

1 Guidance on accelerated manufacturing of ventilators during

2 COVID-19

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43 Introduction

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

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

57 Scope

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

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

63 Regulatory considerations

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

70 Ventilators manufactured in accordance with this guidance should only be placed on the market
 71 following receipt of a national derogation¹ from a national competent authority², in accordance with
 72 Article 11 (13) of Directive 93/42/EEC or Article 59 (1) of Regulation (EU) 2017/745. It is highly
 73 recommended that you contact your national competent authority prior to commencing the
 74 manufacturing of these devices in accordance with this guidance in order to enquire if there are specific
 75 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](#)

76 Recommended features and criteria.

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

80 Ventilation modes

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

86 Positive End Expiratory Pressure (PEEP)

87 The PEEP range should be between 5 to 25 cm H₂O and be adjustable in sufficiently low increments
88 e.g. 2 cm H₂O. The breathing system pressure should never go below the chosen PEEP setting.

89 Respiratory rate

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

92 Tidal volume (V_t)

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

96 Airway pressure safety

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

100 Fraction of inspired oxygen proportion (FiO₂)

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

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

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

108 Finally, all elements in the ventilation pathway should meet biological safety and oxygen safety
109 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

110 contamination of the patient's airway. Parts of ventilators in the breathing system should be
 111 manufactured with materials that have been biocompatibility evaluated on the basis of patient risk⁵.

112 Oxygen supply to ventilator

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

115 Air supply to ventilator

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

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

121 Information Monitoring Displays

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

126 Alarms

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

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

137 Electricity supply

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

142 Other

- 143 • The ventilator should achieve 100% operating duty cycle during the durability time/period
 144 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

185 2. *Programmable electrical medical devices*

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

196 3. *Usability*

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

- 199 – Symbols
- 200 – Units
- 201 – Colours
- 202 – Buttons and knobs

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

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

- 206 • Insulation-Protection should consist of:
- 207 – Accessible parts shall be determined (visual or with a test finger)
- 208 – The applied parts shall be classified (Type B or Type BF or Type CF)
- 209 – The necessary means of protection are:
- 210 ▪ At least two means of protection against mains supply for Ventilator Operators (2 MOOP,
- 211 240VAC, Creepage distance: 5.0mm; Clearance distance: 4.0mm)
- 212 ▪ At least two means of protection against main supply for Patients (2 MOPP, 240VAC,
- 213 Creepage distance: 8.0mm; Clearance distance: 5.0mm)
- 214 • Protective Earthing (if Class I device) should comply with the following:
- 215 – Max. allowed values for the protective earth:
- 216 ▪ with fixed power cord: 200mOhm

- 217 ▪ without fixed power cord: 100mOhm
- 218 • The following limits of leakage currents should be met:
- 219 – Earth leakage currents not exceeding (limits: 5 mA NC; 10 mA SFC)
- 220 – Touch not exceeding the limits (limits: 100 µA NC; 500 µA SFC)
- 221 – Patient leakage currents not exceeding the limits (Type B or BF AP: 10 µA NC; 50 µA SFC
- 222 (d.c. current); 100 µA NC; 500 µA SFC (a.c.), Type CF AP: 10 µA NC; 50 µA SFC (d.c. or
- 223 a.c. current)
- 224 • The following dielectric strength apply:
- 225 ▪ At least 2 means of protection against mains supply for Operator (2 MOOP, 240VAC,
- 226 3000Vac)
- 227 ▪ At least 2 means of protection against mains supply for Patient (2 MOPP, 240VAC,
- 228 4000Vac)
- 229 • Internal components, conductors, connections and wiring shall be mounted secured
- 230 • Mains fuses on the primary side shall be provided
- 231 • No rough surfaces, sharp corners and edges shall exist
- 232 • Hazards related to pressure parts shall be mitigated
- 233 • Oxygen rich environment:
- 234 – For less than 25% oxygen no additional fire risk needs to be considered and for more than 25%
- 235 oxygen, explicit fire hazard reduction measures should be specified.
- 236 • The following temperature limits should be met:
- 237 – Not exceeding the temperature limits of components, touchable parts and patient connections.
- 238 Limit for Applied Parts are 41°C
- 239 • Mechanical strength:
- 240 – No unacceptable hazards after a push test
- 241 – No unacceptable hazards after an impact test
- 242 • Internal Battery:
- 243 – A protection against overcurrent shall be provided for any internal battery

244 Optional features and criteria

245 Spontaneous ventilation

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

252 Synchronised mandatory ventilation

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

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

259 Tidal volume

260 An enhanced version of this features includes the ability to set inspiratory rise-time as a fraction of the
 261 inspiratory time, through waveform control or ratio control. The rate of inspiratory flow can be up to
 262 150 litres per minute.

263 Modular filters

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

274 Gas supply

275 Gas will typically be transmitted via a wall pipeline supply through the use of gas connectors and hoses⁷.
 276 For the measurement of gas at the input port, the 10s average input flow of the ventilator should not
 277 exceed 60 l/min at a pressure of 280 kPa. The transient input flow should not exceed 200 l/min averaged
 278 for 3s.

279 Extended battery use

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

283 Alarms

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

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

⁷ ISO 5359:2008/A1:2011

287 Information Monitoring Displays

288 Enhanced display settings will be capable of showing the following:

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

296 Documentation with the ventilator device

297 All information necessary for the appropriate use of the ventilator should be clearly documented in
 298 the instructions for use⁸. Start-up and troubleshooting instructions for the devices should be made
 299 readily available.

300 Decontamination

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

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

313 Labelling

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

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

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

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

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

⁸ EN ISO 17664:2017.

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

330 Relevant Standards and Documents

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

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 354

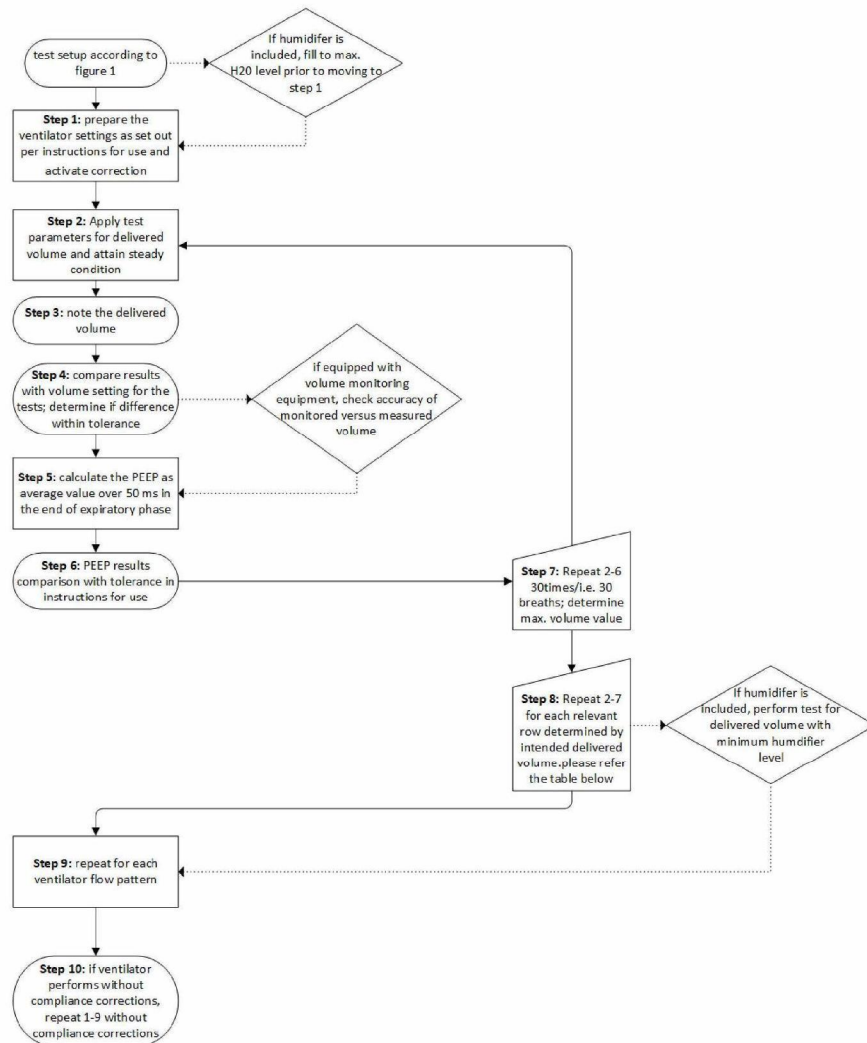


Figure 2 – test of accuracy in volume-controlled inhalation mode

386

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

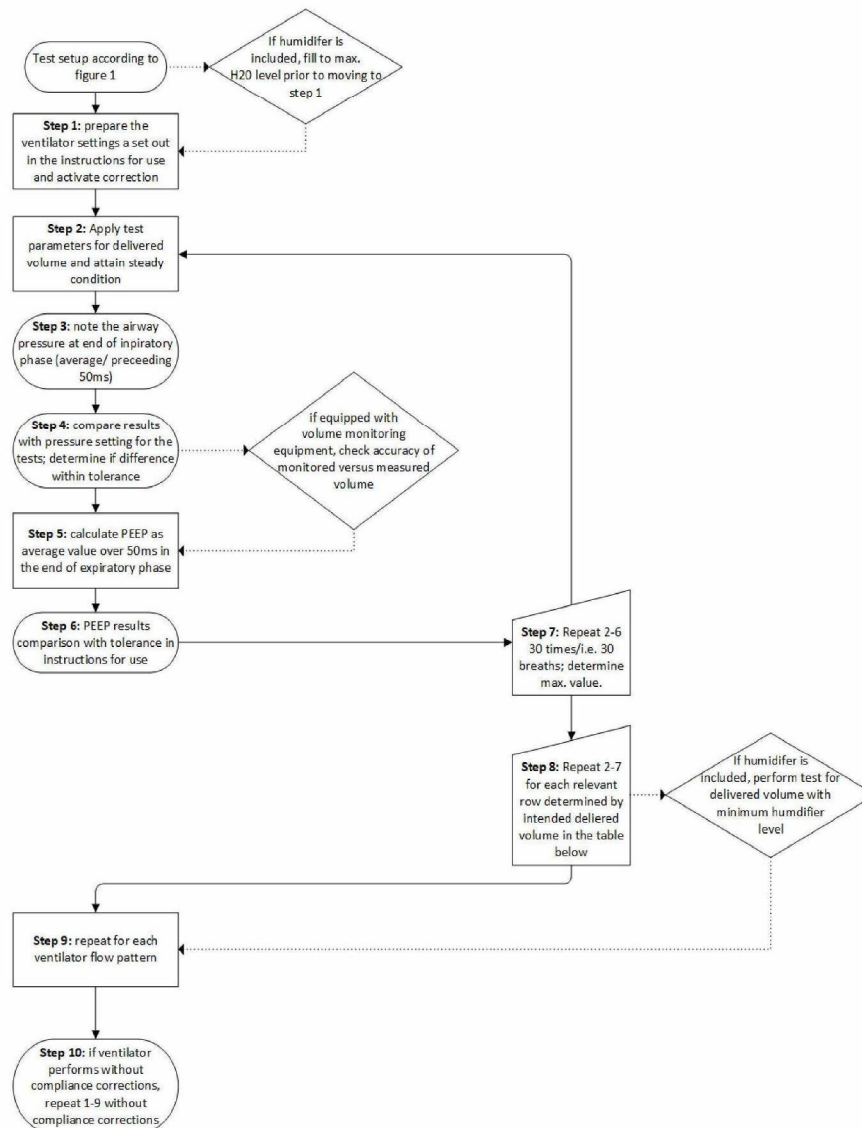
387 Table 1 – test of accuracy in volume-controlled inhalation mode

388 Test of accuracy in in pressure-controlled breathing mode

389 This instructions for use should specify:

- 390 1) Maximum error of the airway pressure (Paw) at the termination of the inhalation phase in
391 comparison with the set value
392 2) Maximum error of PEEP in relation to the set value
393 3) Maximum error of the inspiratory oxygen concentration at the end port connecting to the
394 patient.
395 4) Maximum error in the intended delivery volume
396

397



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

399

400

401

Assessment #	Expected volume delivery (ml)	Lung conformity test (ml/hPa) $\pm 10\%$	Linear lung resistance test (hPa/l/s) $\pm 10\%$	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

402 **Table 1 – test of accuracy in pressure-controlled inhalation mode**403 **Please note:**

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

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

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

409

410 **Other tests**411 *Power supply*

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

414 *Materials testing*

415 Parts of ventilators in the breathing system should be manufactured with materials that have been
416 biocompatibility evaluated on the basis of patient risk⁹.

417 *Electromagnetic compatibility (EMC) Testing*

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

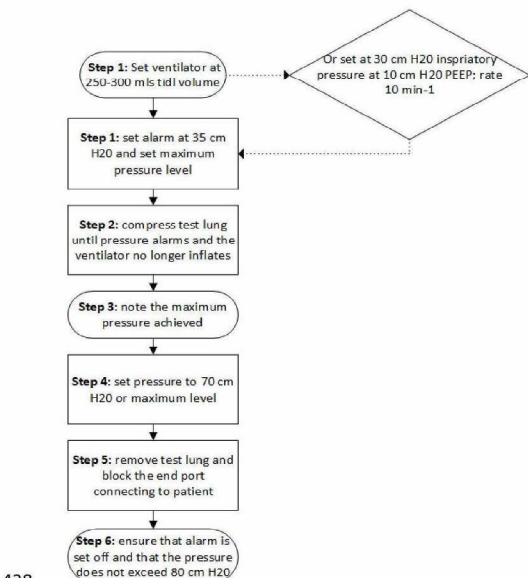
420 *Type specific tests*

421 *Pressurised gas input operated ventilators- Oxygen and / or Air*

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

425 *Pressure Relief Tests*

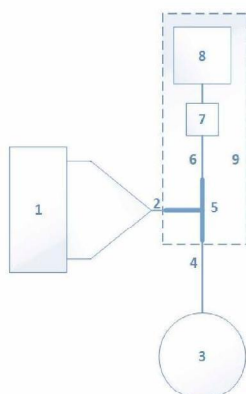
426 In order to verify the high pressure alarm and the over pressure protection the following should be
427 followed:



428

429 **Figure 4 – Pressure Relief Tests**

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

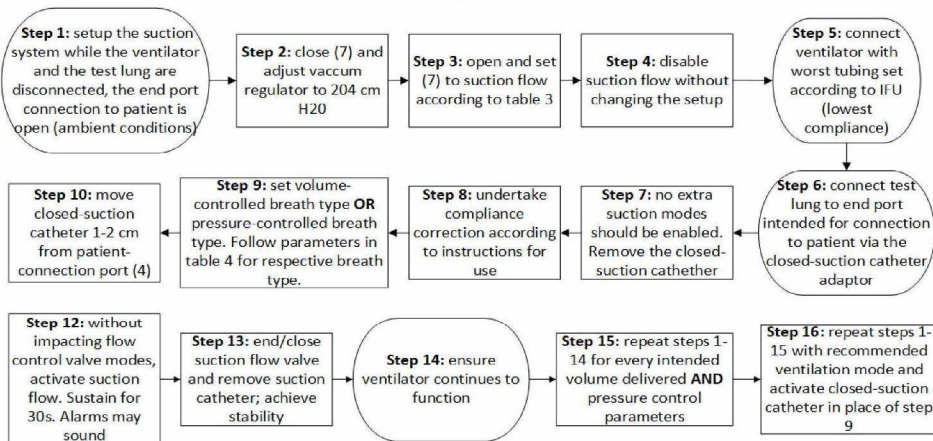
430 • *Closed Suctioning test*

- (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

431

432 The test lung should have the following compliance:

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



433

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