INTERNATIONAL STANDARD

ISO 80601-2-84

First edition
2020-07

Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

Appareils électromédicaux —

Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence

Reference number
ISO 80601-2-84:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*.

This first edition cancels and replaces ISO 10651-3:1997, which has been technically revised. The main changes compared to the previous edition are as follows:

— extension of the scope to include the *EMS ventilator* and its *accessories*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator for the emergency medical services environment*, and thus not only the *ventilator for the emergency medical services environment* itself;

— identification of *essential performance* for *ventilator for the emergency medical services environment* and its *accessories*;

— modification of the tests for environmental conditions (via IEC 60601-1-12);

— modification of the tests for *alarm conditions* (via IEC 60601-1-8);

— modification of the tests for electromagnetic disturbances (via IEC 60601-1-2);

— addition of the following:

  — tests for ventilation performance;

  — test for instability from unwanted lateral movement;

— test for audible acoustic energy;

— tests for mechanical strength (via IEC 60601-1-12);

— tests for environmental conditions (via IEC 60601-1-12);

— tests for *alarm conditions* (via IEC 60601-1-8);

— tests for electromagnetic disturbances (via IEC 60601-1-2);

— inclusion of the *usability engineering process* (via IEC 60601-1-6);

— new symbols;

— requirements for *ventilator for the emergency medical services environment* as a component of an *ME system*;

— tests for *enclosure* integrity (water ingress via IEC 60601-1-12);

— tests for *cleaning* and *disinfection*;

— determination of probability of component failure during the *expected service life*;

— delivered gas maximum enthalpy requirement;

— performance test and disclosure requirements for other *inflation-types*;

— enhanced inspired oxygen *monitoring equipment* requirements;

— consideration of input gas of Oxygen 93 %;

— use of the vocabulary and semantics of ISO 19223:2019;

— consideration of contamination of the breathing gas delivered to the *patient* from the *gas pathways*.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is a major update of the requirements for a *ventilator for the emergency medical services environment*. It includes harmonizing the requirements from ISO 10651-3, which it replaces, with the third edition of IEC 60601-1 including its first amendment, the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-6 including its first amendment, the third edition of IEC 60601-1-8 including its first amendment and the first edition of IEC 60601-1-12.

In this document, the following print types are used:

— Requirements and definitions: roman type;

— *Instructions, test specifications and terms defined in clause 3 of the general standard, in this particular document or as noted: italic type*;

— Informative material appearing outside of tables, such as notes, examples and references, in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Medical electrical equipment —

Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012.

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of an *EMS ventilator* in combination with its *accessories*, hereafter also referred to as *ME equipment:*

— intended for *patients* who need differing levels of support from artificial ventilation including *ventilator-dependent patients*;

— intended to be operated by a *healthcare professional operator*;

— intended for use in the *EMS environment*; and

— intended for invasive or non-invasive ventilation.

NOTE 1 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

* An *EMS ventilator* is not considered to utilize a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the ventilation therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *ventilator breathing system*, or to an *EMS ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *EMS ventilator*.

NOTE 2 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for the following:

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications, which are given in ISO 80601-2-12.

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72[3].

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[4].

— *ventilators* or *accessories* intended for ventilatory support equipment (intended only to augment the ventilation of spontaneously breathing *patients*), which are given in ISO 80601-2-79[5] and ISO 80601-2-80[6] [1].

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[7].

— *operator*-powered resuscitators, which are given in ISO 10651-4[8].

— gas-powered emergency resuscitators, which are given in ISO 10651-5[9].

— *continuous positive airway pressure* (*CPAP*) *ME equipment*.

— high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87[11].

— high-frequency oscillatory *ventilators* (HFOVs)[10], which are given in ISO 80601-2-87[11].

NOTE 4 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-modes*.

— cuirass or "iron-lung" *ventilators*.

201.1.2 Object

Replacement:

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an *EMS ventilator,* as defined in 201.3.201, and its *accessories*.

Accessories are included because the combination of the *EMS ventilator* and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *EMS ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.

[1] ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

201.1.3 Collateral standards

Amendment (add at the end of the subclause):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208 and 212 respectively. IEC 60601-1-3[12] and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005+AMD1:2012 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this particular document.

"Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard (e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8, etc.).

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of

IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of the general standard applies, except as follows:

Replacement:

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

Addition:

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2019, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2018, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-12:2020, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007+AMD1:2013, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2019, ISO 7396-1:2016+AMD1:2017, ISO 8836:2019, ISO 9000:2015, ISO 9360-1:2000, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-10:2007+AMD1:2013, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-12:2020, ISO 80601-2-74:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE An alphabetized index of defined terms is found in Annex DD.

201.3.201
EMS ventilator
ventilator for emergency medical services environment
ventilator intended for use in the *EMS environment*

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 *Essential performance*

Addition:

201.4.3.101* Additional requirements for *essential performance*

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of ventilation at the *patient-connection port* within the *alarm limits* set by the *operator*	
or generation of an *alarm condition*	
expired volume, if equipped	201.12.4.103
gas supply failure	201.13.102
high *airway pressure*	201.12.4.105
internal electrical power source depleted	212.8.2
inspiratory oxygen concentration, if equipped	201.12.4.101
Subclauses 202.4.3.1 and 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.	

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

In the *risk management file*, the *manufacturer* shall:

aa) state the probability of component failure that results in the *ventilator* needing to be taken out of service during the *expected service life*, assuming that the preventative inspection, preventive maintenance and calibration are performed according to the *accompanying documents*; and

bb) summarize the methodology used to determine this probability.

201.4.6 * *ME equipment* or *ME system* parts that contact the *patient*

Amendment (add at end of subclause):

aa) The *VBS* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause.

Addition:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) An *EMS ventilator* shall:

1) operate and meet the requirements of this document throughout its *rated* range of input pressure; and

2) not cause an unacceptable *risk* under the *single fault condition* of an input pressure of 1 000 kPa.

b) An *EMS ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

NOTE 1 Internal pressure regulators can be required to accommodate the *single fault condition* of maximum input pressure as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *VBS*. Under this condition, the flowrate from the *EMS ventilator* is likely to be outside of its specification.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings, by functional testing in single fault condition and inspection of the risk management file.

201.4.11.101.2 Compatibility requirement for *medical gas pipeline systems*

If the *EMS ventilator* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017, then:

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016+AMD1:2017; and

b) under *normal condition*,

1) the maximum input flow required by the *EMS ventilator* for each gas shall not exceed 60 l/min averaged over 10 s at a pressure of 280 kPa, measured at the *gas intake port*; and

2) any transient input flow shall not exceed 200 l/min averaged for 3 s.

or:

3) the *accompanying documents* shall disclose:

i) the maximum input flow required by the *EMS ventilator* for each gas at a pressure of 280 kPa averaged over 10 s, measured at the *gas intake port*;

ii) the maximum transient input flow averaged for 3 s required by the *EMS ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*; and

iii) a warning to the effect that this *EMS ventilator* is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the *risk* that the *EMS ventilator* interferes with the operation of adjacent equipment.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings and by inspection of the accompanying documents.

EXAMPLE Highest driving gas consumption under worst-case settings for Rate and inspiratory volume and worst-case medical gas pipeline system conditions within the rated range for inlet pressure.

201.4.11.101.3 Compatibility requirements for pressure regulators

If the *EMS ventilator* is intended to be connected to an oxygen gas cylinder via a pressure regulator then:

a) the *rated* range of input pressure shall cover the range specified in ISO 10524-1:2018 or ISO 10524-3:2018; and

b) under *normal condition*, the 10 s average input flow required by the *EMS ventilator* for oxygen shall not exceed 40 l/min at a pressure of 360 kPa, measured at the *gas intake port*.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings and by inspection of the accompanying documents.

EXAMPLE Highest driving gas consumption, highest fresh gas delivery and, if provided, the highest rated gas consumption at any gas power supply output.

201.5 General requirements for testing of *ME equipment*

Clause 5 of the general standard applies, except as follows:

Addition:

201.5.101 * Additional requirements for general requirements for testing of *ME equipment*

201.5.101.1 *EMS ventilator* test conditions

a) For testing, the *EMS ventilator:*

   1) shall be connected to gas supplies as specified for *normal use;*

   2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

201.5.101.2 * Gas flowrate and leakage specifications

All requirements for gas flowrate, volume and leakage in this document

a) are expressed at *STPD,*

b) except for those associated with the *VBS*, which are expressed at *BTPS*.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 * *EMS ventilator* testing errors

a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.

b) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the technical description.

Check conformance by inspection of the instructions for use and the technical description.

201.6 Classification of *ME equipment* and *ME systems*

Clause 6 of the general standard applies.

201.7 *ME equipment* identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.3 * Consult *accompanying documents*

Replacement:

The *EMS ventilator* shall be marked with the *safety sign* for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005/COR1:2006, Table D.2, Number 10).

Addition:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

1) fulfil the requirements of 201.102.101; and

2) be marked with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *EMS ventilator*, if applicable. See also 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101.

b) If marking the *accessory* is not practicable, this information may be placed in the instructions for use.

Check conformance by inspection, inspection of the risk management file for any limitations or adverse effects of the accessory, and when necessary, inspection of the instructions for use.

201.7.2.13.101 Additional requirements for physiological effects

a) All natural rubber latex-containing components in the *gas pathways* or *accessories* shall be marked as containing latex.

b) Such marking shall be *clearly legible*.

c) Symbol 5.4.5 from ISO 15223-1:2016[45], (Table 201.D.2.101, symbol 5) may be used.

d) The instructions for use shall disclose all natural rubber latex-containing components.

Check conformance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

a) Packages containing breathing attachments intended for single use or for reuse shall have *clearly legible* markings of the following:

1) a description of the contents.

2) an identification reference to the batch, type or serial number or symbols ISO 7000-2492, (Table 201.D.2.101, symbol 2), ISO 7000[46]-2493 (Table 201.D.2.101, symbol 3) or ISO 7000-2498 (Table 201.D.2.101, symbol 4).

3) the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.2.101, symbol 5), if containing natural rubber latex.

b) For a specific *model or type reference*, the indication of single use shall be consistent for the *model or type reference*.

Check conformance by inspection.

201.7.2.18 External gas source

Amendment (add before the first dash):

aa) the gas name or chemical symbol in accordance with ISO 5359:2014+AMD1:2017,

bb) the *rated* range of gas pressure,

cc) for oxygen gas inputs, the *rated* range of oxygen concentration,

dd) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used,

EXAMPLE Colour coding to match the colour of the flexible supply hose or a gas cylinder intended to be attached to the inlet connector.

NOTE In some countries, other colour coding is used.

Addition:

201.7.2.101* Additional requirements for marking on the outside of *ME equipment* or *ME equipment* parts

a) The *EMS ventilator* shall be provided with a *clearly legible* permanently attached start-up *procedure* that is intended to be performed prior to use.

b) The start-up *procedure* may be provided electronically.

EXAMPLE A start-up *procedure* provided on the graphical *user interface* or provided orally.

c) The marking of *ME equipment*, parts or *accessories* shall include the following:

1) any special storage or handling instructions.

2) any warnings or precautions relevant to the immediate operation of the *EMS ventilator*.

3) an arrow indicating the intended direction of gas flow for the *gas output port* and the *gas return port*. Symbol 0794 of ISO 7000 (Table 201.D.2.101, symbol 6) or Symbol 0795 of ISO 7000 (Table 201.D.2.101, symbol 7) may be used.

d) If applicable, *operator*-accessible marking of *ME equipment*, parts or *accessories* shall include the following:

1) for an *EMS ventilator* intended to be used in the magnetic resonance (MR) environment,

i) Symbol 7.3.1-1 (Table 201.D.2.101, symbol 9) or Symbol 7.3.1-2 (Table 201.D.2.101, symbol 10) of IEC 62570:2014 for an 'MR Safe' *EMS ventilator*, or

ii) Symbol 7.3.2 (Table 201.D.2.101, symbol 11) of IEC 62570:2014 for an 'MR Conditional' *EMS ventilator,*

in accordance with IEC 62570:2014.

2) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*.

3) an indication of the date after which the *ME equipment*, part or *accessory* should not be used, expressed as the year and month. Symbol ISO 7000-2607 (Table 201.D.2.101, symbol 1) may be used.

4) a warning not to obstruct the *gas intake port.*

EXAMPLE 1 WARNING: Gas Intake — Do not obstruct

5) for a sampling gas inlet, either with the text "Gas sample" or the Symbol ISO 7000-0794, (Table 201.D.2.101, symbol 6).

EXAMPLE 2 Input to a diverting respiratory gas monitor integrated into the *EMS ventilator*.

201.7.4.2 * Control devices

Amendment (add between the first and second paragraph):

aa) An *EMS ventilator* with an oxygen concentration control with an error exceeding 20 % [see 201.12.1.101 b) 3) and 201.12.1.102 b) 3)] shall not be marked with quantitative numerical concentration values.

EXAMPLE "No air mix" or "High" for the setting for the maximum achievable oxygen concentration or "Air mix" or "Low" for the setting with a reduced oxygen concentration.

Check conformance by inspection.

201.7.4.3 * Units of measurement

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flow and leakage specifications:

aa) shall be expressed at *STPD;* except

bb) for those associated with the *VBS* which shall be expressed at *BTPS*.

Addition:

201.7.4.101 Labelling of units of measurement

Quantitative numeric indications of parameters and settings shall be labelled with the units of measurement, either:

a) continuously; or

b) on *operator* action.

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

— Name or trade name and address of

  — the *manufacturer*; and

  — where the *manufacturer* does not have an address within the locale, an authorized representative within the locale,

to which the *responsible organization* can refer;

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose the following:

a) if the *EMS ventilator*, its parts or *accessories* are intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *EMS ventilator*, its parts or *accessories* would be reused; and

b) the intended range of *inspiratory volume*.

Check conformance by inspection.

201.7.9.2.2.101* Additional requirements for warnings and safety notices

The instructions for use shall include:

a) a warning statement to the effect of "Warning: This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury."

b) a warning statement to the effect of "Warning: Do not cover the ventilator or place in a position that affects proper operation", including applicable examples.

EXAMPLE 1 **WARNING**: Do not position next to a blanket that blocks the flow of cooling air, thereby causing the ventilator to overheat, thereby interfering with patient ventilation.

EXAMPLE 2 **WARNING**: Do not block the gas intake port thereby interfering with patient ventilation.

c) * a warning statement to the effect of "Warning: Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or additional deterioration of health."

EXAMPLE 3 **WARNING**: Failure to have an alternative means of ventilation such as a self-inflating, manually powered resuscitator (as specified in ISO 10651-4) with mask can result in patient death if the ventilator fails.

d) * a warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health."

If applicable, the instructions for use shall include the following:

e) * a warning statement to the effect of "WARNING: When using nebulisation or humidification, the breathing system filters can require more frequent replacement to prevent increased resistance and blockage.

f) a warning statement to the effect of "Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly causing patient death or additional serious deterioration of health."

g) a warning statement to the effect of "Warning: The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebuliser.

h) a warning statement to the effect of "Warning: Do not use the ventilator in explosive environments. Such use might cause an explosion."

Check conformance by inspection.

201.7.9.2.8.101* Additional requirements for start-up *procedure*

NOTE A start-up *procedure* includes a pre-use functional test that is used to determine whether the *EMS ventilator* is ready for use.

a) The instructions for use or the *user interface* shall include a pre-use checklist.

b) The instructions for use shall disclose a method by which all of the *alarm signals* can be functionally tested by the clinical *operator* to determine if they are operating correctly.

c) Portions of this test method may:

1) be automatically performed by the *EMS ventilator;* or

2) require *operator* action.

EXAMPLE Combination of the power-on self-test routines and *operator* action.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101* Additional requirements for operating instructions

The instructions for use shall disclose:

a) a listing of the following pressures:

1) *maximum limited pressure* ($P_{LIM\,max}$);

2) if provided, the *rated* range to which the *maximum working pressure* ($P_{W\,max}$) can be set, if adjustable;

3) the means by which the *maximum working pressure* is accomplished.

EXAMPLE 1 Pressure cycling, pressure limiting, pressure generation.

b) the *rated* range of the following characteristics of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:

1) inspiratory *gas pathway* resistance,

2) expiratory *gas pathway* resistance, and

3) *VBS* compliance.

i) These specifications may be presented in ranges.

ii) The accuracies of set and monitored volumes may be presented as a function of these characteristics.

NOTE Compliance and resistance can be non-linear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min and the maximum flowrate or the maximum pressure).

c) the conditions under which the *EMS ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use.

EXAMPLE 2 Interval of calibration of a flow sensor.

d) if end-tidal gas concentration measurement is provided, a summary of effects of respiratory rate on the end-tidal gas concentration measurement accuracy.

e) if a connection for a *distributed alarm system* is provided, a description of how to connect and test the connection of a *distributed alarm system*.

f) any special storage, handling, or operating instructions.

g) a cross reference between the *manufacturer*-specific naming of the *ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.

h) whether or not the *EMS ventilator* is intended for use with closed suctioning.

Check conformance by inspection.

201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization*

Amendment: (add after normal use)

or in *single fault condition*

Amendment: (add after bulleted list)

aa) The instructions for use shall identify which portions of the *gas pathways* through the *EMS ventilator* can become contaminated with body fluids or by microbial material conveyed by the expired breathing gases during both *normal condition* and *single fault condition*.

Addition:

201.7.9.2.14.101 * Additional requirements for *accessories*, supplementary equipment, used material

a) The instructions for use of the *EMS ventilator* shall include a statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the *ventilator breathing system*.

b) If applicable, the instructions for use of the *EMS ventilator* shall disclose:

1) any restrictions on the positioning of components within the *ventilator breathing system*; and

EXAMPLE Where such components are *flow-direction-sensitive components*.

2) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *EMS ventilator* (additional requirements are found in 201.16).

Check conformance by inspection and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose:

a) * a summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control necessary for the *operator* to form a mental model of the operation of the *ventilator;*

b) a pneumatic diagram of the *EMS ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the instructions for use;

c) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *EMS ventilator*; and

d) the outside dimensions and mass of the *EMS ventilator.*

If applicable, the technical description shall disclose:

e) the essential technical characteristics of each recommended *breathing system filter*; and

EXAMPLE Deadspace and resistance.

f) a description of the method used to calculate end-tidal gas readings.

Check conformance by inspection.

201.7.9.3.101 Additional requirements for the technical description

The technical description shall disclose:

a) a description of a *procedure* for checking the functioning of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during start-up; and

b) which checks are performed automatically.

Check conformance by inspection of the technical description.

201.8 Protection against electrical *hazards* from *ME equipment*

Clause 8 of the general standard applies.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

Clause 9 of the general standard applies, except as follows:

Addition:

201.9.4.3.101 * Additional requirements for instability from unwanted lateral movement

a) An *EMS ventilator* shall include a means by which the *EMS ventilator* can be attached to prevent unwanted movement during transport while in use.

b) The means shall secure the *EMS ventilator* to withstand accelerations or decelerations of

1) 10 g longitudinal (forward, backward), 10 g transverse (left, right) and 10 g vertical (up, down) for at least 150 ms in each orientation for a road ambulance.

2) 20 g longitudinal (forward, backward), 20 g transverse (left, right), 20 g vertical (down) and 4 g vertical (up) for at least 3 s in each orientation for an air ambulance.

c) Terminal units and electrical socket outlets shall not be used as part of the fixation system.

d) If rail systems are used, they shall conform with ISO 19054:2005+AMD1:2016.

NOTE Rail systems consist of e.g. rail supports, rails, rail clamps, equipment mount holders, equipment mounts, equipment pin holders and equipment pins.

e) The means to secure a *portable EMS ventilator* to withstand forces caused by accelerations or decelerations shall be operable without the use of a *tool*.

f) The technical description shall disclose the technical details of this means for attachment.

Check conformance by inspection and functional testing.

EXAMPLE These tests can be performed by utilizing static loading, acceleration sleds or centrifuges.

201.9.4.4 Grips and other handling devices

Replace list item b) with:

b) A *portable EMS ventilator* shall be designed such that it can be carried by no more than one hand.

1) It shall be possible for the *operator* to:

i) observe the display;

ii) recognize the *alarm signals;* and

iii) actuate the controls while holding the *EMS ventilator* with no more than one hand.

2) A carrying case or handle may be utilized to fulfill this requirement.

Amendment (add to the end of the conformance check):

Check conformance by functional testing while carrying with no more than one hand.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *EMS ventilator* shall be:

1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and

2) disclosed in the instructions for use.

b) The A-weighted sound power level shall be:

1) calculated according to 8.2.5 and 8.6 of ISO 3744:2010; and

2) disclosed in the instructions for use.

Check conformance with the following test:

c) Place the EMS ventilator on the sound-reflecting plane and attach the least favourable VBS from those indicated in the instructions for use.

NOTE The least favourable VBS configuration can vary by ventilation-mode, inflation-type and flow pattern, as applicable.

d) If a humidifier is provided with the EMS ventilator, include the humidifier filled to the least favourable level in the test.

e) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.

— *Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the EMS ventilator.*

— *Connect the patient-connection port to the test lung.*

f) Set the EMS ventilator to the least favourable ventilation-mode, inflation-type and flow pattern, as applicable, that generates ventilation as indicated in Table 201.102.

NOTE The least favourable ventilation-mode, inflation-type and flow pattern can vary by VBS configuration.

g) Using a microphone of the sound level meter, conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weigthed sound pressure level using frequency-weighting A and the time-weighting F of the sound level meter (i.e. L_{AFmax}) at 10 positions in a hemisphere with a radius from the geometric centre of the EMS ventilator in a free field over a reflecting plane as specified in 8.1.1 of ISO 3744:2010. Average the values in accordance with 8.2.2 of ISO 3744:2010.

h) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

i) Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.

j) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.

k) Ensure that the measured sound pressure level is less than or equal to that disclosed in the instructions for use.

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For an *EMS ventilator* intended to provide *tidal volume*		
	V_{insp} ≥300 ml	300 ml ≥ V_{insp} ≥50 ml	V_{insp} ≤50 ml
Tidal volume, V_{tidal}[a]	500 ml	150 ml	30 ml
Rate	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1/2	1/2	1/2
BAP	5 hPa	5 hPa	5 hPa
Linear resistance, *R*[b][13][14][15]	5 hPa(l/s)$^{-1}$ +10 %	20 hPa(l/s)$^{-1}$ ±10 %	50 hPa(l/s)$^{-1}$ ±10 %
Isothermal Compliance, *C*[b]	50 ml hPa^{-1} ±5 %	20 ml hPa^{-1} ±5 %	1 ml hPa^{-1} ±5 %

a V_{tidal} is measured by means of a pressure sensor at the test lung, where $V_T = C \times P_{max}$, and
V_T is the volume delivered to the test lung
C is the isothermal Compliance of the test lung
P_{max} is the maximum pressure measured in the test lung

b The accuracy for *C* and *R* applies over the ranges of the measured parameters.

201.10 Protection against unwanted and excessive radiation *hazards*

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other *hazards*

Clause 11 of the general standard applies, except as follows:

201.11.1.2.2 * *Applied parts* not intended to supply heat to a *patient*

Amendment (add between the existing paragraphs):

Over the *rated* flowrate range and at the maximum *rated* operating temperature, the temperature of the gas delivered by the *ventilator* at the *patient-connection port,* both with and without each

humidifier specified for use in the instructions for use, when averaged over 120 s shall neither exceed

aa) 70 °C; nor

bb) an energy equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m^3 dry air),

when averaged over 120 s.

Table 201.103 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.103 — Examples of permissible combinations of temperature and relative humidity

Temperature °C	Relative humidity %
43	100
44	95
45	90
48	76
50	69
55	52
60	40
65	30
70	23

201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (add additional requirement as new first paragraph):

aa) *Gas pathways* through the *EMS ventilator* and its *accessories* not intended for single use that can become contaminated with body fluids or by microbial material conveyed by the expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

1) for *cleaning* and *disinfection*; or

2) for *cleaning* and *sterilization*

NOTE 1 Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012.

Amendment (add additional requirement and replace the compliance test):

bb) *EMS ventilator enclosures* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of cross infection of the next *patient*.

NOTE 2 ISO 14159[19] provides guidance for the design of *enclosures*.

cc) *Processing procedure* instructions for the *EMS ventilator* and its *accessories* shall:

1) conform with ISO 17664:2017 and ISO 14937:2009; and

2) be disclosed in the instructions for use.

Check conformance by inspection of the risk management file and conformity with ISO 17664:2017. When conformance with this document could be affected by the cleaning or the disinfection of the EMS ventilator or its parts or accessories, clean and disinfect them for the number of processing cycles and in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these procedures, ensure that basic safety and essential performance are maintained. Confirm that the manufacturer has evaluated the effects of multiple process cycles and the effectiveness of those cycles.

201.11.6.7 *Sterilization* of *ME equipment* or *ME system*

Amendment (add note before compliance test):

NOTE Additional requirements are found in 11.6.6 of IEC 60601-1:2005+AMD1:2012.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the compliance statement):

aa) The *manufacturer* of a *ventilator*, *VBS*, its parts and *accessories* shall address in the *risk management process* the *risks* associated with the leaching or leaking of substances into the *gas pathway*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

cc) A *VBS*, its parts or *accessories* that contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, in a concentration that is above 0,1 % weight by weight, shall be marked as containing such substances:

1) on the *VBS*, its parts or *accessories* itself; or

2) on the packaging.

dd) The symbols of

1) EN 15986:2011[47]

2) (Table 201.D.2.101, symbol 8) may be used for phthalates.

3) ISO 7000-2725 (Table 201.D.2.101, symbol 9) may be used for other substances.

ee) If the *intended use* of a *VBS*, its parts or *accessories* includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these substances shall be included in the *risk management file*.

ff) The instructions for use shall contain information:

1) on *residual risks* for these *patient* groups; and

2) if applicable, on appropriate precautionary measures.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

Addition:

201.12.1.101 * *Volume-control inflation-type*

a) If provided with a *volume-control inflation-type*, then with a *volume-control inflation-type* selected and the *EMS ventilator* operating in *normal condition*, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ± (5 +(10 % of the set volume)) ml

b) This disclosure shall include at least:

1) the maximum error of the *inspiratory volume* in relation to the set *tidal volume*;

2) the maximum error of the *PEEP* in relation to the set value of *BAP*; and

3) * the maximum error of the inspiratory oxygen (O_2) concentration at the *patient-connection port* in relation to the set value.

4) The disclosed accuracies shall include the effects of the *rated* input oxygen concentration.

c) All of the errors may be reported separately for the following ranges of intended *tidal volume*:

1) $V_{tidal} \geq 300$ ml

2) 300 ml $\geq V_{tidal} \geq$ 50 ml

3) $V_{tidal} \leq 50$ ml

d) The accuracy of the performance of the *EMS ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configurations indicated in the instructions for use.

NOTE 1 The worst-case *VBS* configuration can be different for each error or *nominal inspiratory volume*.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and with the following tests:

NOTE 2 In some cases, the following tests can be carried out simultaneously.

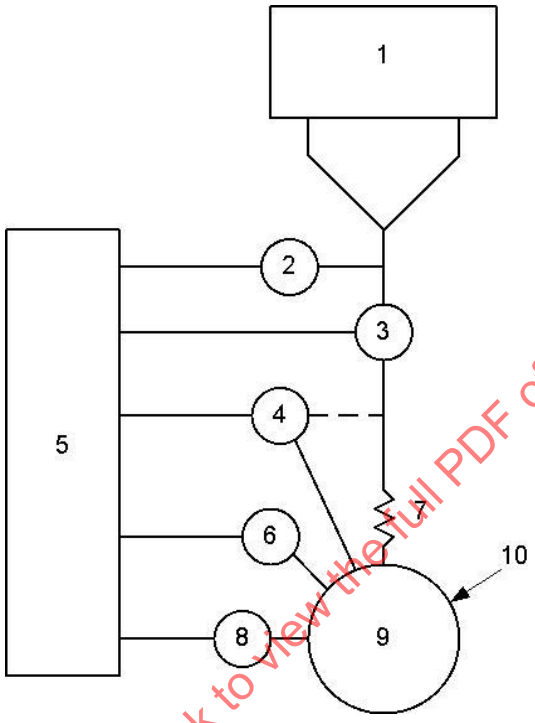
f) Tidal volume and end-expiratory pressure errors

1) Set up the EMS ventilator as shown in Figure 201.101.

2) *If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a humidifier is used, fill the humidifier to the maximum water level prior to determining the VBS compliance.*

3) *Utilize the test parameters and settings of the first applicable row (selected by intended tidal volume) of* Table 201.104.

4) *Wait for steady-state conditions to be achieved.*



Key

1 *EMS 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 *VBS*.

Figure 201.101 — *Volume-control* and *pressure-control inflation-type* accuracy, typical test setup

5) *Determine the tidal volume, for example via integration of the flow signal provided by a calibrated flow sensor located at the patient-connection port or by the product of the test lung compliance and the measured change of lung pressure, compensated for temperature effects due to fast compression of the gas, if necessary.*

NOTE 3 Additional information on the construction of an isothermal test lung is found in Reference [20].

6) *Compare the result with the volume setting for the test and the resulting difference with the tolerance indicated in the instructions for use.*

7) *If the EMS ventilator is equipped with tidal volume monitoring equipment, determine the accuracy of the tidal volume monitoring equipment by comparing its reading to the tidal volume determined in 5). Refer to 201.12.1.104.*

8) *Determine the PEEP as the average of the airway pressure measurements over the last 50 ms of the expiratory phase.*

*** Table 201.104 — *Volume-control inflation-type* testing**

Test number	Test lung parameters		*EMS ventilator* settings				
	Compliance	Linear resistance [13][14][15]	*Tidal volume*	*Rate*[a]	*Inspiratory time*	O_2[b]	*BAP*
	ml/hPa ±10 %	hPa/l/s ±10 %	ml	breaths/min	s	%	hPa (cmH_2O)
1	50	5	500	20	1	30	5
2	50	20	500	12	1	85	10
3	20	5	500	20	1	85	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	12	1	85	10
7	10	50	300	20	1	30	10
8	10	10	200	20	1	85	5
9	3	10	50	30	0,6	30	5
10	3	20	50	30	0,6	30	10
11	3	50	50	20	0,6	60	5
12	3	20	30	30	0,6	30	5
13	3	50	30	20	0,6	85	10
14	1	20	30	30	0,6	85	5
15	1	100	30	30	0,6	30	10
16	1	200	20	50	0,4	30	5
17	1	200	15	50	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

[a] If the *end-expiratory flow* does not reach zero, reduce the *Rate* until it does.

[b] In the case that *EMS ventilator* does not provide the settings as specified in column O_2, select the closest available O_2 *EMS ventilator* setting.

9) Compare the result with the BAP setting for the test and the resulting difference with the tolerance indicated in the instructions for use.

10) Repeat 3) to 9) for 30 consecutive inflations.

11) Repeat 4) to 10) for each applicable row (selected by intended tidal volume) of Table 201.104*.*

12) If a humidifier is included in the VBS, repeat the tidal volume tests with the minimum humidifier water level without re-determining the VBS compliance.

13) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat 2) to 12) for each flow pattern available on the EMS ventilator.

14) If the EMS ventilator permits operation without compliance correction, repeat 2) to 13) without compliance correction.

g) O_2 error

The accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration-measuring device at the patient-connection port or inside the test lung. If the sensor is located at the patient-connection port, the value of the concentration is the flow-weighted average concentration during the inflation phase.

1) Evaluate the measured O_2 concentration with the acceptance criteria derived from the O_2 setting for the test and the measurement uncertainty. Compare the resulting difference with the tolerance indicated in the instructions for use.

2) If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration.

3) If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inflation phase.

4) If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.

5) Compare each result with the acceptance criteria derived from the O_2 setting for the test in f), above, the measurement uncertainty and the tolerance indicated in the instructions for use.

201.12.1.102 * Pressure-controlled *inflation-type*

a) If provided with a pressure-controlled *inflation-type*, with the pressure-controlled inflation type selected and the *EMS ventilator* operating in *normal condition*, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ± (3,0+(5 % of the set pressure)) hPa (± (3,0 +(5 % of the set pressure)) cmH_2O)

b) This disclosure shall include at least:

1) the maximum error of the *airway pressure* (P_{aw}) at the end of the *inflation phase* in relation to the set value;

2) the maximum error of *PEEP* in relation to the set value of *BAP*;

3) * the maximum error of the inspiratory oxygen (O_2) concentration at the *patient-connection port* in relation to the set value.

4) The disclosed accuracies shall include the effects of the *rated* input oxygen concentration.

c) All of the errors may be reported separately for the following ranges of intended *tidal volume*:

1) $V_{tidal} \geq 300$ ml

2) 300 ml $\geq V_{tidal} \geq$ 50 ml

3) $V_{tidal} \leq 50$ ml

d) The accuracy of the performance of the *EMS ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configuration indicated in the instructions for use.

NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal inspiratory volume* range.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and with the following tests:

NOTE 2 In some cases, the following tests can be carried out simultaneously.

f) End-inspiratory and end-expiratory pressure errors

1) Set up the EMS ventilator as shown in Figure 201.101.

2) If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a humidifier is used, fill the humidifier to the maximum water level prior to determining the VBS compliance.

3) Utilize the test parameters and settings of the first applicable row (selected by typical intended tidal volume) of Table 201.105*. Wait until steady-state conditions are achieved.*

4) Determine the airway pressure at the end of the inflation phase as the average over the preceding 50 ms.

5) Compare the result with the pressure setting for the test and the resulting difference with the tolerance indicated in the instructions for use.

6) Determine the tidal volume, for example via integration of the flow signal provided by a calibrated flow sensor located at the patient-connection port or by the product of the test

lung compliance and the measured change of lung pressure, compensated for temperature effects due to fast compression of the gas, if necessary.

NOTE 3 Additional information on the construction of an isothermal test lung is found in Reference [20].

*** Table 201.105 — Pressure-controlled *inflation-type* testing**

Test number	Intended tidal volume[a]	Test lung parameters		*EMS ventilator* settings				
		Compliance	Linear Resistance [13][14][15]	*Rate*[b]	*Inspiratory time*[c]	*Δ inspiratory pressure*[d]	O_2[e]	*BAP*
	ml	ml/hPa ±10 %	hPa/l/s ±10 %	breaths/min	s	hPa	%	hPa (cmH_2O)
1	500	50	5	20	1	10	30	5
2	500	50	20	12	1	15	85	10
3	500	20	5	20	1	25	85	5
4	500	20	20	20	1	25	30	10
5	300	20	20	20	1	15	30	5
6	300	20	50	12	1	25	85	10
7	300	10	50	20	1	30	85	5
8	200	10	10	20	1	25	30	10
9	50	3	10	30	0,6	15	30	5
10	50	3	20	30	0,6	15	30	10
11	50	3	50	20	0,6	25	60	5
12	30	3	20	30	0,6	10	30	5
13	30	3	50	20	0,6	15	85	10
14	30	1	20	30	0,6	30	85	5
15	30	1	100	30	0,6	30	30	10
16	20	1	200	50	0,4	20	30	5
17	15	1	200	50	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

[a] The volume in this column is intended to be used for the selection of the test conditions and parameters based on the intended *inspiratory volume* of the *EMS ventilator*.

[b] If the *end-expiratory flow* does not reach zero, reduce the *Rate* until it does.

[c] The rise time of the *EMS ventilator* should be set to a value that ensures the set pressure can be reached within the *inspiratory time*.

[d] For the purposes of this test, the set pressure is relative to set *BAP*.

[e] If the *EMS ventilator* does not provide the settings as specified in column O_2, select the closest available O_2 *EMS ventilator* setting.

7) If the EMS ventilator is equipped with tidal volume *monitoring equipment, determine the accuracy of the tidal* volume *monitoring equipment by comparing its reading to the tidal* volume *determined in 6). Refer to 201.12.1.104.*

8) *Determine the PEEP as the average of the airway pressure measurements over the last 50 ms of the expiratory phase.*

9) *Compare the result with the acceptance criteria derived from the BAP setting for the test, the measurement uncertainty and the resulting difference with the tolerance indicated in the instructions for use.*

10) *Repeat 2) to 9) for 30 consecutive inflations.*

11) *Repeat 2) to 10) for each applicable row (selected by intended tidal volume) of* * Table 201.105.

12) *If a humidifier is included in the VBS, repeat the airway pressure tests with the minimum humidifier water level without re-determining the VBS compliance.*

13) *If the EMS ventilator permits operation without compliance correction, repeat 2) to 12) without compliance correction.*

g) *O_2 error*

The accuracy *of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration-measuring device at the patient-connection port or inside the test lung. If the sensor is located at the patient-connection port, the value of the concentration is the flow-weighted average concentration as a function of flow during the inflation phase.*

1) *Evaluate the measured O_2 concentration with the acceptance criteria derived from the O_2 setting for the test and the measurement uncertainty. Compare the resulting difference with the tolerance indicated in the instructions for use.*

2) *If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration.*

3) *If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inflation phase.*

4) *If the O_2 concentration-measuring device has pressure dependencies, compensate for these dependencies.*

5) *Compare each result with the acceptance criteria derived from the O_2 setting for the test in 5), above, the measurement uncertainty and the tolerance indicated in the instructions for use.*

201.12.1.103 Other *inflation-types*

a) If other *inflation-types* are provided, then with each other *inflation-type* selected and the *ventilator* operating in *normal condition*,

1) the performance at the *patient-connection port*; and

2) their acceptance criteria;

as determined by the *manufacturer,* shall be disclosed in the instructions for use.

3) The disclosed performance and acceptance criteria shall include the effects of the range of the *rated* input oxygen concentration.

b) All of the acceptance criteria may be separately reported for the following ranges of intended *inspiratory volume*:

1) $V_{insp} \geq 300$ ml;

2) 300 ml $\geq V_{insp} \geq 50$ ml; and

3) $V_{insp} \leq 50$ ml.

c) The acceptance criteria of the performance of the *ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configuration indicated in the instructions for use.

NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal inspiratory volume* range.

d) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the instructions for use, inspection of the risk management file for the rationale, if applicable, and with the tests specified by the manufacturer.

201.12.1.104 *Inspiratory volume monitoring equipment*

If the *EMS ventilator* is equipped with *inspiratory volume monitoring equipment*, the accuracy of the *inspiratory volume monitoring equipment* shall be disclosed in the instructions for use.

Check conformance with the following.

Confirm that the inspiratory volume monitoring equipment accuracy as measured in 201.12.1.101 f) 7) and 201.12.1.102 f) 7) is within the accuracy disclosed in the instructions for use.

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Oxygen monitor

a) The *EMS ventilator*, intended to provide a *inspiratory volume* less than 50 ml and with an oxygen concentration control with an error less than or equal to 20 % [see 201.12.1.101 b) 3) and 201.12.1.102 b) 3)], shall either

1) be equipped with O_2 *monitoring equipment* for measurement of the inspiratory oxygen concentration that is integral to the *ventilator;* or

2) the instructions for use shall contain a statement to the effect that the *EMS ventilator* is to be equipped with O_2 *monitoring equipment* for measurement of the inspiratory oxygen concentration before being put into service.

b) Such O_2 *monitoring equipment* shall confrom with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

4) 201.12.1.102;

5) 201.12.1.103; and

6) 208.6.1.2.

c) Where the O_2 *monitoring equipment* is not an integral part of the *EMS ventilator*, the instructions for use shall include the following;

1) a statement to the effect that the *ventilator* is to be provided with O_2 *monitoring equipment* that conforms with ISO 80601-2-55:2018 before being put into service; and

2) information on where to connect the O_2 *monitoring equipment*.

d) If equipped and the intended *inspiratory volume* is <50 ml, the O_2 *monitoring equipment* shall, in addition, be equipped with an *alarm system* that includes a high oxygen level *alarm condition*.

e) The high oxygen level *alarm condition:*

1) shall be at least *medium priority*, unless

2) an *intelligent alarm system*, based on additional information, determines that the high oxygen level *alarm condition* is suppressed or its priority is changed.

NOTE A low oxygen level *alarm condition* is required by ISO 80601-2-55.

Check conformance by inspection of the instructions for use or application of the tests of ISO 80601-2-55:2018.

201.12.4.102 * Measurement of *airway pressure*

a) The *EMS ventilator* shall be equipped with *monitoring equipment* to measure the *airway pressure*.

b) The site of actual measurement:

1) may be anywhere in the *EMS ventilator breathing system;* but

2) the indicated value shall be referenced to the *patient-connection port*.

c) Under steady-state conditions, the indicated *airway pressure* shall be accurate to within ± (2 +(8 % of the actual reading)) hPa (± (2 +(8 % of the actual reading)) cmH_2O).

Check conformance by functional testing.

201.12.4.103 * Measurement of expired volume and low volume *alarm conditions*

a) An *EMS ventilator* should either:

1) be equipped with *monitoring equipment* for indicating the volume expired through the *patient-connection port;* or

2) if not so equipped, the instructions for use should include a statement to the effect that the *EMS ventilator* is to be equipped with *monitoring equipment* that conforms with this document before being put into service.

If equipped,

b) unless the expired volume *monitoring equipment* is an integral part of the *EMS ventilator*, information on where to connect the expired volume *monitoring equipment* shall be disclosed in the instructions for use.

c) the accuracy of measurement of expired volumes greater than 100 ml shall be within ±20 % of the actual volume expired through the *patient-connection port*).

d) the accuracy of expired volume *monitoring equipment* shall be disclosed in the instructions for use.

e) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

NOTE 1 The use of Oxygen 93 % can reduce the accuracy of measurement due to influence of other gases such as argon on flow measurement.

f) the expired volume *monitoring equipment* shall be equipped with an *alarm system* to indicate when

1) the low-expired volume *alarm limit* is reached; and

2) the high-expired volume *alarm limit* is reached.

g) The low-expired volume and the high-expired volume *alarm conditions*

1) shall be at least *medium priority,* unless

2) an *intelligent alarm system*, based on additional information, determines that

i) the low-expired volume or

ii) the high-expired volume *alarm condition*

is suppressed or its priority is changed.

h) The expired volume *monitoring equipment* may be equipped:

1) with an *alarm system* that starts with *low priority alarm conditions* to indicate when the expired volume reaches either *alarm limit;* and

2) if this state continues, escalates to *medium priority alarm conditions*.

i) The expired volume *alarm limits* may be:

1) pre-adjusted;

2) *responsible organization*-adjustable;

3) *operator*-adjustable;

4) *EMS ventilator*-adjustable; or

5) a combination of *operator*-adjustable and *EMS ventilator*-adjustable.

j) If the *alarm limits* are adjustable by the *EMS ventilator*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the instructions for use.

NOTE 2 Depending on the type of *ventilation-mode* being utilized, there can be more than one active *alarm limit*.

*Check conformance by functional testing using the test conditions described in * Table 201.104 and * Table 201.105 selecting the appropriate rows based on intended tidal volume and inspection of the instructions for use. Select and set up the worst-case VBS configuration indicated in the instructions for use.*

EXAMPLE Minimum or maximum VBS compliance.

For testing with a humidifier, repeat the tests at the minimum and maximum water levels (2 sets of tests for a humidifier).

201.12.4.104 * *Maximum limited pressure protection device*

a) A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* under both:

1) *normal condition*; and

2) *single fault condition*.

b) The *maximum limited pressure* shall not exceed the lower of:

1) 30 hPa (30 cmH_2O) more than the high-pressure *alarm limit*; or

2) 105 hPa (105 cmH_2O).

Check conformance by functional testing.

201.12.4.105 * High *airway pressure alarm condition* and *protection device*

a) The *EMS ventilator* shall be equipped with *monitoring equipment* with an *alarm system* to indicate when the high-pressure limit for *airway pressure* is reached.

b) The high *airway pressure alarm condition:*

1) shall be *high priority*; unless

2) an *intelligent alarm system*, based on additional information, determines that:

i) the high *airway pressure alarm condition* is suppressed; or

ii) its priority is changed.

c) The high *airway pressure alarm limit* may be:

1) independently adjustable;

2) connected to an adjustable pressure limitation; or

3) related to the set pressure of the *EMS ventilator*.

d) If the high *airway pressure alarm limit* is independently adjustable, it shall not be possible to set:

1) the *alarm limit* to a value less than that of the adjustable pressure limitation; and

2) the adjustable pressure limitation to a value more than that of the *alarm limit*.

e) Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm the setting of the high-pressure *alarm limit* to values exceeding the lower of:

1) 30 hPa (30 cmH_2O) more than the *operator*-set pressure; or

NOTE The *operator*-set pressure does not apply when by design the *ventilator* adjusts the *airway pressure* on a breath-by-breath basis.

2) 60 hPa (60 cmH_2O).

f) * *Patient*-generated transient pressure increases should not cause the high-pressure *alarm condition*.

EXAMPLE Transient pressure increase caused by the *patient* coughing.

g) The high *airway pressure alarm condition delay* shall not exceed 200 ms and the *ventilator* shall:

1) act to attempt to cause the pressure to start to decline within that duration; and;

2) act to prevent the pressure from continuing to rise.

h) * Whenever the high *airway pressure alarm condition* occurs, the *ventilator* shall, within no more than two *respiratory cycles* or 15 s, whichever is less, reduce the *airway pressure* to either:

1) the atmospheric pressure; or

2) the set *BAP* level.

i) During *single fault condition*, the *airway pressure* may fall below the set *BAP* level.

Check conformance by functional testing.

201.12.4.106 * Expiratory end-tidal CO_2 *monitoring equipment*

a) An *EMS ventilator* should either:

1) be equipped with CO_2 *monitoring equipment* for the measurement of the expiratory carbon dioxide concentration that is integral to the *ventilator*; or

2) the instructions for use should contain a statement to the effect that the *EMS ventilator* is to be equipped with CO_2 *monitoring equipment* for measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port)* before being put into service.

b) Such CO_2 *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

4) 201.12.1.102;

5) 201.12.1.103; and

6) for expired CO_2 concentration, 208.6.1.2.

c) Where the CO_2 *monitoring equipment* is not an integral part of the *ventilator*, the instructions for use should include the following:

1) a statement to the effect that the *ventilator* is to be provided with CO_2 *monitoring equipment* that conforms with ISO 80601-2-55:2018 before being put into service; and

2) information on where to connect the CO_2 *monitoring equipment*.

Check conformance by inspection.

201.12.4.107 Protection against inadvertent setting of high *airway pressure*

Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm any *airway pressure* settings exceeding 60 hPa (60 cmH_2O). See also 201.12.4.105 b) and 206.101 a) 7).

Check conformity by functional testing.

201.13 *Hazardous situations* and fault conditions for *ME equipment*

Clause 13 of the general standard applies, except as follows:

Addition:

201.13.2.101 Additional specific *single fault conditions*

An *EMS ventilator* shall be so designed and constructed that the following *single fault conditions* shall not cause an unacceptable *risk*:

a) * disruption of the gas delivery to the *patient-connection port* from the *EMS ventilator*;

b) * disruption of the gas flow pathway from the *patient-connection port* to the exhalation valve*;*

c) * when present, removal or failure of an *operator*-detachable *breathing system filter*; and

d) * disruption of a *functional connection* between parts of the *ventilator* or *ME system*.

EXAMPLE 1 Loss of communication between the *ventilator* and its remote (wired or wireless) control or monitoring module.

EXAMPLE 2 Loss of communication between the *ventilator* and its *distributed alarm system*.

EXAMPLE 3 Loss of communication between the *ventilator* and the means for generating remote *alarm signals*.

Check conformance by functional testing and inspection of risk management file.

201.13.102 Failure of one gas supply to an *EMS ventilator*

a) Following the failure of one gas supply connected to a *high-pressure input port*, an *EMS ventilator* shall maintain *normal use*.

b) The *EMS ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this gas-supply failure.

c) The gas supply failure *technical alarm condition*

1) shall be at least *low priority* if ventilation is maintained, unless

2) an *intelligent alarm system*, based on additional information, determines that the gas-supply-failure *technical alarm condition* is suppressed; or

3) shall be at least *medium priority* otherwise, unless

4) an *intelligent alarm system*, based on additional information, determines that the gas-supply-failure *technical alarm condition* is suppressed.

Check conformance by functional testing.

201.13.103 * Independence of ventilation control function and related *risk control* measures

a) A *single fault condition* shall not cause the simultaneous failure of:

1) a ventilation control function; and

2) the corresponding *protection device*.

b) A *single fault condition* shall not cause either:

1) a ventilation-control function and the corresponding *monitoring equipment*; or

2) a ventilation-control function and the corresponding *alarm system*

to fail in such a way that the loss of the ventilation control function is not detected.

Check conformance by inspection and functional testing.

201.14 *Programmable electrical medical systems (PEMS)*

Clause 14 of the general standard applies, except as follows:

Addition:

201.14.101 Software life cycle

a) The *programmable electronic subsystems* (*PESS*) of an *EMS ventilator* shall be developed with a design *process* conforming with IEC 62304:2006+AMD1:2015.

b) The ventilation control *software items* of the *EMS ventilator PESS* without an independent *risk control* measure external to the *PESS* shall be considered as software safety Class C.

Check conformance by inspection of the documentation required by IEC 62304:2006+AMD1:2015 for the software safety class (the requirements are found in 1.4 of IEC 62304:2006+AMD1:2015).

201.15 Construction of *ME equipment*

Clause 15 of the general standard applies, except as follows:

Addition:

201.15.3.5.101 * Additional requirements for rough handling

a) An *EMS ventilator* and its parts, including applicable *accessories* shall have adequate mechanical strength to withstand the mechanical stress caused by *normal use*, pushing and rough handling while operating.

b) For this test, the *EMS ventilator* and its parts, and applicable *accessories*, shall be mounted using the mounting *accessories* indicated in the *accompanying documents*.

If more than one mounting system is described in the *accompanying documents*, multiple tests are required.

NOTE An *EMS ventilator* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

c) During the following test, an *EMS ventilator* shall maintain *basic safety* and *essential performance*.

d) During this testing, volume and pressure *alarm condition alarm limits* shall be set to their least sensitive levels.

Check conformance by performing the following tests:

e) Broadband random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:

1) acceleration amplitude:

— *10 Hz to 100 Hz: 1 $(m/s^2)^2$/Hz;*

— *100 Hz to 200 Hz: –3 dB per octave;*

— *200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz;*

2) duration: 30 min per perpendicular axis (3 total).

201.15.4.1 Construction of connectors

Addition:

aa) *Operator*-detachable *VBS* connectors are exempt from this requirement.

201.15.101Mode of operation

An *EMS ventilator* shall be suitable for *continuous operation*.

Check conformance by inspection.

201.15.102 * Delivered oxygen concentration

a) An *EMS ventilator* shall provide at least two different settings for the inspiratory oxygen concentration.

b) An *EMS ventilator* shall be capable of delivering gas to the *patient* containing an O_2 concentration over the range of flowrates indicated in the instructions for use:

1) of at least 85 % volume fraction in one setting; and

2) of no greater than 65 % volume fraction in a second setting.

Check conformance by inspection of the instructions for use and functional testing.

201.15.103 *Accessory* self-check

a) An *EMS ventilator* should be equipped with means that allow the determination of whether or not the *VBS* resistance and compliance characteristics are outside the values necessary to maintain normal operation.

NOTE Additional requirements are found in 201.7.9.2.8.101.

b) This means may require *operator* action.

Check conformance by functional testing.

201.16 *ME systems*

Clause 16 of the general standard applies, except as follows:

Addition:

201.16.1.101 Additional general requirements for *ME systems*

Accessories connected to the *VBS* shall be considered to:

a) be part of the *EMS ventilator;* or

b) form an *ME system* with the *EMS ventilator*.

Check conformance by application of the relevant tests of this document and IEC 60601-1:2005+AMD1:2012.

201.16.3.101 Additional requirements for power supply

a) An *EMS ventilator*, which depends on an external gas source to supply energy for ventilation shall comprise an *ME system* with the external gas source.

b) A *portable* gas source

1) shall indicate

i) the gas source pressure or

ii) remaining gas source volume

2) indication of gas source pressure or remaining gas source volume shall be

i) visible from the intended *operator's position*; and

ii) *clearly legible* under the conditions of 6.1 of IEC 60601-1-12:2014.

Check conformance by inspection and the relevant tests of IEC 60601-1-12:2014.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

Clause 17 of the general standard applies.

Addition:

201.101 Gas connections

201.101.1 * Protection against reverse gas leakage

For an *EMS ventilator* with two or more *high-pressure input ports*,

a) means shall be provided to limit reverse gas leakage flowrate from *gas intake ports* into the supply system of the same gas to a flowrate less than 100 ml/min in *normal condition* or *single fault condition*.

b) means shall be provided to limit cross leakage from gas supplied through one *high-pressure input port* into the supply system of a different gas to less than 100 ml/h in *normal condition* or *single fault condition*.

Check conformance by functional testing.

201.101.2 Connection to a *high-pressure input port*

201.101.2.1 Connector

If an *operator*-detachable hose assembly is provided for connection between the *EMS ventilator* and either the *medical gas pipeline system* or a pressure regulator, it shall conform with ISO 5359:2014+AMD1:2017.

Check conformance by application of the tests of ISO 5359:2014+AMD1:2017.

201.101.2.2 * Filter

Each *high-pressure input port* shall be provided with a filter having a pore size less than or equal to 100 µm.

NOTE Depending on the sensitivity against particles of the components used in the *gas pathways* (e.g. flow sensors), to particles, filtration of smaller particles can be needed.

Check conformance by inspection.

201.101.3 *VBS* connectors

201.101.3.1 * General

Operator-detachable *VBS* connectors through which the main flow of gas to or from the *patient* passes in *normal condition*, excluding the *patient-connection port*:

a) shall be a 15 mm or a 22 mm connector conforming with ISO 5356-1:2015;

b) may be a 11,5 mm connector conforming with ISO 5356-1:2015 for a neonatal or paediatric use *VBS*; or

c) may be a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.3.2 Other named ports

201.101.3.2.1 *Patient-connection port*

The *patient-connection port* shall be one of the following:

a) a female 15 mm conical connector conforming with ISO 5356-1:2015;

b) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015.

201.101.3.2.2 *Gas output port* and *gas return port*

a) The *gas output port* and the *gas return port* shall be one of the following

   1) a male 22 mm conical connector conforming with ISO 5356-1:2015.

   2) a male 15 mm conical connector conforming with ISO 5356-1:2015.

   3) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.

   4) a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015.

b) Notwithstanding this requirement, an *EMS ventilator* only intended for *inspiratory volumes* of ≤300 ml, may be equipped with a *gas output port* and a *gas return port* using a male 11,5 mm conical connector conforming with ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015.

201.101.3.2.3 *Flow-direction-sensitive components*

Any *flow-direction-sensitive component* of the *VBS* detachable without the use of a *tool* shall be so designed that it cannot be fitted in such a way that it presents an unacceptable *risk* to the *patient*.

Check conformance by inspection of operator-detachable flow-direction-sensitive components and inspection of the risk management file.

201.101.3.2.4 * *Accessory* port

If provided, each *accessory* port shall:

a) conform with ISO 80369-1:2018;

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2[21] will meet this criterion.

b) be provided with a means to secure the *accessory* in position; and

c) be provided with a means to secure closure after removal of the *accessory*.

NOTE 2 This port connects to the *gas pathway* and is generally used for measuring pressure, sampling of gases or for introduction of therapeutic aerosols.

NOTE 3 For the purposes of this document, the temperature probe port specified in ISO 80601-2-74 is not considered an *accessory* port.

Check conformance by inspection.

201.101.3.2.5 Gas *exhaust port*

a) If a connector is provided for the gas *exhaust port*, it shall be a 30 mm connector conforming with ISO 5356-1:2015.

NOTE A 30-mm connector conforming with ISO 5356-1:2015 is suitable for connection to an anaesthesia gas scavenging system (AGSS) that conforms with ISO 80601-2-13[4].

b) An *EMS ventilator* shall be designed so that any provided gas *exhaust port* is not obstructed during use.

Check conformance by inspection and application of the tests of ISO 5356-1:2015.

201.102 Requirements for the *VBS* and *accessories*

201.102.1 * General

All *EMS ventilator breathing systems*, their parts and *accessories* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *EMS ventilator* or by another entity ("third-party manufacturer" or healthcare provider).

Check conformance by the tests of this document.

201.102.2 Labelling

a) The *accompanying document* provided with each *VBS,* its parts or *accessories*, conforming with 201.102.1, shall include at least the *model or type reference* of at least one compatible *EMS ventilator*.

b) Statements shall be included in the *accompanying documents* of each *EMS ventilator* breathing *system*, part or *accessory* to the effect that:

1) *ventilator breathing systems*, their parts and accessories are validated for use with specific ventilators;

2) incompatible parts can result in degraded performance; and

3) the responsible *organization* is responsible for ensuring the compatibility of the *ventilator* and all of the parts used to connect to the *patient* before use.

Check conformance by inspection of the accompanying document.

201.102.3 Breathing tubes

Breathing tubes, other than heated breathing tubes, intended for use in the *VBS* shall conform with clauses and subclauses of ISO 5367:2014:

a) 5.1;

b) 5.3.4;

c) Clause 6; and

d) Clause 7.

Check conformance by application of the tests of ISO 5367:2014.

201.102.4 * Water vapour management

201.102.4.1 * Humidification system

Any *humidifier*, including heated breathing tubes, either incorporated into the *EMS ventilator* or recommended for use with the *EMS ventilator*, shall conform with ISO 80601-2-74:2017.

Check conformance by application of the tests of ISO 80601-2-74:2017.

201.102.4.2 *Heat and moisture exchanger (HME)*

Any *heat and moisture exchanger*, either incorporated into the *VBS* or recommended for use with the *VBS*, shall conform with:

a) ISO 9360-1:2000; or

b) ISO 9360-2:2001.

Check conformance by application of the tests of ISO 9360-1:2000 or ISO 9360-2:2001.

201.102.5 *Breathing system filters*

Any *breathing system filter*, either incorporated into the *EMS ventilator* or recommended for use with the *EMS ventilator*, shall conform with the relevant requirements of:

a) ISO 23328-1:2003; and

b) ISO 23328-2:2002.

Check conformance by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.102.6 * Leakage from complete *VBS*

Unintended leakage from the *VBS* should not exceed:

a) 200 ml/min at 50 hPa (50 cmH_2O) for an *EMS ventilator* intended to provide a *tidal volume* greater than 300 ml; or

b) 100 ml/min at 40 hPa (40 cmH_2O) for an *EMS ventilator* intended to provide a *tidal volume* between 300 ml and 50 ml; or

c) 50 ml/min at 20 hPa (20 cmH_2O) for an *EMS ventilator* intended to provide a *tidal volume* less than 50 ml.

201.103 Spontaneous breathing during loss of power supply

a) A *protection device* shall be provided to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.

b) Under these conditions, the inspiratory and expiratory pressure drop measured at the *patient-connection port* with all recommended *accessories* in place shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

1) 30 l/min for an *EMS ventilator* intended to provide a *tidal volume,* $V_{tidal} \geq$ 300 ml;

2) 15 l/min for an *EMS ventilator* intended to provide a *tidal volume,* 300 ml ≥ $V_{tidal} \geq$ 50 ml;

3) 2,5 l/min for an *EMS ventilator* intended to provide a *tidal volume,* $V_{tidal} \leq$ 50 ml.

NOTE This requirement is intended to allow the *patient* to breathe spontaneously under compromised conditions.

Check conformance by functional testing and measurement of flow, pressure, and resistance at the patient-connection port with that combination of accessories indicated in the instructions for use which produces the highest pressure drop.

201.104 * Indication of duration of operation

a) The *EMS ventilator* should have means to indicate visually the cumulative hours of operation of the *EMS ventilator*, either:

1) automatically; or

2) by *operator* action.

b) The *EMS ventilator* should also have means to indicate visually:

1) the time since the last preventive maintenance; or

2) the time until the next recommended preventive maintenance.

Check conformance by inspection.

201.105 *Functional connection*

201.105.1 General

Basic safety and *essential performance* shall be maintained if connections to a *functional connection* of an *EMS ventilator* are:

a) disrupted; or

b) if the equipment connected to those parts fails.

Check conformance by functional testing.

201.105.2 * Connection to an electronic health record

An *EMS ventilator* should be equipped with a *functional connection* that permits data transmission from the *EMS ventilator* to an electronic health record. The data transmission should be capable of transmitting the information described in Annex BB.

201.105.3 * Connection to a *distributed alarm system*

An *EMS ventilator* should be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

201.106 Display loops

201.106.1 Pressure-volume loops

a) If an *EMS ventilator* is provided with the display of pressure-volume loops the graph shall use:

   1) *inspiratory volume* on the vertical axis; and

   2) *airway pressure* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Increases in *inspiratory volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

Check conformance by inspection.

201.106.2 Flow-volume loops

a) If an *EMS ventilator* is provided with the display of flow-volume loops, the graph shall use:

   1) flowrate on the vertical axis; and

   2) *inspiratory volume* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Gas flow to the *patient* (inspiratory flow) and increases in *inspiratory volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

e) The *EMS ventilator* may be provided with an additional optional display configuration for the flow-volume loop where gas flow from the *patient* (expiratory flow) is represented as a positive value.

Check conformance by inspection.

201.107 * Timed ventilatory pause

201.107.1 *Expiratory pause*

a) An *EMS ventilator* may be equipped with an *operator*-controlled means to pause the *EMS ventilator* in expiration.

b) If an *EMS ventilator* is equipped with a means to pause the *EMS ventilator* in expiration,

1) more than one *expiratory pause* function may be provided.

2) the maximum allowable duration of an *expiratory pause* shall be 60 s.

3) means may be provided to initiate the *expiratory pause* from a *functional connection*.

c) If a *ventilator* is equipped with a timed means to pause the *ventilator* in expiration,

1) the duration of the *expiratory pause* may be *operator*-configurable or *operator*-adjustable.

2) during the *expiratory pause*, any apnoea-related ventilatory *alarm condition* that would be caused by this *expiratory pause* shall be *audio paused* or *alarm paused* for the duration of the *expiratory pause*.

3) in addition to the requirements for *alarm signal* inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the *EMS ventilator* shall indicate the presence of the *expiratory pause* with at least an *information signal* or a *low priority alarm condition*.

NOTE 1 An *expiratory pause* can be equivalent to placing the *EMS ventilator* into standby mode or *CPAP* and automatically resuming ventilation after a pre-determined duration.

NOTE 2 The *expiratory pause* can be used to permit defibrillator ECG analysis with a deflated lung.

Check conformance by inspection and functional testing.

201.107.2 *Inspiratory pause*

a) An *EMS ventilator* may be equipped with an *operator*-controlled means to pause automatic ventilation at end-inspiration.

b) If an *EMS ventilator* is equipped with a means to pause the *EMS ventilator* in inspiration,

1) more than one *inspiratory pause* function may be provided.

2) the maximum duration of a non-adjustable *inspiratory pause* shall be 10 s.

3) the maximum allowable duration of an adjustable *inspiratory pause* shall be 40 s.

4) means may be provided to initiate the *inspiratory pause* from a *functional connection*.

c) If a *ventilator* is equipped with a timed means to pause the *ventilator* in inspiration,

1) the duration of the *inspiratory pause* may be non-adjustable, *responsible organization*-configurable or *operator*-adjustable.

2) the high-pressure *alarm condition* and *protection device* of 201.12.4.105 shall remain active during an *inspiratory pause*.

3) during the *inspiratory pause*, any:

   i) apnoea *alarm condition;* or

   ii) sustained *airway pressure alarm condition*

   that would be caused by this *inspiratory pause* should, for the duration of the *inspiratory pause*, be:

   iii) *audio paused*; or

   iv) *alarm paused*.

4) in addition to the requirements for *alarm signal* inactivation of 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the *ventilator* shall indicate the presence of the *inspiratory pause* with

   i) at least an *information signal;* or

   ii) a *low priority alarm condition*.

Check conformance by inspection and functional testing.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.4.3.1 * Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

— the *EMS ventilator* operated using the worst-case conditions and parameters of Table 201.104 or Table 201.105 selected by intended *tidal volume*, as appropriate. During this testing, set the volume and pressure *alarm limits* to their least sensitive levels.

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 * Additional general requirements

a) The following degradations, if associated with *basic safety* and *essential performance*, shall not be allowed:

   1) component failures;

   2) changes in programmable parameters or settings;

   3) reset to default settings;

   4) change of *ventilation-mode*;

      EXAMPLE Change of *inflation-type*, *ventilation-mode*, *Rate*, *I:E ratio*.

   5) initiation of an unintended operation;

   6) during the testing*:*

i) the *inspiratory volume* of individual *inflations* shall not deviate by more than 35 % of the *inspiratory volume* measured prior to the test;

ii) the *inspiratory volume* averaged over a one-minute interval shall not deviate by more than 25 % of the *inspiratory volume* measured prior to the test; and

iii) the *PEEP,* as measured in the test lung, following individual *inflations* averaged over a one-minute interval shall not deviate by more than 5 hPa from the *PEEP* measured prior to the test.

b) The *EMS ventilator* may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect *basic safety* or *essential performance*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013 applies except as follows:

Addition:

206.101 *Primary operating functions*

a) For an *EMS ventilator*, the following shall be considered *primary operating functions*:

1) setting the *operator*-adjustable controls from the intended *operator's position*;

i) setting *alarm limits*;

ii) inactivating *alarm signals*;

iii) switching between different *ventilation-modes* and *inflation-types*;

iv) setting ventilation control parameters;

EXAMPLE 1 *Tidal volume*, *Rate*, *BAP*, pressure support

2) observing and identifying the monitored ventilation parameters from the intended *operator's* position;

EXAMPLE 2 *Airway pressure* and expired volume

EXAMPLE 3 FiO_2 or $etCO_2$

3) * recognizing the presence of an *alarm condition* in the intended *use environments* from the intended *operator positions*;

EXAMPLE 4 The *operator* in the ambulance next to the *patient*.

EXAMPLE 5 The *operator* at the scene of an emergency situation with sirens and flashing emergency lights.

4) setting the *operator*-adjustable controls while a *portable EMS ventilator* is being carried;

i) setting *alarm limits*;

ii) inactivating *alarm signals*;

iii) switching between different *ventilation-modes* and *inflation-types*;

iv) setting ventilation control parameters;

EXAMPLE 6 *Tidal volume*, *Rate*, *BAP*, pressure support

5) observing and identifying the monitored ventilation parameters while the *portable EMS ventilator* is being carried;

EXAMPLE 7 *Airway pressure* and expired volume

6) configuring

i) the *VBS,* including

ii) connection of the detachable parts of the *VBS* to the *EMS ventilator*;

EXAMPLE 8 *HME*, tubing, *breathing system filter*

7) setting of the adjustable high-pressure *alarm limit* to values exceeding 60 hPa (60 cmH_2O);

8) setting of the *airway pressure* to values exceeding 60 hPa (60 cmH_2O);

9) connecting or disconnecting the *patient-connection port* of the *VBS* to the *patient* interface;

10) starting the *EMS ventilator* from power off;

11) turning off the *EMS ventilator*;

12) performing a basic pre-use functional check of the *EMS ventilator* including the *alarm system;* and

13) connecting the *EMS ventilator:*

i) to each gas supply indicated in the instructions for use including, if applicable

a) when attached in the ambulance; or

b) within its carrying case;

ii) to each power source indicated in the instructions for use, including, if applicable

a) when attached in the ambulance; or

b) within its carrying case; and

14) *processing* the *EMS ventilator* between *patient* uses.

EXAMPLE 9 Readying the *EMS ventilator* for use on the next *patient*. See also 201.11.6.6.

b) The following functions, if available, also shall be considered *primary operating functions*:

1) starting ventilation from standby;

2) activating standby;

3) attaching the *portable EMS ventilator* to an ambulance; and

4) connecting and disconnecting a *distributed alarm system*.

c) The following actions associated with ventilation also shall be considered *primary operating functions*:

NOTE For the purposes of this document, the following functions are considered *primary operating functions* even though they might not be performed on the *EMS ventilator's operator-equipment interface*.

1) adding medication to the gas flowing into the *patient*; and

EXAMPLE 10 Nebulisation or injecting fluids into an *accessory* port connection of the *VBS*

2) providing alternative means of ventilation as indicated in the instructions for use.

206.102 * Training

For an *EMS ventilator*, in the application of the requirements of IEC 62366-1:2015, 5.6 and 5.8, training shall be considered necessary for both:

a) the *operator;* and

b) the designee of the *responsible organization* (e.g. *service personnel* or *processing* personnel).

208 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems*

IEC 60601-1-8:2006+AMD1:2012 applies except as follows:

208.6.3.2.2.1 * 4 m (distant) visual *alarm signals*

Amendment (Add prior the first paragraph):

An *EMS ventilator* shall be equipped with 4 m (distant) visual *alarm signals*.

Addition:

208.6.8.3.101 Additional requirements for global indefinite *alarm signal* inactivation states

An *EMS ventilator* shall not be equipped with a means to initiate a global *alarm off* while connected to a *patient*.

Check conformance by functional testing.

208.6.8.4.101 * Additional requirements for termination of *alarm signal* inactivation

The duration of *audio paused* for the *alarm conditions* required by this document shall not exceed 120 s without *operator* intervention.

NOTE This permits an *operator* to deliberately extend the duration of *audio paused* by no more than 120 s following each direct action.

Check conformance by functional testing.

208.6.12.101 * Additional requirements for *alarm system* logging

a) Notwithstanding the requirements of IEC 60601-1-8:2006+AMD1:2012, the *EMS ventilator* should be equipped with an *alarm system* log with a capacity of at least 1 000 events for all:

1) *high priority alarm conditions*;

2) *medium priority alarm conditions;* and

3) *alarm signal* inactivation states.

b) If equipped with *alarm system* log, the *EMS ventilator* shall

1) not lose the contents of the *alarm system* log during a loss of power for less than 7 d unless deleted by *responsible organization* action.

2) not permit the clinical *operator* to erase the contents of the *alarm system* log.

c) In addition the *EMS ventilator* should provide a log to include, if applicable, at least the following events:

1) any change of *EMS ventilator* settings, including the value applied;

2) any change of *alarm settings,* including the value applied;

3) change of *patient*, including the *patient* attributes;

4) power supply source change, including the source utilized; and

5) results of the pre-use check.

Check conformance by inspection and functional testing.

212 Requirements for *medical electrical equipment* and *medical electrical systems* intended for use in the *emergency medical services environment*

IEC 60601-1-12:2014 applies except as follows:

212.4.2.2.1 Continuous operating conditions

Amendment (replace the first dash with):

aa) where *permanently installed* or *fixed*, a temperature range of 0 °C to +40 °C; or

bb) where not *permanently installed* or *fixed*, a temperature range of -10 °C to +40 °C.

212.8.1.1 * Ingress of water or particulate matter into *ME equipment*

Amendment (in the first sentence of the first paragraph):

Replace 'IP33' with 'IP34'.

212.8.2 Additional requirements for interruption of the power supply to *ME equipment* and *ME system*

Amendment (replace the paragraph following note 2 with):

aa) The *EMS ventilator* shall be equipped with a means to determine the power source that is currently powering the *EMS ventilator.*

Amendment (replace the last paragraph with):

bb) An *EMS ventilator* shall be equipped with an *alarm system* that detects

1) a *technical alarm condition* or presents an *information signal* to indicate a switchover to an *internal electrical power source*.

i) The switchover to an *internal electrical power source alarm condition* shall be at least a *low priority*.

2) a *technical alarm condition* to indicate when the *internal electrical power source* nears depletion, prior to the loss of all power.

i) The *internal electrical power source* nears depletion *alarm condition* shall be at least a *medium priority.*

ii) As the *internal electrical power source* nears depletion, at least 5 min prior to depletion, the *internal electrical power source* nears depletion *technical alarm condition* shall escalate to *high priority*.

3) a *technical alarm condition* to indicate a complete loss of all power sources.

i) The duration of the *alarm signals* for this *technical alarm condition* shall be at least 120 s.

212.8.3 Additional requirements for *internal electrical power source* for *ME equipment*

In the first paragraph, replace '20 min' with '2 h'.

Amendment (add before the compliance check):

aa) The instructions for use shall describe behaviour of recharging of the *internal electrical power source* while the *EMS ventilator* is connected to each *supply mains*.

212.10.1.2 Requirements for mechanical strength for *fixed* or *permanently installed ME equipment* intended for use in a road ambulance

Amendment (replace the second paragraph with the following):

aa) While performing the tests of IEC 60601-1-12:2014, 10.1.2 a), the *EMS ventilator:*

1) shall be operating and maintain *basic safety* and *essential performance*; and

2) may exhibit the temporary degradation of performance of *inspiratory volume* or *PEEP* for a single *inflation*.

bb) While performing the test of IEC 60601-1-12:2014, 10.1.2 b), the *EMS ventilator* shall be operating. After this test, the *EMS ventilator* shall maintain *basic safety* and *essential performance.*

212.10.1.3 * Requirements for mechanical strength for *transportable ME equipment*

Amendment (replace the second paragraph with the following):

aa) While performing the tests of IEC 60601-1-12:2014, 10.1.3 a) and IEC 60601-1-12:2014, 10.1.3 c), the *EMS ventilator:*

1) shall be operating and maintain *basic safety* and *essential performance*; and

2) may exhibit the temporary degradation of performance of *inspiratory volume* or *PEEP* for a single *inflation*.

cc) While performing the test of IEC 60601-1-12:2014, 10.1.3 b), the *EMS ventilator* shall be operating. After this test, the *EMS ventilator* shall maintain *basic safety* and *essential performance.*

In c) replace 'for mass >1 kg and ≤10 kg, 0,5 m' and for 'mass >10 kg and ≤50 kg, 0,25 m' with 'for mass >1 kg and ≤50 kg, 0,75 m'.

212.10.1.4 Requirements for mechanical strength for *ME equipment* intended for airborne use

Amendment (replace the second paragraph with the following):

While performing the tests of IEC 60601-1-12:2014, 10.1.4, the *EMS ventilator* shall be operating and maintaining *basic safety* and *essential performance*.

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for *ME equipment* and *ME systems*

Annex C of the general standard applies, except as follows:

Addition:

201.C.1 Marking on the outside of *ME equipment*, *ME systems* or their parts

Additional requirements for marking on the outside of an *EMS ventilator*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of an *EMS ventilator*, its parts or *accessories*

Description of marking	Subclause
Any special storage or handling instructions	201.7.2.101 c)1)
Any warnings or precautions relevant to the immediate operation of the *ventilator*	201.7.2.101 c)2)
Arrow indicating the direction of the flow for *flow-direction-sensitive components*, if applicable	201.7.2.101 d)2)
Arrow indicating the intended direction of gas flow for the *gas output port* and the *gas return port*	201.7.2.101 c)3)
Containing natural rubber latex, if applicable	201.7.2.13.101 a)
For a sampling gas inlet, either with the text "Gas sample" or the Symbol ISO 7000-0794	201.7.2.101 d)5)
For a *ventilator* intended to be used in the magnetic resonance (MR) environment, Symbol 7.3.1-1 (Table 201.D.2.101, symbol 9) or Symbol 7.3.1-2 (Table 201.D.2.101, symbol 10) of IEC 62570:2014 for an 'MR Safe' *ventilator*	201.7.2.101 i)
For a *ventilator* intended to be used in the magnetic resonance (MR) environment, Symbol 7.3.2 (Table 201.D.2.101, symbol 11) of IEC 62570:2014 for an 'MR Conditional' *ventilator*	201.7.2.101 bb)ii)
For *accessories* supplied separately, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.2.4.101 a)2)
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101 a)1)
For each *VBS*, part and *accessory*, contains phthalates or other substances, if applicable	201.11.7 cc)1)
For oxygen gas inputs, the *rated* range of oxygen concentration	201.7.2.18 cc)
For packaging of breathing attachments, containing natural rubber latex, if applicable	201.7.2.17.101 a)3)
For packaging of breathing attachments, description of the contents	201.7.2.17.101 a)1)
For packaging of breathing attachments, identification reference to the batch, type or serial number	201.7.2.17.101 a)2)
For the packaging of each *VBS*, part and *accessory*, contains phthalates or other substances, if applicable	201.11.7 cc)2)
Gas name or chemical symbol for any gas-specific inputs	201.7.2.18 aa)
Gas-specific colour coding for any gas-specific inputs, if applicable	201.7.2.18 dd)
Indication of the date after which the *ME equipment*, part or *accessory* should not be used, if applicable	201.7.2.101 d)3)
Mandatory action *safety sign*: follow instructions for use	201.7.2.3

Description of marking	Subclause
Quantitative numeric indications of parameters and settings with the units of measurement	201.7.4.3
Rated range of gas pressure	201.7.2.18 bb)
Start-up *procedure* that is intended to be performed prior to use	201.7.2.101 a)
Warning not to obstruct the *gas intake port* , if applicable	201.7.2.101 d)4)

201.C.2 *Accompanying documents*, general

Additional requirements for general information to be included in the *accompanying documents* of an *EMS ventilator* or its parts are found in Table 201.C.102.

Table 201.C.102 — *Accompanying documents*, general

Description of requirement	Subclause
For each *VBS* and *accessory*, the *model or type reference* of at least one compatible *ventilator*	201.102.2 a)
For each *VBS*, part and *accessory*, a statement to the effect that *ventilator breathing systems*, their parts and *accessories* are validated for use with specific *ventilators*	201.102.2 b)1)
For each *VBS*, part and *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b)2)
For each *VBS*, part and *accessory*, a statement to the effect that the *responsible organization* is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the *patient* before use	201.102.2 b)3)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 bb)i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 bb)ii)
Name or trade name and address of the *manufacturer* and where the *manufacturer* does not have an address within the locale an authorized representative	201.7.9.1
Units of measure for volumes, flows and leakages	201.7.4.3
Ventilator is a high-flow device warning, if applicable	201.4.11.101.2 bb)iii)

201.C.3 *Accompanying documents*, instructions for use

Additional requirements for information to be included in the instructions for use of an *EMS ventilator* or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Accuracy of expired volume *monitoring equipment*, if so equipped	201.12.4.103 d)
Accuracy of the *inspiratory volume monitoring equipment*, if so equipped	201.12.1.104
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.9.2.14.101 b)2)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101 d)
Any special storage, handling, or operating instructions	201.7.9.2.9.101 f)
A-weighted sound power level emitted by the *ventilator*	201.9.6.2.101 b)2)
A-weighted sound pressure level emitted by the *ventilator*	201.9.6.2.101 a)2)
Behaviour of recharging of the *internal electrical power source* while the *EMS ventilator* is connected to each *supply mains*	212.8.3 aa)

Description of requirement	Subclause
Conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101 c)
Cross reference between the *manufacturer*-specific naming of the *ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme of ISO 19223	201.7.9.2.16.101 g)
Description of how to connect and test the connection of a *distributed alarm system*, if provided	201.7.9.2.9.101 e)
Description of the algorithm that determines the *alarm limit* values of expired volume *monitoring equipment*, if so equipped	201.12.4.103 j)
Disclosure of any restrictions on the placing of components within the *ventilator breathing system,* if applicable	201.7.9.2.14.101 b)1)
For a *ventilator*, its parts or *accessories* intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *ventilator*, its parts or *accessories* would be reused	201.7.9.2.1.101 a)
For *accessories* supplied separately where marking the *accessory* is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101 b)
For *accessories* supplied separately where marking the *accessory* is not practicable, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.2.4.101 b)
For devices that contain phthalates or other substances for children or treatment of pregnant or nursing women, for each *VBS*, part and *accessory*, information on *residual risks*	201.11.7 ff)1)
For devices that contain phthalates or other substances for children or treatment of pregnant or nursing women, for each *VBS*, part and *accessory*, on appropriate precautionary measures, if applicable	201.11.7 ff)2)
Information on how to connect O_2 *monitoring equipment*, unless such equipment is an integral part of the *ventilator*	201.12.4.101 c)
Information on how to connect the expired volume *monitoring equipment*, if not so equipped	201.12.4.103 b)
Intended range of *inspiratory volume*	201.7.9.2.1.101 b)
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value for a pressure-controlled *inflation* in *normal condition*	201.12.1.102 b)1)
Maximum error of the *inspiratory volume* in relation to the set value for a *volume-control inflation* in *normal condition*	201.12.1.101 b)1)
Maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value for a *volume-control inflation* in *normal condition*, if provided	201.12.1.101 b)3)
Maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value for a pressure-controlled *inflation* in *normal condition*, if provided	201.12.1.102 b)3)
Maximum error of the *PEEP* in relation to the set *BAP* for a pressure-controlled *inflation* in *normal condition*	201.12.1.102 b)2)
Maximum error of the *PEEP* in relation to the set *BAP* for a *volume-control inflation* in *normal condition*	201.12.1.101 b)2)
Maximum limited pressure	201.7.9.2.9.101 a)1)
Means by which the *maximum working pressure* is ensured	201.7.9.2.9.101 a)3)
Method by which all of the *alarm signals* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 b)
Performance and acceptance criteria for other *inflation-types*, if so equipped	201 f).12.1.103
Pre-use checklist	201.7.9.2.8.101 a)

Description of requirement	Subclause
Processing procedure instructions for the *ventilator* and its *accessories*	201.11.6.6 cc)2)
Rated range of expiratory *gas pathway* resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)2)
Rated range of inspiratory *gas pathway* resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)1)
Rated range of *VBS* compliance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)3)
Rated range to which the *maximum working pressure* can be set, if adjustable	201.7.9.2.9.101 a)2)
Statement that *airway pressure* can be subatmospheric during the *expiratory phase* for a *ventilator* that can generate subatmospheric pressure in the *expiratory phase*, if applicable	201.7.9.2.9.101 a)
Statement to the effect that antistatic or electrically conductive hoses or tubing are not be used in the *ventilator breathing system*	201.7.9.2.14.101 a)
Statement to the effect that the *ventilator* is to be equipped with O_2 *monitoring equipment* for the measurement of inspiratory oxygen concentration before being put into service, if not so equipped	201.12.4.101 a)2)
Statement to the effect that the *ventilator* is to be equipped with *monitoring equipment* for indicating expired volume at the *patient-connection port* before being put into service, if not so equipped	201.12.4.103 a)2)
Subatmospheric pressure limit at the *patient-connection port*, for *ventilators* that can generate subatmospheric pressure in the *expiratory phase*	201.7.9.2.9.101 a)
Summary of effects of respiratory rate on end-tidal gas reading accuracy	201.7.9.2.9.101 d)
Warning statement to the effect that do not add any attachments or *accessories* to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health	201.7.9.2.2.101 d)
Warning statement to the effect that do not use the ventilator in explosive environments. Such use might cause an explosion	201.7.9.2.2.101 h)
Warning statement to the effect that nebulisation or humidification can increase the resistance of breathing system filters and that the operator needs to monitor the breathing system filter frequently for increased resistance and blockage	201.7.9.2.2.101 e)
Warning statement to the effect that the ventilator accuracy can be affected by the gas added by use of a nebuliser, if applicable	201.7.9.2.2.101 g)
Warning statement to the effect that the ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury	201.7.9.2.2.101 a)
Warning statement to the effect that the ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected, including applicable examples	201.7.9.2.2.101 b)
Warning statement to the effect that the *ventilator* shall not be used in a hyperbaric chamber, if applicable	201.7.9.2.2.101 f)
Warning statement to the effect that, always have immediate access to alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or additional deterioration of health	201.7.9.2.2.101 c)
Which portions of the *gas pathways* through the *ventilator* can become contaminated with body fluids or by contaminates carried by expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12 aa)

201.C.4 *Accompanying documents*, technical description

Additional requirements for information to be included in the technical description of an *EMS ventilator* or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document	201.7.9.3.101 a)
Description of the method used to calculate end-tidal gas readings, if applicable	201.7.9.3.101 f)
Description of which of the *alarm system* checks are performed automatically	201.7.9.3.101 b)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3 b)
Essential technical characteristics of each recommended *breathing system filter*, if applicable	201.7.9.3.1.101 e)
Outside dimensions and mass of the *EMS ventilator*	201.7.9.3.1.101 d)
Pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the instructions for use	201.7.9.3.1.101 b)
Summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*	201.7.9.3.1.101 c)
Technical details of the means for securing the *ventilator* to avoid unwanted lateral movement	201.9.4.3.101 f)

Annex D
(informative)

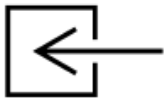
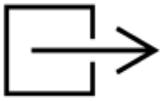
Symbols on marking

Annex D of the general standard applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1		IEC 60878:2015[22] ISO 7000-2607 Symbol 5.1.4 ISO 15223-1:2016	Use by date On packaging. To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging. The expiration date can be a year, year and month, or year, month, day. The date shall be shown adjacent to the symbol. The date may for example be given as follows: 1997-06-12. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. For some medical devices (e.g. in vitro diagnostics), this date is only valid when the medical device is unopened.
2		IEC 60878:2015[22] ISO 7000-2492 Symbol 5.1.5 ISO 15223-1:2016	Batch code To identify the *manufacturer's* batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
3		IEC 60878:2015[22] ISO 7000-2493 Symbol 5.1.6 ISO 15223-1:2016	Catalogue number To identify the *manufacturer's* catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
4		IEC 60878:2015[22] ISO 7000-2498 Symbol 5.1.7 ISO 15223-1:2016	Serial number To identify the *manufacturer's* serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
5		IEC 60878:2015[22] ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:2016	Contains or presence of [natural rubber latex] On medical devices: to indicate that the equipment contains the identified product or substance.

No	Symbol	Reference	Title and description
6		IEC 60878:2015[22] ISO 7000-0794	Input; entrance To identify an entrance, for example exhaust gas entry for measurement (for example of CO_2 value). For electrical (signal) input use symbol IEC 60417-5034.
7		IEC 60878:2015[22] ISO 7000-0795	Output; exit To identify an exit, for example of an hydraulic pump. For electrical (signal) output use symbol IEC 60417-5035.
8		IEC 60878:2015[22] ISO 7000-2725 EN 15986:2011	Contains or presence of [XXX] On medical devices: to indicate that the equipment contains the identified product or substance. Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.
9		IEC 60878:2015[22] Symbol 7.3.1-1 IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. When colour reproduction is not practical, the symbol may be printed in black and white. The use of the coloured icon is strongly encouraged for the added visibility and information provided by the colour.
10		IEC 60878:2015[22] Symbol 7.3.1-2 IEC 62570:2014	MR Safe Alternative graphical symbol representation. Same meaning as IEC 62570-7.3.1-1.
11		IEC 60878:2015 [22] Symbol 7.3.2 IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. The MR Conditional symbol may be supplemented by supplementary marking that describes the conditions for which the item has been demonstrated to be MR Conditional.

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

Subclause 201.1.1 — Scope

ISO 80601-2-84 *ventilators* are not considered a *physiologic closed-loop control system* due to the fact that parameters monitored during delivery of respiratory gases that are also used to control the delivery of these gases are exclusively physical parameters of the delivered gases. Consequently, these parameters are considered equipment variables as specified in IEC 60601-1-10.

A pressure-controlled *ventilator* that uses the breathing system pressure as a feedback to control breathing system pressure is a *closed-loop control system*, but not a *physiologic closed-loop control system*. The breathing system pressure is considered both a 'variable' influenced by the *patient* physical conditions and at the same time a 'feedback variable', but it is not a quantity or condition measured from the *patient's* physiology.

The *patient* by its physical condition is a disturbance on the closed loop system but the *ventilator* does not adjust the ventilation therapy settings based on measurement of these *patient* parameters.

The requirements of this document do not require the *ventilator* to adjust ventilation delivery parameters based on the detection in the change of physiological conditions of the *patient*. All automatic adjustments of *ventilator* equipment parameters or generated *alarm conditions* are only based on the measurement of physical variables related to the delivery of breathing gas to the *patient-connection port*. In this sense the *ventilator* ends at the *patient-connection port*, (i.e. has no direct contact to the physiological parameters of the *patient*) and a change in the *patient's* physiological conditions is a disturbance to the *ventilator's* control system that does not act to control the physiological change but continues to control the physical variable(s) to their original objectives.

Ventilators create *alarm conditions* when detecting faults in the delivery of breathing gases to the *patient-connection port* but do not adjust therapy setting of the *ventilator*.

The following are examples of medical devices that are considered *physiologic closed-loop control system*.

— Insulin infusion pump that adjust the rate of insulin infusion to the *patient* based on the measurement of blood glucose. The physiological feedback mechanism is a blood glucose level monitored by the device.

— External pacemaker that adjusts the pace rate based on the measurement of the cardiac output value. The physiological feedback mechanism is the value detected by the cardiac output monitor.

Unlike a *ventilator*, these devices titrate the *patient* based on the measured physiological parameter. A *ventilator* will not titrate but will either stop ventilation or generate an *alarm condition*.

Subclause 201.4.3.101 — Additional requirements for *essential performance*

The modern *EMS ventilator* with an active exhalation valve has differing *ventilation modes* that can consist of multiple *inflation-types*. This is necessary as *patient* response to ventilation is unpredictable. *Patient*-initiated breaths or *inflations* where the inspiration is terminated by the *patient* can have characteristics that are different from those that have been set by the *operator*. *Essential performance* as "ventilation within the *alarm limits* set by the *operator*" is inclusive of those *inflations* that the *patient* modifies outside of the ventilatory parameters set by the *operator*, but still within the *alarm limits* which are considered safe by the *operator*.

It is expected that the *operator* will set appropriate *alarm limits* which thereby define the *essential performance* for a particular *patient*.

The distributed *essential performance* criteria captured in Table 201.101 have been identified by the committees as the minimum clinical performance necessary to reduce the possibility of exposing the *patient* to unacceptable *risk*. Conformance criteria for some of the clauses within IEC 60601-1, this document and the other applicable collateral standards include "maintain *essential performance*". The committees have recognized the difficulty in confirming that all aspects of *essential performance* are maintained when completing longer duration testing.

Footnote a to Table 201.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document. It is intended to provide criteria that can be used to easily verify that *essential performance* has been maintained. Although the degradation of performance detailed in 202.8.1.101 are associated with *immunity* testing, the same criteria are intended to be used when the conformance criteria from any other clause or subclause require confirmation that *essential performance* is or has been maintained.

Those aspects of *essential performance* that cannot be reasonably linked to the conformance criteria within 202.8.1.101 need to be confirmed via other means. However one need only confirm that the specific requirements indicated in 202.8.1.101 that are likely to have an impact on specific clinical performance are maintained after testing.

Subclause 201.4.6 — *ME equipment* or *ME system* parts that contact the *patient*

Since much of the *VBS* is likely to be draped over or around the *patient*, it is likely to come into direct contact with the *patient* during *normal use*. Also of concern are electrical *hazards* should any circuitry be incorporated into the *VBS*. By ensuring that the *gas pathways* of the *VBS* and its parts or *accessories* are subject to the requirements for *applied parts*, these issues are addressed by the requirements already in the general standard.

Subclause 201.4.11.101 — Additional requirements for pressurized gas input

An *EMS ventilator* designed to be connected to a pressurised gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures, but these pressures can only be maintained if the *EMS ventilator* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that an *EMS ventilator* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurised gas supply.

Pressurised medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant standards, supply medical gasses to gas-specific terminal outlets at a pressure that is within an internationally agreed-upon pressure range of 280 kPa to 600 kPa under *normal condition*. It is expected that *EMS ventilators* should operate to their declared specification with any supply pressure within this range.

In the case of a pressure regulator failure the gas supply pressure could rise to the pressure regulator's supply pressure — which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered *ME equipment* should be designed so as not to present an unacceptable *risk* if its supply pressure rises up to this value.

EMS ventilators with maximum *rated* input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum *rated* input pressure.

Under the *single fault condition* that the supply pressure of any one gas drops below 280 kPa under steady-state conditions, it is understood that an *EMS ventilator* cannot be expected to continue to operate on this gas. However, it is required that in this case the *EMS ventilator* should detect the unacceptable low pressure, produce an *alarm signal* and also, in the case of two pressurised gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the *EMS ventilator*. This requirement is stated in subclause 201.13.102.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems* supplying compressed medical gases through gas-specific terminal outlets are designed so that they can maintain this pressure at the input of gas-powered devices whilst supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline. Account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a 'diversity factor'; a factor agreed between the supplier and *responsible organization* to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flow of 60 l/min to the required proportion of terminal outlets. However, if the flow demand from many adjacent *ventilators* exceeds 60 l/min there is an increased possibility that the *ventilator* input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a *patient*-demand system can result in a *ventilator* requiring transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimise pressure drop, such transient demands can generally be accommodated from the gas stored locally within the pipe work of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the inlet of the *ventilator* to below 280 kPa, due to transient flows in excess of 200 l/min (over 3 s), but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their *ventilator* when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulators conforming to ISO 10524-1.

Ventilators that can draw greater average or transient flows during *intended use* are permitted, but their *accompanying documents* are required to disclose those flows and warn of the need for a different diversity factor.

The average flow of 60 l/min is greater than the test flow used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The committee responsible for *medical gas pipeline systems* standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of standards for *medical gas pipeline systems* and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other standards for supply systems for medical gases permit the fitting of gas-specific terminal outlets to spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101 — Additional requirements for general requirements for testing of *ME equipment*

After due consideration, the committees decided that where this document specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end value of both ranges should be applicable to both ranges. This means that a *manufacturer* is free to use a round number end value (e.g. 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to satisfy also the test requirements of the adjacent range. This permits, for example, one *EMS ventilator* to have a declared range *inspiratory volume* of 300 ml to 1000 ml and another 100 ml to 300 ml, with each *EMS ventilator* only being required to be tested for the conditions specified for ≥300 ml or ≤300 ml respectively.

Subclause 201.5.101.2 — Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally, one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~ 37 °C) irrespective of the temperature of the gas delivered by an *EMS ventilator*. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurised gas to medical equipment, including *EMS ventilators*, follow engineering conventions and specify gas quantities and flow rates at *STPD* conditions. This practice is followed in this document for all requirements concerning gas input.

However, *EMS ventilators* conforming with this document are likely to be inflating the *patient's* lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from an *EMS ventilator*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *EMS ventilators*, it is essential that the information for all *EMS ventilators* is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, *BTPS* is the appropriate set of reference conditions to use.

In *EMS ventilators* a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore the necessary corrections depend on

the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

The necessary corrections also depend on the location of the flow transducer in the *VBS*. The humidity of the gas can be zero when the transducer measures the inspired flow inside the *EMS ventilator*. When, however, the flow transducer is located at the Y-piece, the relative humidity can be anything up to 100 %. When a *heat and moisture exchanger* is used for humidification, the output of the flow transducer depends on whether it is located distal or proximal to the *heat and moisture exchanger*. With a blower- or compressor-based *EMS ventilator* that uses ambient air, the humidity of the drawn-in air can be unknown to the *EMS ventilator*. All these effects together will inevitably introduce some errors in the conversion of the measured flow signal to *BTPS* reference conditions. However, these errors are only in the range of several percent. For *inspiratory volumes* greater than 50 ml, the committee came to the conclusion that the permitted inaccuracy of the measurement of ±(4 +(15 %)) ml is sufficiently wide and includes the inaccuracy of the flow transducer and the inaccuracy of the conversion to *BTPS* conditions. However, it remains the responsibility of the *manufacturer* to verify that the accuracy requirements of 201.12.1 and 201.12.4.103 are met.

Subclause 201.5.101.3 — *EMS ventilator* testing errors

When testing *EMS ventilator* performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognise the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 % then the test acceptance criterion is ±7 %. If a third party is testing to this document, they also need to include measurement uncertainty in their testing. If they subsequently obtain an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

If a third-party tester is testing to this document, they also need to include measurement uncertainty into their testing. If they subsequently obtain an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide this information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.2.3 — Consult *accompanying documents*

The committee agreed that following the instructions for use is a mandatory action for the safe operation of an *EMS ventilator*.

Subclause 201.7.2.101 — Additional requirements for marking on the outside of *ME equipment* or *ME equipment* parts

Although the intended *user group* for an *EMS ventilator* is primarily paramedical service first responders and emergency care physicians, who are routinely trained in the use of their

equipment, their use might not be on a frequent basis. The committees consider that it is important that the *operator* has immediate access to those instructions necessary to place the *EMS ventilator* into use.

This can be in the form of written or illustrated instructions for use:

— attached to the *EMS ventilator*;

— in the instructions for use;

— provided via a graphical *user interface* on the *EMS ventilator*; or

— by other means.

One possible example (although not currently implemented on any *EMS ventilator* known to the committees) would be to provide oral prompts; in the same fashion as provided by public access AEDs (automated external defibrillators). These use a combination of oral prompts and illuminated controls to guide a *operator* through a life-saving medical *procedure*.

The requirement for legibility in clause 7.2 of the general standard would be deemed to be met if the instructions can be interpreted correctly by the *operator*, whether provided in visual or other format.

Subclause 201.7.4.2 — Control devices

See also rationale for 201.15.102.

Many *EMS ventilators* are designed to operate from one single high-pressure oxygen source, and use a venturi injector to entrain air in order to provide one or more 'lower oxygen' settings, in addition to providing ventilation with pure oxygen. This design is often used in *EMS ventilators* intended for first responder applications.

EMS ventilators according to this design typically do not control oxygen concentration to a specified tolerance.

Because of the physical characteristic of the venturi principle, the oxygen concentration depends significantly on the inspiratory flowrate and the mean *airway pressure*.

Marking an *EMS ventilators* utilizing the venturi principle with a quantitative concentration value (such as FiO_2 = 0,40, or 40 %) would be potentially misleading owing to the wide tolerance that would apply.

Subclause 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

c)

In case of a severe *ventilator* failure, the *ventilator* stops ventilating the *patient*. There is no back-up mechanism for an alternative means of ventilation integrated in the *ventilator*; a *ventilator* is not required to be functional under *single fault condition*. To keep the time for a possible interruption of the ventilation of the *patient* as short as possible, an alternative means of ventilation has always to be available close to the *ventilator*.

d)

Additional attachments or other components or subassemblies increase the resistance and compliance of the *VBS*. The additional flow of a pneumatic nebuliser or the sampling flow of a diverting gas monitor could have a negative impact on the accuracy of the measurement of the flowrates and oxygen concentration.

e)

The functionality of *breathing system filters* is affected by a number of aspects of structure, properties and local environment.

At the most basic, a *BSF* is designed to be a filter that removes particles suspended in gas, i.e. a "dry aerosol". The particles primarily targeted in the *VBS* are bacteria or virus particles (although other particles would be subject to retention). The filtering material ("medium") is composed of a matrix of solid material with open passageways to allow gas flow. The passageways in such gas filters are relatively large compared to the bacteria and virus particles that are to be removed. The spatial arrangement of the solid part of the filter medium versus the open spaces in the medium brings the particles in proximity to the surfaces of the medium, where physical forces (electrostatic attraction and Van der Waals forces) attract and bind the particles within the matrix, removing them from the gas flow.

In the practical situation of anaesthesia or respiratory care therapy, environmental factors related to the *patient*, or the therapy can alter the performance of the *BSF* from that which would occur in the simple flow of air with suspended microorganisms though the *BSF*.

One major factor is the presence, phase and amount of moisture present in the airflow.

When there is low humidity in the air (gaseous phase moisture) the gaseous water molecules will generally pass though the filter medium without effect. If there is a sufficiently high relative humidity, some *BSFs* can adsorb or absorb part of this humidity.

If the moisture exists as a liquid aerosol, the water droplets can also be retained by the filter.

The properties of a filter medium that govern the degree to which this interaction with water takes place is its relative affinity for water. A medium which readily attracts water is termed "hydrophilic" and a medium which repels water is termed "hydrophobic". These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

Another example of liquid phase water can be termed "bulk water". An example of this is the collected condensate that occurs in the expiratory limb of the *VBS*. Depending on the management of the circuit, and the positioning of the *BSF*, this bulk water can actually completely cover and occlude the filter. If a sufficient pressure is applied, the liquid water can be forced though the pores of the filter medium. This requires relatively low pressure for a hydrophilic filter and relatively high pressure for a hydrophobic filter.

The practical consequences of the latter scenario is that if liquid is forced though a hydrophilic *BSF*, gas flow blockage can be relieved, but any microorganisms removed by the filter can be carried past the filter with the liquid stream. In the case of a hydrophobic filter, the pressure in the *VBS* is usually not sufficient to force liquid though the medium, so the microbial retention is not compromised. Airflow occlusion persists, however, until steps are taken to remove the bulk water.

In addition, there can be a temporal aspect to the properties of relative hydrophilicity or hydrophobicity whereby prolonged exposure to water alters these properties during the *expected*

service life of the *BSF*. A *BSF* is typically labelled with an *expected service life*, in hours or days, that reflects its ability to perform to its labelled specifications in the clinical environment.

It should be obvious that the potential influence of water on performance differs in anaesthesia and respiratory care applications, although many, if not most, *BSFs* are indicated for use in both applications.

Additional effects on *BSF* functionality can be caused by the introduction of substances other than water or gas into the device. Such substances can originate from the *patient* (e.g. sputum, exudates, blood, vomitus) or substances introduced by the *operator* into the *VBS* (e.g. gross amounts of medications intended to be nebulised for administration though the *VBS*).

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at *ventilator* or physiologic pressures. In the case of nebulised medications, the type of nebuliser, and its operating parameters are variables that affect the likelihood or magnitude of significantly increased *BSF* flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during *operator* or *patient* manipulation of the *VBS* has been implicated as a source of acute *BSF* blockage.

The cause of increased flow resistance in a *BSF* can be gross blockage of the medium passages, or the effects of surfactant properties of the substances introduced into the *BSF* upon the hydrophobicity of the filter medium. It should be noted that medications indicated for nebulisation can contain surfactant materials that are not identified in the medications' labelling with respect to their presence or their quantity, and these can change without notice for a given medication. The effect of these substances upon flow resistance differs among individual models and brands of *BSFs*.

The *operator* needs to be aware that these effects can be manifested as increases in the amount of positive *airway pressure* required for an *EMS ventilator*-provided breath, or as an increase in expiratory flow resistance. These effects can result in a step-wise increase in intrapulmonary pressure that, if not detected, can lead to pneumothorax.

Awareness of the possibility, albeit infrequent or rare, of such significant increases in *BSF* flow resistance, and inclusion in a trouble-shooting scheme for this and other causes of impaired ventilation can reduce or eliminate adverse events occurring secondary to *BSF* flow occlusion.

Direct *patient* monitoring, and usage of the appropriate settings for, and prompt attention to, *EMS ventilator alarm conditions* are essential to provide maximum *patient* safety.

Once a *BSF* is recognized to be a source of impaired ventilation, simply removing the occluded *BSF* and replacing it with another *BSF* returns ventilation to a normal state.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up *procedure*

In some designs, adequate checking of the *alarm system* can be performed with a combination of *operator* action and the power-on self-test routines that verify the integrity of the software and the computer controlling the *EMS ventilator*, as well the measuring sensors and the *alarm signal* generation.

Subclause 201.7.9.2.9.101 — Additional requirements for operating instructions

Some *EMS ventilators* are designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. Thus, knowledge of these *VBS* characteristics is important for the *operator* to be aware of the *EMS ventilator* capability. Also, knowledge of the maximum *VBS* resistance (at *nominal* and maximum flowrates) is important because an occlusion *false positive alarm condition* can be caused by the use of high resistance components in the *VBS*. These

characteristics of the *VBS* need to be inclusive of any inhalation or exhalation particle/*BSF*, *humidifier*, nebuliser, water collection vessels and connectors needed for operation.

Subclause 201.7.9.2.14.101 — Additional requirements for *accessories*, supplementary equipment, used material

The use of antistatic or electrically conductive materials in the *VBS* is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the *risk* of electrical shock to the *patient*.

Subclause 201.7.9.3.1.101 — Additional general requirements

a)

The *manufacturer* is expected to express the description of the *EMS ventilator* in general terms so the reader can understand the important behaviour of the *EMS ventilator* (e.g. mean values and their time specifications, number of breaths and delays, etc.).

Subclause 201.9.4.3.101 — Additional requirements for instability from unwanted lateral movement

In developing the requirements for this clause, the committees reviewed the test limits for acceleration from EN 1789[23] and from RTCA DO160G[24].

It was noted that this is a requirement for crash safety — the *EMS ventilator* cannot detach from its attachment in the event of a collision of the vehicle in which it is being used, as this would create a *risk* of traumatic injury both to the *patient* and to attending *operators*.

For road ambulance use, 4.5.9 of EN 1789[23] provides requirements for *medical device* restraints to withstand acceleration profiles with peak acceleration in each direction of 10 g. This is applied as an acceleration impulse, involving a peak acceleration in the range of 80 m/s^2 to 120 m/s^2, (8,2 g to 12,2 g) with a profile with an overall period between 80 ms and 150 ms. It was noted that this is equivalent to being brought to a stop from a speed in the range of 17,3 km/h to 51,8 km/h.

The committees agreed that an appropriate test for the *EMS ventilator* attachment that would ensure conformance to the requirements in EN 1789[23] under all allowed test conditions would be to require a test at 10 g for a period of 150 ms. This is equivalent to a crash from a speed of 52,9 km/h.

For use in an air vehicle, the most appropriate requirement identified is from 7.2.1 of RTCA DO160[24]. The standard includes a table listing acceleration profiles for crash tests applicable to various different types of aircraft. These include different profiles for orientation along and perpendicular to the direction of travel. The committees adopted the worst-case stress for each axis for all types of aircraft, assuming that the mounting could assume a vertical direction, but could not assume forward-to-back or sideways orientation with respect to the direction of travel.

This results in test acceleration values of 20 g vertically downwards; 4 g vertically upwards; and 20 g in any horizontal direction. Testing is required both for multiple impulses (with an impulse duration of not greater than 11 ms) and for sustained acceleration for 3 s.

The committees agreed that an appropriate test for the *EMS ventilator* attachment for an *EMS ventilator* intended for air transport use would be to require a test at 20 g for a period of 3 s horizontal and vertically downwards, and 4 g vertically upwards.

Subclause 201.11.1.2.2 — *Applied parts* not intended to supply heat to a *patient*

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without *harm* to the respiratory tract[16]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract[17]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (265,6 kJ/kg) for 45 min[18].

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a *ventilator* in clinical practice, the delivered gas energy limit of 197 kJ/m³ of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,9786 m³/kg of dry air and an enthalpy content of 197 kJ/m³ of dry air. Assuming the volume breathed by the *patient* is the same whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/m³ of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the *patient*.

Sustained delivered gas temperatures above 41 °C, depending on the combination of gas temperature, level of water saturation and *patient* exposure time, can be hazardous. Confirmed by studies conducted by the US Navy Medical Research and Development Command[17], concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the *patient* with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 181,3 kJ/m³ of dry gas breathed by the *patient*.

The enthalpy content of 197 kJ/m³ has been in long time in use to limit the energy transfer of humidified breathing air to the respiratory tract of a *patient* with by-passed upper airways and no negative feedback with regard to this limitation was known at the time of the consideration of this document. The committees asked for clinical advice as to whether in addition to the enthalpy limitation, the temperature needed also to be limited. A German group of clinicians after considering the issue and the literature available came to the following conclusion:

The literature shows:[16][17][18]

— thermal inhalational traumas with temperatures above 100 °C but with unknown humidity content;

— the very low RH of about 5 % only at 100 °C with an enthalpy content of 197 kJ/m³;

— the good experience with the limit of enthalpy content of 197 kJ/m³ of dry air in humidified breathing gases;

— the physical facts that a blower/turbine type *ventilator* increases the temperature of the gas taken from the environment in the range of 15 °C to 25 °C;

— *ventilators* are used in environments up to 45 °C;

— an additional temperature limitation is intended to limit the temperature under worst-case condition; and

  — a sufficient safety margin to protect the *patient* from thermal injuries of its airways.

The clinician group recommended to keep the thermal energy limitation of 197 kJ/m^3 and add a maximum temperature limitation of 70 °C[16], whichever is lower. The committees agreed and confirmed this proposal.

Subclause 201.11.6.6 — *Cleaning* and *disinfection* of *ME equipment* or *ME system*

The *essential principles* of ISO 16142-1 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the *patient* on whom they are being used or the employees or third parties interacting with them.

This means that *ventilators*, their *accessories* and parts cannot be used if there is a unacceptable *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *ventilator*, *accessory* or part.

Therefore prior to reuse, *ventilators*, their *accessories* and parts require an appropriate level of *disinfection*, depending on their use, but rarely need to be sterile.

Recommendations for hygienic *processing* of *ventilators*, their *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* in this document are intended to:

— make the *responsible organization* for *processing* the *ventilator* aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the *processing* of *ventilators*, their *accessories* and parts to comply with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regard to implementing the hygiene measures required for the *patient's* safety.

The *manufacturer* is encouraged to concentrate on four essential aspects of *cleaning* and *disinfection*:

bb) the external *enclosure* of the *ventilator;*

cc) the *ventilator's* removable breathing circuit, including *accessories* and parts (e.g. *humidifier*, removable flow sensor, connectors, water traps, *breathing system filters*);

dd) the internal *gas pathways* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition*, which generally reside within the *ventilator's enclosure* and are normally replaced or processed between *patients*; and

ee) the internal *gas pathways* that cannot become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition,* which generally reside within the *ventilator's enclosure* and are not normally removed or processed between *patients*.

Regarding the *cleaning* and *disinfection* or *cleaning* and *sterilization* of a), b) and c), above, *manufacturers* are required to provide detailed, *validated procedures* for ensuring safe and effective *processing* to protect the next *patient*, caregivers, technicians and third parties from pathogenic contamination. *Manufacturers* are required to document these *procedures* in the *accompanying documents* of the *ventilator*. Since the *gas pathways* described in d) above are not contaminated by a *patient*, *manufacturers* are not required to provide, *validated procedures* for

processing them. Item c) and to some extent item d), the *disinfection* of the *ventilator's* internal *gas pathways*, have received renewed attention due the recent outbreaks of contagious diseases like Legionnaires', SARS (severe acute respiratory syndrome) and influenza that affect the respiratory system.

Most modern *ventilators* are designed to permit removal, either for replacement or *processing*, of those portions of the internal *gas pathways* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition*. *Responsible organizations* need to follow their infection control *procedures* when transferring a *ventilator* from one *patient* to another.

In the event that the *responsible organization* suspects that the internal *gas pathways* of a given *ventilator* might have become contaminated with pathogenic material from the previous *patient*, the committee suggests a three-step *process* in the following order to assess next actions:

— ensure that the breathing circuit and all *accessories* have been removed and dealt with according to applicable *procedures;*

— thoroughly disinfect all outer surfaces of the *ventilator enclosure*, including the outer surfaces of the *gas output port* and *gas return port;* and

— only after executing the previous two steps, swab the inner surfaces of the *gas output port* and *gas return port* and culture the swabs to determine if pathogenic material is present.

If contagious pathogens are detected, the *responsible organization* should follow the *manufacturer's processing procedures* found in the *accompanying documents* to protect the next *patient*, caregivers, technicians and third parties from those detected pathogens. The *responsible organization* should be aware that sensitive and expensive sensors are likely located in the expiratory *gas pathways*. Follow the *accompanying documents* of the affected *ventilators* to ensure that delicate and possibly fragile sensors are not damaged during the *processing procedure*.

Any *ventilator* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the device or the next *patient* on whom the device is used. Hence *ventilators*, their re-usable *accessories* and parts that have been used should, when necessary, undergo a *processing process*, following the *manufacturer's* instructions, prior to reuse on another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of a *ventilator*, its *accessories* or parts:

— protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing procedure*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles); and

— the necessity to guarantee the proven standardised *procedures* have consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedures* should be determined by:

— the potential degree and type of contamination of the *ventilator*, *accessories* or parts; and

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *ventilator*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* is required.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if the:

— documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*; and

— reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the *ventilator*, *accessories* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator* or other persons; and

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by a processed *ventilator*, *accessories* or parts are determined by the following factors:

ff) undesired effects, which can result from:

- the previous use,
- the previous *processing procedures*, and
- transportation and storage;

gg) the *risks* from subsequent uses, such as the following:

- residues from the previous use (such as secretions, other body fluids, and drugs);
- residues from the previous *processing procedures* such as *cleaning* agents, disinfectants and other substances, including their reaction products;
- changes of physical, chemical or functional properties of the device; and
- changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints); and

dd) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing procedures* and the feasibility of the *processing procedure* for the *ventilator*, *accessories* or parts, the *manufacturer* should consider the following points:

— the *risks* involved in the *processing procedure*;

— the cost effectiveness of the *processing procedure*;

— the practicability of the *processing procedure*;

— the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing procedure*;

— the efficiency of the *processing procedure*;

— the reproducibility of the *processing procedire*;

— quality management requirements of the *processing procedure*; and

— the environmental impact of the *processing procedure* and the disposal of the *ventilator*, *accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *ventilator*, *accessories* or parts, depending on the type of use.

The *responsible organization* should verify that *cleaning* and *disinfection* of the *ventilator*, *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected *ventilator*, *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually comes in contact, either directly or indirectly, with the next *patient*, *operator* or another person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, a safety and functional testing of the *ventilator* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *ventilator*.

The extent and type of the tests depends on the *ventilator*, *accessory* or part and these need to be defined in the *accompanying document*.

Subclause 201.12.1.101 — *Volume-control inflation-type*

b) 3)

A *ventilator* that is intended for use with a *medical gas pipeline system* containing Oxygen 93 (from an oxygen concentrator) requires a wider *rated* range of input oxygen concentration than a *ventilator* intended only for use with a *medical gas pipeline system* containing oxygen. For a *ventilator* intended for use only with oxygen, the *rated* range of concentration for the oxygen inlet

would typically be “99,5 % ± 0,5 %” (or alternatively “99,0 % to 100,0 %”). For a *ventilator* intended for use with a *medical gas pipeline system* containing Oxygen 93, the *rated* concentration could be as wide as “90 % to 100 % O_2” where the *medical gas pipeline system* is backed up with oxygen. The *manufacturer* is required to disclose the effects of variation in the inlet oxygen concentration within the *rated* range on delivered oxygen accuracy.

For example, the disclosed tolerance needs to be broadened to account for variation in inlet oxygen concentration. A *ventilator* that is indicated for *rated* range “90 % to 100 % O_2” and that does not measure the inlet concentration, and that has a blending accuracy of ±4,5 %, would have a delivered oxygen concentration tolerance of ±5 % when used with oxygen, but might have a delivered oxygen concentration tolerance of ±10 % when configured for use with Oxygen 93. The variation in inlet concentration sums with the blending error term to yield a delivered concentration error.

Alternatively, a *ventilator* with identical blending accuracy of ±4,5 % and that measures the inlet concentration with an accuracy of ±1,5 % might have a delivered oxygen concentration tolerance of ±6 % (and a restricted setting range of 21 % to 90 %), when used with Oxygen 93.

The *manufacturer* is not expected to repeat testing with the oxygen inlet concentration being varied across the *rated* range. It is expected that the effect of variation in the inlet oxygen concentration that is theoretically derived can be used to adjust the results of testing with a known concentration to determine blending accuracy.

Table 201.104 — Volume-*control inflation-type testing*

The lung resistance values used in Tables 201.104 and 201.105 are essentially unchanged from the test cases specified in now withdrawn ASTM F1100:90[30]. The only difference has been the addition of five further infant test cases to extend downwards the range of *tidal volume*.

ASTM F1100[30] included a note that resistance values are for ‘parabolic resistors’. These are simple devices comprising an orifice plate with a cylindrical hole that are easy to manufacture to good tolerance. However, these have a variation in pressure with flow that follows a quadratic. This results in an effective increase in resistance with flow, much more so than for resistance in the lung, and also more than for resistance of a tracheal tube. While linear resistors can be constructed, they typically rely on use of porous media or small-scale laminar-flow structures to achieve a linear pressure-flow profile, and are more difficult to manufacture to close tolerance.

In the first edition of ISO 80601-2-12, the test lung configuration values were retained; however the tables were amended to specify use of linear resistance. At the time, this was thought to be more representative of clinical use, and the increasing availability and use of electronically-controlled test lungs meant that modelling linear resistance was less challenging.

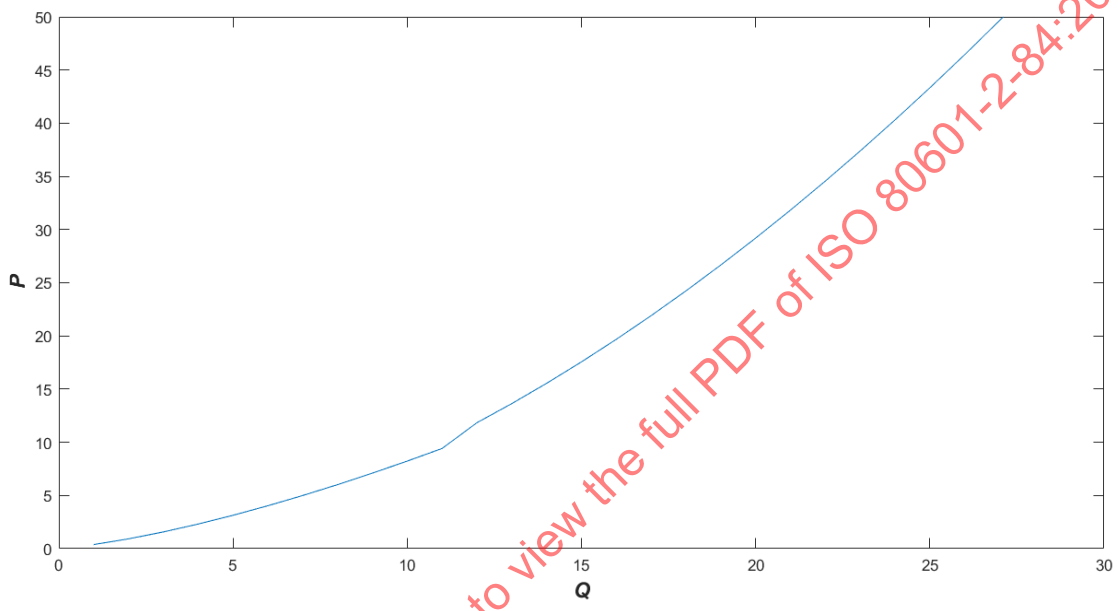
However it has become clear that in some cases this leads to clinically implausible test cases, particularly those test cases that use R200 resistance (intended to represent a 3,0 mm tracheal tube) with *tidal volumes* of 30 ml or greater. Test lung resistors are calibrated at a test flow of 1 l/s (60 l/min). Both a parabolic and a linear resistor with *nominal* resistance of R200 provide a pressure drop of 200 hPa at 60 l/min test flow. However the parabolic resistor will have a pressure drop of only 50 hPa at a test flow of 30 l/min, while the linear resistor pressure drop is 100 hPa. The effect is even more pronounced at lower flow rates — the pressure drop at 15 l/min is 12,5 hPa for the parabolic, versus 50 hPa for the linear, resistor.

In normal breathing patterns, flow in the lung is approximately laminar (owing to the preponderance of the resistance being in the very small-scale passages in the lower levels of the tracheobronchial tree). Typical values for total pulmonary system resistance in mouth-breathing humans vary from approximately 20 hPa/l/s to 25 hPa/l/s in neonates, to less than 5 hPa/l/s in adults[31]. These values are significantly increased in restrictive airway disease. However the very

high values of resistance found in the *ventilator* test case tables largely represent the resistance of the tracheal tube.

Measurements of pressure drop versus flowrate for seven sizes of tracheal tubes have been published[32]. A 7,0 mm tracheal tube has a resistance at 1 l/s that is close to R10 (10 hPa/(l/s)), however the resistance is lower at lower flow rates, for example at a flowrate of 0,25 l/s the resistance is approximately R4 (4 hPa/(l/s)).

For smaller sizes of tracheal tubes, the resistance changes significantly as flow increases above a critical value, which represents the onset of turbulence. Figure AA.1 demonstrates this effect.



Key

P pressure drop (hPa)

Q flowrate (l/min)

Figure AA.1 — Pressure drop calculation for 3.0 mm tracheal tube, 100 % RH room air at sea level, 37°C, using approach specified by Jarreau[32]

The critical flow ranges from 0,25 l/s for a 3,5 mm tracheal tube, to 0,63 l/s for a 7,0 mm tracheal tube. The critical flow is evident in Figure AA.1 as a notch in the pressure curve at approximately. 12 l/min (0,2 l/s). Below the critical flow, the pressure drop scales approximately as flow to power 1,3, while above the critical flow the pressure drop scales approximately as flow to power 1,8.

Table AA.1 shows the test cases from ISO 80601-2-12:2020, Table AA.1. The first five columns are taken from that table. It should be noted that parabolic resistors are commonly available in a limited number of values, typically Rp5, Rp20, Rp50, and Rp200, and that the table was constructed to use these standard values.

The next two columns show the average flow required (assuming a rectangular flow waveform) and the peak flow required (assuming a worst-case linear decreasing flow pattern, terminating at zero flow). The right hand columns show the worst-case pressure drop for worst-case flow assuming a parabolic resistor, or a linear resistor, respectively.

It is clear that changing the resistor specification from parabolic to linear has very significantly altered the pressure drop due to resistance in all test cases with an *inspiratory volume* less than

300 ml. In several cases, such as #11, #13 and #15, the resulting pressure drop is far in excess of the pressure drop appropriate to this *patient* model. However, in other test cases such as #18 through #21, the parabolic resistor is clearly too low a resistance to be appropriate.

Calculated pressure drop across a number of sizes of tracheal tubes at specified flow rates appropriate to that size *patient* are tabulated in Table AA.2, expressed both as actual pressure drop, and as a resistance value (expressed in hPa/(l/s)).

Table AA.1 — Flow and pressure drop for linear and parabolic resistors

Test #	C mL/hPa	R hPa/(L/s)	V_{insp}, mL	Insp Time, s	Mean Flow, l/min	Peak Flow, l/min	ΔP, hPa (parabolic)	ΔP, hPa (linear)
1	50	5	500	1	30	60	5,0	5,0
2	50	20	500	1	30	60	20,0	20,0
3	20	5	500	1	30	60	5,0	5,0
4	20	20	500	1	30	60	20,0	20,0
5	20	20	300	1	18	36	7,2	12,0
6	20	50	300	1	18	36	18,0	30,0
7	10	50	300	1	18	36	18,0	30,0
8	10	20	200	1	12	24	3,2	8,0
9	3	20	50	0,6	5	10	0,6	3,3
10	3	50	50	0,6	5	10	1,4	8,3
11	3	200	50	0,6	5	10	5,6	33,.3
12	3	50	30	0,6	3	6	0,5	5,0
13	3	200	30	0,6	3	6	2,0	20,0
14	1	50	30	0,6	3	6	0,5	5,0
15	1	200	30	0,6	3	6	2,0	20,0
16	1	200	20	0,4	3	6	2,0	20,0
17	1	200	15	0,4	2,25	4,5	1,13	15,0
18	1	50	10	0,4	1,5	3	0,13	2,5
19	0,5	50	5	0,4	0,75	1,5	0,03	1,3
20	0,5	200	5	0,4	0,75	1,5	0,13	5,0
21	0,5	200	5	0,4	0,75	1,5	0,13	5,0

Table AA.2 — Flow and pressure drop for linear and parabolic resistors

Tracheal tube diameter mm	Test Case Flow l/min	Pressure Drop hPa	Resistance hPa/(l/s)
2,5	0,5	0,36	43
2,5	2,0	1,96	59
3,0	1,0	0,4	23
3,0	4,0	2,3	35
4,0	3,0	0,5	9
4,0	10,0	2,5	15
5,0	5,0	0,4	4,5
5,0	24,0	3,6	9,0
7,0	20,0	0,6	1,8

7,0	60,0	3,7	3,7

The test cases need to account for both the resistance of the tracheal tube, and the resistance of the *patient's* pulmonary system. This suggests that for *tidal volumes* of no greater than 20 ml (test cases #16 to #21) resistance values of 50 hPa/(l/s) to 200 hPa/(l/s) remain appropriate. For test cases with *inspiratory volumes* of 30 ml to 50 ml, representing term neonates or infants, resistance values of 20 hPa/(l/s) to 100 hPa/(l/s) would be appropriate; for test cases of 50 ml or greater, resistance values should be 5 hPa/(l/s) to 50 hPa/(l/s). Based on this, the resistance values in Table 201.104 and Table 201.105 have been adjusted from the values contained in previous standards.

Subclause 201.12.1.102 — Pressure-controlled inflation-type

b) 3)

See rationale for 201.12.1.102 b) 3).

Table 201.104 — *Pressure-controlled inflation-type testing*

See rationale for Table 201.104.

Subclause 201.12.4.101 — Oxygen monitor

After a long discussion, the committees concluded that it is not the length of intended use but the *patient* population (i.e. neonatal use) that should be used to make oxygen monitoring mandatory. Monitoring the oxygen level and including level *alarm conditions* is an ineffective *risk control* for an *EMS ventilator* that does not control the oxygen concentration (e.g. venturi entrainment) since the delivered concentration varies widely with flow and pressure.

Subclause 201.12.4.102 — Measurement of *airway pressure*

The site in the *VBS* at which pressure is sensed varies from *ventilator* to *ventilator*. Generally, the *manufacturer* chooses one of two strategies:

— measuring the *airway pressure* by direct sampling at the *patient-connection port*: or

— indirectly estimating the pressure at the *patient-connection port* by measuring the pressures at two locations in the *ventilator*, on the inspiratory side of the *VBS* (at the "to *patient*" port) and on the expiratory side of the *VBS* (at the "from *patient*" port), and, after mathematical manipulation, averaging the two values.

Even if the first strategy is chosen, the actual pressure transducer will be located inside of the *ventilator enclosure* with narrow-diameter "plastic" tubing linking the pressure-sampling port at the *patient-connection port* to the sampling nipple on the pressure transducer. And for safety reasons a separate transducer will likely measure the pressure on the inspiratory side at the "to *patient*" port. The displayed *airway pressure,* however, is always expected to estimate accurately the true value that would be measured at the *patient-connection port*. Pressure measurement via the first strategy accurately reflects the true *airway pressure* within the error of the pressure transducer.

If the *manufacturer* selects the second strategy for the prediction of the true *airway pressure*, at least two methodologies can be used to arrive at estimates of this *airway pressure*.

Assuming that during inspiration the gas in the expiratory limb is essentially stagnant, one can conclude that the pressure measured on the expiratory side of the *VBS* reflects the true *airway pressure*. And conversely during exhalation, if one assumes stagnant conditions in the inspiratory limb, the pressure measured on the inspiratory side of the *VBS* can be taken as the *airway*

pressure. However, if "bias" or "base" flows during inspiration and exhalation result in significant pressure losses across these individual limbs, these pressure losses need to be estimated. The *airway pressure* on the inspiratory side, $P_Y^I(t)$, can be approximated by Formula (AA.1):

$$P_Y^I(t) = P_I(t) - \dot{V}_I(t) \times R_I \quad \text{(AA.1)}$$

where

$P_I(t)$ is the measured pressure on the inspiratory side of the *VBS*,

$\dot{V}_I(t)$ is the flow in the inspiratory limb, and

R_I is the resistance of the inspiratory limb.

The *airway pressure* on the expiratory side, $P_Y^E(t)$, can be approximated by Formula (AA.2):

$$P_Y^E(t) = P_E(t) + \dot{V}_E(t) \times R_E \quad \text{(AA.2)}$$

where

$P_E(t)$ is the measured pressure on the expiratory side of the *VBS*,

$\dot{V}_E(t)$ is the flow in the expiratory limb, and

R_E is the resistance of the expiratory limb.

Taking the average of the inspiratory and expiratory pressures is shown in Formula (AA.3), which arrives at the best estimate of the *airway pressure*, $\bar{P}_Y(t)$.

$$\bar{P}_Y(t) \cong \frac{P_Y^I(t) + P_Y^E(t)}{2} \quad \text{(AA.3)}$$

The application of this last method requires a method to estimate R_I and R_E. With appropriate algorithms and regular cross checking of the two pressure transducers, the reliability and accuracy of $\bar{P}_Y(t)$ is assured.

Subclause 201.12.4.103 — Measurement of expired volume and low-volume *alarm conditions*

It is desirable to have a fast-responding measurement of volume and narrow *alarm limits*. However, as there is often considerable variation in a *patient's* ventilatory pressures and volumes, narrow *alarm limits* inevitably lead to clinically insignificant *alarm conditions*. As a result, *operators* choose to set wide *alarm limits* to reduce the number of insignificant *alarm conditions* despite the fact that this can compromise *patient* care when there is a prolonged small change in their ventilation. Therefore, it is recommended that an *EMS ventilator* be designed to initially use a lower priority *alarm condition*, which escalates to a higher priority if the *alarm limit* violation persists. The initial *alarm condition* priority and the priorities and timing of the escalation should be determined by the severity of the potential *harm* to the *patient* in combination with the length of time that the *operator* has to prevent the *harm* from occurring.

Subclause 201.12.4.104– *Maximum limited pressure protection device*

The value chosen for the *maximum limited pressure*[34][35] is a compromise between the need to avoid barotrauma and the need to provide an adequate range of pressure to meet the desire of *operators* to supply both high *PEEP* and high insufflation pressures for specific *patients* who have not responded favourably to optimal ventilation-management strategies aimed at lung protection

and lung recruitment. In such cases the *operator* can, as a last resort, elect to ventilate using high *PEEP* and high insufflation pressure.

The predecessor standards ISO 10651-3:1997 specified the *maximum limited pressure* not exceeding 100 hPa or 120 % of the *maximum working pressure*, whichever is greater and EN 794-3:1998+AMD1:2005+AMD2:2009 specified a *maximum limited pressure* of 100 hPa. These values were based on the clinical need to supply a pressure up to 70 hPa at the *patient-connection port* under emergency and transport conditions for critical *patients*.

The design of pressure limiting in *EMS ventilators* in general is implemented via pneumatic / mechanical pop-off devices. The opening of the pop-off device needs a significant time. The combination of this delay and the relative high resistance of the pop-off device when open, creates a significant increase of pressure (above the opening pressure) during the relief action.

Therefore, an additional pressure margin was needed to provide working pressures up to 100 hPa to the *patient-connection port*.

The technology available to limit the pressure in the *VBS* has changed so that a smaller additional pressure margin is needed to ensure the ability to provide sufficient pressure to the *patient-connection port*.

Considering the *risk* of barotrauma caused by high pressures supplied to the *patient's* lungs, considering the pressures necessary to ventilate most of the *patients* around the world and considering the technology available as of today a survey was initiated to determine:

— the *maximum working pressure* clinically needed to ventilate most *patients*; and

NOTE The consensus was that "to ventilate most *patients*" means that in 90 % to 95 % of the cases *patients* can sufficiently ventilated with this ventilatory pressure.

— the needed pressure difference between the *maximum limited pressure* and the *maximum working pressure* with today's technology.

The following national member bodies participated in this survey: FR, US, GB, DK, NZ, AU, CN, SE, JP, SA, DE and CA.

The conclusion of this survey was that:

— the maximum clinical pressure necessary at the *patient-connection port* is 90 hPa;

— the maximum needed pressure difference between the *maximum limited pressure* and the *maximum working pressure* at the *patient-connection port* is 15 hPa.

Based on the above, the conclusion of the committees was to limit *maximum limited pressure* to 105 hPa or 30 hPa more than the *maximum working pressure*, whichever is less.

Subclause 201.12.4.105 — High *airway pressure alarm condition* and *protection device*

e)

The high *airway pressure alarm condition* can occur in several scenarios, with different appropriate responses. It should be noted that it is implicit that in *normal condition*, the exhalation resistance of the *VBS* (including breathing circuit, filters, and exhalation valve) is sufficiently low so that the pressure can return to set *BAP* within one *respiratory cycle* of the end of a *ventilator* inspiration.

Patient cough

A cough is a transient forced expiration due to involuntary contraction of the abdominal muscles and opening of the glottis and vocal chords, resulting in a very rapid and short duration expiratory flow. This is most commonly triggered by pulmonary irritant receptors, and is a defensive mechanism that ejects foreign matter from the bronchi and trachea.

This action triggers a rapid but transient increase in pressure at the *patient-connection port*. The pressure elevation is generated by the *patient* respiratory muscles. In this scenario, it can be appropriate to transition to exhalation, as this would assist the forced expiration and clearance of foreign material. However, the volume of air ejected has come from the lungs, and the normal operation of the *ventilator expiratory phase* control of pressure would be sufficient to restore pressure to a value close to set *BAP*, within the normal exhalation period. There is no clinical reason to open a pressure-relief valve.

Patient forced expiration

In some cases, a *patient* can make a forced expiratory effort during the *ventilator inflation phase*, resulting in a pressure increase at the *patient-connection port*. As this is a *patient*-generated pressure, the same rationale applied to cough would apply to this scenario, and transition to exhalation phase is an appropriate and sufficient response. Even in the worst-case scenario, the exhaled volume would be unlikely to exceed twice the normal exhaled volume, and the time required to reduce the pressure to set *BAP* would not significantly exceed one *respiratory cycle*.

Inappropriate volume for *patient* compliance

In a *volume-control* or volume-targeted *ventilation-mode*, the pressure can exceed the high pressure *alarm limit* due to reduced pulmonary compliance. In this scenario it would be preferable to apply a pressure limitation (with a threshold less than the high pressure *alarm limit*). However in the absence of this function, the appropriate action would be to transition to the exhalation phase. As the *inspiratory volume* is not increased, there is no reason why the normal operation of the *ventilator* in the *expiratory phase* would not reduce the *airway pressure* to set *BAP* within one *respiratory cycle*.

Inspiratory limb occlusion

In this *single fault condition*, the *patient* is not subject to the high pressure. *Ventilators* that do not incorporate a pressure-monitoring line from the *patient-connection port* might be unable to differentiate this from a high *airway pressure* state. Because the *patient* is not subjected to the high *airway pressure*, an obstruction *alarm condition* is not considered necessary.

Expiratory limb, *breathing system filter* or expiratory valve occlusion

For most software-controlled *ventilators*, this only results in a high *airway pressure alarm condition* if it occurs during the *expiratory phase*, as when the exhalation valve remains closed during *ventilator* inspiration. In some cases (such as a 'pressure limited' *ventilation-mode*), the *patient* pressure can exceed the *alarm limit* if the occlusion prevents the *maximum limited pressure protection device* from operating.

Terminating outlet flow — either by terminating the *inflation phase*, or terminating the base or continuous flow — causes the pressure to stop increasing, but might not result in the pressure falling below the *alarm limit*. This constitutes the 'action to cause the pressure to start to decline'. If the pressure fails to return close to set *BAP* within one *respiratory cycle*, this is evidence that the expiratory resistance is excessive, and the *ventilator* should provide an alternative means to relieve the pressure. Typically this would involve opening some form of 'safety valve' in the inspiratory part of the *VBS*. Assuming that the inspiratory limb of the circuit has comparable resistance to the expiratory limb, it can then take one further *respiratory cycle* to restore pressure at or below set *BAP*. Hence the committees have specified that the pressure is required to be

reduced to the set *BAP* or atmospheric pressure within no more than two *respiratory cycles* or 15 s.

Flow delivery 'fails open'

In *single fault conditions* such as a mechanical failure of a pressure regulator or a flow control valve, or a failure of software control of a flow source, resulting in uncontrolled flow of gas to the *ventilator* outlet, transition to the *expiratory phase* (which opens the exhalation valve) should be sufficient to control the *risk*. However, the pressure might not reach the limit within 200 ms. If the pressure remains above the high *airway pressure alarm limit* (for example because of a catastrophic flow valve failure) it can then be appropriate to also open some form of pressure-relief valve to divert the outlet flow and restore the *patient-connection port* to atmospheric pressure.

g)

Atmospheric pressure

In *normal condition*, termination of *ventilator* inspiration, and the normal action of the expiratory valve, allows pressure to be relieved to *PEEP* within one *respiratory cycle* without loss of control of *PEEP*. *Normal condition* would include any *patient*-generated effect. However, if there is a *single fault condition*, such as an obstruction of the breathing circuit or a flow delivery fault, other means can be required to reduce the pressure, and in this scenario, it is not expected that the *ventilator* is able to maintain control of *PEEP*.

Set *BAP* level

As noted above, the worst-case time required to reduce the *airway pressure* to a value less than or equal to set *BAP* is two *respiratory cycles*. To account for the possibility that the mandatory *Rate* has been set to a value significantly less than the *patient's* normal resting breathing rate, the committees have limited the recovery time to a maximum of 15 s. This reflects literature that shows typical breathing rates in adults[26], including geriatric populations[27], that are rarely less than 10 breaths/min, and hence would require no more than 12 s for two *respiratory cycles*.

Subclause 201.12.4.106 — Expiratory end-tidal CO_2 *monitoring equipment*

The monitoring of expiratory end-tidal CO_2 is employed clinically as a surrogate for arterial CO_2 tension. It therefore provides an alternative to monitoring expired *tidal volume* in assessing the adequacy of ventilation of the lungs. However, in the event of an occlusion or leak within the *VBS*, minute ventilation can be significantly reduced, while arterial CO_2 rises. This can result in end-tidal CO_2 monitored values that remain within the clinically acceptable range as the *patient tidal volume* is reduced below the level of physiologic dead space. The committee did not believe that safety could be ensured by monitoring of end-tidal CO_2 unless monitoring *inspiratory volume* or expired volume was also in use.

It is not intended that this constrain a *manufacturer* to integrate the CO_2 *monitoring equipment* into the *ventilator*. This allows for cases such as when the end-tidal CO_2 *monitoring equipment* is integrated within a vital signs monitor from a separate *manufacturer*.

Subclause 201.13.2.101 — Additional specific *single fault conditions*

a)

Disruption of the gas delivery to the *patient* independent of the root cause for the disruption (e.g. by disconnection or blockage of the inspiratory breathing / tubing system) is the most reasonably foreseeable event in the daily practice of ventilation around the world that might quickly lead to serious irreversible injury or the death of a *ventilator-dependent patient*.

b)

Disruption of the gas flow pathway between the *patient* and the *ventilator* independent of the root cause for the disruption (e.g. by disconnection or blockage of the expiratory breathing / tubing system) is the most reasonably foreseeable event in the daily practice that, depending on the *VBS* in use, might lead to pressure loss. This can consequentially lead to the inability to build up a *VBS* pressure sufficient to ventilate the *patient,* which in further consequence might lead to serious irreversible injury or the death of a *ventilator-dependent patient*.

c)

Operation of an *EMS ventilator* without an *operator*-detachable *breathing system filter* in place is considered reasonably foreseeable when considering those parts of the *VBS* that might become contaminated with body fluids or by contaminates carried by expired gases. If an *EMS ventilator* can operate without the *breathing system filter*, then one has to assume that it has been operated without the *breathing system filter* and therefore those parts of the *VBS* might have been contaminated. Additional information is found in the rationale for 201.11.6.6.

d)

Operation of a *ventilator* using an *operator*-detachable remote control or monitoring module is considered as a state-of-the-art option today. Independent how the communication between the "ventilator module" and the remote control or monitoring module is facilitated (e.g. wired or wireless) this communication needs be so designed and constructed that a failure or loss of this communication does cause an unacceptable *risk* to the *patient*. Further this communication (e.g. between the "ventilator module", the remote control or monitoring module, the *distributed alarm system* or a simple remote *alarm signal* communicator) also needs designed to be *single fault condition safe.*

Subclause 201.13.103 — Independence of ventilation control function and related *risk control* measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

Subclause 201.15.3.5.101 — Additional requirements for rough handling

An *EMS ventilator* is intended to operate while the *patient* is being transported and is expected to maintain *basic safety* and *essential performance* while it is being moved. Some degradation is permitted, but the *patient* is expected to continue to be adequately and safely ventilated. Rationale for 202.8.1.101 contains additional information regarding appropriate acceptance criteria for *essential performance*.

The committees recognized that during environmental stress (for example, vibration associated with transport in a moving vehicle) *ventilator* performance can degrade. In such a situation, the duration of altered performance would be at most, few tens of minutes. However, it is imperative for *patient* safety that *essential performance* is maintained.

This document references the vibration test levels defined in IEC 60601-1-12:2014 as survival test. This document provides levels that represent the worst-case exposure in the intended environment.

The committees compared these test levels with those for operating vibration found in standards ISO 10651-3[1] and EN 794-3[2], currently applicable to *EMS ventilators*; to the vibration levels given in IEC 60601-1-11 for the *home healthcare environment*. The committees also investigated test levels provided for operating vibration in now obsolete FDA guidance (1993 Ventilator Guidance) and appropriate vibration profiles (for example, for lorry transport) in MIL-STD-

810G[36]. In all cases, the vibration levels are significantly lower than those specified in IEC 60601-1-12. Table AA.3 compares these requirements.

Table AA.3 — Comparison of vibration requirements

Document	Frequency coverage Hz	Vibration profile		Vibration amplitude g_{rms}
ISO 10651-3	10 – 500	10 Hz – 200 Hz 200 Hz – 500 Hz	0,01 g^2/Hz 0,003 g^2/Hz	1,7
EN 794-3	10 – 500	10 Hz – 200 Hz 200 Hz – 500 Hz	0,01 g^2/Hz 0,003 g^2/Hz	1,7
IEC 60601-1-11	10 – 2 000	10 Hz – 100 Hz 100 Hz – 200 Hz 200 Hz – 2 000 Hz	0,1 g^2/Hz −3dB / octave 0,05 g^2/Hz	10,3
IEC 60601-1-12	10 – 2 000	10 Hz – 100 Hz 100 Hz – 200 Hz 200 Hz – 2 000 Hz	0,5 g^2/Hz −7dB / octave 0,1 g^2/Hz	16,0

The committees took regard to statements by *manufacturers* that state-of-the-art homecare *ventilators* are able to pass the testing mandated by ISO 80601-2-72, using vibration profiles defined in IEC 60601-1-11; but that no *manufacturer* was able to confirm that a *ventilator* could operate and provide *essential performance* at the vibration levels stated in IEC 60601-1-12. In particular, at frequencies below 100 Hz, that would be expected to transmit to the *patient*, the test levels in IEC 60601-1-12 are five times greater than in any of the other sources.

Whereas the shock, drop and electromagnetic compatibility for *ME equipment* for the *EMS environment* largely relate to use at an incident scene, operating vibration is primarily a function of motorized transport, and the requirements in a moving ambulance are not deemed to be significantly different from those for a *home healthcare environment ventilator* being used in a car, truck or other motorized vehicle. Accordingly, we have adopted the vibration profile from IEC 60601-1-11 for operational vibration testing.

Subclause 201.15.102 — Delivered oxygen concentration

EMS ventilators are normally supplied only by one type of supply gas, generally oxygen.

EMS ventilators have requirements regarding weight, size, handling, robustness and costs. As a result, an *EMS ventilator* typically is not equipped with accurate oxygen blender functions.

Nevertheless, an *EMS ventilator* is required to provide at least one additional adjustable oxygen concentration with the following intentions.

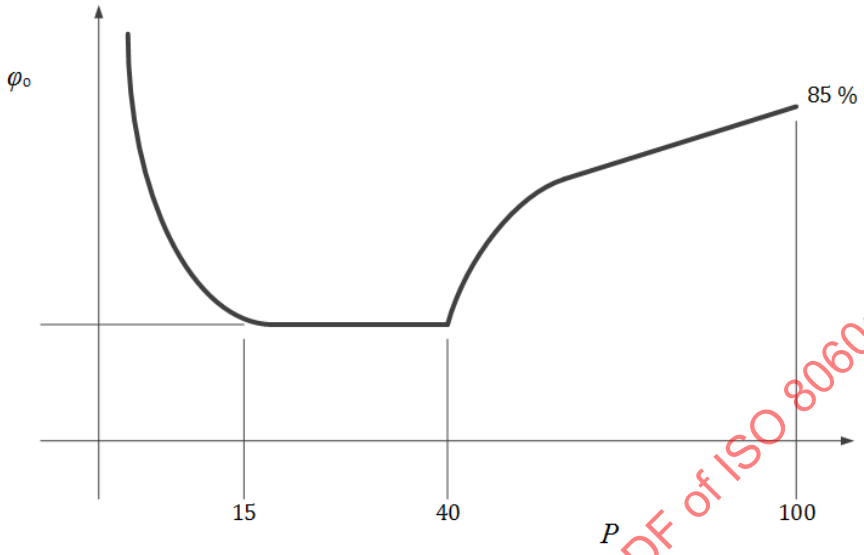
— High concentrations of oxygen applied for a longer period of time are likely to be toxic for the *patient*. A reduction of the inspiratory oxygen concentration to approximately 60 % reduces the *risk* of toxicity significantly.

— The operating time of *EMS ventilator* supplied via gas cylinders can be substantially extended via a gas-mixing function.

Inspiratory oxygen concentrations of approximately 60 % volume fraction can be easily designed via the injector principle, where high-pressure oxygen is used as driving gas and ambient air is entrained from the atmosphere.

Because of the physical characteristic of the venturi principle, the oxygen concentration depends significantly on the inspiratory flow and the mean *airway pressure*.

Figure AA.2 shows the typical dependency of the resulting inspiratory oxygen concentration from the inspiratory flow at a mean *airway pressure* of e.g. 30 hPa.



Key

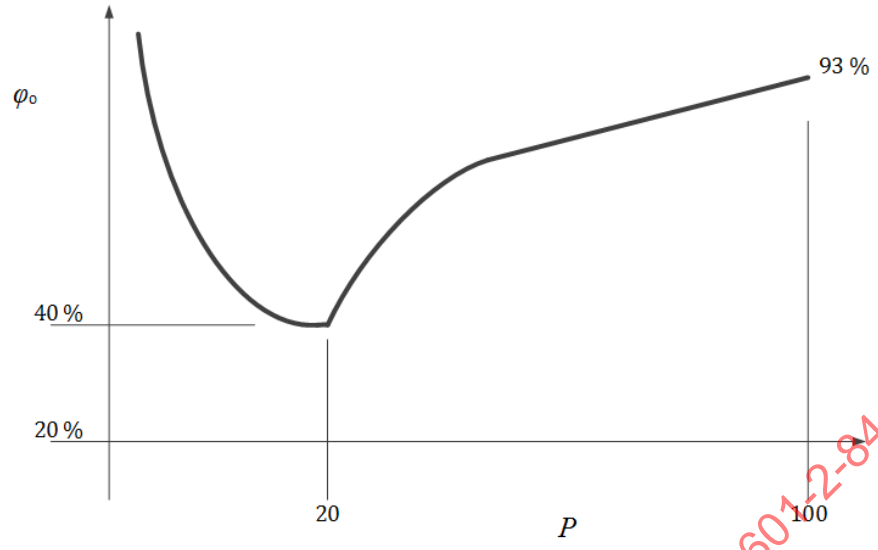
φ_0 oxygen concentration (volume %)

P pressure (hPa)

Figure AA.2 — Entrainment oxygen concentration as a function of flow at 30 hPa pressure

There is only a limited working range in which the oxygen concentration is on the desired constant level.

At a low flowrate, the venturi is not able to intake sufficient air to achieve the desired oxygen concentration. At high flowrates, the performance limit of the venturi is reached. In both cases, the inspiratory oxygen concentration can rise significantly. Figure AA.2 and Figure AA.3 illustrate this effect.



Key

φ_0 oxygen concentration (volume %)

P pressure (hPa)

Figure AA.3 — Entrainment oxygen concentration as a function of flow at 60 hPa pressure

Subclause 201.101.1 — Protection against reverse gas leakage

These conditions are necessary to maintain *patient* safety by protecting the *medical gas pipeline system* from contamination via reverse flow.

The basic requirements of this subclause were introduced into standards more than a decade ago because of the *harm* due to reverse gas leakage that was known to have occurred in connection with medical devices that use multiple gas sources.

With devices fitted with multiple *gas intake ports* for the same gas, the *hazardous situation* results from the undetected loss of backup gas supplies due to back leakage into the primary supply. With *gas intake ports* for different gasses, the *hazard* is contamination of one gas source by gas from another source. The contamination *hazard* is particularly likely to occur while the medical device is left in a condition where it is connected to the gas supplies but is not drawing flow from the gas supply system.

Ventilators are frequently equipped with multiple *gas intake ports* either to achieve a greater flow or to use a local backup supply (e.g. a gas cylinder, in parallel with a *medical gas pipeline systems* supply). With such systems, the backup supply could be depleted prematurely during use or, when connected but not in use, could deplete without detection and not be available when required in an emergency.

With a *ventilator* equipped with more than one different *gas intake port*, even very small leakages from one of the gas systems to the other can cause considerable contamination in a *medical gas pipeline system* over extended periods during which little flow is withdrawn.

More than 10 y of experience has demonstrated that these requirements are effective *risk control* measures.

Subclause 201.101.2.2 — Filter

The intention of filtration of the gas from the *high-pressure inlet port* is to protect the sensitive components (e.g. flow sensors) of the *ventilator gas pathways* from particles. This gas is provided from a *medical gas pipeline system* or from a gas cylinder.

The standards for high-pressure oxygen compatibility[37] and pressure regulators require input filtering that prevents particles greater than 100 µm from entering.

Despite of these requirements in the following cases particles with larger sizes could occur:

— particles collected in *high-pressure input ports* and port connectors;

— *high-pressure input ports* of *ventilators* while disconnected; or

— malfunction of the *medical gas pipeline system*, medical air compressors, oxygen concentrators or filters.

Depending on the design of a specific *ventilator* (e.g. in case that particle-sensitive sensors are used) significantly smaller filter sizes than 100 µm can be required.

Subclause 201.101.3.1 — General

Non-standard *VBS* connectors can represent an unacceptable *risk* as attempts are made to fit a standard *VBS* to an *EMS ventilator* in an emergency situation. Non-standard *VBS* connectors can cause leaks if used with similar but not compatible connectors.

Subclause 201.101.3.2.4 — *Accessory* port

The use of Luer taper or Luer-lock connectors conforming with ISO 594-1[38], ISO 594-2[39] or ISO 80369-7[40] are not permitted for use in a *VBS* as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

Subclause 201.102.1 — General

It is the responsibility of the *manufacturer* of a *ventilator breathing system*, its parts or *accessories* to verify that their product conforms with the requirements of this document.

Subclause 201.102.4 — Water vapour management

Water management refers to the complete *process* by which moisture, in the form of water vapour, is added to the breathing gas delivered to the *patient's* lungs and the *process* by which humidified breathing gas is conducted back to the *ventilator's* expiratory system and exhausted into the room. Intrinsic to this *process* is the necessity to remove bulk water due to condensation of moisture attributable to pressure and temperature changes in the *VBS*. Even if breathing gas reaches the *patient-connection port* without any added moisture, the expired breathing gas directed back to the *ventilator* will contain some moisture. Water management in the *VBS* requires attention, whether or not the *VBS* contains an active *humidifier*, with or without heated wires in the inspiratory or the expiratory limbs of the *VBS*, or a passive or an active *HME* at the *patient-connection port*.

Proper management of the *patient's* airway secretions and mucociliary transport system requires that the *ventilator* compensate for the humidity deficit caused by intubation, which bypasses the upper airways where the normal humidification *process* would begin. Excess moisture delivered to the *patient-connection port* can flood the cilia located in the bronchial airways, diminishing their ability to move mucus toward the trachea. On the other hand insufficient humidification of the inspired breathing gas dries the bronchial airways, which leads to thickening of the mucous

secretions and likely increased airway resistance or worse. A balanced approach to humidification is needed to maintain healthy cilia. Liquefied mucus can be readily aspirated using a *suction catheter*.

Optimal humidification of the *patient's* airways results from an understanding of the physics of the techniques chosen to add water vapour to the inspiratory gas stream. Depending on the system selected for delivering humidified breathing gas to the *patient* (for example, active vapour *humidifier* with or without heated wires, conventional *HME* or active *HME*), condensate can accumulate in the inspiratory limb of the *VBS*. If condensation occurs, the *VBS* will need to provide a method by which the liquid can be removed.

In all but the most unusual circumstances, gas leaving the alveoli is saturated at 37 °C. Rainout occurs as the moist gas cools and moves toward the *patient-connection port*, and is conducted back to the *ventilator*. If an *HME* is fitted at the *patient-connection port*, approximately 50 % to 70 % of the water vapour will be trapped in the *HME*. Whatever the configuration of the expiratory limb of the *VBS*, the water vapour content of the exhaled gas will be significant, nearing saturation. Without heated wires, the returning gas cools, causing significant condensation. As in the inspiratory limb, this liquid needs to be removed. The presence of heated wires in the expiratory limb lessens or eliminates condensation before the expired gas enters the *gas return port* of the *ventilator*, but from this point to the *exhaust port* the gas tends to cool further, so more moisture will condense. The *VBS* needs to include some means to manage this additional condensed water.

Subclause 201.102.4.1 — Humidification system

An *EMS ventilator* is rarely used with active humidification due to the short-term usage during transport. Normally, an *HME* is used.

Subclause 201.102.6 — Leakage from complete *VBS*

Assuming that the leakage flow can be modelled as if an ideal orifice were producing it, then the leakage flowrate, Q_{leak}, would follow Formula (AA.4).

$$Q_{leak} = G \times \sqrt{P} \qquad \text{(AA.4)}$$

where

G is the orifice conductance and

P is the driving pressure.

Using the leakage limits from ISO 80601-2-12:2020 and Formula (AA.4), the orifice conductance G can be calculated for each of the *inspiratory volume* ranges. For example, the leakage limit for *inspiratory volumes* ≥300 ml is 200 ml/min at a pressure of 50 cmH_2O, which yields a value for G of 28,28 ml/(min·$hPa^{1/2}$). Conductance values for the other *inspiratory volume* ranges can be similarly calculated. Table AA.1 summarizes these results.

Table AA.1 — Calculated conductance values by *inspiratory volume* range

Inspiratory volume **range** ml	**Leakage limit from ISO 80601-2-12** ml/min	**Pressure, P** hPa (cmH_2O)	**Calculated conductance, G** $ml/(min \cdot hPa^{1/2})$
$V_{insp} \leq 50$	50	20	11.18
$50 \geq V_{insp} \geq 300$	100	40	15,81
$V_{insp} \geq 300$	200	50	28,28

Using these calculated conductance values, it is then possible to find the corresponding *VBS* leakage limit at any pressure. Figure AA.4 demonstrates these relationships.

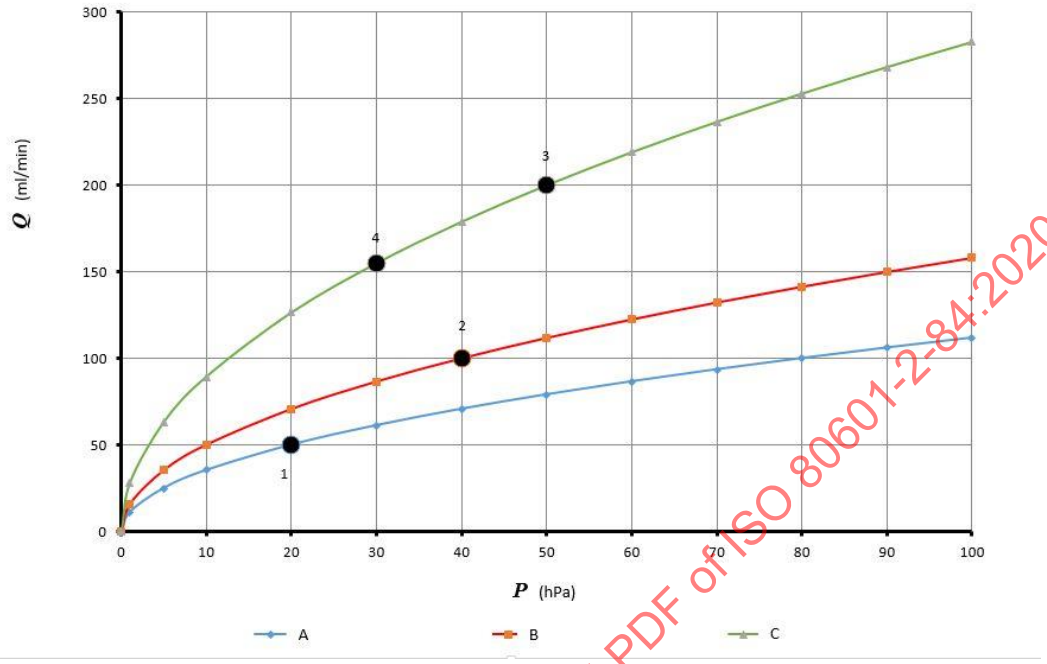
Using Figure AA.4, one can derive the 60 hPa (60 cmH_2O) *VBS* leakage flowrate limits. This is the pressure at which most of the *operator*-accessible parts of the *VBS* are specified at for leakage flowrate.

— for $V_{insp} \leq 50$ ml, $Q_{leak} = 87$ ml/min

— for $50 \text{ ml} \geq V_{insp} \geq 300$ ml, $Q_{leak} = 122$ ml/min

— for $V_{insp} \geq 300$ ml, $Q_{leak} = 219$ ml/min

These leakage flowrate limits represent the permissible leakage of the entire *VBS*. It is common to allocate 90 % of the leakage flowrate to the *operator*-accessible parts of the *VBS* and 10 % to the parts of the *VBS* internal to the *ventilator*.



Key

1 leakage limit from ISO 80601-2-12 for $V_{insp} \leq 50$ ml

2 leakage limit from ISO 80601-2-12 for 50 ml $\geq V_{insp} \geq 300$ ml

3 leakage limit from ISO 80601-2-12 for $V_{insp} \geq 300$ ml

4 leakage limit from ISO 80601-2-13[4]

A (blue) – Q_{leak} for $V_{insp} \leq 50$ ml

B (red) – Q_{leak} for 50 ml $\geq V_{insp} \geq 300$ ml

C (green) – Q_{leak} for $V_{insp} \geq 300$ ml

NOTE This assumes leakage behaves as an orifice according to Formula (AA.4).

Figure AA.4 — *VBS* leakage flowrate limits as a function of pressure as specified in ISO 80601-2-12 and ISO 80601-2-13[4]

Subclause 201.104 — Indication of duration of operation

EMS ventilators require maintenance for continued safe use. A practicable means to ensure that this information is available to the *operator* or the *responsible organization* is to require that the *EMS ventilator* keep track of how long it has been in operation.

Subclause 201.105.2 — Connection to electronic health record

Electronic documentation of *patient* care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual *patient* through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. In some countries, there is a governmental directive to provide electronic health records by 2015[41]. Electronic data transmission to the electronic health record is essential to meet this requirement. Annex BB contains information that *manufacturers* can find useful as requirements for data interfaces.

The data transmission should be capable of being provided with such a *functional connection* in accordance with ASTM F2761-09[42].

Subclause 201.105.3 — Connection to a *distributed alarm system*

See rationale for 208.6.2.2.1.

Subclause 201.107 — Timed ventilatory pause

Pausing mechanical ventilation is necessary for certain clinical *procedures*.

EXAMPLE Permitting defibrillator ECG analysis with a deflated lung, measuring respirophasic blood pressure variation, turning the *patient*.

Currently, in order to avoid nuisance *alarm signals* and to avoid cycling the *ventilator* while the *VBS* is disconnected from the *patient*, *operators* usually turn off the *ventilator* and thereby incur the *risk* of undetected prolonged apnoea by subsequently forgetting to turn the *ventilator* back on.

In addition, there are situations where, to permit the minimum disruption of ventilation, the initiation of the ventilatory pause needs to come from external equipment. This is particularly important for those *procedures* (e.g. when manual synchronization would be less effective)[43].

As part of the *risk management process*, special attention should be paid to ensuring that the *patient's* lungs remains adequately ventilated when either externally generated or repetitive ventilatory pauses occur.

The *expiratory pause* should be capable of being provided with such a *functional connection* in accordance with ASTM F2761-09[42].

Subclause 202.4.3.1 — Compliance criteria

It is not the intent of the committees to require that the *immunity* tests be performed multiple times (e.g. with *volume-control inflation-type* and *pressure-control inflation-type* at several *inspiratory volumes*), but that the *manufacturer* should determine which *inflation-type* and *inspiratory volume* represents the worst-case condition for a given *immunity* test and use those conditions.

Subclause 202.8.1.101 — Additional general requirements

The committees recognized that during environmental stress (for example, shock, vibration, electromagnetic disturbances) *ventilator* performance can degrade. In such a situation, the duration of altered performance would be about minutes to, at most, a few tens of minutes. Shock and drop disturbances can be even shorter (i.e. less than 100 ms). The question then became how to express the percent change in pressure and volume performance that would not cause *harm* to a *patient* during a brief interval of environmental stress. In today's environment of Lung Protective Ventilation (LPV) in which according to clinical research, caution should be exercised when total lung pressures and *inflation* volumes encroach on pressures of 35 cmH_2O and volumes of 12 ml/kg, respectively. The committees examined various scenarios in which pressures and volumes exceed the above values. High-side deviations in the range of 5 % to 10 % offer little relief because the error of the monitoring falls in this same range. The issue, therefore, is what higher deviation is acceptable. The committees considered two situations:

a) an average of 25 % over a one minute interval; and

b) a single *inflation* deviation of 35 %.

With respect to a total lung pressure of 35 cmH_2O and *tidal volume* of 12 ml/kg, the average values equal 43,8 cmH_2O and 15 ml/kg, respectively. Given that the maximum duration of few tens of minutes (i.e., ≤30 min) a *patient* would be expected to tolerate these pressure and volume

