Guidance on accelerated manufacturing of ventilators during COVID-19

Contents

Introduction

The coronavirus disease 2019, abbreviated as COVID-19, is a global pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This current pandemic has posed a challenge to national health systems across the EU and globally, putting strain on the existing hospital supply. Medical devices such as respiratory ventilators are urgently needed for the fight against COVID-19. While existing ventilator manufacturers have stepped up production to meet the increasing demand, willingness to reinforce existing supply chains by non-traditional actors including consortia of university hospitals, doctors, engineers and regulators is recognised. Given the exceptional challenges the COVID-19 pandemic brings, cooperation and collaboration of all actors is paramount to succeeding against SARS-COV-2.

The purpose of this document is to provide recommendations for actors capable of manufacturing ventilators for use in hospitals or nursing homes during the current COVID-19 pandemic. It must be borne in mind that respiratory assistance is part of a holistic care system which consists of multiple devices, trained healthcare professionals and medicine.

Scope

This document describes examples of existing specifications for minimally acceptable performance criteria and features for a COVID-19 ventilator to be used in EU hospitals or nursing homes during the current SARS-CoV2 outbreak. Additionally, considerations for optional performance criteria and features are suggested.

This guidance does not apply retrospectively to any existing or approved ventilators.

Regulatory considerations

Ventilators manufactured in accordance with this guidance should only be used for adult patients requiring respiratory assistance due to SARS-COV-2. These devices are intended to provide therapeutic benefit in the initial stages of care to adult patients requiring urgent ventilation. These devices will not be suitable for use in all cases and each individual patient's health profile and pre-existing conditions should be carefully considered. In certain cases, other, more sophisticated ICU invasive ventilators will be necessary.

Ventilators manufactured in accordance with this guidance should only be placed on the market following receipt of a national derogation[1] from a national competent authority[2], in accordance with Article 11 (13) of Directive 93/42/EEC or Article 59 (1) of Regulation (EU) 2017/745. It is highly recommended that you contact your national competent authority prior to commencing the manufacturing of these devices in accordance with this guidance in order to enquire if there are specific considerations in place in the specific member states.

[1] For further information on regulatory pathways for ventilators during the COVID-19 pandemic, including derogations, consult MDCG 2020-9 Regulatory Requirements for Ventilators and Related Accessories

[2] Contact information can be found on the medical devices sectorial website of the European Commission here

Recommended features and criteria.

Where accelerated manufacturing of ventilators takes place for the purposes described in the introduction and scope of this document, the following minimally acceptable performance criteria and features are recommended.

Ventilation modes

The ventilator should include an invasive IPPV (Intermittent Positive Pressure Ventilation) mode and an optional non-invasive CPAP (Continuous Positive Airway Pressure) and/or BIPAP (Bilevel Positive Airway Pressure) modes which should allow the operator to set the tidal volume and respiratory rate. The operator should be able to select the desired output mode as either Pressure-Controlled Ventilation (PCV) or Volume-Controlled Ventilation (VCV).

Positive End Expiratory Pressure (PEEP)

The PEEP range should be between 5 to 25 cm H_2O and be adjustable in sufficiently low increments e.g. 2 cm H_2O.The breathing system pressure should never go below the chosen PEEP setting.

Respiratory rate

The respiratory rate range should be between 5 to 30 breaths per minute and should be adjustable in increments of 2 breaths or smaller.

Tidal volume (Vt)

The Tidal volume (Vt) range should be between 200 mL and 1000 mL, adjustable in increments of 50 mL or smaller. The rate of inspiratory flow should be up to 100 litres per minute and the inspiratory time should be adjustable from 0.5 seconds to 2 seconds.

Airway pressure safety

Peak inspiratory pressure, (which is the highest level of pressure applied to the lungs during inhalation) should be adaptable by the operator to achieve the set tidal volume The operator-adjustable limit should range up to 50 cm H2O. In addition, a mechanical failsafe valve should activate at 80 cm H_2O.

Fraction of inspired oxygen proportion (FiO_2)

The FiO2, which is the percentage of oxygen in the air mixture delivered to the patient, should have pre-set options of 50, 60 and 100% and control options ranging from 30% up to 100%. These should be adjustable in increments of 10% or smaller.

The standard breathing system outlet and inlet port connectors should have a 22mm outside diameter so that they may be connected to and supply the 22mm 'female' breathing system connectors.[3]

The connectors should be rigid (non-plastic) and, to accommodate Heat and Moisture Exchange (HME) filters, should be separated by a minimum of 10cm.

Finally, all elements in the ventilation pathway should meet biological safety and oxygen safety standards for 100% oxygen.[4] This is of particular importance for the minimisation of fire risk or

[3] ISO 5356-1:2015
[4] EN 60601-1 and ISO 80601-2-55

contamination of the patient's airway. Parts of ventilators in the breathing system should be manufactured with materials that have been biocompatibility evaluated on the basis of patient risk[5].

Oxygen supply to ventilator

The oxygen supply should be achievable through both cylinder packaged oxygen or from wall pipeline supplies. Oxygen pressures from both pipeline or cylinder should be between 280 and 600 kPa.

Air supply to ventilator

Given that during the COVID-19 pandemic, pressurised air will not necessarily be available in all care environments, it is preferable that pressurised air not be required for the operation of the ventilator.

However, if pressurised air is required, all gas connectors and hoses should use standard non-interchangeable connectors, be colour coded according to applicable standards [6] and be capable of connection to wall pipeline air supply with a range 280 to 600 kPa.

Information Monitoring Displays

Monitoring information displays connected to the ventilator should show: breathing frequency, tidal volume, inspiratory time, PEEP, FiO2, ventilation mode. Mechanical displays on control instruments, such as knobs and sliders may be provided. Moreover, screens should be produced with material not subject to blurring, smudging, fogging or misting following cleaning processes.

Alarms

The machine should generate an audible alarm if the following occurs:

- supply of gas or electricity fails
- the machine is switched off while connected to a patient
- inspiratory and PEEP pressure are not achieved
- expiratory tidal volume is not achieved by 10%
- inspiratory tidal volume is exceeded by 10%
- occlusion/blocking of end port connecting to patient
- disconnection
- apnoea alarm if any apnoea ventilation mode is provided
- battery depletion alarm: indication at least 5 minutes before totally discharged

Electricity supply

In case the ventilator is powered by mains electricity, it should connect to 220 - 240V AC mains, and in case of mains electricity supply failure, it should have a 30 minute backup battery. In addition, emissions (such as RF (Radio Frequency) or EM (Electro Magnetic Emissions) that could interfere with other critical machinery should be avoided.

Other

- The ventilator should achieve 100% operating duty cycle during the durability time/period prescribed by the manufacturer (14, 20, etc. days)

[5] EN ISO 18562-1:2017
[6] ISO 32:1977 and EN ISO 5359:2008

- The ventilator should be easily displaceable within hospital premises and sturdy in case of simple accidents.
- The ventilator should be resistant to standard disinfection and cleaning procedures

Considerations for the production process

The following considerations should be taken into account when manufacturing the COVID-19 ventilator:

1. Choice of raw materials

Where possible, materials for manufacture that provide the key functionality should be selected, without the need for additives such as plasticisers. For example, in the case of rigid components, polycarbonate or ABS (Acrylonitrile Butadiene Styrene) provide suitable properties without additional components, and can be reinforced, if necessary, with materials such as glass fibres. For flexible components used in tubing and connectors, the polyolefins such as polyethylene and polypropylene are generally suitable without further additives. Conversely, polyvinylchloride (PVC) is not acceptable in parts directly in contact with the patient airway and is discouraged elsewhere in construction.

2. Contamination from the manufacturing process

It is assumed that manufacture will be performed via generally accepted processes such as injection moulding or extrusion and that it will take place in a well-organised room (although a cleanroom is not specifically required) where general levels of dust, dirt and contamination are kept at a low level through common sense manufacturing practices. Based on this assumption, there is no requirement for specific tests of particulate contamination in the breathing circuit.

Given the production start-up processes often require the use of mould release agents, their use at this stage is acceptable provided the first pieces (e.g. up to 20) which will contain higher levels of release agent are discarded and no further release agent is added.

3. Hazard mitigation

The risk from solid particle emissions is assumed to be minimal if the manufacturing process is well-controlled , as set out in point 2 of this section. There should be minimal volatile organic compounds (VOCs organic molecules with boiling points in the 50-260°C range) exposure because of the suitable choice of low-additive materials as described in point 1 of this section. .

Substances which can be leached out of the materials via water, liquids or gases should be minimized by design and trapped via an HME filter between the ventilator and the system delivering gases to the patient.

Considerations for the ventilator device

1. Risk management

At least the following risk management elements from EN ISO 14971:2012 should be considered:

- Identification of risks in normal and fault condition
- Evaluation of those risks
- Selection of risk mitigation measures
- Verification of the taken risk mitigation measures (correct implementation and effectiveness)
- Benefit /risk conclusion

2. Programmable electrical medical devices

- The design input documents should at least cover all performance and safety related functions.
- A software architecture and design document will be provided which shows at least the following:
  - Function of major components of the architecture (what is this part of the software used for).
  - Relationship between those components (e.g. kind of data exchanged).
  - External connections and interfaces.
- A verification plan shall be created describing how the performance and safety related requirements are verified.
- Verification records of all performance and safety related requirements shall be kept.

3. Usability

The design of the user interface should follow established medical device criteria for (including but not limited to the following): (:

- Symbols
- Units
- Colours
- Buttons and knobs

A usability evaluation during the design with representative operators shall be considered covering risk related use scenarios.

4. Electrical Safety following EN 60601-1:2005+ A1: 2012

- Insulation-Protection should consist of:
  - Accessible parts shall be determined (visual or with a test finger)
  - The applied parts shall be classified (Type B or Type BF or Type CF)
  - The necessary means of protection are:
    - At least two means of protection against mains supply for Ventilator Operators (2 MOOP, 240VAC, Creepage distance: 5.0mm; Clearance distance: 4.0mm)
    - At least two means of protection against main supply for Patients (2 MOPP, 240VAC, Creepage distance: 8.0mm; Clearance distance: 5.0mm)
- Protective Earthing (if Class I device) should comply with the following:
  - Max. allowed values for the protective earth:
    - with fixed power cord: 200mOhm

- without fixed power cord: 100mOhm

- The following limits of leakage currents should be met:
  - Earth leakage currents not exceeding (limits: 5 mA NC; 10 mA SFC)
  - Touch not exceeding the limits (limits: 100 µA NC; 500 µA SFC)
  - Patient leakage currents not exceeding the limits (Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.), Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
- The following dielectric strength apply:
  - At least 2 means of protection against mains supply for Operator (2 MOOP, 240VAC, 3000Vac)
  - At least 2 means of protection against mains supply for Patient (2 MOPP, 240VAC, 4000Vac)
- Internal components, conductors, connections and wiring shall be mounted secured
- Mains fuses on the primary side shall be provided
- No rough surfaces, sharp corners and edges shall exist
- Hazards related to pressure parts shall be mitigated
- Oxygen rich environment:
  - For less that 25% oxygen no additional fire risk needs to be considered and for more than 25% oxygen, explicit fire hazard reduction measures should be specified.
- The following temperature limits should be met:
  - Not exceeding the temperature limits of components, touchable parts and patient connections. Limit for Applied Parts are 41°C
- Mechanical strength:
  - No unacceptable hazards after a push test
  - No unacceptable hazards after an impact test
- Internal Battery:
  - A protection against overcurrent shall be provided for any internal battery

Optional features and criteria

Spontaneous ventilation

Inspiratory pressure and PEEP may be set by the operator of the ventilator. Spontaneous ventilation entails that the ventilator will sense when a patient starts to inhale and automatically apply the operator-specified inspiratory pressure. Equally, the ventilator will detect when the patient begins to exhale and will apply the operator-specified expiratory pressure accordingly. In the case where the patient stops breathing in pressure support mode, the ventilator's fail safe automatically returns to mandatory ventilation.

Synchronised mandatory ventilation

This operates in the same manner as mandatory ventilation, with the additional features that mandatory inhales are synchronized to match the patient's detected respiratory effort through flow or pressure sensing, [also known as synchronized intermittent mandatory ventilation volume control (SIMV-VC) or pressure control (SIMV-PC)]

Synchronised mandatory ventilation provides additional inspiratory pressure support to those patients who can already breathe somewhat autonomously.

Tidal volume

An enhanced version of this features includes the ability to set inspiratory rise-time as a fraction of the inspiratory time, through waveform control or ratio control. The rate of inspiratory flow can be up to 150 litres per minute.

Modular filters

The device design should incorporate measures to avert fluid entering through the structure. To avoid bacterial or viral loads on device parts or components of the patient ventilation pathway, the device design should also permit compatibility with separately sourced HME- filters. To enable inhalation and exhalation, such filters should be placed at the respective ports of the device. The HME filters are typically 10cm in size, and device design should accommodate both filters in the case of dual port devices. In addition, to ensure internal device components are not comprised, filters should also be inserted into all entry and exist points exposed to room air, to prevent entry of dirt or foreign matter. Procedures for and timings of filter replacements should be clearly set out in the device's instructions for use. Where a hot water humidifier is incorporated in the device design, the need to put in place measures to avert undesired fluid entry should be investigated.

Gas supply

Gas will typically be transmitted via a wall pipeline supply through the use of gas connectors and hoses[7]. For the measurement of gas at the input port, the 10s average input flow of the ventilator should not exceed 60 l/min at a pressure of 280 kPa. The transient input flow should not exceed 200 l/min averaged for 3s.

Extended battery use

In addition to the 30 min battery backup power, the ventilator should preferably contain hot swappable batteries that can run on a battery supply for an extended period, for example, 2 hours for within-hospital transfer

Alarms

Enhanced alarm capabilities would generate an audible alarm if the following occurs:

- inspiratory airway pressure is exceeded
- respiratory rate exceeds the set limit

[7] ISO 5359:2008/A1:2011

Information Monitoring Displays

Enhanced display settings will be capable of showing the following:

- current/ measurements of actual tidal volume, breathing rate, PEEP, peak and plateau pressure, FiO2, inspiratory to expiratory time ratio (I:E).
- waveforms of key parameters including but not limited to flow, pressure and volume versus time
- real-time confirmation of each patient inhale, including an alarm triggered where the patient's respiratory rate falls below the acceptable limit, in pressure support mode (where feature is available).

Documentation with the ventilator device

All information necessary for the appropriate use of the ventilator should be clearly documented in the instructions for use[8]. Start-up and troubleshooting instructions for the devices should be made readily available.

Decontamination

As ventilators used in the healthcare setting are in continuous proximity to patients and parts thereof are in direct contact with patients, it is paramount that decontamination by health care professionals can be effectively executed. Many factors should be considered in determining how effective decontamination of the device can take place and the design of the ventilator itself plays a significant part. Therefore, it is highly recommended that the manufacturer of the COVID-19 ventilator device provides an overview of the adequate decontamination process in the accompanied instructions for use. For example, information related to the disinfection of external surfaces in the likely event of respiratory secretions or blood splatter should be specified.

In particular, information regarding the frequency and method of required decontamination should be clearly outlined. Additionally, if certain surfaces require decontamination at a higher rate than others (i.e. parts which are in constant proximity to the patient), this should also be specified. Procedures for and timings of filter replacements should be clearly set out in the device's instructions for use.

Labelling

Any ventilator manufactured in accordance with this guidance should be clearly labelled as being a COVID-19 device.

Further to the ventilator being accompanied by the necessary instructions for use, specific instructions should be built into device labelling as appropriate.

The critical functions and controls of the ventilator should be clearly described on the using standard medical device terminology as understood and recognised in the respective official member state languages. All pictograms and colours used should be clear and self-explanatory. It is also recommended that any pictograms developed are validated by an independent test group not familiar with the specific device in question.

It is important that the documentation accompanying the devices contains the following information:

The necessary input flow required for the ventilator to be fully operational? (notable a 10 s average) for gas at a pressure of 280 kPa measured at the gas input port and the maximum transient input flow

[8] EN ISO 17664:2017.

averaged for 3 s required by the ventilator for each gas at a pressure of 280 kPa, measured at the gas input port. An explicit warning should be provided indicating if the ventilator is a high flow device which should only be connected to a pipeline installation. Additionally, any risk of interference with other devices should be clearly indicated.

Relevant Standards and Documents

1. ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport
2. ISO 80601-2-84:2018 Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (very similar to IEC 60601)
3. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
4. ISO 19223:2019 Lung ventilators and related equipment. Vocabulary and semantics
5. EN ISO 5359:2008/A1:2011 Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases
6. EN 60601-1-11:2010Medical electrical equipment - General requirements for basic safety and essential performance
7. EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators
8. IEC 62353:2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
9. Rapidly manufactured ventilators are likely to include software. Included software falls under the definition of a medical device and should meet requirements that will ensure product performance and safety. For example, see Appendix C (software development requirements) from the MHRA guideline:https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876167/RMVS001_v3.1.pdf
10. EN 60601-1:2006/A1:2013ISO 80601-2-55:2018 Particular requirements for the basic safety and essential performance of respiratory gas monitors

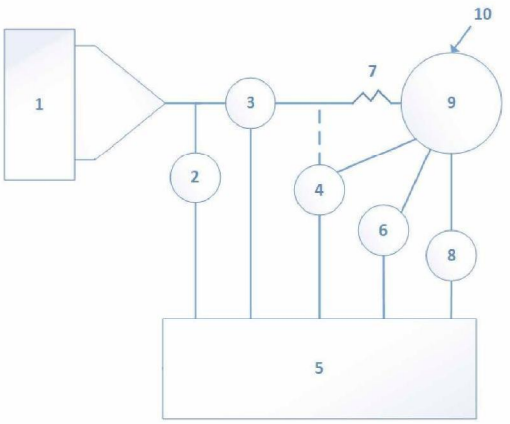
Annex A: Ventilator test conditions

Testing of ventilators requires three parallel tracks. The first is that the device meets minimum requirements specified above of mechanical robustness, appropriate labelling, disinfectability, freedom from e.g. plasticizers, avoidance of accidental re-use of one-time-only parts, battery backup power, alarms etc.

The second is determining that the ventilator consistently and repeatedly meets the minimum ventilation conditions as set out in this document.

The third requires that testing be appropriately conducted to ensure that the device is performing as intended and will do so during daily use in the emergency care setting, especially considering that staff not necessarily fully acquainted with this specific device will be the main users.

The test setup for measuring the accuracy of volume and pressure controlled inhales should be done in following way:



(1) Ventilator under test
(2) Pressure sensor
(3) Flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms
(4) Oxygen sensor
(5) Data acquisition system, with minimum sample rate of 200 samples/s
(6) Temperature sensor
(7) Test lung resistance (R_{lung})
(8) Pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
(9) Test lung compliance (C_{lung})
(10) Test lung

The oxygen sensor may be placed in the Ventilation breathing System

Figure 1 – Ventilator test set-up

Test of accuracy in volume-controlled inhalation mode

The ventilator operating in normal condition, the accuracy as determined for the test settings and conditions should be detailed. The accuracy of performance of the ventilator should also be specified.

This instructions for use should specify:

1) Maximum error between delivered volume in comparison with the set value
2) Maximum error between the PEEP in comparison to the set value
3) Maximum error of inspiratory oxygen concentration (FiO_2) at the end port connecting to the patient.

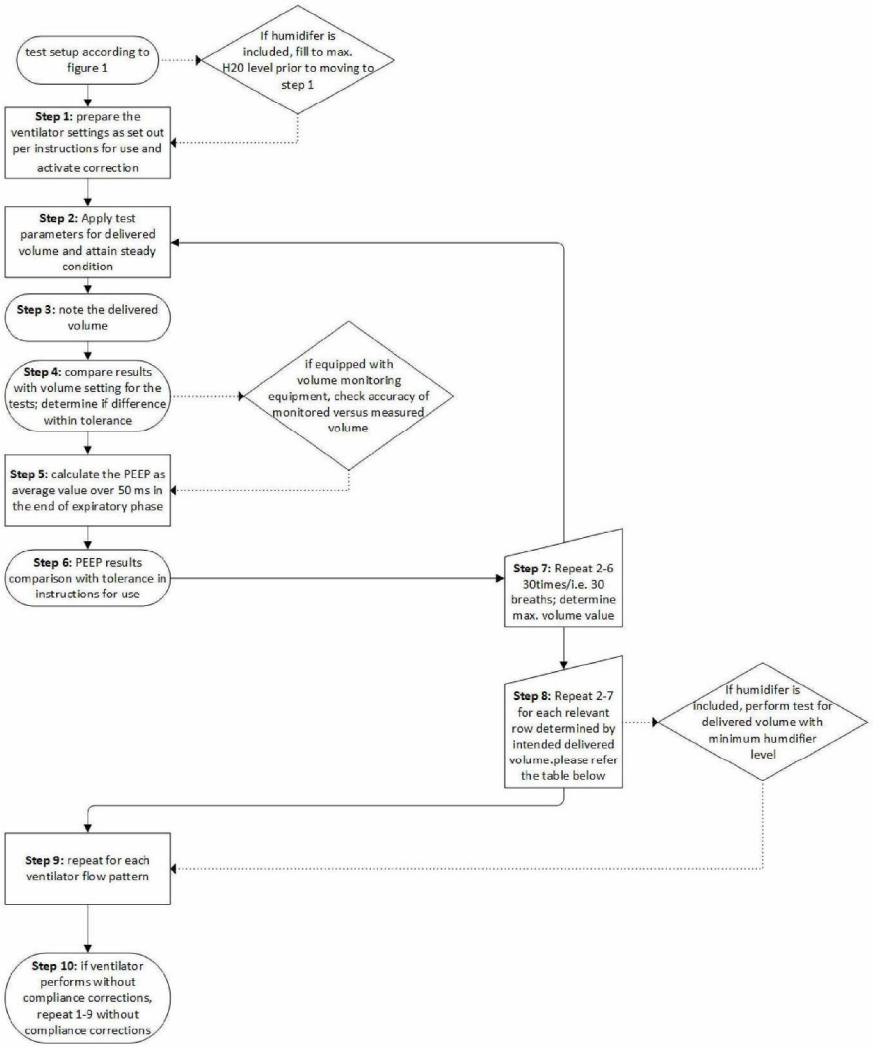


Figure 2 – test of accuracy in volume-controlled inhalation mode

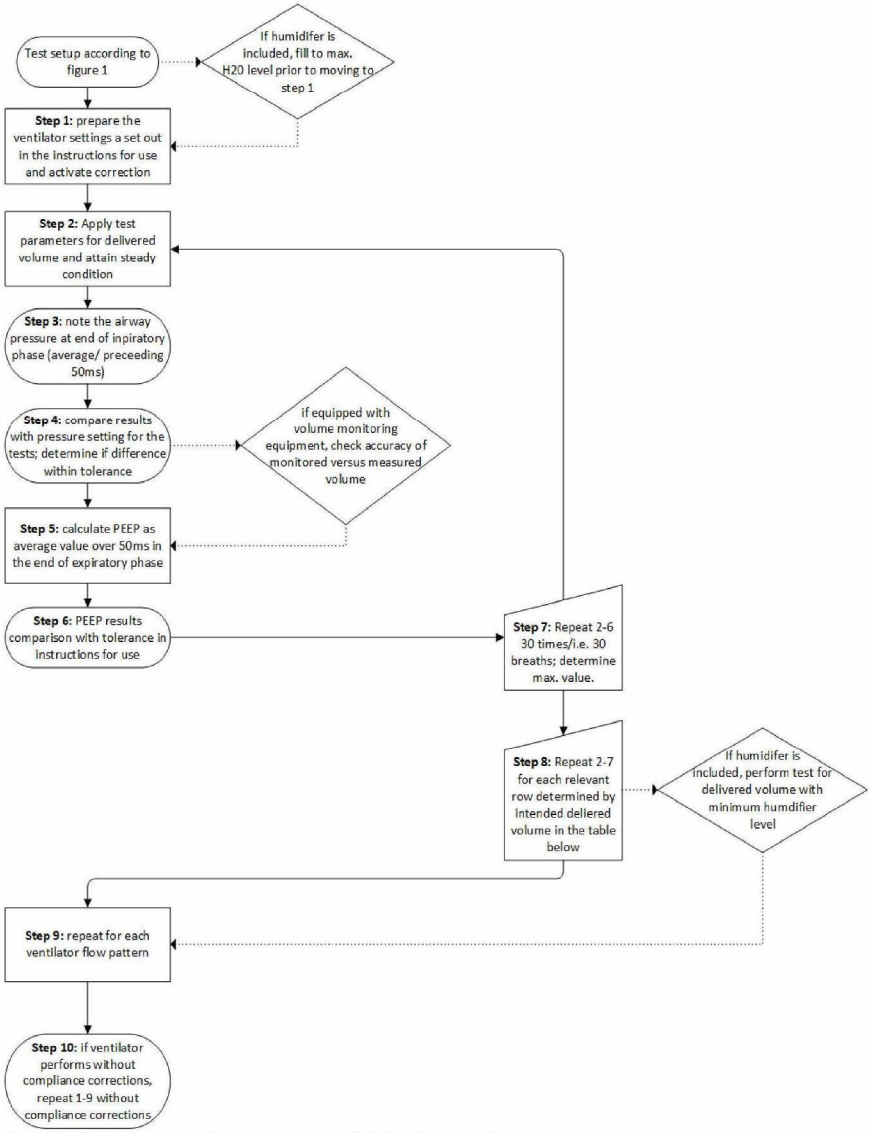
Assessment #	Test lung compliance	Linear test lung resistance	Ventilator/tidad Volume	Ventilation Rate	Inhalation time	Fraction of inspired oxygen	PEEP
	(ml/hPa) ± 10%	(hPa/l/s) ± 10%	(ml)	breaths/min	(s)	(%)	(hPa)
1	50	5	500	20	1	30	5
2	50	20	500	20	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	20	1	90	10
7	10	50	300	20	1	30	10
8	10	20	200	20	1	90	5
9	3	20	50	30	0.6	30	5
10	3	50	50	30	0.6	30	10
11	3	200	50	30	0.6	60	5
12	3	50	30	30	0.6	30	5
13	3	200	30	30	0.6	90	10
14	1	50	30	30	0.6	90	5
15	1	200	30	30	0.6	30	10
16	1	200	20	60	0.4	30	5
17	1	200	15	60	0.4	60	10
18	1	50	10	60	0.4	60	5
19	0.5	50	5	60	0.4	60	10
20	0.5	200	5	30	0.4	30	5
21	0.5	200	5	60	0.4	30	10

Table 1 – test of accuracy in volume-controlled inhalation mode

Test of accuracy in in pressure-controlled breathing mode

This instructions for use should specify:

1) Maximum error of the airway pressure (Paw) at the termination of the inhalation phase in comparison with the set value
2) Maximum error of PEEP in relation to the set value
3) Maximum error of the inspiratory oxygen concentration at the end port connecting to the patient.
4) Maximum error in the intended delivery volume



398 **Figure 3 – Test of accuracy in pressure-controlled breathing mode**

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Assessment #	Expected volume delivery (ml)	Lung conformity test (ml/hPa) ± 10%	Linear lung resistance test (hPa/l/s) ± 10%	Ventilation rate (breaths /min)	Inhalation time (s)	Pressure (hPa)	Fraction of inspired oxygen (%)	PEEP
1	500	50	5	20	1	10	30	5
2	500	50	20	20	1	15	90	10
3	500	20	5	20	1	25	90	5
4	500	20	20	20	1	25	30	10
5	300	20	20	20	1	15	30	5
6	300	20	50	20	1	25	90	10
7	300	10	50	20	1	30	30	10
8	200	10	20	20	1	25	90	5
9	50	3	20	30	0.6	15	30	5
10	50	3	50	30	0.6	15	30	10
11	50	3	200	30	0.6	25	60	5
12	30	3	50	30	0.6	10	30	5
13	30	3	200	30	0.6	15	90	10
14	30	1	50	30	0.6	30	90	5
15	30	1	200	30	0.6	30	30	10
16	20	1	200	60	0.4	20	30	5
17	15	1	200	60	0.4	15	60	10
18	10	1	50	60	0.4	10	60	5
19	5	0.5	50	60	0.4	15	60	10
20	5	0.5	50	30	0.4	10	30	5
21	5	0.5	200	60	0.4	15	30	10

Table 1 – test of accuracy in pressure-controlled inhalation mode

Please note:

Expected volume delivery (ml) specified in this table is the volume utilised to choose the appropriate test conditions and bounds based on the expected delivery

Inhalation time(s) – Rise time of the Ventilator is set to a value that ensures the pressure can be reached within the inhalation time

Pressure (hPa) – under test conditions pressure should correspond to chosen PEEP

Other tests

Power supply

For ventilators which depend on power directly provided through the mainssupply, the ventilator should be tested as to be operable for at least 30 minutes in the event of an electricity failure or outage.

Materials testing

Parts of ventilators in the breathing system should be manufactured with materials that have been biocompatibility evaluated on the basis of patient risk[9].

Electromagnetic compatibility (EMC) Testing

As the ventilator should be EMC protected, it is recommended that tests for protection against radiate immission, radiated emission and electrical discharge are conducted.

Type specific tests

Pressurised gas input operated ventilators- Oxygen and / or Air

Under standard condition, and measured at the gas input location, the transient flow should not go beyond 200 l/min on average of 3s. The 10 second average input flow should not go beyond 60 l/min at 280 kPa.[10]

Pressure Relief Tests

In order to verify the high pressure alarm and the over pressure protection the following should be followed:

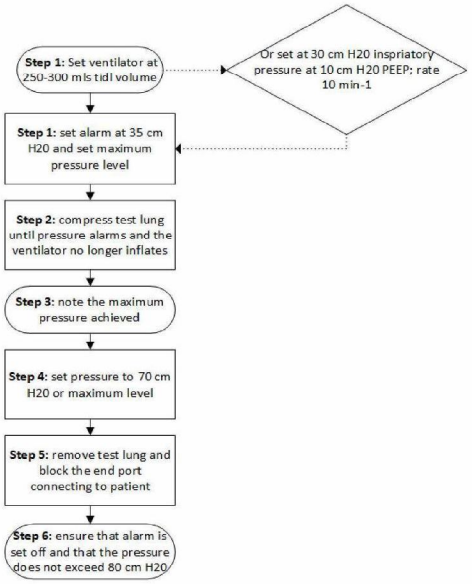
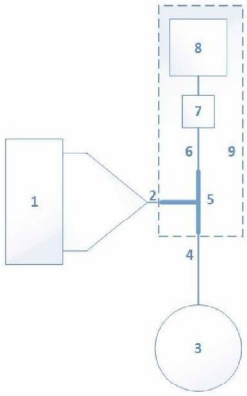


Figure 4 – Pressure Relief Tests

[9] EN ISO 18562-1:2017
[10] EN ISO 7396-1:2007/A2:2010

430 • *Closed Suctioning test*



(1) Ventilator under test
(2) End port connecting to the patient prior to incorporation of closed-suction catheter adaptor
(3) Lung under test
(4) End port connection to patient post adding closed-suction catheter adaptor
(5) Closed-suction catheter adaptor
(6) 14 Fr Closed-suction catheter
(7) Flow control valve (could also be in 8)
(8) Suction equipment
(9) Suction system

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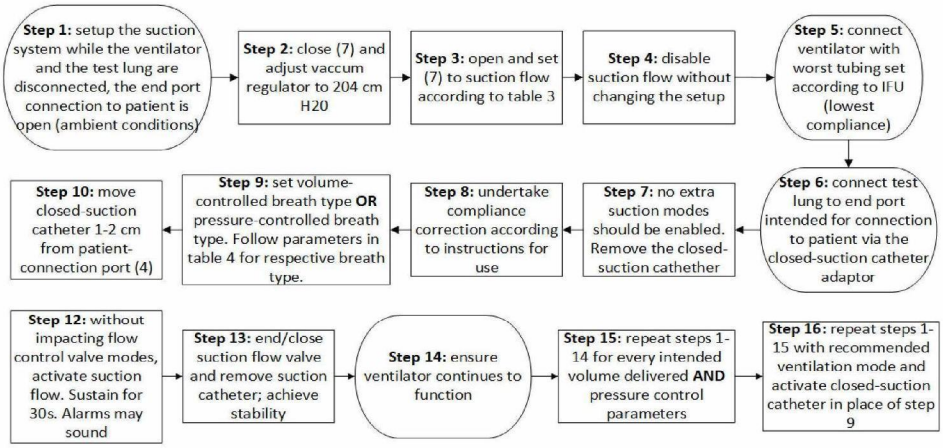
432 The test lung should have the following compliance:

Volume delivered	Compliance
Vdel W 300 ml	10 ml/hPa ± 10 %
300 ml W Vdel W 50 ml	3 ml/hPa ± 10 %
Vdel u 50 ml	0,5 ml/hPa ± 10 %



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Volume delivered	Suction flow
300 mL	30 l/min
300 ml W Vdel W 50 ml	15 l/min
Vdel u 50 ml	5 l/min

434 **Table 3 for Step 3**