



BSI Standards Publication

Medical electrical equipment

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-12:2020. It is identical to ISO 80601-2-12:2020. It supersedes BS EN ISO 80601-2-12:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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requirements for basic safety and essential performance of
critical care ventilators (ISO 80601-2-12:2020)

Appareils électromédicaux - Partie 2-12: Exigences
particulières relatives à la sécurité de base et aux
performances essentielles des ventilateurs
pulmonaires pour utilisation en soins intensifs (ISO
80601-2-12:2020)

Medizinische elektrische Geräte - Teil 2-12: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von
Beatmungsgeräten für die Intensivpflege (ISO 80601-
2-12:2020)

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European foreword

This document (EN ISO 80601-2-12:2020) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by September 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80601-2-12:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-12:2020 has been approved by CEN as EN ISO 80601-2-12:2020 without any modification.

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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 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 SC 62D, *Electric equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-12:2011), which has been technically revised. It also incorporates the Technical Corrigendum ISO 80601-2-12:2011/Cor 1:2011. The main changes compared to the previous edition are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-2:2014 and IEC 60601-1-6:2010+AMD1:2013.
- determination of probability of component failure during the *expected service life*;
- delivered gas maximum enthalpy requirement;
- new test protocol for *internal electrical power source* operation time;
- performance test and disclosure requirements for other *inflation-types*;
- additional protections against hazardous outputs;
- clarification of performance requirements during abnormal testing;
- consideration of input gas of Oxygen 93 %; and
- harmonization of terminology with ISO 19223, where appropriate.

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

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 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 four 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 201.12 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 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 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

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 a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment*:

- intended for use in an environment that provides specialized care for *patients* whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a *professional healthcare facility*;

NOTE 1 For the purposes of this document, such an environment is referred to as a critical care environment. *Ventilators* for this environment are considered life-sustaining.

NOTE 2 For the purposes of this document, such a *ventilator* can provide transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 3 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

- intended to be operated by a *healthcare professional operator*; and
- intended for those *patients* who need differing levels of support from artificial ventilation including for *ventilator-dependent patients*.

A critical care *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 a *ventilator breathing system*, or to a *ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

NOTE 4 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 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document is not applicable to *ME equipment* or an *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on artificial ventilation.

NOTE 6 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

This document is not applicable to *ME equipment* that is intended solely to augment the ventilation of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

- *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13^[2];
- *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84^[3], the future replacement for ISO 10651-3^[4];
- *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72:2015^[5];
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79:2018^[6] and ISO 80601-2-80:2018^{[7]1};
- obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70^[9];
- *continuous positive airway pressure (CPAP) ME equipment*;
- high-frequency jet ventilators (HFJVs) and high-frequency oscillatory ventilators (HFOVs), which are given in ISO 80601-2-87^[63];

NOTE 7 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

- oxygen therapy constant flow *ME equipment*; and
- cuirass or “iron-lung” ventilation equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator* and its *accessories*.

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

Accessories are included because the combination of the *ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *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 as indicated in Annex DD.

201.1.3 Collateral standards

Amendment (add after existing text):

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 and IEC 60601-1-8 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3^[12], IEC 60601-1-9^[13], IEC 60601-1-11 and IEC 60601-1-12 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 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 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 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, 203 for IEC 60601-1-3^[12], 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 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 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, *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, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *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 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 80601-2-55:2018, *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 basic safety and essential performance of respiratory humidifying equipment*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures (IP Code)*

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

IEC 60601-1-10:2007, *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 intended for use in the emergency medical services environment*

IEC 60601-2-2:2017, *Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

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, ISO 8836:2014, ISO 9000:2015, ISO 9360-1:2000, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, 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, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 60601-2-2:2017, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, 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 Annex EE.

201.3.201

emergency intake port

dedicated *gas intake port* through which ambient air is drawn when the supply of *fresh gas* is insufficient or absent

[SOURCE: ISO 4135:2001^[14], 3.2.3, modified — Removed "air" from term, replaced 'may be' with 'is', added '*gas*' and 'or absent' and deleted 'and/or inflating gas'.]

201.3.202

flow-direction-sensitive component

component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient safety*

[SOURCE: ISO 4135:2001^[14], 3.1.7, modified — Added 'or *accessory*' and replaced 'must' with 'has to'.]

201.3.203

fresh gas

respirable gas delivered to a *ventilator breathing system*

[SOURCE: ISO 4135:2001^[14], 3.1.8, modified — Added '*ventilator*' and note to entry.]

Note 1 to entry: *Fresh gas* does not include the following:

- air drawn through the *emergency intake port*;
- air drawn through leaks in the *ventilator breathing system*;
- gas exhaled by the *patient*.

201.3.204

gas intake port

port through which gas is drawn for use by the *patient*

[SOURCE: ISO 4135:2001^[14], 3.2.11, modified — Added "gas" to term, replaced 'a ventilator or by a patient' with 'for use by the *patient*'.]

201.3.205

healthcare professional

appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services to families or communities

Note 1 to entry: This term functions as an adjective.

201.3.206

high-pressure input port

input port to which gas is supplied at a pressure exceeding 100 kPa

[SOURCE: ISO 4135:2001^[14], 3.2.10.1, modified — Replaced 'may be' with 'is'.]

201.3.207

minimum limited pressure

$P_{LIM\ min}$

lowest *airway pressure* during *normal use* or under *single fault condition*

Note 1 to entry: The *minimum limited pressure* can be subatmospheric.

201.3.208

monitoring equipment

ME equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*

201.3.209

**** professional healthcare facility***

facility that is continually staffed by suitably trained *healthcare professional operators*

EXAMPLE Hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services

201.3.210

protection device

part or function of *ME equipment* that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

201.3.211

ventilator-dependent

<*patient*> dependent upon artificial ventilation in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood. For the purposes of this document, dependent means the loss of therapy can require immediate medical intervention.

EXAMPLE *Patients* with Duchenne muscular dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

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.

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, maintenance and calibration are performed according to the *accompanying documents*; and
- bb) summarize the methodology used to determine this probability.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of ventilation at the <i>patient-connection port</i> within the <i>alarm limits</i> set by the <i>operator</i>	a
or generation of an <i>alarm condition</i>	
oxygen level	201.12.4.101
<i>airway pressure</i>	201.12.4.106
CO ₂ level, if provided	201.12.4.104
disconnection	201.12.4.109
expired volume, if provided	201.12.4.103
<i>internal electrical power source</i> nears depletion	201.11.8.101
gas supply failure	201.13.2.102
obstruction	201.12.4.108
PEEP	201.12.4.107
^a Subclause 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.	

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) A *ventilator* with a pressurized gas input 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 1 000 kPa.
- b) A *ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

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 *ventilator* is likely to be outside of its specification.

Check conformity 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*

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

- a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016; and
- b) under *normal condition*,
- 1) the maximum input flowrate required by the *ventilator* for each gas shall not exceed 60 l/min averaged over 10 s at a pressure of 280 kPa, measured at the *gas intake port*; and
 - 2) any transient input flowrate shall not exceed 200 l/min averaged over 3 s,
- or:
- 3) the *accompanying documents* shall disclose:
- i) the maximum input flowrate required by the *ventilator* for each gas at a pressure of 280 kPa averaged over 10 s, measured at the *gas intake port*;
 - ii) the maximum transient input flowrate averaged for 3 s required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*; and

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

Check conformity 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 *set rate* and *tidal volume* and worst-case *medical gas pipeline system* conditions within the *rated* range for inlet pressure.

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 *Ventilator test conditions*

- a) For testing, the *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 * *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 conformity 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 *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 201.102.1; 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 *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 conformity by inspection, inspection of the risk management file for any limitations or adverse effects of the accessory, and where 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, (Table 201.D.2.101, symbol 10) may be used.
- d) The instructions for use shall disclose all natural rubber latex-containing components.

Check conformity 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 5.1.5 (Table 201.D.2.101, symbol 7), 5.1.6 (Table 201.D.2.101, symbol 8) or 5.1.7 (Table 201.D.2.101, symbol 9) from ISO 15223-1:2016.
 - 3) the word “LATEX”, or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.2.101, symbol 10), 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 conformity 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;
- 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 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 *ME equipment*, parts or *accessories* shall have *clearly legible* markings including
 - 1) any special storage, handling or operating instructions.
 - 2) any warnings or precautions relevant to the immediate operation of the *ventilator*.
 - 3) an arrow indicating the intended direction of gas flow:
 - i) for the *gas output port*; and
 - ii) for the *gas return port*.
 - 4) Symbol 0794 of ISO 7000 (Table 201.D.2.101, symbol 11) or Symbol 0795 of ISO 7000 (Table 201.D.2.101, symbol 12) may be used.
- b) If applicable, *operator-accessible ME equipment*, parts or *accessories* shall have *clearly legible* markings of the following
 - 1) for a *ventilator* intended to be used in the magnetic resonance (MR) environment,
 - i) Symbol 7.3.1-1 (Table 201.D.2.101, symbol 14) or Symbol 7.3.1-2 (Table 201.D.2.101, symbol 15) of IEC 62570 for an ‘MR Safe’ *ventilator*, or

- ii) Symbol 7.3.2 of IEC 62570 (Table 201.D.2.101, symbol 16) for an 'MR Conditional' *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 *ME equipment*, part or *accessory* should not be used, expressed as the year and month.
 - i) Symbol 5.1.4 of ISO 15223-1:2016 (Table 201.D.2.101, symbol 1) may be used.
- 4) a warning not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas intake – Do not obstruct

- i) A symbol evaluated according to IEC 62366-1 as information for safety may be utilized.

Check conformity by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3 applies, except as follows:

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

All gas volume, flowrate and leakage specifications:

- aa) shall be expressed at *STPD*; except
- bb) for those associated with the *VBS* which shall be expressed at *BTPS*.

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;

Addition:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose the following:

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

Check conformity 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: 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 curtain that blocks the flow of cooling air, thereby causing the equipment to overheat, thereby interfering with patient ventilation.

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

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

EXAMPLE 3 **WARNING:** Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4:2002^[15]) with mask can result in patient death if the ventilator fails.

- c) * a warning statement to the effect of “WARNING: Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.”

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

- d) * a warning statement to the effect of “Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- e) * a warning statement to the effect of “Warning: The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- f) * a warning statement to the effect of “Warning: The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- 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: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the *rated* range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.”
- i) * a warning statement to the effect of “Warning: When using nebulisation or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.

Check conformity 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 *ventilator* is ready for use.

- a) The instructions for use shall disclose a method by which the following can be functionally tested by the *healthcare professional operator* to determine if they are operating correctly:
 - 1) the assembled *VBS*;
 - 2) switchover to and operation from the *internal electrical power source*; and
 - 3) all of the *alarm signals*, including the *alarm signals* from any *distributed alarm systems*.
- b) Portions of this test method may:
 - 1) be automatically performed by the *ventilator*; or
 - 2) require *healthcare professional operator* action.

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

Check conformity 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.

 - 4) a 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;
 - 5) the *minimum limited pressure* at the *patient-connection port*, for *ventilators* that can generate subatmospheric pressure in the *expiratory phase*.
- 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 *ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use.

EXAMPLE 2 Acceptable range of water level in a *humidifier*.

EXAMPLE 3 Interval of calibration of a flow sensor.

- d) an explanation of the meaning of the IP classification marked on the *ME equipment*.
- e) an indication as to whether the *ventilator* is intended for non-invasive ventilation.

EXAMPLE 4 This ventilator is intended for use with mask ventilation.

- 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.

Check conformity 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 *ventilator* can become contaminated with body fluids or by contaminants carried by 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 *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 *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 *ventilator* (additional requirements are found in 201.16).

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

201.7.9.2.16.101 * Additional requirements for reference to the technical description

Where the technical description is supplied as a separate document from the instructions for use, then the instructions for use shall:

- a) list the contents of the technical description; and
- b) wherever appropriate, provide a cross reference to the additional information available in the technical description.

Check conformity by inspection.

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 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 *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the instructions for use; and
- c) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*.

If applicable, the technical description shall disclose

- d) the essential technical characteristics of each recommended *breathing system filter*.

EXAMPLE Dead space and resistance.

Check conformity 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 function 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 conformity 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:

201.9.6.2.1.101 * Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *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 conformity with the following test:

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

NOTE 1 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 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 ventilator.*

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

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

NOTE 2 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 weighted 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 ventilator in a free field over a reflecting plane as specified in 8.1.1 of ISO 3744:2010. Average the values in conformance with 8.2.2 of ISO 3744:2010.

*** Table 201.102 — Test conditions for acoustic tests**

Adjustable parameter	Test condition		
	For a ventilator intended to provide <i>tidal volume</i>		
	$V_{\text{tidal}} \geq 300 \text{ ml}$	$300 \text{ ml} \geq V_{\text{tidal}} \geq 50 \text{ ml}$	$V_{\text{tidal}} \leq 50 \text{ ml}$
Tidal volume, V_{tidal}^a	500 ml	150 ml	30 ml
Set rate	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1:2	1:2	1:2
BAP	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)
Linear resistance, $R^{b[17][18][19]}$	$5 \text{ hPa(l/s)}^{-1} \pm 10 \%$	$20 \text{ hPa(l/s)}^{-1} \pm 10 \%$	$50 \text{ hPa(l/s)}^{-1} \pm 10 \%$
Isothermal Compliance, C^b	$50 \text{ ml hPa}^{-1} \pm 10 \%$	$20 \text{ ml hPa}^{-1} \pm 10 \%$	$1 \text{ ml hPa}^{-1} \pm 10 \%$
^a V_{tidal} is measured by means of a pressure sensor at the test lung, where $V_t = C \times (P_{\text{max}})$, 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.			

- 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 that disclosed in the instructions for use.

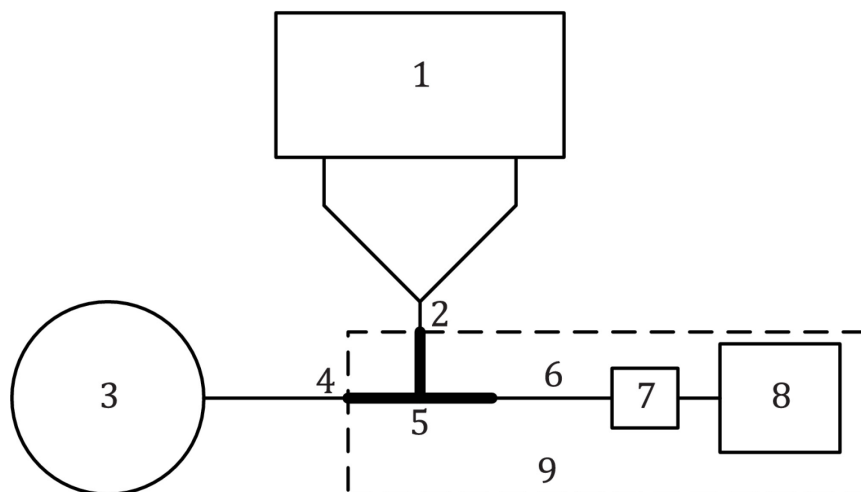
201.9.101 * Additional requirements for suction procedures

- a) The instructions for use shall disclose recommended ventilation settings for use with a closed suction catheter.
- b) A ventilator shall continue to function as intended after the use of a closed suction catheter:
- 1) for each ventilation-mode with the lowest tidal volume of each intended tidal volume range indicated in the instructions for use; and
 - 2) using the VBS configuration with the lowest compliance of those indicated in the instructions for use.

NOTE 1 For the purposes of this requirement, *pressure-control* based ventilation with a volume target is considered a form of *volume-control*.

Check conformity by inspection of the instructions for use and with the following test:

- c) Connect a suction system, as shown in Figure 201.101, leaving the patient-connection port of the closed suction catheter adaptor open to air and the ventilator disconnected. Utilize a closed suction catheter of minimum inside diameter of 2,95 mm (French (Charriere) equivalent size 14 F).



Key

- 1 ventilator under test
- 2 patient-connection port of VBS before adding the closed suction catheter adaptor
- 3 test lung
- 4 patient-connection port of VBS after adding the closed suction catheter adaptor
- 5 closed suction catheter adaptor
- 6 14 Fr closed suction catheter conforming with ISO 8836:2014
- 7 flow control valve (can be incorporated in 8)
- 8 suction equipment conforming with ISO 10079-1:2015^[20] or ISO 10079-3:2014^[21]
- 9 suction system

Figure 201.101 — Typical closed suctioning test setup

- d) Adjust the suction equipment as follows:
- Close the flow control valve and adjust the vacuum regulator of the suction equipment to an occluded vacuum of 200 hPa (204 cmH₂O) below ambient atmospheric pressure.
 - Open and set the flow control valve to give a free air flow (suction flow) of:
 - i) 30 l/min, for a ventilator intended to provide tidal volume, $V_{\text{tidal}} \geq 300$ ml;
 - ii) 15 l/min, for a ventilator intended to provide tidal volume, $300 \text{ ml} \geq V_{\text{tidal}} \geq 50$ ml; and
 - iii) 5 l/min, for a ventilator intended to provide tidal volume, $V_{\text{tidal}} \leq 50$ ml.
- e) Disable the suction flow without affecting the flow control valve setting.
- f) Connect the ventilator as shown in Figure 201.101 utilizing the lowest compliance VBS indicated in the instructions for use for the intended tidal volume range.
- g) Connect a test lung to the patient-connection port of the closed suction catheter adaptor. Utilize a test lung with compliance:
- 10 ml/hPa $\pm$ 10 %, for a ventilator intended to provide tidal volume, $V_{\text{tidal}} \geq 300$ ml;

- 3 ml/hPa $\pm$ 10 %, for a ventilator intended to provide tidal volume, $300 \text{ ml} \geq V_{\text{tidal}} \geq 50 \text{ ml}$; and
 - 0,5 ml/hPa $\pm$ 10 %, for a ventilator intended to provide tidal volume, $V_{\text{tidal}} \leq 50 \text{ ml}$.
- h) Do not enable any special suction procedure ventilator operational mode and retract the closed suction catheter.
- i) Perform any compliance correction as indicated in the instructions for use.
- j) Select a volume-control inflation-type with the following settings:
- minimum tidal volume for the intended tidal volume range;
 - set rate: 10 min^{-1} ; and
 - trigger: off or, if not so equipped, at the most insensitive method and setting.
- k) Wait until stability is achieved.
- l) Advance the closed suction catheter between 1 cm and 2 cm beyond the patient-connection port.
- m) Enable the suction flow, without affecting the flow control valve setting, and maintain for 30 s.
- NOTE 2 Some alarm conditions might become active. This is an expected possibility.
- n) Terminate the suction flow by closing the suction equipment valve and retract the suction catheter.
- NOTE 3 Retracting the suction catheter into its supplied sleeve can be important to seal the gas pathway and reduce gas leakage.
- o) Wait until stability is achieved.
- p) Confirm that the ventilator continues to function as intended.
- EXAMPLE The tidal volume is within specification.
- q) Repeat c) to p) for each intended tidal volume range.
- r) Repeat c) to q) using a pressure-control inflation-type with the following parameters in lieu of d):
- ventilation pressure of 5 cmH₂O or, if the ventilator cannot be set that low, the lowest setting;
 - set rate: 10 min^{-1} ; and
 - trigger: off or, if not so equipped, at the most insensitive setting.
- s) Repeat c) to q) using the recommended ventilation-mode and settings for use with a closed suction catheter in lieu of d) unless the recommended ventilation-mode and settings have already been tested.

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 (specific enthalpy not to exceed 197 kJ/m³ dry air).

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

Addition:

201.11.6.5.101 * *Additional requirements for ingress of water or particulate matter into ME equipment or ME system*

a) *Enclosures of ventilators* shall provide at least an IP21 degree of protection to the harmful ingress of water.

- b) *Enclosures of ventilators* should provide an IP22 degree of protection to the harmful ingress of water.

Check conformity by the tests of IEC 60529:1989+AMD1:1999+AMD2:2013 with the ventilator placed in the least favourable position of normal use and by inspection. After these procedures, confirm that basic safety and essential performance are maintained.

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 ventilator and its accessories* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

- 1) for *cleaning* and *disinfection*; or
- 2) *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 conformance test):

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

NOTE 2 ISO 14159:2002^[22] provides guidance for the design of *enclosures*.

- cc) *Processing instructions for the 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 conformity by inspection of the risk management file. When conformity with this document could be affected by the cleaning or the disinfection of the ventilator or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life 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 conformance 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 conformance statement):

- aa) The *manufacturer* of a *ventilator*, *VBS*, its parts or *accessories* shall address in the *risk management process* the *risks* associated with the leaching or leaking of substances into the *gas pathway*.
- 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 of any article, shall be marked as containing such substances:
 - 1) on the *VBS*, its parts or *accessories* itself; or
 - 2) on the packaging.
 - 3) The symbol of:
 - i) EN 15986:2011^[25] (Table 201.D.2.101, symbol 13) may be used for phthalates.
 - ii) ISO 7000-2725 (Table 201.D.2.101, symbol 9) may be used for other substances.
 - 4) If the *intended use* of a *VBS*, its parts or *accessories* includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these substances shall be included in the *risk management file*.
 - 5) The instructions for use shall contain information:
 - i) on *residual risks* for these *patient* groups; and
 - ii) if applicable, on appropriate precautionary measures.

Addition:

201.11.8.101 * Additional requirements for interruption of the power supply/supply mains to ME equipment

The *ventilator* shall be equipped with

- a) an *internal electrical power source* capable of powering the *ventilator* for at least 30 min when the *supply mains* falls outside the values necessary to maintain normal operation.
- b) a means of determining the remaining capacity or operation time provided by the *internal electrical power source*.
 - 1) This indication may be qualitative.
- c) a means to determine the power source that is currently powering the *ventilator*.

A *ventilator* shall

- d) be equipped with an *alarm system* that detects a *technical alarm condition* or
 - 1) the *alarm condition* for switchover to an *internal electrical power source* shall be at least a *low priority*.
- e) generate an *information signal* to indicate a switchover to an *internal electrical power source*.

- f) be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when the *internal electrical power source* nears depletion, at least 10 min prior to the loss of ventilation.
- 1) The *internal electrical power source* nears depletion *alarm condition* shall be at least a *medium priority*.
 - 2) As the *internal electrical power source* depletes further, at least 5 min prior to the loss of ventilation, the depletion *internal electrical power source technical alarm condition* shall escalate to *high priority*.

The instructions for use shall disclose

- g) for each intended *tidal volume* under the conditions of Table 201.102, the operational time of the *ventilator* when powered from
- 1) an aged (see k), fully charged *internal electrical power source* and
 - 2) an external reserve electrical power source, if provided.

NOTE For the purposes of this document, an external reserve electrical power source is part of an *ME system* providing electrical power external to the *ventilator*.

- h) the means by which the secondary *supply mains*, if provided, can be tested.
- i) the behaviour of the *ventilator* after a switchover:
- 1) to the *internal electrical power source*; or
 - 2) to the external reserve electrical power source, if provided.

EXAMPLE 1 Describing which *accessories* or integrated components such as a heated exhalation manifold or a heated *humidifier* no longer remain functional after a switchover to the *internal electrical power source* or a secondary *supply mains*, if provided.

EXAMPLE 2 Describing any limitations to the ventilation function after switchover.

- j) the behaviour of the *ventilator* while:
- 1) the *internal electrical power source* is recharging; and
 - 2) the external reserve electrical power source is recharging, if provided.

Check conformity by inspection of the instructions for use, functional testing and the following test.

- k) Age a new *internal electrical power source* by operating the *ventilator* from the *internal electrical power source* using the worst-case intended *tidal volume* and inflation-type under the conditions of Table 201.102:
- 1) until the *high priority internal electrical power source* nears depletion *technical alarm condition* becomes active;
 - 2) recharge the *internal electrical power source* by connecting the *ventilator* to *supply mains*;
 - 3) * repeat 1) and 2) 10 times; and

- 4) **for a transit-operable ventilator, repeat 1) and 2) an additional 40 times.*
- 5) *Instead of using the ventilator, discharging and charging circuits may be used with an equivalent profile simulating worst-case conditions:*
 - i) *over the discharging time; and*
 - ii) *over the charging time.*
- l) *Operate the ventilator using an intended tidal volume and inflation-type under the conditions of Table 201.102.*
- m) *Confirm that the medium priority alarm condition occurs at least 10 min prior to the loss of ventilation.*
- n) *Confirm that the high priority alarm condition occurs at least 5 min prior to the loss of ventilation.*
- o) *Repeat l) to n) for each remaining range of intended tidal volume.*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

- aa) The controls of a *ventilator* shall be *clearly legible* under the conditions specified in 7.1.2 of IEC 60601-1:2005+AMD1:2012.

Check conformity by application of the tests in 7.1.2 of IEC 60601-1:2005+AMD1:2012.

Addition:

201.12.1.101 * Volume-control inflation-type

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

EXAMPLE $\pm(5 + (10 \% \text{ of the set volume})) \text{ ml}$

- 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 range of the *rated* input oxygen concentration.
- c) All of the errors may be reported separately for the following ranges of intended *tidal volume*:
- 1) $V_{\text{tidal}} \geq 300 \text{ ml}$;
 - 2) $300 \text{ ml} \geq V_{\text{tidal}} \geq 50 \text{ ml}$; and
 - 3) $V_{\text{tidal}} \leq 50 \text{ ml}$
- d) The accuracy 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 configurations indicated in the instructions for use.
- NOTE 1 The worst-case VBS configuration can be different for each error or *nominal tidal volume*.
- NOTE 2 In determining the worst-case configuration, consider use with active and passive humidification.
- e) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the *risk management file*.

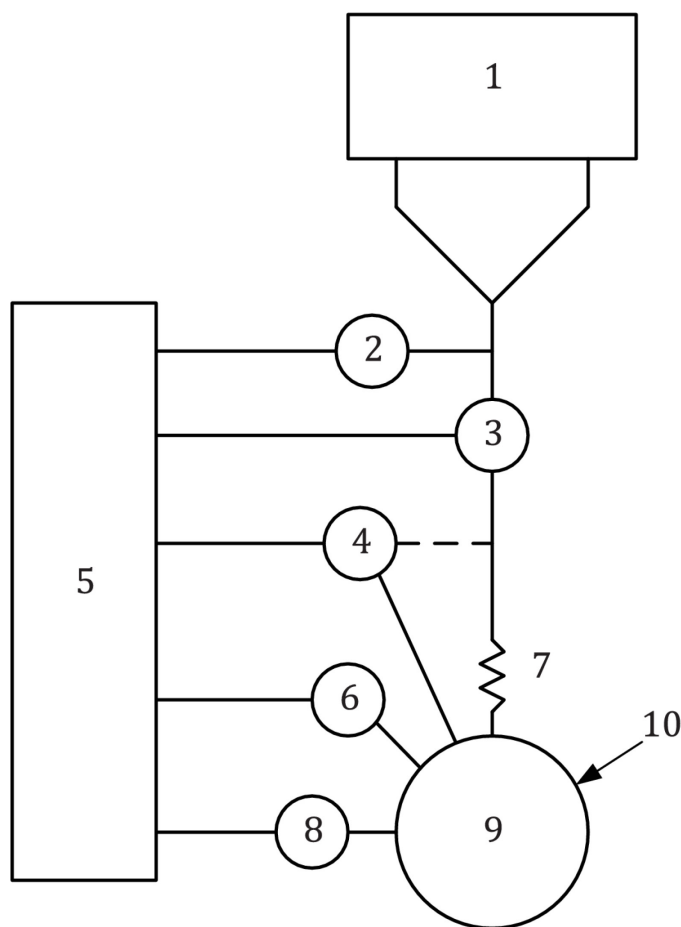
Check conformity by inspection of the risk management file for the rationale, if applicable, and with the following tests:

NOTE 3 In some cases, the following tests can be carried out simultaneously.

f) Tidal volume and end-expiratory pressure errors

- 1) *Set up the ventilator as shown in Figure 201.102.*
- 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.*
- 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 4 Additional information on the construction of an isothermal test lung is found in Reference [23].



Key

- 1 ventilator under test
- 2 pressure sensor
- 3 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms
- 4 oxygen sensor
- 5 data acquisition system, with minimum sample rate of 200 samples/s
- 6 temperature sensor
- 7 test lung resistance (R_{lung})
- 8 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
- 9 test lung compliance (C_{lung})
- 10 test lung

The oxygen sensor may be placed in the VBS.

Figure 201.102 — Typical test setup for volume- and pressure-control inflation-type accuracy

- 6) Compare the result with the acceptance criteria derived from the volume setting for the test, the measurement uncertainty and the tolerance indicated in the instructions for use.
- 7) If the ventilator is equipped with tidal volume monitoring equipment, determine the accuracy of the tidal volume monitoring equipment by comparing its reading adjusted for the measurement uncertainty to the tidal volume determined in 5). Refer to Table 201.104.
- 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		Ventilator settings				
	Compliance ml/hPa ±10 %	Linear resistance ^{[17][18][19]} hPa/l/s ±10 %	Tidal volume ml	Set rate ^a breaths/min	Inspiratory time s	O ₂ %	BAP hPa (cmH ₂ O)
1	50	5	500	20	1	30	5
2	50	20	500	12	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	12	1	90	10
7	10	50	300	20	1	30	10
8	10	10	200	20	1	90	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	90	10
14	1	20	30	30	0,6	90	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 set rate until it does.

- 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 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 ventilator.

- 14) If the ventilator permits operation without compliance correction, repeat 2) to 10) 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. 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. 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.
- 2) If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.
- 3) 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-control inflation-type

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

EXAMPLE $\pm(3,0 + (5 \% \text{ of the set pressure}))$ hPa; $(\pm(3,0 + (5 \% \text{ of the set pressure})))$ cmH₂O

- 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 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 range of the rated input oxygen concentration.

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

- 1) $V_{\text{tidal}} \geq 300$ ml;
- 2) $300 \text{ ml} \geq V_{\text{tidal}} \geq 50$ ml; and
- 3) $V_{\text{tidal}} \leq 50$ ml.

d) The accuracy 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 tidal volume* range.

In determining the worst-case configuration consider use with active and passive humidification.

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

Check conformity 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 ventilator as shown in Figure 201.102.*
- 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 acceptance criteria derived from the pressure setting for the test, the measurement uncertainty 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 [23].

- 7) *If the ventilator is equipped with tidal volume monitoring equipment, determine the accuracy of the tidal volume monitoring equipment by comparing its reading adjusted for the measurement uncertainty to the tidal volume determined in 6). Refer to Table 201.104.*
- 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 ventilator permits operation without compliance correction, repeat 2) to 12) without compliance correction.

g) O₂ error

The accuracy of the inspiratory O₂ concentration of the gas delivered is assessed by placing the sensor of an O₂ 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 O₂ concentration with the acceptance criteria derived from the O₂ setting for the test, the measurement uncertainty. Compare the resulting difference with the tolerance indicated in the instructions for use. 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. 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.*

If the O₂ concentration measuring device has pressure dependencies, compensate for these dependencies.

- 2) *Compare each result with the acceptance criteria derived from the O₂ setting for the test in f), above, the measurement uncertainty and the tolerance indicated in the instructions for use.*