above	**N/A**
	c) The alarm condition delay shall not exceed more than		**P**
	1) two respiratory cycles or	Not such case	**N/A**
	2) 5 s……..:	Complied	**P**
	d) Whenever the obstruction alarm condition occurs, the ventilator shall, within no more than one respiratory cycle, reduce the airway pressure to either		**P**
	1) atmospheric pressure; or		**N/A**
	2) the set BAP level		**P**
	e) The ventilator should be equipped with a protection device to allow spontaneous breathing when obstruction occurs.	Inspected and complied	**P**
	f) If equipped with the protection device, the pressure drop measured at the patient-connection port, with all recommended accessories in place, shall not exceed 6,0 hPa (6,0 cmH2O) at a flowrate of:		**P**
	1) 30 l/min for a ventilator intended to provide tidal volume, Vtidal ≥ 300 ml……..:	No such volume	**N/A**
	2) 15 l/min for a ventilator intended to provide tidal volume, 300 ml ≥ Vtidal ≥ 50 ml……..:		**P**
	3) 2,5 l/min for a ventilator intended to provide tidal volume, Vtidal ≤ 50 ml……:		**P**
	g) The accompanying document shall describe:		**P**
	1) the means by which the obstruction alarm condition is determined; and	See DOC-0486 Rev. A02 Operating manual Ventoux 7 VENTILATOR ALARMS AND BACKUP VENTILATION	**P**
	2) a means to test the obstruction alarm condition	Same as above	**P**
201.12.4. 109	**Disconnection alarm condition**		**P**
	a) The ventilator shall be equipped with an alarm system that detects a technical alarm condition to indicate when conditions in the VBS reach the alarm limit for disconnection.	See DOC-0486 Rev. A02 Operating manual Ventoux, 7.4.3 Technical Alarms	**P**
	b) The disconnection technical alarm condition shall be at least medium priority.		**P**
	c) The alarm off or audio off of the disconnection technical alarm condition alarm signals shall not be provided when the ventilator is operating in any	Provided	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	ventilator-operational mode intended for a ventilator-dependent patient.		
	d) The alarm off or audio off of the disconnection technical alarm condition alarm signals may be provided when the ventilator is operating in any ventilator-operational mode not intended for a ventilator-dependent patient.	Provided	**P**
	e) The instructions for use shall disclose the maximum alarm condition delay of the disconnection technical alarm condition……:	2 minutes for Audio Off	**P**
	f) The instructions for use shall disclose any use scenarios in which decannulation might not be detected as a VBS disconnection	No known scenarios	**N/A**
201.12.4. 110	**Protection against inadvertent setting of high airway pressure**		**N/A**
	Means shall be provided to require the operator to perform a deliberate sequence of actions to confirm any airway pressure settings exceeding 60 hPa (60 cmH2O)……..:	No such means provided	**N/A**
201.12.101	**Protection against accidental or unintentional adjustments**		**P**
	a) The ventilator shall include a means for the healthcare professional operator to confirm the ventilation-mode and settings:		**P**
	1) during the start-up procedure; and	See DOC-0486 Rev. A02 Operating manual Ventoux, 6 Ventilator Settings	**P**
	2) when the ventilation-mode is changed during use.	Same as above	**P**
	b) Means of protection shall be provided against accidental or unintentional adjustment of controls that can create a hazardous situation, including against accidently turning the ventilator off.	See IEC 60601-1-6 test report	**P**
	c) The usability of these means of protection shall be evaluated in the usability engineering process.	See IEC 60601-1-6 test report	**P**

201.13	**Hazardous situations and fault conditions for ME equipment**		**P**
201.13.2. 101	**Additional specific single fault conditions**		**P**
	A ventilator shall be so designed and constructed that the following single fault conditions shall not cause an unacceptable risk……..: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See RM File - DOC-0428-A03 Ventoux Risk Analysis	**P**
	a) disruption of the gas delivery to the patient-connection port from the ventilator	See attached table 13.2 at IEC 60601-1 report	**P**
	b) when present, disruption of the gas flow pathway from the patient-connection port to the ventilator;	See attached table 13.2 at IEC 60601-1 report	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	c) removal or failure of a healthcare professional operator-detachable breathing system filter;	No such filter	**N/A**
	d) disruption of a functional connection between parts of the ventilator or ME system	See attached table 13.2 at IEC 60601-1 report	**P**
201.13.2. 102	**Failure of one gas supply to a ventilator**		**P**
	a) Following the failure of one gas supply connected to a high-pressure input port, a ventilator shall maintain normal use.	See attached table 13.2 at IEC 60601-1 report	**P**
	b) The ventilator shall be equipped with an alarm system that detects a technical alarm condition to indicate this gas supply failure.	Inspected and complied	**P**
	c) The gas supply failure technical alarm condition:		**P**
	1) shall be at least low priority; unless	See attached table 13.2 at IEC 60601-1 report	**P**
	2) an intelligent alarm system, based on additional information, determines that the gas supply failure technical alarm condition is suppressed	No such alarm system	**N/A**
201.13.2. 103	**Independence of ventilation control function and related risk control measures**		**P**
	a) A single fault condition shall not cause the simultaneous failure of:		**P**
	1) a ventilation control function; and	Complied, See attached table 13.2 at IEC 60601-1 report	**P**
	2) the corresponding protection device		
	b) A single fault condition shall not cause either:		**P**
	1) a ventilation control function and the corresponding monitoring equipment; or	Complied, See attached table 13.2 at IEC 60601-1 report	**P**
	2) a ventilation control function and the corresponding alarm system to fail in such a way that the loss of the ventilation control function is not detected		**N/A**
201.13.2. 104	**Failure of functional connection to a ventilator control or monitoring means**		**P**
	a) Following the failure of a functional connection to a ventilator control or monitoring means, the ventilator shall continue to ventilate the patient.	Inspected	**P**
	b) The ventilator shall be equipped with an alarm system that detects a technical alarm condition to indicate this communication failure.	Equipped with an alarm system	**P**
	c) The communication failure technical alarm condition:		**P**
	1) shall be at least medium priority; unless	Medium priority	**P**
	2) an intelligent alarm system, based on additional information, determines that the communication failure technical alarm condition:		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	i) is suppressed; or	No such system	**N/A**
	ii) the priority is changed	Same as above	**N/A**

201.14	**Programmable electrical medical systems (PEMS)**		**P**
201.14.101	**Software life cycle**		**P**
	a) The programmable electronic subsystems (PESS) of a ventilator shall be developed with a design process conforming with IEC 62304:2006+AMD1:2015.	See IEC 62304 test report	**P**
	b) The ventilation control software items of the ventilator PESS without an independent risk control measure external to the PESS shall be considered as software safety Class C.	Considered	**P**

201.15	**Construction of ME equipment**		**P**
201.15.3.5.101	**Additional requirements for rough handling**		**P**
201.15.3.5.101.1	**Shock and vibration (robustness)**		**P**
	a) A ventilator and its parts, including applicable accessories shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling	Complied	**P**
	b) Stationary ME equipment is exempt from the requirements of this subclause	Portable Equipment	**N/A**
	c) After the following tests, the ventilator shall:	See appended table 201.15.3.5.101.1 d	**P**
	1) maintain basic safety and essential performance; and		**P**
	2) conform with the requirements of 201.12.1 and 201.12.4		**P**
	d) Shock test in conformance with IEC 60068-2-27:2008……:	Test type: Type 1	**P**
	e) Broadband random vibration test in conformance with IEC 60068-2-64:2008	See appended table 201.15.3.5.101.1 e	**P**
201.15.3.5.101.2	**Shock and vibration for a transit-operable ventilator during Operation**		**N/A**
	a) A ventilator and its parts, including applicable accessories, intended for transit-operable use shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling while operating	Not considered as transit-operable	**N/A**
	If more than one mounting system is described in the accompanying documents, multiple tests are required	Not considered as transit-operable	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	c) During the following test, a ventilator shall maintain basic safety and essential performance while ventilating a test lung using the worst-case conditions and parameters of Table 201.102, selected by intended tidal volume, as appropriate.	Not considered as transit-operable	**N/A**
	d) Perform the tests with a volume-control inflation-type or a pressure-control inflation-type, as applicable……:	Not considered as transit-operable	**N/A**
	e) For volume-control inflation-types, during the testing, the error of:		**N/A**
	1) the inspiratory volume of individual inflations shall not deviate by more than 35 % of the inspiratory volume measured prior to the test;	Not considered as transit-operable	**N/A**
	2) the inspiratory volume averaged over a one min interval shall not deviate by more than 25 % of the inspiratory volume measured prior to the test	Not considered as transit-operable	**N/A**
	3) the PEEP of individual inflations shall not deviate by more than 5,0 hPa (5,0 cmH2O) from the PEEP measured prior to the test;	Not considered as transit-operable	**N/A**
	4) the delivered FiO2 (inspiratory oxygen concentration) averaged over a one min interval shall not deviate by more than the deviation disclosed by the manufacturer in the instructions for use.	Not considered as transit-operable	**N/A**
	f) For pressure-control inflation-types, during the testing, the error at the patient-connection port		**N/A**
	1) of the pressure of the individual inflations shall not deviate by more than 35 % of the pressure measured prior to the test;	Not considered as transit-operable	**N/A**
	2) of the pressure averaged over a one min interval shall not deviate by more than 25 % of the pressure measured prior to the test	Not considered as transit-operable	**N/A**
	3) of the PEEP of individual inflations shall not deviate by more than 5,0 hPa (5,0 cmH2O) from the PEEP measured prior to the test;	Not considered as transit-operable	**N/A**
	4) of the delivered FiO2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the manufacturer in the instructions for use	Not considered as transit-operable	**N/A**
	g) During this testing, the alarm limits for volume and pressure alarm conditions shall be set to their least sensitive levels	Not considered as transit-operable	**N/A**
	h) Shock test in conformance with IEC 60068-2-27:2008	Not considered as transit-operable	**N/A**
	i) Broadband random vibration test in conformance with IEC 60068-2-64:2008	Not considered as transit-operable	**N/A**
	j) Free fall in conformance with IEC 60068-2-31:2008, using Procedure 1	Not considered as transit-operable	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.15.4.1	**Construction of connectors**		**P**
	aa) Healthcare professional operator-detachable gas pathway connectors are exempt from this requirement.		**P**
201.15.101	**Mode of operation**		**P**
	A ventilator shall be suitable for continuous operation.	Continuous connection	**P**
201.15.102	**Delivered oxygen concentration**		**P**
	A ventilator shall be capable of supplying gas with an O2 concentration over the range from ambient to at least 95 % of the input oxygen concentration to the patient.	Can produce O2 between 21-100%	**P**
201.15.103	**Accessory self-check**		**N/A**
	a) A ventilator shall be equipped with means that allow the determination of whether or not the VBS resistance and compliance characteristics fall outside the values necessary to maintain normal operation.	No such function	**N/A**
	b) This means may require operator action.	Same as above	**N/A**
201.16	**ME systems**		**N/A**
201.16.1. 101	**Additional general requirements for ME systems**		**N/A**
	Accessories connected to the VBS shall be considered to	Not defined as ME system	**N/A**
	a) be part of the ventilator; or	Same as above	**N/A**
	b) form an ME system with the ventilator	Same as above	**N/A**
201.16.2. 101	**Additional general requirements for accompanying documents of an ME system**		**N/A**
	If applicable, a description of the use scenarios and ranges of ventilation settings over which elevated temperature of the gas at the ventilator gas output port can lead to the failure of a respiratory gas humidifier to function according to its specification.	Not defined as ME system	**N/A**
201.101	**Gas connections**		**P**
201.101.1	**Protection against reverse gas leakage**		**N/A**
	For a ventilator with two or more high-pressure input ports,	Has only one pressure input port	**N/A**
	a) means shall be provided to limit reverse gas flowrate (leakage) from gas intake ports into the supply system of the same gas to a flowrate less than 100 ml/min in normal condition or single fault condition……:	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) means shall be provided to limit cross leakage from gas supplied through one high-pressure input port into the supply system of a different gas to less than 100 ml/h in normal condition or single fault condition……:	Same as above	**N/A**
201.101.2	**Connection to a high-pressure input port**		**P**
201.101.2.1	**Connector**		**P**
	If an operator-detachable hose assembly is provided for connection between the ventilator and either a medical gas pipeline system or a pressure regulator, it shall conform with ISO 5359:2014	Provided	**P**
201.101.2.2	**Filter**		**N/A**
	Each high-pressure input port shall be provided with a filter having a pore size less than or equal to 100 µm.	No such filter	**N/A**
201.101.3	**VBS connectors**		**P**
201.101.3.1	**General**		**P**
	Operator-detachable VBS connections through which the main flow of gas to or from the patient passes in normal condition, excluding the patient-connection port		**P**
	a) shall be a 15 mm or a 22 mm connector conforming with ISO 5356-1:2015;	Complied	**P**
	b) may be a 11,5 mm connector conforming with ISO 5356-1:2015 for a neonatal or paediatric use VBS; or	Complied	**P**
	c) may be a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015	No such connector	**N/A**
201.101.3.2	**Other named ports**		**P**
201.101.3.2.1	**Patient-connection port**		**P**
	The patient-connection port shall be one of the following:		**P**
	a) a female 15 mm conical connector conforming with ISO 5356-1:2015; or	Complied	**P**
	b) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.	No such connector	**N/A**
201.101.3.2.2	**Gas output port and gas return port**		**P**
	a) The gas output port and the gas return port shall be one of the following:		**P**
	1) a male 22 mm conical connector conforming with ISO 5356-1:2015.	Gas Outlet: ISO 22 mm OD conical; Air/Oxygen Inlet: ISO 30 mm female fitting	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	2) a male 15 mm conical connector conforming with ISO 5356-1:2015.	No such port	**N/A**
	3) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.	No such port	**N/A**
	4) a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015.	Same as above	**N/A**
	b) Notwithstanding this requirement, a ventilator only intended for tidal volumes of ≤300 ml, may be equipped with a gas output port and a gas return port using a male 11,5 mm conical connector conforming with ISO 5356-1:2015	Same as above	**N/A**
201.101.3.2.3	**Emergency intake port**		**N/A**
	a) An emergency intake port shall not be equipped with an operator-accessible connector.	No such port	**N/A**
	b) An emergency intake port shall be designed to prevent obstruction when the ventilator is in use.	Same as above	**N/A**
201.101.3.2.4	**Flow-direction-sensitive components**		**N/A**
	Any flow-direction-sensitive component of the VBS detachable without the use of a tool shall be so designed that it cannot be fitted in such a way that it presents an unacceptable risk to the patient…….: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk, the exhalation valve for the patient circuits is designed such way, that it cannot be assembled in the wrong way	**N/A**
201.101.3.2.5	**Accessory port**		**N/A**
	If provided, each accessory port shall:		**N/A**
	a) conform with ISO 80369-1:2018;	No such port	**N/A**
	b) be provided with a means to secure the accessory in position; and	Same as above	**N/A**
	c) be provided with a means to secure closure after removal of the accessory.	Same as above	**N/A**
201.101.3.2.6	**Gas exhaust port**		**N/A**
	a) If a connector is provided for the gas exhaust port, it shall be a 30 mm connector conforming with ISO 5356-1:2015.	No such port	**N/A**
	b) A ventilator shall be designed so that any provided gas exhaust port is not obstructed during use.	Same as above	**N/A**
201.101.3.2.7	**Temperature sensor port**		**N/A**
	The VBS may be equipped with a temperature sensor port conforming with 201.101.8 of ISO 80601-2-74:2017.	No such port	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.102	**Requirements for the VBS and accessories**		**P**
201.102.1	**General**		**P**
	All ventilator breathing systems, their parts and accessories shall conform with the requirements of this document, whether they are produced by the manufacturer of the ventilator or by another entity (“third-party manufacturer” or healthcare provider).	Complied	**P**
201.102.2	**Labelling**		**P**
	a) The accompanying document provided with each VBS, its parts or accessories, conforming with 201.102.1, shall include at least the model or type reference of at least one compatible ventilator.	See Copy of marking plate in IEC 60601-1 report	**P**
	b) Statements shall be included in the accompanying document of each ventilator breathing system, its parts or accessories to the effect that:		**P**
	1) ventilator breathing systems, their parts and accessories are validated for use with specific ventilators	See DOC-0486 Operating manual Ventoux	**P**
	2) incompatible parts can result in degraded performance; and	Not specified	**N/A**
	3) the responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use	See DOC-0486 Operating manual Ventoux	**P**
201.102.3	**Breathing tubes**		**P**
	Breathing tubes, intended for use in the VBS shall conform with the following clauses and subclauses of ISO 5367:2014: a) 5.1; b) 5.3.4; c) Clause 6; and d) Clause 7		**P**
201.102.4	**Water vapour management**		**N/A**
201.102.4.1	**Humidification system**		**N/A**
	Any humidifier, including heated breathing tubes, either incorporated into the ventilator or recommended for use with the ventilator, shall conform with ISO 80601-2-74:2017.	No humidification system	**N/A**
201.102.4.2	**Heat and moisture exchanger (HME)**		**N/A**
	Any heat and moisture exchanger, either incorporated into the VBS or recommended for use with the VBS, shall conform with:		**N/A**
	a) ISO 9360-1:2000; or	No HME	**N/A**
	b) ISO 9360-2:2001.	Same as above	**N/A**
201.102.6	**Breathing system filters**		**N/A**
	Any breathing system filter, either incorporated into the ventilator or recommended for use with the ventilator, shall conform with the relevant requirements of:		**N/A**
	a) ISO 23328-1:2003; and	No such parts	**N/A**
	b) ISO 23328-2:2002.	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.102.7	**Ventilator breathing systems**		**P**
201.102.7.1	**Leakage from complete VBS**		**P**
	Unintended leakage from the VBS should not exceed		**P**
	a) 200 ml/min at 50 hPa (50 cmH2O) for a ventilator intended to provide a tidal volume greater than 300 ml……:	No such volume	**N/A**
	b) 100 ml/min at 40 hPa (40 cmH2O) for a ventilator intended to provide a tidal volume between300 ml and 50 ml……:	Complied	**P**
	c) 50 ml/min at 20 hPa (20 cmH2O) for a ventilator intended to provide a tidal volume less than 50 ml:	Complied	**P**
201.102.7.2	**Non-invasive ventilation**		**P**
	a) The instructions for use for a ventilator intended for non-invasive ventilation shall include a warning statement to the effect that the exhaled volume and exhaled CO2 of the patient can differ from the measured exhaled volume and exhaled CO2 due to leaks around the mask	See DOC-0486 Operating manual Ventoux, 9.6 NIV Sun Mode	**P**
	b) A ventilator intended for non-invasive ventilation should either:		**P**
	1) be equipped with CO2 monitoring equipment for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the patient-connection port) in accordance with ISO 80601-2-55; or	Equipped with CO2 monitoring equipment	**P**
	2) if not so equipped, the instructions for use should contain a statement to the effect that the ventilator is to be provided with CO2 monitoring equipment for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the patient connection port) in accordance with ISO 80601-2-55 before being put into service	Same as above	**N/A**

201.103	**Spontaneous breathing during loss of power supply**		**P**
	a) A protection device shall be provided to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation	Considered and complied	**P**
	b) Under these conditions, the inspiratory and expiratory pressure drop measured at the patient-connection port with all recommended accessories in place shall not exceed 6,0 hPa (6,0 cmH2O) at a flowrate of:		**P**
	1) 30 l/min for a ventilator intended to provide a tidal volume, Vtidal ≥ 300 ml……:	No such volume	**P**
	2) 15 l/min for a ventilator intended to provide a tidal volume, 300 ml ≥ Vtidal ≥ 50 ml……:	Complied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) 2,5 l/min for a ventilator intended to provide a tidal volume, Vtidal ≤ 50 ml……..:	Complied	**P**

201.104	**Indication of duration of operation**		**P**
	a) The ventilator shall have means to indicate visually the cumulative hours of operation of the ventilator, either	Inspected and complied	**P**
	1) automatically; or	Shown automatically	**P**
	2) by operator action.	Same as above	**N/A**
	b) The ventilator should also have means to indicate visually		**P**
	1) the time since the last preventive maintenance; or		**N/A**
	2) the time until the next recommended preventive maintenance	25000 hours See DOC-0486 Rev. A02 Operating manual Ventoux, 12.2.1 Periodic Maintenance	**P**

201.105	**Functional connection**		**P**
201.105.1	**General**		**P**
	Basic safety and essential performance shall be maintained if connections to a functional connection of a ventilator are		**P**
	a) disrupted; or		**P**
	b) if the equipment connected to those parts fails.		**P**
201.105.2	**Connection to an electronic health record**		**N/A**
	a) A ventilator shall be equipped with a functional connection that permits data transmission from the ventilator to an electronic health record	No such part	**N/A**
	b) The data transmission should be capable of transmitting the information described in Annex BB.	Same as above	**N/A**
201.105.3	**Connection to a distributed alarm system**		**P**
	A ventilator shall be equipped with a functional connection that permits connection to a distributed alarm system	Complied	**P**
201.105.4	**Connection for remote control**		**N/A**
	A ventilator may be equipped with a functional connection for connection for external control of the ventilator.	No remote control	**N/A**

201.106	**Display loops**		**N/A**
201.106.1	**Pressure-volume loops**		**N/A**
	a) If a ventilator is provided with the display of pressure-volume loops the graph shall use:	No loops at the equipment	**N/A**
	1) inspiratory volume on the vertical axis; and		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	2) airway pressure on the horizontal axis.		**N/A**
	b) Positive values shall be on the top and the right of the display.	Same as above	**N/A**
	c) Increases in inspiratory volume shall be positive values.	No loops at the equipment	**N/A**
	d) The volume shall be reset to the origin at the beginning of each breath.	Same as above	**N/A**
201.106.2	**Flow-volume loops**		**N/A**
	a) If a ventilator is provided with the display of flow-volume loops, the graph shall use:	No loops at the equipment	**N/A**
	1) flowrate on the vertical axis; and		**N/A**
	2) inspiratory volume on the horizontal axis.		**N/A**
	b) Positive values shall be on the top and the right of the display.	Same as above	**N/A**
	c) Gas flow to the patient (inspiratory flow) and increases in inspiratory volume shall be positive values.	No loops at the equipment	**N/A**
	d) The volume shall be reset to the origin at the beginning of each breath.	Same as above	**N/A**
	e) The ventilator may be provided with an additional optional display configuration for the flow-volume loop where gas flow from the patient (expiratory flow) is represented as a positive value.		**N/A**
201.107	**Timed ventilatory pause**		**N/A**
201.107.1	**Expiratory pause**		**N/A**
	a) A ventilator may be equipped with a healthcare professional operator-controlled means to pause the ventilator in expiration.	No such pause exists	**N/A**
	b) If a ventilator is equipped with a means to pause the ventilator in expiration,		**N/A**
	1) more than one expiratory pause function may be provided.	No such pause exists	**N/A**
	2) the maximum allowable duration of an expiratory pause shall be 60 s……..:	Same as above	**N/A**
	3) means may be provided to initiate the expiratory pause from a functional connection	Same as above	**N/A**
	c) If a ventilator is equipped with a timed means to pause the ventilator in expiration	No such pause exists	**N/A**
	1) the duration of the expiratory pause may be operator-configurable or operator-adjustable	Same as above	**N/A**
	2) during the expiratory pause, any apnoea-related ventilatory alarm condition that would be caused by this expiratory pause shall be audio paused or alarm paused for the duration of the expiratory pause……:	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) in addition to the requirements for alarm signal inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the ventilator shall indicate the presence of the expiratory pause with at least an information signal or a low priority alarm condition……:		**N/A**
201.107.2	**Inspiratory pause**		**N/A**
	a) A ventilator may be equipped with a healthcare professional operator-controlled means to pause automatic ventilation at end-inspiration	No such pause exists	**N/A**
	b) If a ventilator is equipped with a means to pause the ventilator in inspiration		**N/A**
	1) more than one inspiratory pause function may be provided;	No such pause exists	**N/A**
	2) the maximum duration of a non-adjustable inspiratory pause shall be 10 s……:		**N/A**
	3) the maximum allowable duration of an adjustable inspiratory pause shall be 40 s……:		**N/A**
	4) means may be provided to initiate the inspiratory pause from a functional connection		**N/A**
	c) If a ventilator is equipped with a timed means to pause the ventilator in inspiration		**N/A**
	1) the duration of the inspiratory pause may be non-adjustable, responsible organization configurable or operator-adjustable		**N/A**
	2) the high-pressure alarm condition and protection device of 201.12.4.105 shall remain active during an inspiratory pause	No such pause exists	**N/A**
	3) during the inspiratory pause, any:		**N/A**
	i) apnoea alarm condition; or		**N/A**
	ii) sustained airway pressure alarm condition		**N/A**
	That would be caused by this inspiratory pause should, for the duration of the inspiratory pause, be:		**N/A**
	iii) audio paused; or		**N/A**
	iv) alarm paused		**N/A**
	d) In addition to the requirements for alarm signal inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the ventilator shall indicate the presence of the inspiratory pause with:		**N/A**
	1) at least an information signal; or		**N/A**
	2) a low priority alarm condition.		**N/A**
202	**Electromagnetic disturbances — Requirements and tests**		**P**
202.4.3.1	**Compliance criteria**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	the ventilator operated using the worst-case conditions and parameters of Table 201.104 or Table 201.105, selected by intended tidal volume, as appropriate. During this testing, set the volume and pressure alarm condition alarm limits to their least sensitive levels	See IEC 60601-1-2 Test report	**P**
	the ventilator operated using the worst-case conditions and parameters of Table 201.104 or Table 201.105, selected by intended tidal volume, as appropriate. During this testing, set the volume and pressure alarm condition alarm limits to their least sensitive levels	Considered	**P**
202.8.1.101	**Additional general requirements**		**P**
	a) The following degradations, if associated with basic safety and essential performance, shall not be allowed:		**P**
	1) component failures;	Considered	**P**
	2) changes in programmable parameters or settings;	Considered	**P**
	3) reset to default settings;	Considered	**P**
	4) change of ventilation-mode;	Considered	**P**
	5) initiation of an unintended operation;	Considered	**P**
	6) For volume-control inflation-types, during the testing, the error of:		**P**
	i) inspiratory volume of individual inflations shall not deviate by more than 35 % of the inspiratory volume measured prior to the test;	Considered	**P**
	ii) inspiratory volume averaged over a one min interval shall not deviate by more than 25 % of the inspiratory volume measured prior to the test	Considered	**P**
	iii) PEEP of individual inflations shall not deviate by more than 5 hPa (5,0 cmH2O) from the PEEP measured prior to the test;	Considered	**P**
	iv) of the delivered FiO2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the manufacturer in the instructions for use.	Considered	**P**
	7) For pressure-control inflation-types, during the testing, the error at the patient-connection port:		**P**
	i) of the pressure of individual inflations shall not deviate by more than 35 % of the pressure measured prior to the test	Considered	**P**
	ii) of the pressure averaged over a one min interval shall not deviate by more than 25 % of the pressure measured prior to the test	Considered	**P**
	iii) of PEEP of individual inflations shall not deviate by more than 5 hPa (5,0 cmH2O) from the PEEP measured prior to the test;	Considered	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	iv) of the delivered FiO2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the manufacturer in the instructions for use	Considered	**P**
	b) The ventilator may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect basic safety or essential performance.	Considered	**P**

206	**Usability**		**P**
206.101	**Primary operating functions**		**P**
	a) For a ventilator, the following shall be considered primary operating functions:	See IEC 60601-1-6 test report	**P**
	1) setting the healthcare professional operator-adjustable controls		**P**
	i) setting alarm limits	Can be defined only by service personnel	**N/A**
	ii) inactivating alarm signals	No such function available	**N/A**
	iii) switching between different ventilation-modes and inflation-types	See IEC 60601-1-6 test report	**P**
	iv) setting ventilation control parameters	See IEC 60601-1-6 test report	**P**
	2) observing and identifying the monitored ventilation parameters	See IEC 60601-1-6 test report	**P**
	3) configuring the VBS including	See IEC 60601-1-6 test report	**P**
	4) setting of the adjustable high pressure alarm limit to values exceeding 60 hPa (60 cmH2O)	See IEC 60601-1-6 test report	**P**
	5) setting of the airway pressure to values exceeding 60 hPa (60 cmH2O)	See IEC 60601-1-6 test report	**P**
	6) identifying any limitation of the ventilator's ability to detect decannulation based on the intended patient profile and the VBS configuration	See IEC 60601-1-6 test report	**P**
	7) connecting or disconnecting the patient-connection port of the VBS to the patient-interface;	See IEC 60601-1-6 test report	**P**
	8) starting the ventilator from power off	See IEC 60601-1-6 test report	**P**
	9) turning off the ventilator	See IEC 60601-1-6 test report	**P**
	10) performing a basic pre-use functional check of the ventilator including the alarm system	See IEC 60601-1-6 test report	**P**
	11) processing the ventilator between patient uses	See IEC 60601-1-6 test report	**P**
	b) The following functions, if available, also shall be considered primary operating functions		**P**
	1) starting ventilation from standby	See IEC 60601-1-6 test report	**P**
	2) activating standby	See IEC 60601-1-6 test report	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) activating manoeuvres that help assess lung function or the effectiveness of ventilator parameter settings	See IEC 60601-1-6 test report	**P**
	4) activating a closed suctioning function	No such function	**N/A**
	5) attaching the ventilator and, where applicable the VBS, to a trolley	See IEC 60601-1-6 test report	**P**
	c) The following actions associated with ventilation also shall be considered primary operating functions		**P**
	1) humidifying/conditioning gases delivered through the VBS	See IEC 60601-1-6 test report	**P**
	2) adding medication to the gas flowing into the patient	See IEC 60601-1-6 test report	**P**
	3) suctioning the patient's airway	No such function	**N/A**
	4) X-raying the patient	No such function	**N/A**
	5) providing alternative means of ventilation with a manual resuscitator	No such function	**N/A**
	6) positioning the patient	No such function	**N/A**
	7) connecting and disconnecting a distributed alarm system	See IEC 60601-1-6 test report	**P**
206.102	**Training**		**P**
	In the application of the requirements in 5.6 and 5.8 of IEC 62366-1:2015, training shall be considered necessary for both	See IEC 60601-1-6 test report	**P**
	a) the healthcare professional operator and	See IEC 60601-1-6 test report	**P**
	b) the designee of the responsible organization (e.g. service personnel or processing personnel).	See IEC 60601-1-6 test report	**P**
208	**General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		**P**
208.6.3.2.2.2.101	**Additional requirements for 1 m (operator's position) visual alarm signals and information signals**		**P**
	High priority alarm signals should be accompanied by information describing possible causes of the alarm condition and appropriate actions to take in response. Operator action may be required to display this information.	See DOC-0486 Operating manual Ventoux, 7 Ventilator Alarms and Backup Ventilation	**P**
208.6.8.3.101	**Additional requirements for global indefinite alarm signal inactivation states**		**P**
	a) A ventilator shall not be equipped with a means to initiate a global alarm off while connected to a patient.	No such means	**P**
	b) A ventilator shall not be equipped with a means to initiate a global audio off unless the ventilator is connected to a distributed alarm system	Not connected to distributed alarm system	**N/A**
208.6.8.4.101	**Additional requirements for termination of alarm signal inactivation**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	The duration of audio paused for the alarm conditions required by this document shall not exceed 120 s without healthcare professional operator intervention.	120 sec measured	**P**
208.6.12. 101	**Additional requirements for alarm system logging**		**P**
	a) Notwithstanding the requirements of IEC 60601-1-8:2006+AMD1:2012, the ventilator shall:		**P**
	1) be equipped with an alarm system log with a capacity of at least 1 000 events in total for:		**P**
	i) high priority alarm conditions;		**P**
	ii) medium priority alarm conditions; and		**P**
	iii) alarm signal inactivation states		**P**
	2) time stamp all events according to IEC 60601-1-8:2006+AMD1:2012, 6.12 a).		**P**
	3) not lose the contents of the alarm system log during a loss of power for less than 7 d unless deleted by responsible organization action.		**P**
	4) not permit the healthcare professional operator to erase the contents of the alarm system log.		**N/A**
	b) In addition, the ventilator should provide a log to include at least the following events:		**P**
	1) any change of ventilator settings, including the value applied		**P**
	2) any change of alarm settings, including the value applied	Cannot be changed by operator	**N/A**
	3) change of patient, including the patient attributes		**P**
	4) power supply source change, including the source utilized		**P**
	5) results of the pre-use check.		**P**

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Clause	Requirement + Test	Result - Remark	Verdict

201.4.11.101.2	**TABLE: Input flow**					**P**
Ventilator settings .....:		VT=2200 [ml] (ventilator's maximum)				—
Ambient temperature and pressure .....:		22°C	1013hPa			—
		Measured		**Corrected**		
Gas input	**Pressure**	**Peak flow (3 s)**	**Average flow (10 s)**	**Peak flow (3 s)**	**Average flow (10 s)**	**Remarks**
O2	2.8 bar	150 lpm	57 lpm	-	-	Peak Flow is displayed value, Average flow is the SW calculated value.

Supplementary information: See attachment 6

All values corrected to STPD where applicable (see 201.5.101.2).

Gases used for tests (see 201.5.101.1):

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Clause	Requirement + Test	Result - Remark	Verdict

201.9.6.2.1.101	**TABLE: Acoustic energy**		**P**
VBS used ..... :		copy table if tested with different VBS	—
Accessories..... :		SPO2, CUFF, Patient circuit	—
Humidifier (water level) ..... :		N/A	—
Test lung..... :		Isolated	—
Ventilator settings..... :		1. Vtidal > 300 ml 2. 50 ml <Vtidal > 300 ml 3. Vtidal < 50 ml	—

Measurement No.	**Location**	**Sound pressure level**	**Sound power level**	**Remarks**
-	Background	45 dBA	---	
1	Right EUT side	53.8 dBA	Worst Case	Vtidal > 300 ml
2	Back EUT side	60.4 dBA	Worst Case	
3	Left EUT side	57.5 dBA	Worst Case	
4	Front EUT side	57.2 dBA	Worst Case	
5	Right EUT side	49.7 dBA	Worst Case	50 ml < Vtidal > 300 ml
6	Back EUT side	52.2 dBA	Worst Case	
7	Left EUT side	50.4 dBA	Worst Case	
8	Front EUT side	50.6 dBA	Worst Case	
9	Right EUT side	48.6 dBA	Worst Case	Vtidal < 50 ml
10	Back EUT side	52.2 dBA	Worst Case	
11	Left EUT side	47.9 dBA	Worst Case	
12	Front EUT side	46.7 dBA	Worst Case	
-	**Calculated average**	52.3 dBA	---	

Supplementary information:

ISO 80601-2-12			
Clause	Requirement + Test	Result - Remark	Verdict

201.9.101	**TABLE: Suction procedures**		**P**
VBS used ..... :	ALYARD Turbo-Cleaning closed suction system for adult (Ventoux S/N 05210010)		—
Accessories ..... :	VX64-0002 VX-DL Adult Single Use P.C.		—
Suction flow ..... :	20 LPM		
Test lung ..... :	Michigan Instruments Test Lung 5601i S/N AI01072 IMT PF-300 Flow Analyzer S/N BA103581		—
Ventilator mode..... :	volume controlled		—
Ventilator settings ..... :	Vt: 500 ml Rate: 15 BPM Ti: 1.2 sec PEEP: 5 CmH2O		—
Ambient temperature and pressure ..... :	22°C	1013hPa	—

Parameter	**Before suction**	**After suction**		**Remarks**
Volume	499 ml	501 ml		
Frequency	15 BPM	15 BPM		
Airway pressure	16 cmH2O	16 cmH2O		
Peep	5 PEP	5 PEP		
Gas mixture	air	air		

Supplementary information: Reference – DOC-0763 VX-closed suction internal report

Gases used for tests (see 201.5.101.1): air

201.11.1.2.2	**TABLE: Temperature at Patient connection port**			**N/A**
Ambient Pressure (hPa) ..... :	-			—
Ambient temperature (°C) ..... :	-			—

Flow rate	**Max. temperature measured, (°C)**	**Relative humidity** %	**Energy** kJ/m3 dry air	**Comment**

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101	**TABLE: Accuracy of volume-controlled ventilation**	**P**
VBS used ..... :	Ventoux S/N 05210010	
Accessories..... :	VX64-0002 VX-DL Adult Single Use P.C.	
Humidifier (water level) ..... :	N/A	
Test lung..... :	Michigan Instruments Test Lung 5601i S/N AI01072 IMT PF-300 Flow Analyzer S/N BA103581	
Ventilator settings (except those listed below)..... :	AC-VC, Waveform=Square	
Ambient temperature and pressure ..... :	22°C	1013hPa

	Set			**Measured (indicate worst case from 30 breaths)**			**Insp. Volume (201.12.1.104)**		**Expired Volume (201.12.4.103)**	
Test No.	**Volume** ml	**BAP** hPa/ cmH2O	**O_2** %	**Volume** ml	**BAP** hPa/ cmH2O	**O_2** %	**Measured**	**Indicated**	**Measured**	**Indicated**
1	500	5	30	512	4.6	30	-	502	-	-
2	500	10	90	488	10.3	95	-	495	-	-
3	500	5	90	504	4.6	86	-	506	-	-
4	500	10	30	509	9.9	28	-	499	-	-
5	300	5	30	288	5	29	-	301	-	-
6	300	10	90	321	10.3	93	-	309	-	-
7	300	10	30	292	10	29	-	298	-	-
8	200	5	90	193	4.8	87	-	204	-	-
9	50	5	30	47	5	28	-	53	-	-
10	50	10	30	49	10	28	-	53	-	-
11	50	5	60	52	4.7	57	-	50	-	-
12	30	5	30	25	4.6	27	-	32	-	-
13	30	10	90	36	8.9	88	-	25	-	-
14	30	5	90	37	4.2	92	-	43	-	-
15	30	10	30	29	9.8	29	-	29	-	-
16	20	5	30	-	-	-	-	-	-	-
17	15	10	60	-	-	-	-	-	-	-
18	10	5	60	-	-	-	-	-	-	-
19	5	10	60	-	-	-	-	-	-	-
20	5	5	30	-	-	-	-	-	-	-
21	5	10	30	-	-	-	-	-	-	-

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Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.102	**TABLE: Accuracy of pressure-controlled ventilation**	**P**
VBS used ..... :	Ventoux S/N 05210010	
Accessories ..... :	VX64-0002 VX-DL Adult Single Use P.C.	
Humidifier (water level) ..... :	N/A	
Test lung ..... :	Michigan Instruments Test Lung 5601i S/N AI01072 IMT PF-300 Flow Analyzer S/N BA103581	
Ventilator settings (except those listed below) ..... :	AC-VC, Slope=3	
Ambient temperature and pressure ..... :	22°C	1013hPa

	Set			**Measured (indicate worst case from 30 breaths)**				**Insp. Volume (201.12.1.104)**		**Expired Volume (201.12.4.103)**	
Test No.	**Insp. Press.** (Paw)	**PEEP** (BAP)	**O_2** %	**Volume** ml	**Insp. Press.** (Paw)	**PEEP** (BAP)	**O_2** %	**Measured**	**Indicated**	**Measured**	**Indicated**
1	10	5	30	477	14	4.8	30	-	485	-	-
2	15	10	90	518	23	10	89	-	514	-	-
3	25	5	90	518	29	4.9	87	-	525	-	-
4	25	10	30	508	33.8	9.2	31	-	500	-	-
5	15	5	30	318	19.5	4.9	29	-	328	-	-
6	25	10	90	344	34.2	9.7	86	-	347	-	-
7	30	10	30	299	34	4.8	87	-	322	-	-
8	25	5	90	280	35.4	10.4	31	-	296	-	-
9	15	5	30	31	20.7	4.6	31	-	26	-	-
10	15	10	30	38	23	9.8	27	-	41	-	-
11	25	5	60	41	31.8	4.7	57	-	27	-	-
12	10	5	30	12	15.5	4.7	28	-	-	-	-
13	15	10	90	26	25.6	8.7	87	-	36	-	-
14	30	5	90	24	35.6	4.9	87	-	-	-	-
15	30	10	30	13	26.2	8.8	28	-	-	-	-
16	20	5	30	-	-	-	-	-	-	-	-
17	15	10	60	-	-	-	-	-	-	-	-
18	10	5	60	-	-	-	-	-	-	-	-
19	15	10	60	-	-	-	-	-	-	-	-
20	10	5	30	-	-	-	-	-	-	-	-
21	15	10	30	-	-	-	-	-	-	-	-

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Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101	**TABLE: Accuracy of Other inflation-types**		**N/A**
Inflation type ..... :	copy table for each applicable setup		
VBS used..... :			
Accessories ..... :			
Humidifier (water level)..... :			
Test lung ..... :			
Ventilator settings (except those listed below) ..... :			
Ambient temperature and pressure ..... :	°C	hPa	

	Set			**Measured**				**Indicated**			
Test No.											
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											

ISO 80601-2-12			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.105	**TABLE: O2 concentration change test**		**N/A**
VBS used ..... :		-	—
Input oxygen concentration..... :		-	—
Minimum bias flow or continuous flow. ..... :		-	—

Tidal volume ml	**Set rate** min-1	**I:E**	**Resistance** hPa	**Measured Time 21% to 90%**	**Disclosed time in IFU**

Supplementary information:

201.15.3.5.101.1 d	**TABLE: Shock test**	**P**
Peak acceleration..... :	Type 1:150 m/s2 (15 g) or Type 2: 300 m/s2 (30 g)	
Duration ..... :	Type 1:11 ms or Type 2: 6 ms	
Pulse shape..... :	half-sine	
Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	**Axis Shock Applied**	**BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No**	**Remarks**
Positive	Z	Yes	Pass
Negative	Z	Yes	Pass
Positive	X	Yes	Pass
Negative	X	Yes	Pass
Positive	Y	Yes	Pass
Negative	Y	Yes	Pass

Supplementary information: Tested with Type 1 method

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Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5 .101.1 e	**TABLE: Broad-band random vibration test**	**P**
1 Acceleration amplitude..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2 Acceleration amplitude..... :	100 Hz to 600 Hz: – 6 db per octave	
Duration ..... :	10 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	**Acceleration amplitude**	**BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No**	**Remarks**
1	1	Yes	Pass
2	1	Yes	Pass
3	1	Yes	Pass
1	2	Yes	Pass
2	2	Yes	Pass
3	2	Yes	Pass

Supplementary information:

201.15.3.5. 101.2 h	**TABLE: Shock test for a transit-operable ventilator during operation: Volume control**	**N/A**
Test from table 201.102..... :	Copy for each applicable test	
Peak acceleration ..... :	Type 1:50 m/s2 (5 g)	
Duration..... :	6 ms	
Pulse shape ..... :	half-sine	
Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	**Axis Shock Applied**	**Insp. Volume/ Inflation**	**Insp. Volume/ 1min**	**PEEP (BAP)**	**FiO2/1min**	**Remarks**

Supplementary information:

ISO 80601-2-12			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5. 101.2 h	**TABLE: Shock test for a transit-operable ventilator during operation: Pressure control**	**N/A**

Test from table 201.102..... :	Copy for each applicable test
Peak acceleration ..... :	Type 1:50 m/s2 (5 g)
Duration..... :	6 ms
Pulse shape ..... :	half-sine
Number of shocks..... :	3 shocks per direction per axis (18 total)

Direction Shock Applied	Axis Shock Applied	Pressure/ Inflation	Pressure /1min	PEEP (BAP)	FiO2/1min	Remarks

Supplementary information:

ISO 80601-2-12			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5. 101.1 i	**TABLE: Broad-band random vibration test for a transit-operable ventilator during operation: Volume control**					**N/A**
1 Acceleration amplitude ..... :				10 Hz to 100 Hz: 0,33 $(m/s^2)^2/Hz$		
2 Acceleration amplitude ..... :				100 Hz to 500 Hz: – 6 db per octave		
Duration..... :				30 min per perpendicular axis (3 total)		
Perpendicular axis subjected to broad-band random vibration test	**Acceleration amplitude**	**Insp. Volume/ Inflation**	**Insp. Volume/ 1min**	**PEEP (BAP)**	**FiO2/1min**	**Remarks**
1	1					
2	1					
3	1					
1	2					
2	2					
3	2					
Supplementary information:						

201.15.3.5. 101.1 i	**TABLE: Broad-band random vibration test for a transit-operable ventilator during operation: Pressure control**					**N/A**
1 Acceleration amplitude ..... :				10 Hz to 100 Hz: 0,33 $(m/s^2)^2/Hz$		
2 Acceleration amplitude ..... :				100 Hz to 500 Hz: – 6 db per octave		
Duration..... :				30 min per perpendicular axis (3 total)		
Perpendicular axis subjected to broad-band random vibration test	**Acceleration amplitude**	**Pressure/Inflation**	**Pressure/ 1min**	**PEEP (BAP)**	**FiO2/1min**	**Remarks**
1	1					
2	1					
3	1					
1	2					
2	2					
3	2					
Supplementary information:						

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Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5 .101.1 J	**TABLE: Free fall test for a transit-operable ventilator during operation: Volume control**		**N/A**
1	Fall height for mass ≤ 1 kg .....:	0,25 m	
2	Fall height for mass > 1 kg and ≤ 10 Kg .....:	0,1 m	
3	Fall height for mass > 10 kg and ≤ 50 Kg .....:	0,05 m	
4	Fall height for mass > 50 kg .....:	0,01 m	
5	Number of falls……..:	2	

Specified altitude (m)	Mass (Kg)	Fall No.	Insp. Volume/Inflation	Insp. Volume/ 1min	PEEP (BAP)	FiO2/1min	Remarks
0,25	≤ 1	1					
0,25	≤ 1	2					
0,1	> 1 & ≤ 10	1					
0,1	> 1 & ≤ 10	2					
0,05	> 10 & ≤ 50	1					
0,05	> 10 & ≤ 50	2					
0,01	> 50	1					
0,01	> 50	2					
Supplementary information:							

ISO 80601-2-12			
Clause	Requirement + Test	Result - Remark	Verdict

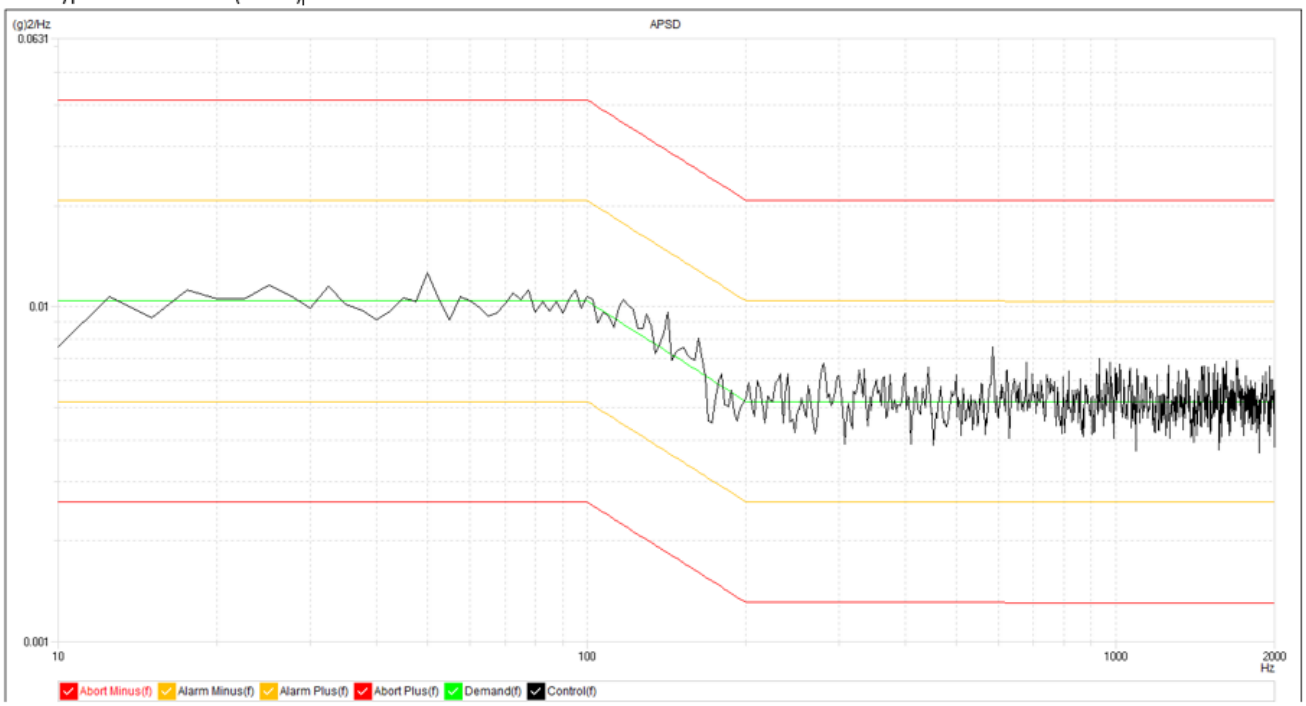
201.15.3.5 .101.1 J	**TABLE: Free fall test for a transit-operable ventilator during operation: Pressure control**		**N/A**
1	Fall height for mass ≤ 1 kg .....:	0,25 m	
2	Fall height for mass > 1 kg and ≤ 10 Kg .....:	0,1 m	
3	Fall height for mass > 10 kg and ≤ 50 Kg .....:	0,05 m	
4	Fall height for mass > 50 kg .....:	0,01 m	
5	Number of falls……..:	2	

Specified altitude (m)	**Mass (Kg)**	**Fall No.**	**Pressure/ Inflation**	**Pressure/ 1min**	**PEEP (BAP)**	**FiO2/1min**	**Remarks**
0,25	≤ 1	1					
0,25	≤ 1	2					
0,1	> 1 & ≤ 10	1					
0,1	> 1 & ≤ 10	2					
0,05	> 10 & ≤ 50	1					
0,05	> 10 & ≤ 50	2					
0,01	> 50	1					
0,01	> 50	2					

Supplementary information:

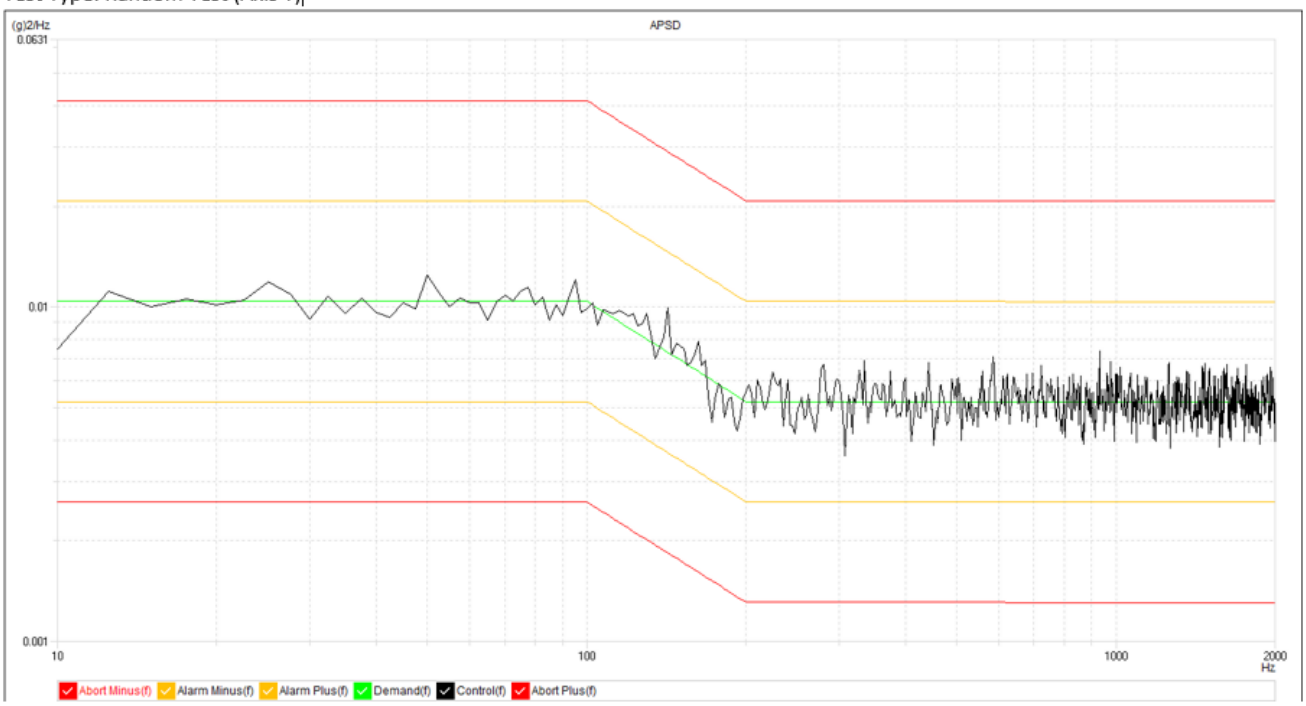
Attachment 1
Environmental test results

Test Type: Random Test (Axis X)



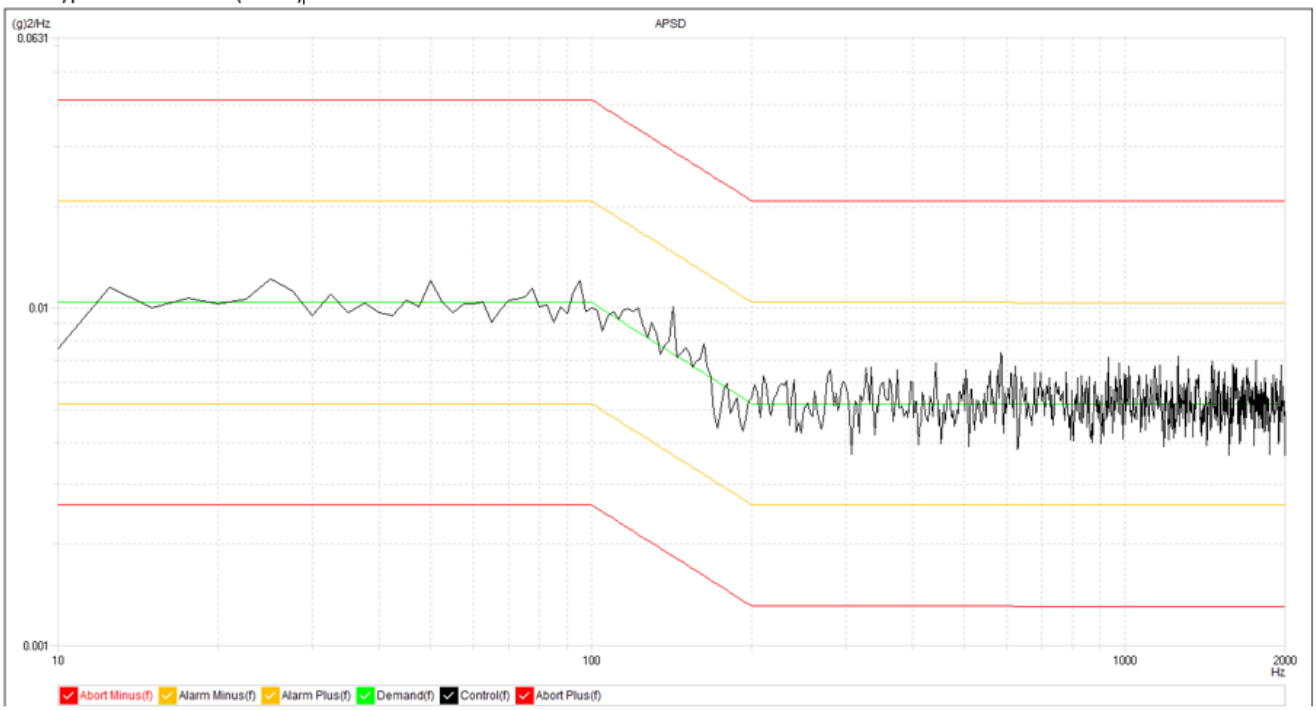
Demand RMS: 3.323 g Control RMS: 3.3349 g Drive RMS: 0.1141 V Level: 0 dB
Test Time: 00:30:50 Remaining Time: 00:00:00 Total Time: 00:31:12
Sampling Freq.: 5120 Hz Lines: 800 Frame Time: 400 ms Delta F: 2.5 Hz DOF: 120
The Saved Time: 11/09/2021 10:17:47 AM

Test Type: Random Test (Axis Y)



Demand RMS: 3.323 g Control RMS: 3.3306 g Drive RMS: 0.1237 V Level: 0 dB
Test Time: 00:30:50 Remaining Time: 00:00:00 Total Time: 00:31:13
Sampling Freq.: 5120 Hz Lines: 800 Frame Time: 400 ms Delta F: 2.5 Hz DOF: 120
The Saved Time: 11/09/2021 11:11:40 AM

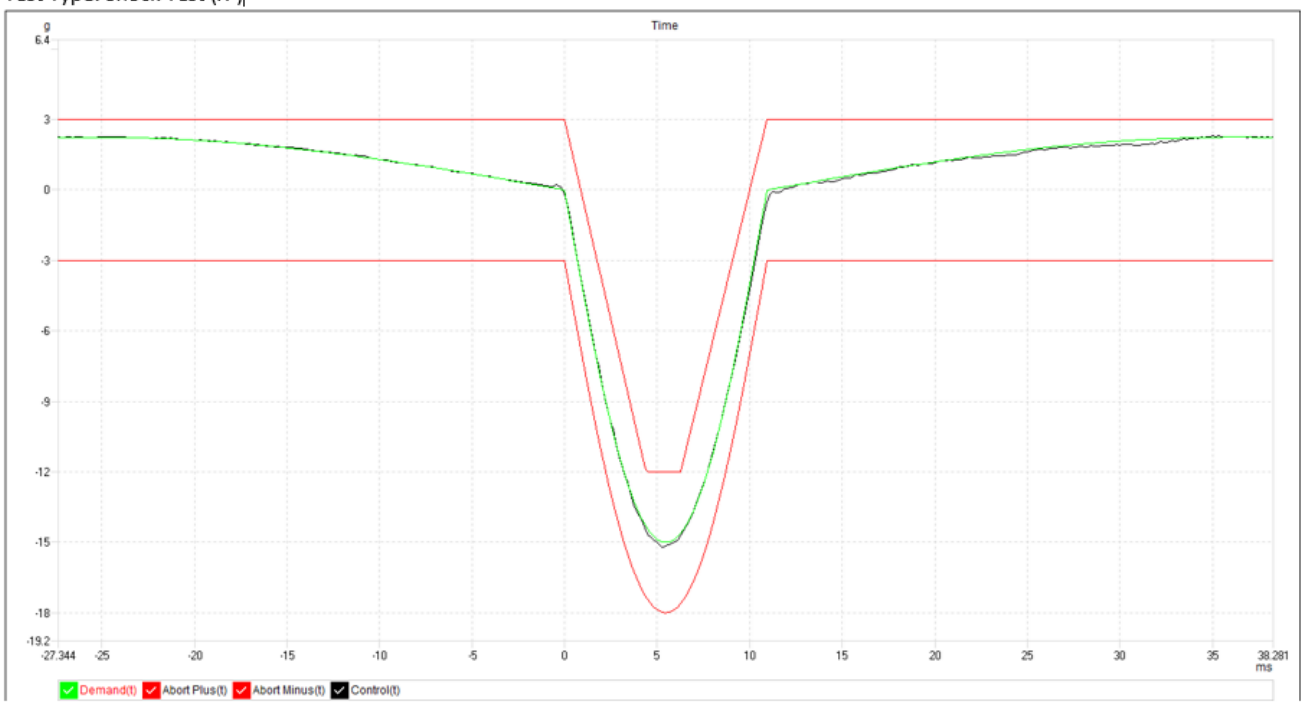
Test Type: Random Test (Axis Z)



Demand RMS: 3.323 g Control RMS: 3.34 g Drive RMS: 0.0799 V Level: 0 dB
Test Time: 00:30:50 Remaining Time: 00:00:00 Total Time: 00:31:13
Sampling Freq.: 5120 Hz Lines: 800 Frame Time: 400 ms Delta F: 2.5 Hz DOF: 120
The Saved Time: 11/09/2021 12:21:33 PM

Shock Test - Run(2021-11-09 10-27-32)

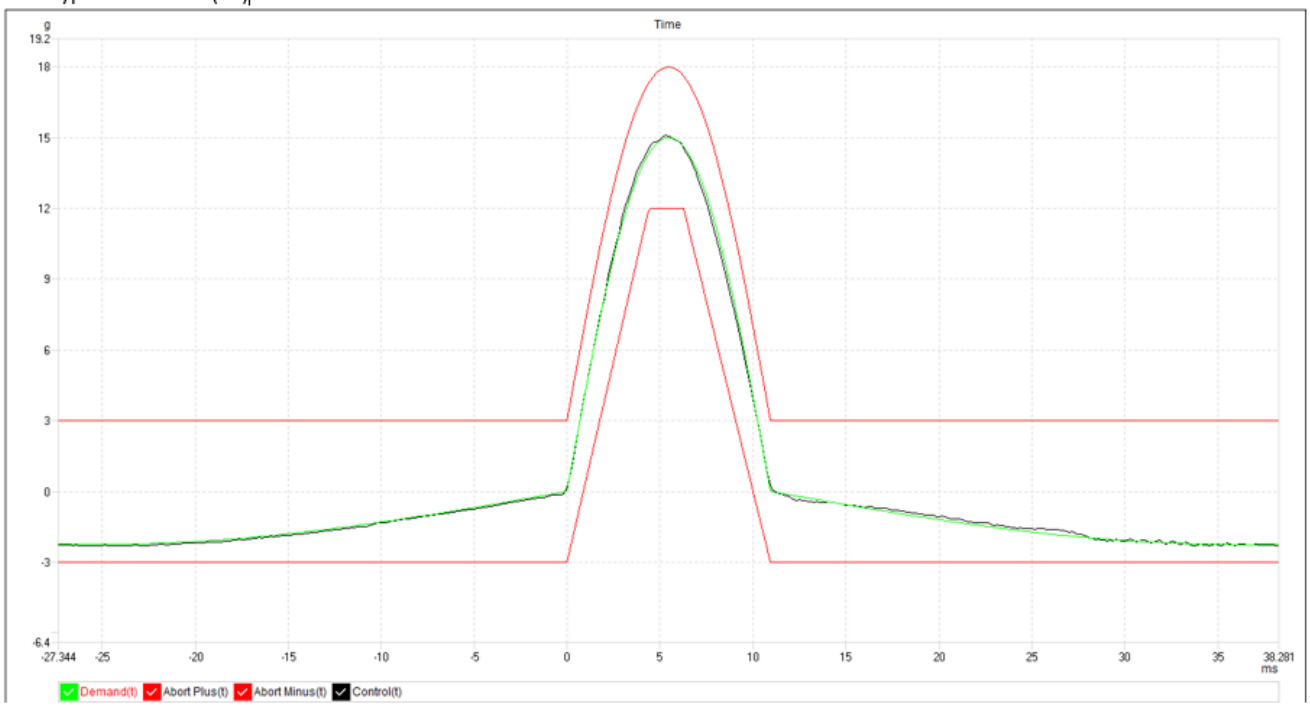
Name: Shock Test
Test Type: Shock Test (X-)



Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 15.221 g Control D: 11.406 ms Control V: -1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 10:28:15 AM

Shock Test - Run(2021-11-09 10-26-22)

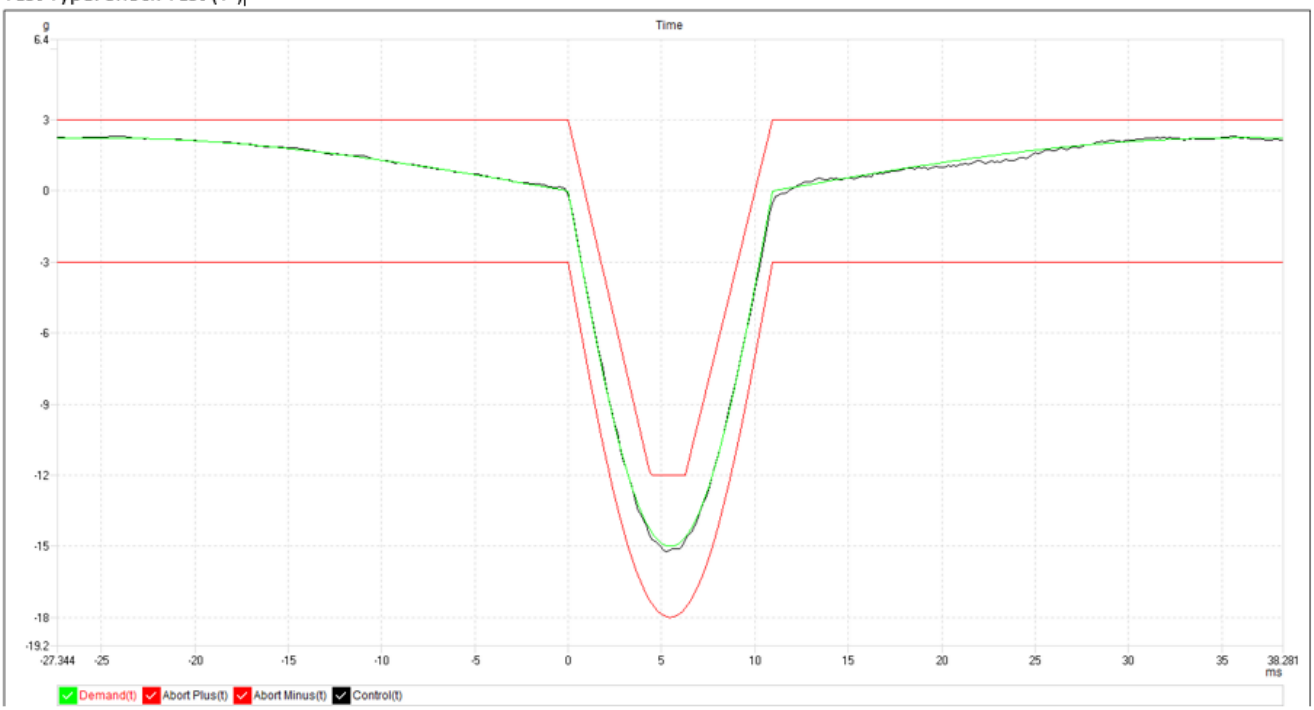
Name: Shock Test
Test Type: Shock Test (X+)



Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 15.105 g Control D: 11.25 ms Control V: 1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 10:27:04 AM

Shock Test - Run(2021-11-09 10-36-56)

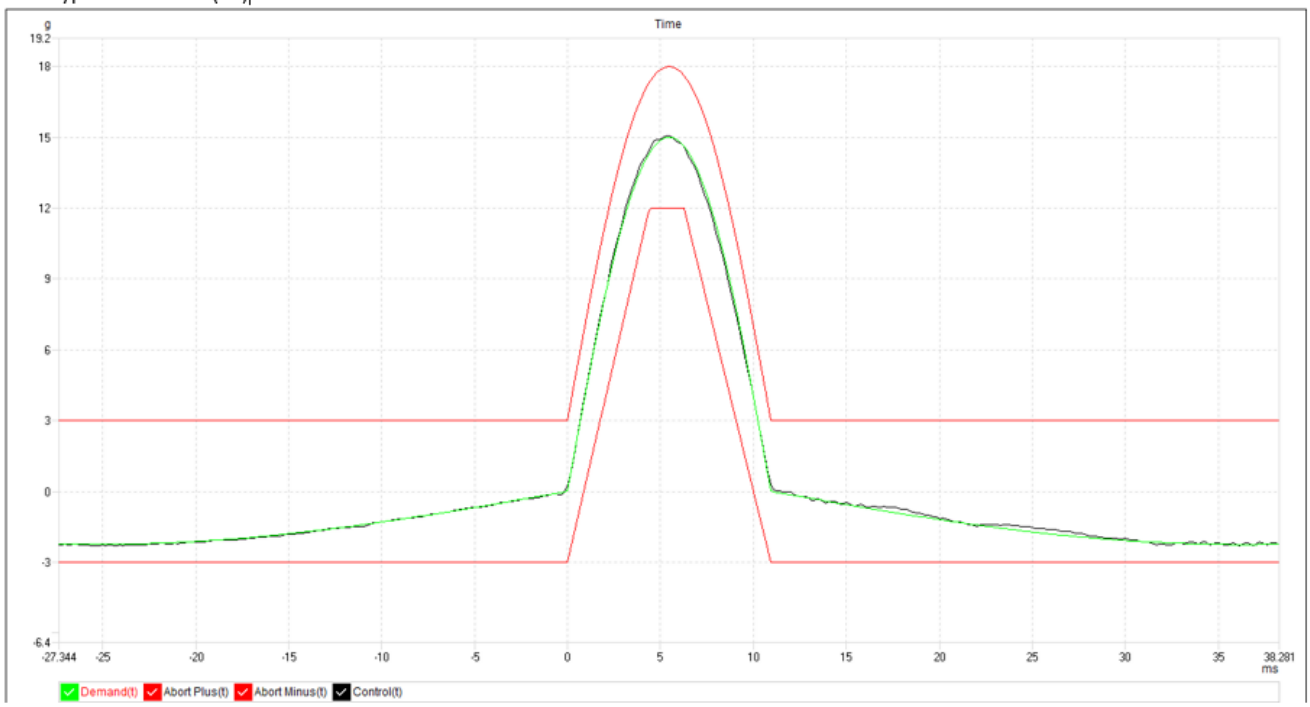
Name: Shock Test
Test Type: Shock Test (Y-)



Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 15.234 g Control D: 11.563 ms Control V: -1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 10:37:35 AM

Shock Test - Run(2021-11-09 10-38-06)

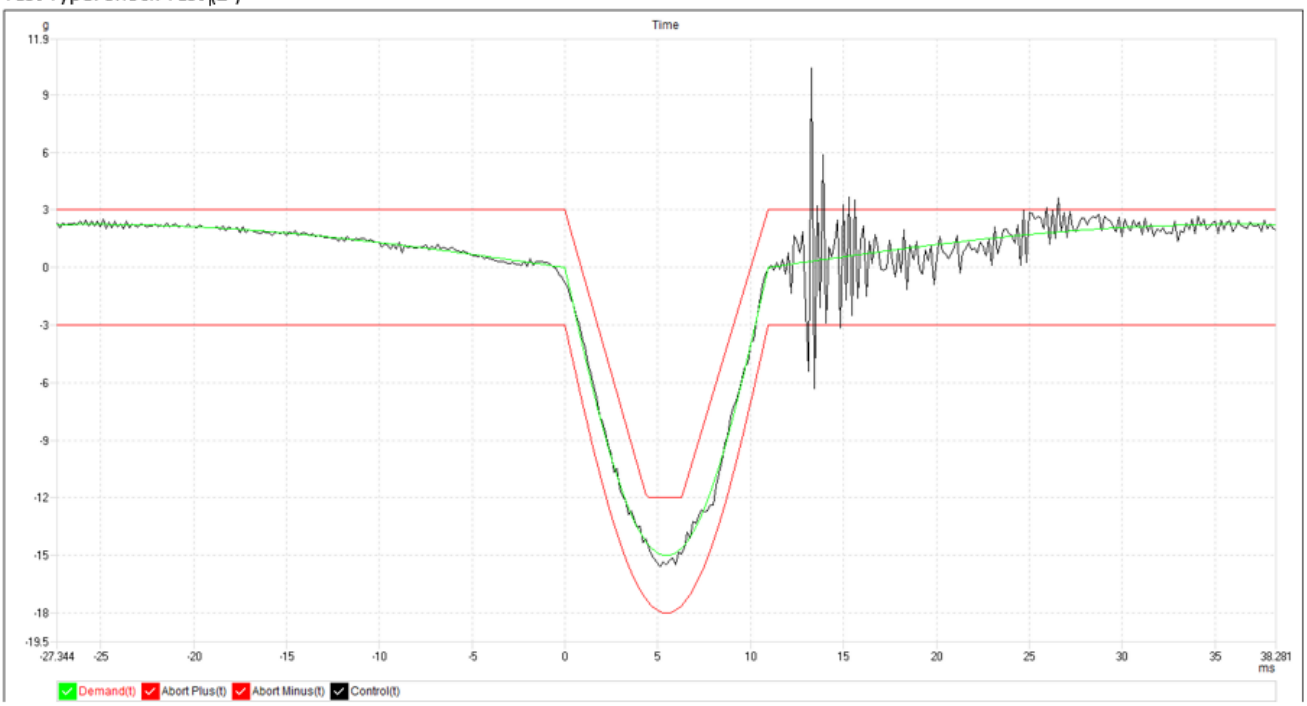
Name: Shock Test
Test Type: Shock Test (Y+)



Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 15.085 g Control D: 11.25 ms Control V: 1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 10:38:49 AM

Shock Test - Run(2021-11-09 12-26-17)

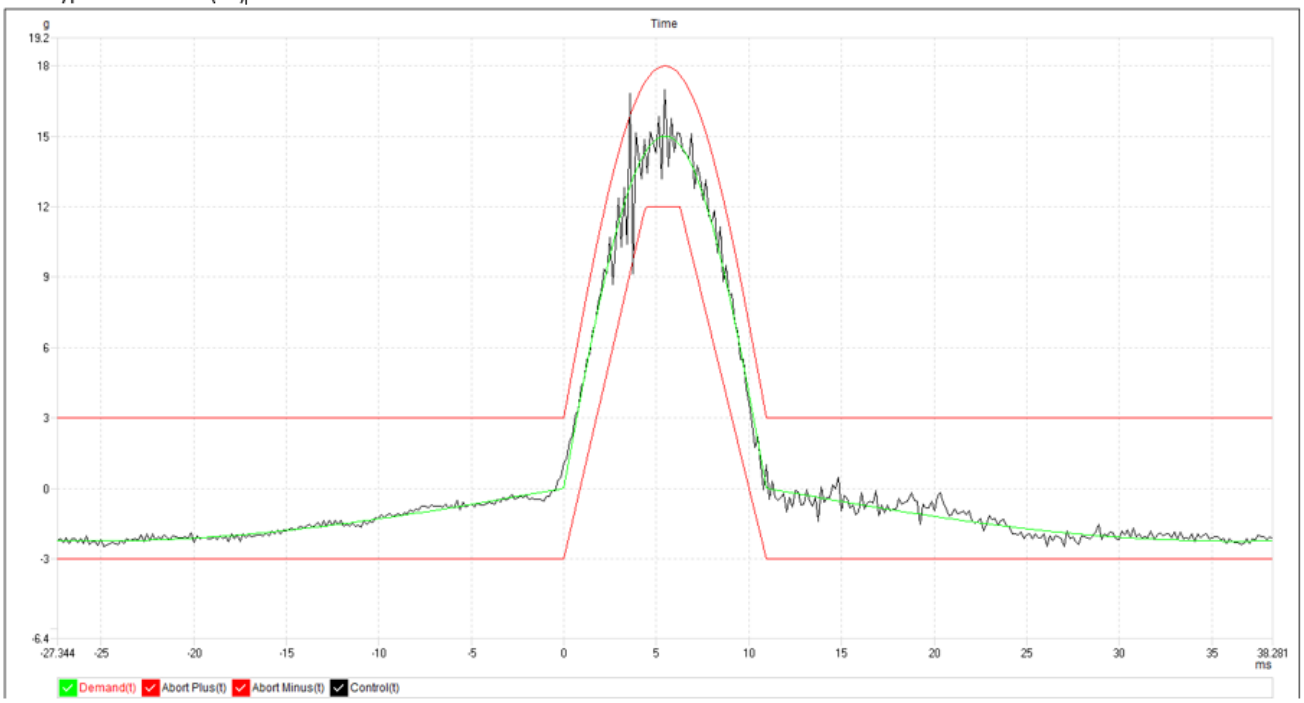
Name: Shock Test
Test Type: Shock Test (Z-)



Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 15.592 g Control D: 11.406 ms Control V: -1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 12:27:15 PM

Shock Test - Run(2021-11-09 12-24-44)

Name: Shock Test
Test Type: Shock Test (Z+)



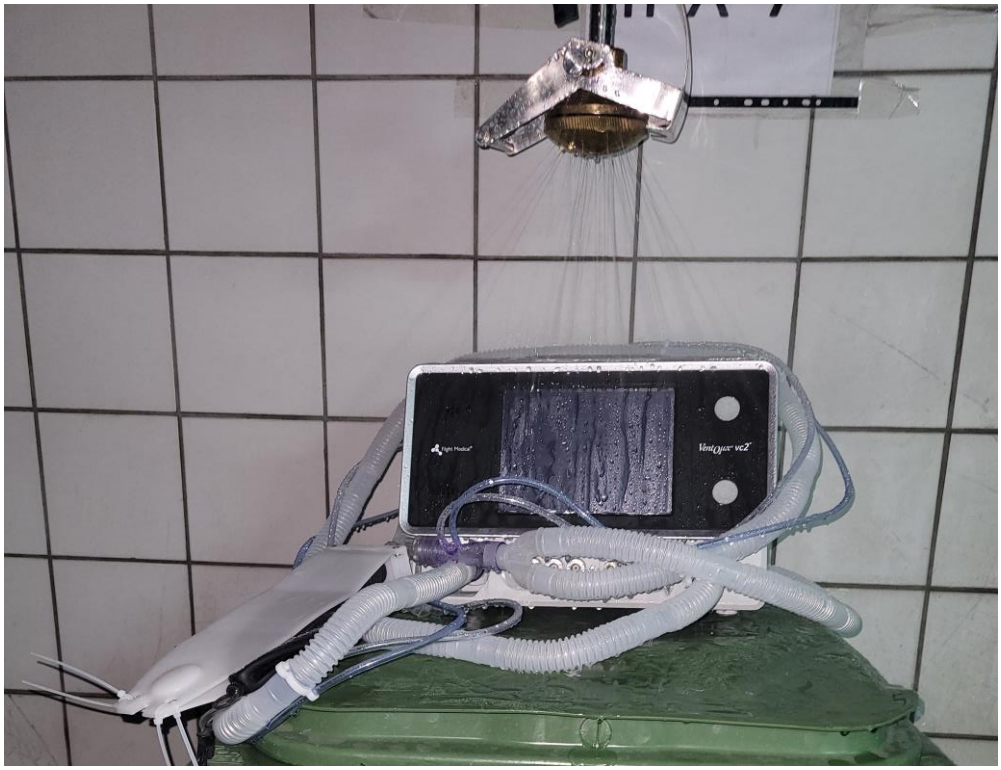
Pulse Wave Type: Half Sine Amplitude: 15 g Pulse Duration: 11 ms V: 1.0 m/s
Level: 0 dB Control Peak: 17.001 g Control D: 11.25 ms Control V: 1.0 m/s
Test Pulses: 5 Remain Pulses: 0 Sampling Freq.: 6400 Hz Block size: 2048 Pulse Interval: 1.5 s
The Saved Time: 11/09/2021 12:25:39 PM

Attachment 2
Photographs

Photograph № 1 - Shock and Vibration

Photograph № 2 - Shock and Vibration

Photograph № 3 – IP34



End of Test Report