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Test Report issued under the responsibility of:

TEST REPORT
EN 794-3
Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators

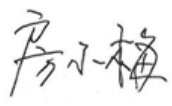
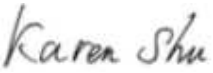
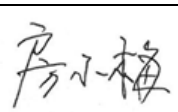
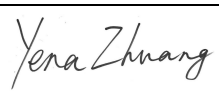
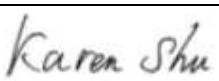
Report Number. ..... :	E471662-D1_794-3
Date of issue..... :	2015-01-16
Total number of pages	34
Testing Laboratory..... :	UL-CCIC Company Limited
Address ..... :	No. 8 Nanyun Er Road, Guangzhou Science Park, Guangzhou 510663, China
Applicant's name..... :	Beijing Aeonmed Co., Ltd
Address ..... :	11B2,Fengtai Science Park, 100070 Beijing, PEOPLE'S REPUBLIC OF CHINA
Test specification:	
Standard ..... :	EN 794-3:1998+A2:2009.
Test procedure ..... :	Informative Report
Non-standard test method…….. :	N/A
Test Report Form No..... :	
Test Report Form(s) Originator ..... :	
Master TRF..... :	

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description .....:	Ventilator
Trade Mark ..... :	aeonmed
Manufacturer ..... :	Beijing Aeonmed Co Ltd
Model/Type reference..... :	Shangrila510S

Ratings ..... :	Rating for External Power Adapter Used: 100-240 Vac, 50/60 Hz, 1.2 A (Model MENB1040A1203N01) OR 100-240 Vac, 50/60 Hz, 1.5 A-0.7A (Model SNP-A047-M) Rating for Ventilator DC input: 12Vdc, 1.5A

Testing procedure and testing location:		
☒ Testing procedure: Witness		
Testing location/ address .....:	**Beijing Aeonmed Co., Ltd** 11B2,Fengtai Science Park, 100070 Beijing, PEOPLE'S REPUBLIC OF CHINA	
Tested by (name + signature) .....:	**Fang Xiaomei**	
Witnessed by (name + signature) ....:	**Yena Zhuang**	
	Karen Shu	
Approved by (name + signature).....:	**Chenchen Lee**	
☒ Testing procedure: Witness		
Testing location/ address .....:	**Beijing institute of medical device testing** No.7, Xingguang 2nd street, opto-mechatronics industrial park, Tongzhou district, Beijing, 101111, China	
Tested by (name + signature) .....:	**Fang Xiaomei**	
Witnessed by (name + signature) ....:	**Yena Zhuang**	
	Karen Shu	
Approved by (name + signature).....:	**Chenchen Lee**	

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

See IEC 60601-1 Test Report

Summary of testing:	
Tests performed (name of test and test clause): Clause 10.101 EXTERNAL PNEUMATIC POWER Clause 21.102 FREE FALL Clause E 49.101 SPONTANEOUS BREATHING DURING POWER FAILURE Clause 50.101 ACCURACY OF OPERATING DATA Clause 51.101 ELECTRICAL OR PNEUMATIC DRIVING POWER Clause 51.102 PRESSURE LIMITATION UNDER NORMAL USE Clause 51.103 PRESSURE LIMITATION UNDER SINGLE FAULT CONDITION Clause 51.104 HIGH PRESSURE ALARM Clause 51.106 MEASURING DEVICE FOR EXPIRATORY VOLUME Clause 51.107 BREATHING SYSTEM INTEGRITY ALARM (DISCONNECTION) Clause 51.109.2 THE SILENCED TIME OF THE ALARM Clause 54.102 DELIVERED OXYGEN CONCENTRATION Clause 56.3 THE REVERSE FLOW OF GASES Clause 56.103 INSPIRATORY AND EXPIRATORY RESISTANCES 56.104 LEAKAGE FROM COMPLETE VBS	**Testing location:** **Beijing Aeonmed Co., Ltd** 11B2,Fengtai Science Park, 100070 Beijing, PEOPLE'S REPUBLIC OF CHINA
Clause 21.101 VIBRATION AND BUMP	**Beijing institute of medical device testing** No.7, Xingguang 2nd street, opto-mechatronics industrial park, Tongzhou district, Beijing, 101111, China

Summary of compliance with National Differences

List of countries addressed: N/A

☐ The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

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.....:	Refer to Part 1 test report
Ventilatory modes .....:	A/C, A/C-V, A/C-P, SIGH, SIMV, SPONT, CPAP, Manual.
Tested VBS .....:	As part of the system
Gas supply options.....:	N/A
Pneumatic power (if applicable).....:	N/A
Integrated monitoring .....:	As part of the system
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing..... :	
Date of receipt of test item..... :	2014-12-01
Date (s) of performance of tests..... :	2014-12-09 ~ 2014-12-11
General remarks:	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
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) ..... :	Beijing Aeonmed Co., Ltd Chaobai St., Yanjiao Development Zone, 065201 Sanhe, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
General product information: The following evaluations were "**EXCLUDED FROM EVALUATION**", The client has been advised that where this standard is recognized or harmonized in accordance with national or regional regulations, suitable evidence of compliance should exist as required by those regulations	

1. EN 794-3:1998+A2:2009, clause 36 Electromagnetic compatibility
2. EN 794-3:1998+A2:2009, clause 48 Biocompatibility
3. EN 794-3:1998+A2:2009, Clause 51.106 Measuring device for expiratory volume

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
4	**General requirements and general requirements for tests**		**Pass**
4.1	Modifications to clause 3 of EN 60601-1:1990		**Pass**
	Clause 3 of EN 60601-1:1990 applies with the following additions:	See the report 60601-1 Clause 5	Pass
	In 3.6 add the following:		Pass
aa)	Applicable single fault conditions are: - short and open-circuits of components or wiring which can: - cause sparks to occur, or; - increase the energy of sparks, or; - increase temperature (see section seven). - Incorrect output resulting from software error. NOTE See also 54.1.	See the report 60601-1 Clause 4	pass
bb)	R) An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.	See the report 60601-1 Clause 4	Pass
3.10	Clinical evaluation		Pass
	A clinical evaluation shall be performed and documented in the risk management file. Check compliance by inspection of the risk management file.	See 510S RM file, Item H107	Pass
4.2	Clause 4 of EN 60601-1:1990		Pass
	Clause 4 of EN 60601-1:1990 applies.	See the report 60601-1	Pass
5	**Classification**		**Pass**
	Clause 5 of EN 60601-1:1990 applies. NOTE A ventilator can have applied parts of different types.	See the report 60601-1 Clause 6	Pass
6	**Identification, marking and documents**		**Pass**
	Clause 6 of EN 60601-1:1990 applies with the following additions and modifications:	See the report 60601-1 Clause 7	Pass
	In 6.1 add the following to item j): The marking(s) for the rated input requirements of the ventilator required in 6.1 j) of EN 60601-1:1990 shall be given in amperes.	DC12V 1.5A	Pass
	In 6.1 add the following items:		Pass
6.1 aa)	All operator-interchangeable flow-direction sensitive components shall be permanently marked with a clearly legible arrow indicating the direction of flow.	Expiratory Value	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
6.1 bb)	Any high pressure gas input port shall be marked on or in the vicinity with the name or symbol of the gas as given in EN 739, with the range of supply pressures in kPa and with the maximum flow requirement in l/min (see 6.8.3a), 2nd dash, 6th bullet).	O_2 250kPa – 600kPa Max 180L/min	Pass
6.1 cc)	If operator-accessible ports are provided, they shall be marked. The following terms may be used:		Pass
	- Driving gas input port: "DRIVING GAS INPUT PORT"	No such port	N/A
	- Inflating gas input port: "INFLATING GAS INPUT"	No such port	N/A
	- Fresh gas intake port: "FRESH GAS INTAKE"	Complied by inspection	Pass
	- Fresh gas input port: "FRESH GAS"	No such port	N/A
	- Emergency air intake port: "WARNING: EMERGENCY AIR INTAKE – DO NOT OBSTRUCT"	Complied by inspection	Pass
	- Manual ventilation port: "BAG"	No such port	N/A
	- Gas return port: "GAS RETURN"	No such port	N/A
	- Gas exhaust port: "EXHAUST"	No such port	N/A
	Alternatively, other terms, pictograms or symbols may be used, in which case they shall be explained and referred to in the above terms.	No other terms, pictograms or symbols used	N/A
6.1 dd)	Labelling and packaging of the ventilator and accessories (e.g. breathing system attachments)		Pass
	The labeling and marking of the packages of the devices shall contain the following:		Pass
	- If the intended purpose of the device is not obvious to the operator, the attachment or its package shall be provided with an instruction leaflet or operating instructions;	Operating instructions provided	Pass
	- The name or trade name and address of the manufacturer and the name and address of authorized representative. For attachments imported into the community, 6.1e) of this European Standard applies where the manufacturer does not have a registered place of business in the Community;	Compliance by inspection See 60601-1 report	Pass
	- Device identification and content information	Compliance by inspection	Pass
	- Where appropriate, the symbol STERILE in accordance with EN 980 and the method of sterilization;	Compliance by inspection See the package and IFU of the ‘Reusable Exhalation Value’	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	- Where appropriate, the batch code preceded by the symbol LOT in accordance with EN 980 or serial number;	symbol LOT	Pass
	- Where appropriate, an indication of the date by which the device can be used, expressed as the year and month;	Compliance by inspection	Pass
	- Where appropriate, an indication that the device is for singe use #. For single use devices the manufacturer shall disclose the risks associated with reusing in the instructions for use or upon request;	Compliance by inspection	Pass
6.1 ee)	If gas-specific colour coding of flow controls and flexible hoses is provided, it shall be in accordance with ISO 32. See annex DD for special national conditions.	No gas-specific flow controls and flexible hoses provided	N/A
6.1 ff)	If the ventilator is designed to be fixed only, a warning that the ventilators shall be maintained fixed.	Not fixed device	N/A
6.1 gg)	A statement that volume-limited ventilators are not to be used on unattended patients (see also 51.102).	See the instruction 1.3.1	Pass
6.1 hh)	For volume-limited ventilators, with no VBS pressure measuring device, marking of the maximum limitation pressure under normal use as specified in 51.102.	There is VBS pressure measuring device	N/A
	In 6.8.2 add the following items:		Pass
6.8.2 aa)	The instructions for use shall additionally include the following:		Pass
	- R) If the ventilator has an internal power source, a specification of the minimum operating time during which the ventilator meets the specifications under normal use as stated by the manufacturer.	See the instruction 5.1	Pass
	If the ventilator is pneumatically powered, the range of supply pressures and flow requirements (see10.101).	See the instruction 9.4.2	Pass
	If the ventilator is provided with a reserve power supply, a description of the functioning after a Switch over to the reserve power supply.	See the instruction 5.1	Pass
	- A method of testing the following alarms prior to connection of the breathing system to the patient:	See the instruction 8.2	Pass
	- High pressure alarm;		Pass
	- Breathing system integrity alarm, if provided;		Pass
	- Power failure alarm;		Pass
	- Low oxygen concentration alarm, if provided.		Pass
	- The intended use of the ventilator (e.g. for adult, paediatric, neonatal, range of body mass).	See the instruction 1.1.1	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	- Emergency		Pass
	- In resuscitation at the scene of an accident, drowning, etc.:		Pass
	- Longer-term use in continuing emergency (e.g. fire, mining accident).		Pass
	- Transport:		Pass
	- Between hospital rooms and departments;		Pass
	- Between hospitals and/or other sites;		Pass
	- Emergency situation;		Pass
	- Long-distance planned transport.		Pass
	- If the ventilator incorporates a gas mixing system the manufacturer shall disclose the information necessary for safe operation of the mixing system. See 6.8.3 a), 2nd dash, 15th bullet;	See the instruction 2.4	Pass
	- Each ventilator shall be provided with a check list that summarises the test procedure recommended by the manufacturer which has to be preformed prior to use. The use of electronic displays, e.g. a cathode ray tube (CRT), is permitted;	See the instruction 3.1	Pass
	- A recommendation that an alternative means of ventilation should be available;	See the instruction 4.2	Pass
	- A statement that volume-limited ventilators are not to be used on unattended patients;	See the instruction 1.3.1	Pass
	- The mass of the ventilator and any associated equipment e.g. cylinders, batteries, regulators, carrying cases, etc, and the external dimensions of the ventilator;	See the instruction 9.2, 9.9	Pass
	- Unless entrainment of air is prevented, recommendations for use in hazardous or explosive atmospheres shall be given, including a warning that if the ventilator will entrain or permit the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous. If applicable, the manufacturer shall describe how to prevent or minimize such entrainment or inhalation, for example, by the use of a non-return valve or a filter.	See the instruction 6	Pass
bb)	Manufacturers of software controlled devices shall disclose by what means the possibility of hazards arising from errors in the software program is minimized. For medical devices which incorporate software or which are medical software in themselves, the software development process shall comply with EN 62304.	See the instruction 1.3.2	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
cc)	The instructions for use shall contain the date of issue or the latest revision.	Edition 00.00 Oct 2014	Pass
	In 6.8.2 d) add the following:		Pass
	R) The instructions for use shall contain:		Pass
	- Instructions for the dismantling and reassembly of components for cleaning and sterilization (if applicable). This shall include an illustration of the parts in their correct relationship. The manufacturer shall recommend a functional test of operation to be carried out after reassembly;	See the instruction 4.3, 6	Pass
	- Recommendations for the preferred methods of cleaning and disinfection or sterilization of the ventilator and its components;	See the instruction 6	Pass
	- A recommended functional test for operation to be carried out immediately prior to use.	See the instruction 4	Pass
	In 6.8.3 a) add the following items:		Pass
	R) The requirement given applies with the following addition:		Pass
	- Unless otherwise specified, parameters shall be assumed to be expressed under ATPD conditions;	See the instruction 1.3.2	Pass
	- The technical description shall additionally include disclosure of the following information, as far as applicable:		Pass
	- A listing of the following pressures:		Pass
	i) Maximum limited pressure (Plim max);	≤ 8 kPa	Pass
	ii) Minimum (subatmospheric) limited pressure (Plim min);	No need	N/A
	iii) Range of values to which the maximum working pressure (Pw max) can be set and the means by which the maximum is assured (e.g. pressure cycling, pressure-limiting, pressure generation);	See the instruction 9.7.5	Pass
	iv) A statement whether negative pressure (subatmospheric) is available in the expiratory phase;	No negative pressure exist in the expiratory phase	N/A
	v) Range of values to which the minimum (subatmospheric) working pressure (Pw min) can be set and the means by which the minimum is assured.	No minimum working pressure limited	N/A
	- A listing of the ranges of the following parameters:		Pass
	i) Delivered ventilation (i.e. minute volume);	No provided	N/A
	ii) Delivered volume (i.e. tidal volume);	0～2000mL	Pass
	iii) Ventilatory frequency;	1 ~ 120bpm	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	iv) I:E ratio or % inspiratory time;	4:1—1:10	Pass
	v) Cycling pressure;	Only one tube	N/A
	vi) End-expiratory pressure;	0kPa 3kPa	Pass
	vii) Delivered concentration of oxygen, if preset or adjustable by controls on the ventilator.	40%~100%, adjustable	Pass
	- If there is a facility for negative pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the expiratory phase and the inspiratory phase;	No negative pressure exist in the expiratory phase	N/A
	- A technical description of the means of triggering;	See the instruction 3.3	Pass
	- The purpose, type, range and sensing position of all measuring and display devices either incorporated into the ventilator or recommended by the manufacturer for use with the ventilator;	See the instruction 9.5.4	Pass
	- R) The conditions under which any measured or displayed flow, volume or ventilation is to be expressed (e.g. ATPD, BTPS2)) and the condition and composition of gas in the corresponding sensor so that the display complies with the accuracy requirements specified in 50, 51.102 and 51.106.	See the instruction 1.3, 9.4.2	Pass
	- For alarms used with the ventilator, a statement of their type, capabilities, principle of the alarm detection, and, if appropriate, disabling or delay of annunciation.	See the instruction 8.2	Pass
	A statement of the estimated life of the battery and suitable replacement batteries.	See the instruction 7.4	Pass
	- The internal volume of any breathing attachments or other components or sub-assemblies, supplied or recommended by the manufacturer of the ventilator, to be placed between the patient connection port and the patient; The manufacturer shall disclose the test method on request.	See the instruction 9.4.1	Pass
	- The inspiratory and expiratory resistance, compliance and internal volume of the complete ventilator breathing system and/or any breathing attachment or other components or subassemblies recommended by the manufacturer of the ventilator for inclusion in the ventilator breathing system; Resistance shall be disclosed for flows of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use, whichever is applicable.	See the instruction 9.3	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	- Disclosure of the functional characteristics or manufacturer's identification of operator detachable breathing system components including the microbial filter fitted or recommended by the manufacturer;	No microbial filter	N/A
	- A diagram of the pneumatic system of the ventilator and a diagram for each ventilator breathing system either supplied or recommended by the manufacturer;	See the instruction 9.4	Pass
	- Details of any restriction on the sequence of components within the ventilator breathing system, e.g. where such components are flow-direction sensitive;	See the instruction 5.2	Pass
	- Interdependence of controls, if applicable;	See the instruction 3.4, 3.5	Pass
	- Disclosure of accuracies and ranges of displayed values and calibrated controls. NOTE The accuracies should be expressed in the form of maximum zero error (bias) quoted in appropriate units plus a sensitivity error quoted e.g. as a percentage of the reading.	See the instruction 9.5	Pass
	- Disclosure of how the delivered tidal or minute volumes and oxygen concentrations are affected by pressure at the patient connection port, in particular the maximum deviations from the calibrated or stated settings of these parameters at mean pressures of 0,5 kPa, 1,5 kPa, 3 kPa and 6 kPa (5 cmH2O, 15 cmH2O, 30 cmH2O and 60 cmH2O).	See the instruction 9.8	Pass
	- The approximate duration of the gas supply, expressed as time per litre of the volume of the cylinder when charged at a typical nominal pressure and when the ventilator is set with typical ventilator settings. The chosen pressure and the ventilator settings shall be declared.	See the instruction 9.3.2	Pass
	In 6.8.3 add the following:		Pass
aa)	Extreme conditions		Pass
	The manufacturer shall declare how the ventilator will respond as the environmental and supply conditions are extended outside the limits given in clause 10, changing one parameter at a time, whilst the other parameters are maintained within the limits given in clause 10, as well as combinations given by the manufacturer.	See the instruction 1.3.1	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	Outside the environmental and supply conditions specified in clause 10 but within the limits declared, the ventilator shall not cause a safety hazard to the patient or operator. NOTE The ventilator might continue to function, but outside the specified tolerances.	See the instruction 1.3.1	Pass
7	**Power input**		**Pass**
	Clause 7 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 4.11	Pass
8	**Basic safety categories**		Pass
	Clause 8 of EN 60601-1:1990 applies.	See the report 60601-1	Pass
9	**Removable protective means**		**N/A**
	Not used.		N/A
10	**Environmental conditions**		Pass
	Clause 10 of EN 60601-1:1990 applies with the following modifications and additions:	See appended Table 50.101	Pass
10.2.1	R) Environment		Pass
	Replace items a), b), and c) with the following:		Pass
a)	An ambient temperature range of - 10 °C to + 40 °C;	See appended Table 50.101	Pass
b)	A relative humidity of 15 % RH to 95 RH %;	See appended Table 50.101	Pass
c)	An atmospheric pressure range of 70 kPa to 110 kPa.	See the instruction 9.2	Pass
	In 10.2.2 add the following:		Pass
aa)	R) The ventilator shall operate and meet the requirements of this European Standard throughout the following internal and/or external electrical power tolerances:		Pass
	- AC voltage: - 25 % + 15 % of nominal value;	See appended Table 50.101 See the report 60601-1	Pass
	- DC voltage: - 15 % + 25 % of nominal value;	See the report 60601-1	Pass
	- AC frequency: - 5 % + 5 % of nominal value.		Pass
	In clause 10 add the following:		Pass
10.101	External pneumatic power		Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3:1994 or a pressure regulator complying with EN 738-1), it shall operate and meet the requirements of this European Standard for a pneumatic power supply throughout a range of 280 kPa to 600 kPa and shall cause no safety hazard under the single fault condition of the medical gas supply of up to 1000 kPa inlet pressure.	See appended Table 10.101 a) & Table 10.101 b)	Pass
10.102	Extreme conditions		Pass
	The ventilator shall function under the extreme conditions and combinations of these as declared by the manufacturer in 6.8.3 aa).	See Clause 50.101	Pass
13	**General**		Pass
	Clause 13 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
14	**Requirements related to classification**		Pass
	Clause 14 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 6	Pass
15	**Limitation of voltage and/or energy**		Pass
	Clause 15 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
16	**Enclosures and protective covers**		Pass
	Clause 16 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
17	**Separation**		Pass
	Clause 17 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
18	**Protective earthing, functional earthing and potential equalization**		Pass
	Clause 18 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
19	**Continuous leakage currents and patient auxiliary currents**		Pass
	Clause 19 of EN 60601-1:1990 applies with the following addition:	See the report 60601-1 Clause 8	Pass
	In 19.4 add the following item to h):		Pass
	101 R) The patient leakage current shall be measured from those applied parts classified as the same type (see 14.6 of EN 60601:1990). The parts shall be connected together electrically. Parts connected to the protective earth terminal shall be tested separately.	Only one applied part.	N/A

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
20	**Dielectric strength**		Pass
	Clause 20 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 8	Pass
21	**Mechanical strength**		Pass
	Clause 21 of EN 60601-1:1990 applies with the following additions:	See the report 60601-1 Clause 9	Pass
21.101	The ventilator shall be submitted to the following tests:		Pass
	- Vibration (sinusoidal) according to IEC 60068-2-6,	See appended Table 21.101	Pass
	- Random vibration wide band – Reproducibility Medium according to IEC 60068-2-36	See appended Table 21.101	Pass
	- Bump according to IEC 60068-2-29	See appended Table 21.101	Pass
21.102	The ventilator shall, while functioning, be submitted to the following test:		Pass
	- Free fall according to IEC 60068-2-32:1975,	See appended Table 21.102	Pass
22	**Moving parts**		**N/A**
	Clause 22 of EN 60601-1:1990 applies.	No moving parts	N/A
23	**Surfaces, corners and edges**		Pass
	Clause 23 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 9	Pass
24	**Stability in normal use**		Pass
	Clause 24 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 9	Pass
25	**Expelled parts**		N/A
	Clause 25 of EN 60601-1:1990 applies.	No expelled parts	N/A
26	**Vibration and noise**		Pass
	Clause 26 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 9	Pass
27	**Pneumatic and hydraulic power**		Pass
	Clause 27 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 9	Pass
28	**Suspended masses**		**Pass**
	Clause 28 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 9	Pass
29	**X-radiation**		N/A
	Clause 29 of EN 60601-1:1990 applies.		N/A
30	**Alpha, beta, gamma, neutron radiation and other particle radiation**		N/A
	Clause 30 of EN 60601-1:1990 applies.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
31	**Microwave radiation**		N/A
	Clause 31 of EN 60601-1:1990 applies.		N/A
32	**Light radiation (including lasers)**		N/A
	Clause 32 of EN 60601-1:1990 applies.		N/A
33	**Infra-red radiation**		N/A
	Clause 33 of EN 60601-1:1990 applies.		N/A
34	**Ultra-violet radiation**		N/A
	Clause 34 of EN 60601-1:1990 applies.		N/A
35	**Acoustical energy (including ultra-sonics)**		N/A
	Clause 35 of EN 60601-1:1990 applies.		N/A
36	**Electromagnetic compatibility**		**N/A**
	Clause 36 of EN 60601-1:1990 applies with the following additions:		N/A
36.101	General		N/A
	The ventilator shall continue to function and meet the requirements of this European standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2 with the level of 3 V/m replaced with 10 V/m throughout the frequency range of 80 MHz to 2 GHz.	exclude from UL evaluation	N/A
	If an anomaly occurs, such as display interruption, false alarm or loss of function, without the integrity of the associated protective system being compromised, this shall not be considered a safety hazard provided it is possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.		N/A
	Discharges shall be applied only to accessible parts as defined in IEC 61000 - 4 - 2 with a level for contact discharges of ± (2, 4, 6) kV and for air discharges of ± (2, 4, 8) kV.		N/A
36.102	Transients		N/A
	The ventilator shall continue to function and meet the requirements of this European Standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	If an anomaly occurs, such as display interruption, false alarm or loss of function, without the integrity of the associated protective system being compromised, this shall not be considered a safety hazard provided it is possible to restore normal operation within 30 s after the transients have been applied.		N/A
37	**Locations and basic requirements**		N/A
	Clause 37 of EN 60601-1:1990 applies.		N/A
38	**Marking, accompanying documents**		N/A
	Clause 38 of EN 60601-1:1990 applies.		N/A
39	**Common requirements for Category AP and Category APG equipment**		N/A
	Clause 39 of EN 60601-1:1990 applies.		N/A
40	**Requirements and test for Category AP equipment, parts and components thereof**		N/A
	Clause 40 of EN 60601-1:1990 applies.		N/A
41	**Requirements and test for Category APG equipment, parts and components thereof**		N/A
	Clause 41 of EN 60601-1:1990 applies.		N/A
42	**Excessive temperatures**		Pass
	Clause 42 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 11	Pass
43	R) Fire prevention		Pass
	Clause 43 of EN 60601-1:1990 applies together with the following additions:	See the report 60601-1 Clause 11	Pass
	In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, shall not, at the same time, be subjected to conditions in which:	See the report 60601-1 Clause 11	Pass
	- The temperature of the material is raised to its minimum ignition temperature; and	See the report 60601-1 Clause 11	Pass
	- An oxidant is present.	O2	N/A
	If sparking can occur under normal or single fault conditions, the materials subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.	No sparking.	N/A
44	**Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection**		Pass
	Clause 44 of EN 60601-1:1990 applies with the following additions:	See the report 60601-1 Clause 11	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	In 44.6 add the following:		Pass
	The ventilator shall be splash-proof	IPX4	Pass
	In 44.7 add the following:		Pass
	Ventilator breathing system attachments and sub-assemblies intended for reuse shall be so constructed that they can be dismantled for cleaning, disinfection or sterilization.	The breathing tube can be dismantled	Pass
45	**Pressure vessels and parts subject to pressure**		N/A
	Clause 45 of EN 60601-1:1990 applies.	No pressure vessels	N/A
48	**Biocompatibility**		N/A
	Clause 48 of EN 60601-1:1990 applies.	exclude from UL evaluation	N/A
49	**Interruption of the power supply**		**Pass**
	Clause 49 of EN 60601-1:1990 applies (see also 51.101) together with the following additions:	See the report 60601-1 Clause 11	Pass
49.101	Spontaneous breathing during power failure		Pass
	The ventilator shall be designed in such a manner that under conditions of power failure, either electrical or pneumatic, as applicable, the patient can breathe spontaneously.	Emergency air intake provided.	Pass
	During failure, the resistance at the patient connection port to inspiratory and expiratory flows shall not exceed 0,6 kPa (6 cmH2O) at 30 l/min for adult use, 0,6 kPa at 15 l/min for paediatric use and 0,6 kPa at 2,5 l/min for neonatal use.	See appended Table 49.101	Pass
	This test is performed without use of attachable accessories which may affect inspiratory and expiratory resistance as declared by the manufacturer in 6.8.3.		Pass
49.102	Off switch		N/A
	Means shall be provided to prevent inadvertent operation of the off switch.	No Off switch	N/A
50	**Accuracy of operating data**		**Pass**
	Clause 50 of EN 60601-1:1990 applies with the following addition:	See the report 60601-1 Clause 12	Pass
50.101	While the ventilator is in normal use, all displays of measured values shall be within the manufacturer's disclosed range of accuracies when tested under the operating conditions given in 10.2.1, 10.101 and 10.102 of this European Standard.	See appended Table 50.101	Pass
51	**Protection against hazardous output**		**Pass**

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	Clause 51 of EN 60601-1:1990 applies together with the following additions:	See the report 60601-1 Clause 12	Pass
51.101	Electrical or pneumatic driving power		Pass
	The ventilator shall have a power failure alarm which activates a continuous visual signal or an auditory signal of at least 7 s duration if the internal or external, electrical or pneumatic, power supply falls below the values specified by the manufacturer.	Complied by inspection See appended Table 51.101	Pass
	This signal shall not conflict with EN 475.	Complied by inspection	Pass
51.101.2	Reserve power supplies		Pass
	If a switch-over (automatic or manual) to a reserve power supply has occurred this shall be visually indicated.	A battery icon active on the screen	Pass
51.102	Pressure limitation under normal use		Pass
	Means shall be provided to reduce the risk of barotrauma under normal use.	The max pressure set is 60cmH2O	Pass
	If a ventilator breathing system (VBS) pressure measuring device is provided for this purpose, its accuracy shall be within ± (2% of the full scale reading + 8 % of the actual reading) and it shall be in combination with an adjustable setting device having a range including 6,6 kPa (66 cmH2O), i.e. 6,0 kPa ± 10 % or a preset pressure limitation not exceeding 6,6 kPa (66 cmH2O), i.e. 6,0 kPa + 10 %.	See appended Table 51.102	Pass
	For volume-limited ventilators with no VBS pressure measuring device, the VBS pressure shall be limited to less than 6,6 kPa (66 cmH2O), i.e. 6,0 kPa + 10 % during normal use and the setting of the pressure limiting device shall be clearly marked as specified in 6.1 hh).	VBS pressure measuring device provided	N/A
51.103	Pressure limitation under single fault condition		Pass
	The maximum achievable pressure at the patient connection port under single fault condition shall not exceed 10 kPa (100 cmH2O).	See appended Table 51.103	Pass
51.104	High pressure alarm		Pass
	A high pressure alarm shall be provided. It shall activate an auditory signal when the inspiratory pressure alarm level is reached.	“Paw High !!!”	Pass
	It shall not be possible to set the alarm level above the maximum pressure permitted by the means of pressure limitation referred to in 51.103.	80cmH_2O	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	The alarm is tested during controlled ventilation of the test lung (see figure 101 and table 101) and while simulating relevant single fault conditions. The pressure at the patient connection port is measured.	See appended Table 51.104	Pass
51.105	Ventilation monitoring		Pass
	Means shall be provided to prevent or indicate hypoventilation due to inadvertent reduction in inspiratory flow.	Complied by inspection	Pass
	a) Monitoring the pressure as described in 51.102;	Complied by inspection	Pass
	b) Monitoring the volume as described in 51.106;	Complied by inspection	Pass
	c) Monitoring the breathing system (disconnect) as described in 51.107;	“Paw Low !!!” alarm	Pass
	d) Monitoring the oxygen concentration as described in 51.108 or the carbon dioxide concentration in the expiratory gases.	Complied by inspection	Pass
51.106	Measuring device for expiratory volume		N/A
	If a measuring device for the expiratory tidal volume or minute volume is provided	Exclude from evaluation - All provided	N/A
	the accuracy shall be within ± 20 % of actual reading for the range specified by the manufacturer.	Exclude from evaluation - See appended Table 51.106	N/A
51.107	Breathing system integrity alarm (disconnection)		Pass
	If a ventilator breathing system integrity alarm is provided it shall generate an auditory signal in the case of disconnection of the patient from the ventilator and a means for silencing the alarm shall be provided in accordance with 51.109.	“ Paw Low !!! ”	Pass
	The operational apparatus is attached to a test lung and operated in accordance with the instruction for use. The auditory alarm signal shall sound within 20 s following disconnection.	See appended Table 51.107	Pass
	In the case of IMV it is permissible to delay the alarm for the period between 2 IMV strokes but not longer than 45 s.	See appended Table 51.107	Pass
51.108	Oxygen monitor and alarm		Pass
	If the ventilator is fitted with an oxygen monitor for measurement of the inspiratory oxygen concentration, it shall be in compliance with prEN 12598:1996 and shall have a low-concentration auditory alarm.	FiO_2 Low!!	Pass
51.109	Alarms		Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	Electrically generated visual alarms, if provided, shall comply with EN 475. If visual alarms are generated by other means, e.g. pneumatically, they shall comply with the colours specified in EN 475.	visual alarms is electrically generated.	Pass
51.109.1	The characteristics of any auditory alarm shall be disclosed by the manufacturer.	See the instruction 9.5	Pass
51.109.2	The maximum time for which an auditory alarm signal can be silenced shall be 120 s.	See appended Table 51.109.2	Pass
51.109.3	If an auditory alarm signal(s) can be disabled by the operator there shall be a visual indication that it has been disabled.	Complied by inspection	Pass
51.109.4	If adjustable alarms are provided they shall be indicated continuously or on operator demand.	Continuously	Pass
51.110	Protection against inadvertent adjustments		Pass
	Means of protection shall be provided against inadvertent adjustment of controls which can create a hazardous output.	By enclosure design Through the three-dimensional design of front panel, forming a low-lying area, where the adjusting device located, to prevent wrong operation	Pass
	For pressure-sensitive finger pads, capacitive finger switches and microprocessor oriented "soft" controls, a specific sequence of key or switch operations is considered suitable.	Not pressure-sensitive finger pads	N/A
52	**Abnormal operation and fault conditions**		**Pass**
	Clause 52 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 13	Pass
53	**Environmental tests**		**Pass**
	Clause 53 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 5	Pass
54	**General**		**Pass**
	Clause 54 of EN 60601-1:1990 applies together with the following modification and addition:	See the report 60601-1 Clause 15	Pass
54.1	Arrangements of functions		Pass
	Replace 54.1 with the following: R) A single fault condition shall not cause a monitoring and/or alarm device, as specified in clause 51, and the corresponding ventilation control function to fail in such a way that the monitoring function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored ventilator function.	Complied by inspection	Pass
54.101	Leaching of substances		Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	All parts of the ventilator shall be designed and manufactured to minimize health risks due to substances leached or leaking from the device during use.	Substances filter provided	Pass
54.102	Delivered oxygen concentration		Pass
	The ventilator shall be capable of delivering at least 95 % O2 (V/V).	See appended Table 54.102	Pass
54.103	The ventilator, or its carrying case if applicable, shall be provided with means for lifting and carrying.	Complied by inspection	Pass
54.104	Usability		Pass
	The manufacturer shall address in a usability engineering process the risk resulting from poor usability (see IEC 60601-1-6 and EN 62366).	See the report 60601-1-6	Pass
55	**Enclosures and covers**		**Pass**
	Clause 55 of EN 60601-1:1990 applies with the following additions:	See the report 60601-1 Clause 9	Pass
55.101	Physical dimensions		Pass
55.101.1	Size		Pass
	The external dimensions of the ventilator shall be given (see 6.8.2 aa), 8th dash).	See the instruction 9	Pass
56	**Components and general assembly**		**Pass**
	Clause 56 of EN 60601-1:1990 applies with the following additions and modifications:	See the report 60601-1 Clause 15	Pass
	In 56.3 add the following items:		Pass
aa)	If more than one high pressure input port is provided, each port shall be fitted with means to prevent reverse flow either to the atmosphere or to the supply system.	Only one high pressure input port provided	N/A
	The reverse flow of gases from one to another high pressure input port of the same gas type shall not exceed 100 ml/min (ATPD) under normal condition.	See appended Table 56.3	N/A
	The reverse flow of gases from one to another high pressure input port of a different gas shall not exceed 100 ml/h (ATPD) under normal and single fault conditions.	See appended Table 56.3	N/A
bb)	High pressure gas input port connectors		Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
	If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3:1994 or a pressure regulator complying with EN 738-1), each high pressure gas input port connector shall be either the body of a Non-Interchangeable Screw-Threaded (NIST) connector complying with EN 739 or a probe complying with EN 737-1 and prEN 737-6:1996. See annex DD for special national conditions.	Complying with ISO 5359	Pass
cc)	Connection to the medical gas supply system		Pass
	If a user-detachable hose assembly is provided for connection between the ventilator and the medical gas supply system, it shall comply with EN 739. If a hose assembly is permanently connected to the ventilator, the connector to the medical gas supply system shall be a probe complying with EN 737-1.	Complying with ISO 5359	Pass
dd)	Ventilator breathing system connectors		Pass
	Ventilator breathing system connectors, if conical, shall be 8,5 mm, 15 mm or 22 mm size connectors complying with EN 1281-1 and EN 1281-2.	Complying with ISO5356-1, 22mm	Pass
	Non-conical connectors shall not engage with conical connectors complying with EN 1281-1 or EN 1281-2 unless they comply with the engagement, disengagement and leakage requirements of EN 1281-1 or EN 1281-2.	Conical connector	N/A
ee)	Gas exhaust port connector		N/A
	If a gas exhaust port connector is provided, it shall be one of the following:	No provided	N/A
	- A 30 mm male conical connector complying with EN 1281-1 or;		N/A
	- A permanent connection or proprietary connector incompatible with EN 1281-1 and EN 737-1.		N/A
ff)	Emergency air intake port		Pass
	An emergency air intake port shall be provided and shall not accept any connector complying with EN 1281-1 and EN 1281-2.	Complied by inspection	Pass
gg)	Patient connection port		Pass
	The patient connection port connector, if conical, shall be either 8,5 mm female or coaxial 15 mm/22 mm complying with EN 1281-1 and EN 1281-2.	Complying with ISO5356-1, 22mm	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
hh)	Manual ventilation port		N/A
	If a manual ventilation port is provided, the connector shall be either 22 mm conical female complying with EN 1281-1 or male cylindrical connector that will accept a breathing tube complying with prEN 12342:1996.	No provided	N/A
ii)	Flow direction-sensitive component connectors		Pass
	Any flow direction-sensitive, operator-detachable component shall be so designed that it cannot be fitted in such a way as to present a hazard to the patient.	Complied by inspection	Pass
jj)	Accessory port		N/A
	If an accessory port is provided, it shall not be compatible with connectors as specified in EN 1281-1 or EN 1281-2 and shall be provided with a means to secure engagement and closure.	No such port	N/A
kk)	Monitoring probe port		N/A
	If a port is provided for the introduction of a monitoring probe, it shall not be compatible with connectors complying with EN 1281-1 or EN 1281-2 and shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.	No such port	N/A
	In clause 56 add the following:		Pass
56.101	Reservoir bags and breathing tubes		Pass
56.101.1	Any reservoir bags intended for use in the ventilator breathing system shall comply with EN 1820. Breathing tubes with an internal diameter of more than 18 mm, intended for use in the ventilator breathing system, shall comply with prEN 12342:1996.	Complied by inspection	Pass
56.101.2	Respiratory gas-conducting components (packaging and decontamination)		Pass
56.101.2.1	If a claim is made in the labeling that a device is sterile it shall have been sterilized using an appropriate, validated method as specified in EN 550, EN 552, EN 554 and EN 556.	Complied by inspection of Expiration valve's IFU	Pass
56.101.2.2	Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.	See the instruction 6	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict
56.101.2.3	Device packaging and/or labeling shall differentiate between the same or similar products placed on the market, both sterile and non-sterile.	Complied by inspection	Pass
56.101.2.4	All parts of the ventilator which are subject to contamination by exhaled gases during any form of ventilation and are intended to be reused, shall be disinfectable or sterilizable.	See the instruction 6	Pass
56.102	Humidifiers and heat and moisture exchangers		N/A
	Any humidifier or heat and moisture exchanger either incorporated into the ventilator or recommended by the manufacturer for use with the ventilator shall comply with prEN ISO 8185:1995 and ISO 9360 respectively.	No such device	N/A
56.103	Inspiratory and expiratory resistances		Pass
	The inspiratory and expiratory resistance measured at the patient connection port shall, during spontaneous breathing and normal operation, not exceed 0,6 kPa (6 cmH2O) at 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use.	See appended Table 56.103	Pass
56.104	Leakage from the complete ventilator breathing system		Pass
	Leakage from the ventilator breathing system shall not exceed 200 ml/min for adult breathing systems, 100 ml/min for paediatric breathing systems or 50 ml/min for neonatal breathing systems.	See appended Table 56.104	Pass
57	**Mains parts, components and layout**		**Pass**
	Clause 57 of EN 60601-1:1990 applies together with the following additions:	See the report 60601-1 Clause 15	Pass
	In 57.3 a) add the following:		Pass
	Any supply cord of an electrically powered ventilator shall be a non-detachable cord or shall be protected against accidental disconnection from the ventilator.	Means for accidental disconnection provided	Pass
58	**Protective earthing – Terminals and connections**		**Pass**
	Clause 58 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 15	Pass
59	**Construction and layout**		**Pass**
	Clause 59 of EN 60601-1:1990 applies.	See the report 60601-1 Clause 15	Pass

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict

10.101 a)	TABLE: Overpressure		
Range of input pressure (kPa)	**Testing pressure (kPa)**	**Observed Results**	**Remarks**
250-600	1000	Device normal operated, No unacceptable risk	Pass
Supplementary Information:			

10.101 b)	TABLE: Time-weighted flow					Pass
Ventilator settings :			Normal operated (under AC-V mode, Freq_ 12bpm, I:E_ 4:1, Pinsp_60, PEEP_ 0, Flow_ Max)			—
Ambient temperature and pressure :			**22.2**°C		**1029hPa**	—
		Measured		**Corrected**		
Gas input	**Pressure**	**Peak flow (3 s)**	**Average flow (10 s)**	**Peak flow (3 s)**	**Average flow (10 s)**	**Remarks**
O_2 pressure inlet	280kPa	129 L/min	36.71 L/min	135.6L/min	38.6L/min	Pass
Supplementary information:						

21.101	TABLE: VIBRATION AND BUMP				Pass
Ambient temperature and pressure :			**19.8°C**	**1025hPa**	—
Test Type	**Test conditions**	**Result**			**Remark**
Vibration (sinusoidal) test	**Frequency range: 10 Hz-1000Hz Amplitude/acceleration: 0,35 mm/49 ms-2 Sweep rate: 1 octave/min Number of sweep cycles: 4 in each axis**	No.	Indicated Value	Measured Value	Device normal operated, No unacceptable risk
		1[1)]	504mL	465 mL	
		2[2)]	504 mL	460 mL	
Random vibration wide band test	**ASD3) 10Hz-200Hz: 0,01 g2/Hz ASD 200Hz-500Hz: 0,003 g2/Hz Total rms acceleration: 1,7 gms Duration/axis/mounting: 30 min**	No.	Indicated Value	Measured Value	Device normal operated, No unacceptable risk
		1[1)]	501 mL	432 mL	
		2[2)]	496 mL	442 mL	
Bump test	**Peak acceleration: 15 g Pulse duration: 6 ms Number of bumps: 4000 Direction: Vertical, with the ventilator in its normal operating position(s)**	No.	Indicated Value	Measured Value	Device normal operated, No unacceptable risk
		1[1)]	500 mL	452 mL	
		2[2)]	480 mL	486 mL	
Supplementary information 1) Before the test. 2) After the test					

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict

21.102	TABLE: FREE FALL				Pass
Ambient temperature and pressure :		**21.2°C**	**1025hPa**		**—**
Test Type	**Test conditions**	**Result**			**Remark**
Free fall test	**Height of fall: 0,75 m Number of falls: 1 on each of the 6 faces**	No.	Indicated Value	Measured Value	Device normal operated, No unacceptable risk
		1[1)]	553 mL	489 mL	
		2[2)]	540 mL	482 mL	
		3[3)]	532 mL	494 mL	
Supplementary information: **A/C Mode: f: 16, I:E : 1:2, Peep: 0** 1) Before the test. 2) After two free fall test 3) After all the test					

49.101	TABLE: Spontaneous breathing during power failure		Pass
Test No	**Test conditions**	**Result**	**Remark**
1	**30l/min to ventilator**	0.22kPa	Pass
2	**15 l/min to ventilator**	0.16kPa	Pass
3	**2.5 l/min to ventilator**	0.08kPa	Pass
Supplementary information: N/A			

50.101	TABLE: ACCURACY OF OPERATING DATA	Pass
Ventilator settings :	**Normal operated (A/C Mode: f: 16, I:E : 1:2, Peep: 0)**	**—**
Test condition	**Remarks**	
AC: -25%*100V, f:-5%*50Hz, 40°C, 95%	Device normal operated, No unacceptable risk	
AC: 15%*240V, f:5%*60Hz, -10°C, 15%	Device normal operated, No unacceptable risk	
Supplementary information: Note: The test condition is based on the standard EN794-3.		

51.101	TABLE: ELECTRICAL OR PNEUMATIC DRIVING POWER		Pass
Ambient temperature and pressure.....:	**22.0°C**	**1033hPa**	**—**
Alarm description	**Duration time**	**Remarks**	
O2 Deficiency!!	>7s	Pass	
AC Power Lost!	>7s	Pass	
Supplementary information:			

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict

51.102	TABLE: Pressure limitation under normal use		Pass
Ambient temperature and pressure.....:	**22.0°C**	**1028hPa**	**—**

The accuracy of the ventilator breathing system (VBS) pressure measuring device

Pressure Set	Indicated value	The measurement of the pressure measuring device	Remarks
60 cmH_2O	62.1 cmH_2O	62.62 cmH_2O	Pass
30 cmH_2O	30.6 cmH_2O	28.7 cmH_2O	Pass
5 cmH_2O	4.2 cmH_2O	3.0 cmH_2O	Pass

The pressure limitation of VBS

Measured	Remarks
62.62 cmH_2O	Pass

Supplementary information:
A/C-P mode: f: 15, Pinsp: 60, I:E : 1:1, PEEP: 0

51.103	TABLE: Pressure limitation under single fault condition		Pass
Ambient temperature and pressure.....:	**22.2°C**	**1027hPa**	**—**

Measured	Remarks
78.9 cmH_2O	Pass

Supplementary information:

51.104	TABLE: High pressure alarm		Pass
Ambient temperature and pressure..... :	**22.0°C**	**1027hPa**	**—**

Test Conditions	Set value	Measured	Remarks
Adult Use	9.1 cmH_2O	8.6 cmH_2O	Pass
Paediatric Use	23.0 cmH_2O	22.4 cmH_2O	Pass
Neonatal use	30.3 cmH_2O	30.0 cmH_2O	Pass

Supplementary information:

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict

51.106	TABLE: Measuring device for expiratory volume		N/A
Accessories .....:	--		—
Test lung .....:	MFR:Michigan Instruments Model: 560li		—
Ventilator settings (except those listed below).....:	--		—
Ambient temperature and pressure.....:	22.0°C	1027hPa	—

--	Set					Measured		Monitor
Test Conditions	**Volume ML**	**Frequency Min-1**	**I/E ratio**	**Resistance kPa/l/s**	**Isothermal compliance ml/kPa**	**Volume ML**	**Indicated Volume ML**	**Error (%)**
Adult Use	**500**	**10**	**1/2**	**0.5**	**500**	614	504	17.9
Paediatric Use	**300**	**20**	**1/2**	**2**	**200**	305	251	17.7
Neonatal use	**30**	**30**	**1/2**	**5**	**10**	30	23	23.3

Supplementary information:

1) The accuracy in EN794-3 standard= ±20%.

2) <FOR REFERENCE ONLY>

For Neonatal use, the indicated volume is beyond the accuracy range of the standard. But the accuracy claimed in user manual is ±40mL (<200mL).

According to the other ventilator standard, for example, ISO 80601-2-12-2011, Clause 201.12.1.101, the similar requirement is that with a volume-controlled breath type selected and the VENTILATOR operating in NORMAL CONDITION, the accuracy as determined for the test settings and conditions specified in this standard shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error. The compliance of the result is determined by comparing the result with the volume setting for the test and the resulting difference with the tolerance indicated in the instructions for use.

51.107	TABLE: Breathing system integrity alarm (disconnection		Pass
Ambient temperature and pressure..... :	**22.2°C**	**1027hPa**	—

Test Mode	Time	Remarks
IMV mode	4s	Pass
Other mode	4s	Pass

Supplementary information:

51.109.2	TABLE: THE SILENCED TIME OF THE ALARM		Pass
Ambient temperature and pressure..... :	**22.2°C**	**1027hPa**	—

EN 794-3			
Clause	Requirement + Test	Result - Remark	Verdict

51.109.2	TABLE: THE SILENCED TIME OF THE ALARM	Pass

Alarm	Duration Time	Remarks
FiO2 Low!!	118s	Pass

Supplementary information:

54.102	TABLE: Delivered oxygen concentration		Pass
Ambient temperature and pressure ..... :	**22.2°C**	**hPa**	**—**

Set value	Delivered oxygen concentration measure value	Ventilator Indicated value	Remarks
100%	96%	96%	Pass

Supplementary information:

56.3	TABLE: The reverse flow of gases		N/A
Ambient temperature and pressure ..... :	**--**	**--**	**—**

Test No.	Test location	Result	Remark
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Supplementary information:

56.103	TABLE: INSPIRATORY AND EXPIRATORY RESISTANCES	Pass

Test No	Test conditions	Result	Remark
1	60l/min to ventilator	0.45 kPa	Pass
2	30 l/min to ventilator	0.21 kPa	Pass
3	5 l/min to ventilator	0.11 kPa	Pass

Supplementary information:

56.104	TABLE: Leakage from complete VBS		Pass
Ambient temperature and pressure ..... :	**22.2°C**	**1027hPa**	**—**

Test No	Test conditions	Result	Remark

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Clause	Requirement + Test	Result - Remark	Verdict

56.104	**TABLE: Leakage from complete VBS**		**Pass**
1	**Provided 5kPa to VBS**	10 ml/min	Pass
2	**Provided 4kPa to VBS**	10 ml/min	Pass
3	**Provided 2kPa to VBS**	8 ml/min	Pass
Supplementary information:			