
Medical electrical equipment —

Part 2-12:

**Particular requirements for basic
safety and essential performance of
critical care ventilators**

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*

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-12:2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Contents

Foreword	v
Introduction	vii
201. 1 Scope, object and related standards	1
201. 1.1 Scope	1
201. 1.2 Object	3
201. 1.3 Collateral standards	3
201. 1.4 Particular standards	3
201. 2 Normative references	4
201. 3 Terms and definitions	6
201. 4 General requirements	25
201. 5 General requirements for testing of <i>ME equipment</i>	29
201. 6 Classification of <i>ME equipment</i> and <i>ME systems</i>	30
201. 7 <i>ME equipment</i> identification, marking and documents	30
201. 8 Protection against electrical hazards from <i>ME equipment</i>	37
201. 9 Protection against mechanical hazards of <i>ME equipment</i> and <i>ME systems</i>	37
201. 10 Protection against unwanted and excessive radiation hazards	41
201. 11 Protection against excessive temperatures and other hazards	41
201. 12 Accuracy of controls and instruments and protection against hazardous outputs	45
201. 12.1 Accuracy of controls and instruments	45
201. 13 Hazardous situations and fault conditions for <i>ME equipment</i>	63
201. 14 Programmable electrical medical systems (PEMS)	65
201. 15 Construction of <i>ME equipment</i>	66
201. 16 <i>ME systems</i>	70
201. 17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	70
201. 101 Gas connections	70
201. 102 Requirements for the VBS and accessories	74
201. 103 Spontaneous breathing during loss of ventilation	76
201. 104 Indication of duration of operation	76
201. 105 Functional connection	77
201. 106 Display loops	77
201. 107 Timed ventilatory pause	78
202 Electromagnetic disturbances — Requirements and tests	80
206 Usability	81
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	83
Annex C (informative) Guide to marking and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	86

Annex D (informative) <i>Symbols on marking</i>	92
Annex AA (informative) Particular guidance and rationale	94
Annex BB (informative) Data interfaces	134
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	143
Annex DD (informative) Reference to the <i>essential principles</i>	146
Bibliography	149
Alphabetized index of defined terms	154

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-12:2023

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC 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) or the IEC list of patent declarations received (see <https://patents.iec.ch>).

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. In the IEC, see www.iec.ch/understanding-standards.

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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, 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 third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been technically revised.

The main changes are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.
- added requirements for the display legibility for *operators* wearing personal protective equipment;
- added requirements for display during calibration of gas monitors;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements;
- added requirements for *ventilator system recovery*;

- added requirements and definitions for *cybersecurity*; and
- harmonization with ISO 20417, where appropriate.

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

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 and www.iec.ch/national-committees.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-12:2023

Introduction

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.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” is used to describe a possibility or capability.

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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-12:2023

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of a critical care *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 2 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 3 For the purposes of this document, such a critical care *ventilator* can provide ventilation during transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 4 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 use a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the *artificial 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 5 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+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 6 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 7 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:

NOTE 8 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

- *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;
- *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84;
- *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72;
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 and ISO 80601-2-80;
- obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;
- *continuous positive airway pressure (CPAP) ME equipment*.
- high-frequency *ventilators*, which are given in ISO 80601-2-87;

NOTE 9 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

- respiratory high-flow therapy equipment, which are given in ISO 80601-2-90;

NOTE 10 A critical care *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

- 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*, as defined in 201.3.306, and its *accessories*.

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*^[42] and *labelling*^[43] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.

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.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively.

IEC 60601-1-3, IEC 60601-1-9, 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+AMD1:2012+AMD2:2020 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this 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 are 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+AMD2:2020 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+AMD2:2020 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 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 3.154, 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+AMD2:2020 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+AMD2:2020 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.

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 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 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2023, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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

ISO 80601-2-74:2021, *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+AMD1:2019, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

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

IEC Guide 115:2021, *Application of uncertainty of measurement to conformance assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

201.3.201

accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202

acknowledged

state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: *Acknowledged* only affects *alarm signals* that are active at the time of the *operator* action.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37]

201.3.203

airway device

device intended to provide a *gas pathway* to and from the *patient's* airway

[SOURCE: ISO 4135:2022, 3.8.1.2]

201.3.204**airway pressure** P_{aw}

pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.205**alarm condition delay**

time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.206**alarm limit**

threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.207**alarm off**

state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.4]

201.3.208**alarm paused**

state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.209**alarm setting**

alarm system configuration, including but not limited to:

- *alarm limits*;
- the characteristics of any *alarm signal* inactivation states; and
- the values of variables or parameters that determine the function of the *alarm system*

Note 1 to entry: Some algorithmically-determined *alarm settings* can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.8]

201.3.210**artificial ventilation**

intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the ventilation of a *patient*

EXAMPLE Means used to provide *artificial ventilation* are manual resuscitation; mouth-to-mouth resuscitation; automatic ventilation; mechanical ventilation.

Note 1 to entry: Common classifications of areas of application of *artificial ventilation* are: emergency; transport; home-care; anaesthesia; critical care; rehabilitation.

Note 2 to entry: Classifications used to denote means used for *artificial ventilation* include: positive-pressure; negative-pressure; gas-powered; *operator*-powered; electrically-powered.

Note 3 to entry: Negative-pressure ventilation elevates the relative pressure in the airway by intermittently lowering the pressure in the *lungs*.

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.211

assured inflation-type rate

number of assured *inflation-type* initiations in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.2.1, modified — deleted notes.]

201.3.212

attack

attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset

[SOURCE: IEC 81001-5-1, 3.5]

201.3.213

audio off

state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.12]

201.3.214

audio paused

state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

201.3.215

BAP

quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

201.3.216

bias flow

flow that passes through the *ventilator breathing system* to the *exhaust port* but is not intended to contribute to the work of *lung* ventilation

[SOURCE: ISO 19223:2019, 3.7.7, modified — deleted notes.]

201.3.217

biocompatibility

ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: A medical devices or *accessory* may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device or *accessory*.

[SOURCE: ISO 18562-1:2023, 3.6]

201.3.218

body temperature and pressure saturated

BTPS

ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.219

breathing system

pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of *artificial ventilation* or respiratory therapy

[SOURCE: ISO 4135:2022, 3.6.1.1, modified — deleted notes.]

201.3.220

breathing system filter

BSF

device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

[SOURCE: ISO 23328-2:2002, 3.1]

201.3.221

cleaning

removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]

201.3.222

communicator

COM

function of the *alarm system* that generates *alarm signals* to notify an *operator* (e.g. to the presence of an *alarm condition*)

Note 1 to entry: A *communicator* can receive an *operator* response.

Note 2 to entry: An *operator* response is not limited to direct *operator* action.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.46, modified — deleted note 3.]

201.3.223

connector

fitting to join two or more components

EXAMPLE *Connectors* for *low-pressure hose assembly* are any of a range of mating components intended to maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.224

continuous flow

gas flowing continuously through the *ventilator breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's* inspiratory effort

[SOURCE: ISO 19223:2019, 3.7.8, modified — deleted notes.]

201.3.225

CPAP

continuous positive airway pressure

ventilation-mode or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at a set *airway-pressure* level, above ambient pressure

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted notes.]

201.3.226

cybersecurity

state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1, 3.30]

201.3.227

Δ inspiratory pressure

differential *airway pressure* relative to baseline *airway pressure* during an *inflation phase*

Note 1 to entry: In addition to its direct reference, this term or an appropriate *symbol* may be used, in context or by qualification, to designate this concept as a set quantity or a measured quantity.

Note 2 to entry: There is currently no agreed convention as to whether an inspiratory pressure is always to be expressed as an absolute quantity relative to ambient pressure or an absolute quantity for one group of *inflation-types* and relative for another. This has unacceptable *patient-safety* implications that need to be addressed in a vocabulary of *lung* ventilation. The *symbol*, Δ , is currently sometimes used as a prefix to make this distinction, and that convention has been adopted as a requirement in this document. Without a prefix, or any other indication, respiratory pressures are always to be considered to be relative to ambient pressure. The addition of a Δ prefix, is used to indicate a pressure that is relative to the set *BAP* level. In *ventilation-modes* where there is a second, higher, baseline *airway pressure*, then the prefix for a pressure relative to that higher-pressure level becomes ΔH . These prefixes are applicable to relevant terms, *symbols* and displayed values but not to *inflation-types*.

Note 3 to entry: The sum of the set *BAP* level and the Δ *inspiratory pressure* equals the inspiratory pressure. This applies to both settings and measurements of this parameter.

[SOURCE: ISO 19223:2019, 3.6.7, modified — deleted note 4.]

201.3.228

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-2:2021, 3.5]

201.3.229**distributed alarm system****DAS**

alarm system that involves more than one item of equipment of a *ME system* intended for delivery of *alarm conditions* with technical confirmation

Note 1 to entry: The parts of a *distributed alarm system* can be widely separated in distance.

Note 2 to entry: A *distributed alarm system* is intended to notify *operators* of the existence of an *alarm condition*.

Note 3 to entry: For the purposes of this document, technical confirmation means that each element of a *distributed alarm system* confirms or guarantees the successful delivery of the *alarm condition* to the next element or appropriate *technical alarm conditions* are created as described in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.11.2.2.1.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.17]

201.3.230**distributed information system about alarm conditions****DIS**

system that involves more than one item of equipment in a *ME system* intended to provide information about *alarm conditions* but does not guarantee delivery of that information

Note 1 to entry: A *distributed information system about alarm conditions* is not intended to notify *operators* of the existence of an *alarm condition* as a *risk control* measure. A *distributed information system about alarm conditions* is intended to provide information about an *alarm condition* while the *operator* is aware of the existence of the *alarm condition* by an *alarm system*.

Note 2 to entry: A *distributed information system about alarm conditions* is not intended for confirmed delivery of *alarm conditions*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.48]

201.3.231**emergency intake**

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

[SOURCE: ISO 4135:2022, 3.4.2.3]

201.3.232**EMS environment****emergency medical services environment**

actual conditions and settings, in which *operators* interact with the *ME equipment* or *ME system*, in and around the scene of an emergency outside of a *professional healthcare facility* where a *patient* can be given medical care, basic or advanced life support as well as during professional transport to a *professional healthcare facility* or between *professional healthcare facilities*

EXAMPLE 1 Responding to and providing life support at the scene of an emergency to a *patient* reported as experiencing injury or illness in a pre-hospital setting, and transporting the *patient*, while continuing such life support care, to an appropriate *professional healthcare facility* for further care.

EXAMPLE 2 Providing monitoring, treatment or diagnosis during transport between *professional healthcare facilities*.

Note 1 to entry: For the purposes of this standard, use of equipment intended for the *EMS environment* and temporarily used in the *home healthcare environment* by emergency medical personnel is considered use in the *EMS environment*.

Note 2 to entry: For the purposes of this standard, the *operators* of equipment intended for the *EMS environment* are presumed to be professional medical personnel or personnel with relevant specialized training.

Note 3 to entry: *Professional healthcare facilities* include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms and multiple treatment facilities.

Note 4 to entry: Emergency medical services are known by various names in different countries and regions.

Note 5 to entry: For the purposes of this standard, transport includes road, rotary and fixed-wing ambulances.

[SOURCE: IEC 60601-1-12:2014+AMD1:2020, 3.1]

201.3.233

end-expiratory flow

expiratory flow at the point of initiation of an *inflation* or an inspiration

[SOURCE: ISO 19223:2019, 3.7.6, modified — deleted notes.]

201.3.234

essential function

function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the *manufacturer*, and operational availability for the medical device

Note 1 to entry: *Essential functions* include, but are not limited to, the safety instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the medical device safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.235

essential principles

essential principles of safety and performance

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

201.3.236

exhaust port

port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.237**expiratory pause**

portion of the *expiratory phase* from the end of expiratory flow to the start of inspiratory flow

[SOURCE: ISO 19223:2019, 3.4.4, modified — deleted notes.]

201.3.238**expiratory phase**

interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.2, modified — deleted notes.]

201.3.239**false positive alarm condition**

presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

Note 1 to entry: A *false positive alarm condition* can be caused by spurious information produced by the *patient*, the *patient*-equipment interface, other equipment or the *alarm system* itself.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.21]

201.3.240**firecall**

method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a *firecall* is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as "break glass" feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

201.3.241**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 4135:2022, 3.1.4.15]

201.3.242**fresh gas**

respirable gas delivered to a *ventilator breathing system*

[SOURCE: ISO 4135:2022, 3.1.1.16, modified — Added 'ventilator' and deleted notes.]

201.3.243**gas intake port**

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

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in apposition to an *inlet*, at which gas is provided by a medical gas supply system.

[SOURCE: ISO 4135:2022, 3.1.4.21]

201.3.244

gas output port

port of the *ventilator* through which gas is delivered at respiratory pressures to an *operator*-detachable part of the *ventilator breathing system*

[SOURCE: ISO 19223:2019, 3.14.3]

201.3.245

gas pathway

interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

Note 1 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

EXAMPLE 1 The *ventilator breathing system*, *inlet* filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or *masks* and mouthpieces.

[SOURCE: ISO 18562-1:2023, 3.11]

201.3.246

gas return port

port of the *ventilator* through which gas is returned at respiratory pressures through an *operator*-detachable part of the *ventilator breathing system*, from the *patient-connection port*

[SOURCE: ISO 19223:2019, 3.14.4]

201.3.247

healthcare professional

<adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

201.3.248

heat and moisture exchanger

HME

device intended to retain a portion of the *patient's* expired moisture and heat, and return it to the respiratory tract during inspiration

[SOURCE: ISO 9360-1:2000, 3.1]

201.3.249

high-pressure inlet

inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 600 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.1.4.24]

201.3.250**home healthcare environment**

dwelling place in which a *patient* lives or other places where *patients* are present, excluding *professional healthcare facility* environments where *operators* with medical training are continually available when *patients* are present

EXAMPLE In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: *Professional healthcare facilities* include 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.

Note 2 to entry: For the purpose of this collateral standard, nursing homes are considered *home healthcare environments*.

Note 3 to entry: Other places where a *patient* is present include the outdoor environment, while working and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1]

201.3.251**humidifier**

device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, bubble-through and ultrasonic *humidifiers* and active *heat and moisture exchangers*.

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.252**I:E ratio**

ratio of the *inspiratory time* to the *expiratory time* in a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.19, modified — deleted notes.]

201.3.253**immunity**

the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.254**inflation**

ventilator action intended to increase the volume of gas in the *lungs* by the application of an elevated-pressure waveform to the *patient-connection port* until a specified termination criterion is met

[SOURCE: ISO 19223:2019, 3.3.1, modified — deleted notes.]

201.3.255**inflation phase**

interval from the start of the rise in *airway pressure* resulting from the initiation of an *inflation* to the start of the expiratory flow resulting from its termination

[SOURCE: ISO 19223:2019, 3.4.10, modified — deleted notes.]

201.3.256

inflation-type

inflation characterized by its temporal delivery pattern following initiation, and its termination criteria

[SOURCE: ISO 19223:2019, 3.3.2, modified — deleted notes.]

201.3.257

information for safety

information provided to the user or *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for use* of a medical device to prevent use error or avoid a *hazardous situation*

EXAMPLE 3 Explanation of a safety feature of a medical device.

Note 1 to entry: *Information for safety* may be found in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a medical device or *accessory*.

[SOURCE: ISO 20417:2021, 3.9]

201.3.258

information supplied by the manufacturer

information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device and its *manufacturer*, and provide essential information about its safety, performance and appropriate use to the user or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

201.3.259

inlet

opening through which gas or other material is pushed by an elevated upstream pressure

[SOURCE: ISO 4135:2022, 3.1.4.26, modified — deleted note.]

201.3.260

inspiratory pause

interval from the end of inspiratory flow to the start of expiratory flow within a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.12, modified — deleted notes.]

201.3.261

inspiratory time

t_i

duration of an *inflation phase* or inspiratory phase

[SOURCE: ISO 19223:2019, 3.4.8, modified — deleted notes.]

201.3.262

inspiratory volume

V_{insp}

volume of gas delivered through the *patient-connection port* during an *inspiratory phase* or *inflation phase*

[SOURCE: ISO 19223:2019, 3.8.3, modified — deleted notes.]

201.3.263

instructions for use

IFU

portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a user can be either a *lay user* or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 5 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 6.]

201.3.264

intelligent alarm system

alarm system that makes logical decisions based on monitored information without *operator* intervention

EXAMPLE 1 An *alarm system* that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An *alarm system* that suppresses an *alarm condition* when a related *alarm condition* of higher priority has recently generated an *alarm signal*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.24]

201.3.265

latching alarm signal

alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate *operator* action

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.26]

201.3.266

low-pressure hose assembly

assembly consisting of a flexible hose with permanently attached gas-specific *inlet* and *outlet connectors* and designed to conduct a *medical gas* at pressures less than 1 400 kPa

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.2.3.1]

201.3.267

lung

each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during ventilation provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

[SOURCE: ISO 19223:2019, 3.1.16, modified — deleted notes.]

201.3.268

marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

201.3.269

mask

device which provides a non-invasive interface between the *patient's airway* and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.270

maximum limited pressure

$P_{lim,max}$

highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 19223:2019, 3.13.3, modified — deleted notes.]

201.3.271

maximum working pressure

$P_{w,max}$

highest *airway pressure* that can be generated by the *ventilator* during *intended use* and *normal condition*

[SOURCE: ISO 19223:2019, 3.13.4, modified — deleted notes.]

201.3.272

medical gas pipeline system

combination of a supply system, a monitoring and *alarm system* and a pipeline distribution system with terminal units for provision of medical gases or vacuum

[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.273**minimum limited pressure** $P_{\text{lim,min}}$ lowest *airway pressure* that can occur during *normal use* or under *single fault condition*Note 1 to entry: The *minimum limited pressure* can be subatmospheric.

[SOURCE: ISO 4135:2022, 3.1.4.41.4]

201.3.274**monitoring equipment**equipment or part that measures and indicates the value of a variable to the *operator*Note 1 to entry: *Monitoring equipment* includes devices that are not electrical in operation, such as a pressure gauge.

Note 2 to entry: The value can be displayed continually or intermittently.

Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for external communication.[SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced "user" with "*operator*".]**201.3.275****operator interface**means by which the *operator* and the *ME equipment* interactNote 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.Note 3 to entry: For the purposes of this standard, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

Note 4 to entry: See IEC 62366-1:2015+AMD1:2020, 3.26.

[SOURCE: IEC 60601-1-6:2010+AMD2:2020, 3.1]

201.3.276**operator's position**intended position of the *operator* with respect to the *alarm signal* generating part of the *alarm system*Note 1 to entry: A *distributed alarm system* can have multiple *operator's positions*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.30]

201.3.277**outlet**

opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.278**patient-connection port**port of a *breathing system* intended for connection to an *airway device*

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a *connector* suitable for connection to an *airway device* such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized *connectors*, for example, a *connector* conforming to ISO 5356-1.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified — deleted note 4.]

201.3.279

PEEP

positive end-expiratory pressure

<actual and measured value> respiratory pressure at the end of an *expiratory phase*

[SOURCE: ISO 19223:2019, 3.10.4, modified — deleted notes.]

201.3.280

physiological alarm condition

alarm condition arising from a monitored *patient*-related variable

EXAMPLE 1 High exhaled anaesthetic agent concentration.

EXAMPLE 2 Low exhaled *tidal volume*.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.31]

201.3.281

physiologic closed-loop control system

part of *ME equipment* or *ME system* used to adjust a physiologic variable (y) relative to a command variable (c) using a feedback variable (f)

[SOURCE: IEC 60601-1-10:2007+AMD2:2020, 3.19]

201.3.282

pressure-control

inflation-type that acts to generate a constant inspiratory pressure at a set level, after a set rise time

[SOURCE: ISO 19223:2019, 3.3.4, modified — deleted notes.]

201.3.283

primary operating function

function that involves user interaction that is related to the safety of the medical device

Note 1 to entry: Often a *primary operating function* is interacted with by a series of tasks that can be broken down into a series of user interactions.

Note 2 to entry: The concept of safety includes loss or degradation of performance resulting in an unacceptable *risk* to the *patient*, including use error that prevents the user from effectively using the medical device to achieve its intended medical purpose. In IEC 60601-1, this is referred to as *essential performance*.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.11]

201.3.284**processing**

<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

201.3.285**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

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.286**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

201.3.287**respiratory cycle**

complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease, of gas volume in the *lung* regardless of how it is generated

[SOURCE: ISO 19223:2019, 3.4.16, modified — deleted notes.]

201.3.288**security level**

level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]

201.3.289**set rate**

number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]

201.3.290**single use**

<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

[SOURCE: ISO 20417:2021, 3.26]

201.3.291**software item**

any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

Note 1 to entry: Three terms identify the software decomposition. the top level is the software system. The lowest level that is not further decomposed is the software unit. All levels of composition, including the top and bottom levels, can be called *software items*. A *software system*, then, is composed of one or more *software items*, and each *software item* is composed of one or more software units or decomposable *software items*. The responsibility is left to the *manufacturer* to provide the definition and granularity of the *software items* and software units.

[SOURCE: IEC 62304:2006+AMD1:2015, 3.25, modified — deleted note 2.]

201.3.292

spontaneous breath rate

total number of spontaneous breaths initiated in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.3, modified — deleted notes.]

201.3.293

standard temperature and pressure dry

STPD

pressure of 101,325 kPa at a temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.294

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

201.3.295

sterilization

process used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 17664-1:2021, 3.17]

201.3.296

suction catheter

flexible tube designed for introduction into the respiratory tract or an *airway device* to remove material by suction

[SOURCE: ISO 8836:2019, 3.17]

201.3.297

symbol

graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.29]

201.3.298**system recovery**

method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.299**technical alarm condition**

alarm condition arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artefact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.36]

201.3.300**technical description**

portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected service life* of a medical device

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified — replaced 'expected lifetime' with '*expected service life*' and deleted note 2.]

201.3.301**tidal volume**

V_T

volume of gas that enters and leaves the *lung* during a breath

[SOURCE: ISO 19223:2019, 3.8.1, modified — deleted notes.]

201.3.302**total respiratory rate**

number of *respiratory cycles* in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.2, modified — deleted notes.]

201.3.303**transit-operable**

<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

EXAMPLE Transportable *ME equipment* that is body-worn, hand-held, attached to a wheelchair, or used in a car, bus, train, boat or plane.

Note 1 to entry: For the purpose of this standard, *transit-operable* use in the *home healthcare environment* can include use indoors, outdoors and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.4]

201.3.304

validation

confirmation, through the provision of *objective evidence*, that specified requirements have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “*validated*” is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

201.3.305

ventilation-mode

specified manner in which a *ventilator* performs its ventilatory function when connected to a *patient*

[SOURCE: ISO 19223:2019, 3.11.2, modified — deleted notes.]

201.3.306

ventilator

medical device or *medical electrical equipment* intended to provide *artificial ventilation*

[SOURCE: ISO 19223:2019, 3.1.1, modified — deleted notes.]

201.3.307

ventilator breathing system

VBS

pathways through which gas flows to or from the *patient* at respiratory pressures, bounded by the port through which respirable gas enters, the *patient-connection port* and the *gas exhaust port*

Note 1 to entry: These pathways typically extend within and outside the body of the *ventilator*, with those outside being *operator-detachable*.

Note 2 to entry: The *port* of entry of a respirable gas into the *ventilator breathing system* can be inside the body of the *ventilator* and should not be confused with an external connection port into which respirable gas enters before being reduced to respirable pressures.

[SOURCE: ISO 19223:2019, 3.1.18, modified — deleted notes 3 and 4.]

201.3.308

ventilator operational-mode

way in which a *ventilator* is set to operate

EXAMPLE Standby; calibration; *ventilator breathing system* check; start-up *procedure*.

Note 1 to entry: NIV (non-invasive ventilation) also becomes an operational mode if it is selectable as an option.

Note 2 to entry: In the absence of the selection of a specific alternative *operational mode(s)*, when ventilation is started, typically after a *ventilator* setup routine, a *ventilator* will commence ventilation using its intended *ventilation-mode* and as configured by the *operator's* settings and selections.

[SOURCE: ISO 19223:2019, 3.11.1, modified — deleted note 3.]

201.3.309**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.

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

[SOURCE: ISO 4135:2022, 3.1.5.19]

201.3.310**volume-control**

inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

[SOURCE: ISO 19223:2019, 3.3.3, modified — deleted notes.]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 4 applies, except as follows:

Addition:

201.4.3.101 Additional requirements for essential performance

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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 <i>patient-connection port</i> within the <i>alarm limits</i> set by the <i>operator</i> or generation of an <i>alarm condition</i>	a
oxygen level	201.12.4.101
<i>airway pressure</i>	201.12.4.106
disconnection	201.12.4.109
<i>internal electrical power source</i> nears depletion	201.11.8.101
gas supply failure	201.13.2.102
obstruction	201.12.4.108
<i>PEEP</i>	201.12.4.107
<i>system recovery</i> , if provided	201.4.3.102
for delivered volume of greater than 50 ml, expired volume	201.12.4.103.1
for delivered volume of less than 50 ml, one of:	
CO ₂ level; or	201.12.4.104
expired volume	201.12.4.103.2
a 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.	

201.4.3.102 *System recovery*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) Following a malfunction, the *ventilator* shall perform a *system recovery* to attempt to restore *essential performance* of the *ventilator*.

NOTE 2 A *ventilator* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *ventilator*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of ventilation. Ventilation would thus be interrupted until an alternative means of ventilation is connected. *System recovery*, as specified in this subclause, attempts to automatically re-establish ventilation in a shorter period. If necessary, the *ventilator* can be replaced later when it is less consequential for the *patient's* therapy.

- b) *System recovery* may result in the temporary:

- 1) cessation in the ventilation of the *patient*; or
- 2) reduction in the function of *ventilator* subassemblies without impacting the ventilation of the *patient*.

EXAMPLE The temporary blanking of the display.

- c) During a *system recovery* with a cessation of ventilation:

- 1) the *ventilator* shall allow spontaneous *patient* breathing in accordance with 201.103; and
- 2) the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of ventilation.

- i) The *system recovery* with a cessation of ventilation *alarm condition* shall be *high priority*.
- d) During a *system recovery* without a cessation of ventilation, the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of ventilation.
 - 1) The *alarm condition* for *system recovery* without a cessation of ventilation shall be at least *low priority* with an auditory *alarm signal*.
- e) Following a *system recovery* without *operator* intervention, the *ventilator* shall attempt to operate with the same system configuration settings, ventilation settings and *alarm settings* as before the *system recovery*.
 - 1) If the system configuration settings, ventilation settings or *alarm settings* are different after the *system recovery*, the *ventilator* shall be equipped with an *alarm system* to indicate any change in settings.
 - 2) The change in settings *alarm condition* shall be at least *medium priority*.
- f) The duration of a *system recovery* with a cessation of ventilation should be as short as practicable to avoid an unacceptable *risk* to the *patient*.
- g) The maximum duration of a *system recovery* of ventilation shall be disclosed in the *instructions for use*.

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

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

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.

Replacement (replace the compliance check):

Conformity is checked by inspection of the design documentation and the *risk management file*.

201.4.5 Alternative *risk control* measures or test methods for *ME equipment* or *ME system*

Amendment (add prior to the compliance check):

- aa) Subsequent revisions of dated references (new editions or amendments) may be used in substitution of a referenced document provided the *manufacturer* can demonstrate the *hazard* or *hazardous situation* addressed in the dated normative reference is adequately resolved in the subsequent revision.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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* in accordance with this subclause.

Addition:

201.4.11.101 Additional requirements for pressurized gas input

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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* for risks associated with overpressure conditions.

201.4.11.101.2 Compatibility requirement for medical gas pipeline systems

If the *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

NOTE Taking account of requirements for over-pressure and under-pressure, this corresponds to a range 280 kPa to 600 kPa.

- 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, measured at the *gas intake port* with an input pressure of 280 kPa; 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* within the *rated* range for *inlet* pressure.

201.5 General requirements for testing of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies, except as follows:

Addition:

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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.

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) For the purposes of this document, acceptance criteria for declared tolerances of testing shall use:

- 1) *procedure 1* (calculation of uncertainty of measurement) from IEC Guide 115:2021, 4.4.2; or
- 2) *procedure 2* (accuracy method) from IEC Guide 115:2021, 4.4.3.

NOTE 2 This is a change from previous revisions of this document, which required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor $k = 2$, for confidence of $\sim 95\%$) is no more than 30% of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for delivered volume of $\pm(10 \text{ ml} + 10\% \text{ of set volume})$ then the uncertainty of the measurement cannot exceed $\pm(3 \text{ ml} + 3\% \text{ of set volume})$.

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

Check conformity by inspection of the *technical description*.

201.6 Classification of ME equipment and ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 ME equipment identification, marking and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows:

Addition:

201.7.1.101 Information to be supplied by the manufacturer

- a) The *information supplied by the manufacturer* of a ventilator and its *accessories* shall conform with ISO 20417:2021.
- b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.
 - 1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.
 - 2) The term "*medical device*" shall assume the same meaning as *ME equipment*.
 - 3) The term "*user*" shall assume the same meaning as *operator*.
 - 4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

201.7.2.3 Consult accompanying documents

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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+AMD1:2012+AMD2:2020, Table D.2, *safety sign* 10).

Addition:

201.7.2.4.101 Additional requirements for accessories

a) *Accessories* supplied separately shall:

- 1) fulfil the *marking* requirements of ISO 20417:2021, 6.1.1 c); 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 201.7.2.101.

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*, if applicable, and where necessary, inspection of the *instructions for use*.

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 hose or a gas cylinder intended to be attached to the *connector of an inlet*.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) 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, in accordance with IEC 62570:2014:

- i) *symbol 7.3.1-1* (Table 201.D.2.101, *symbol 3*) or *symbol 7.3.1-2* (Table 201.D.2.101, *symbol 4*) of IEC 62570:2014 for an 'MR Safe' ventilator; or
 - ii) *symbol 7.3.2* of IEC 62570:2014 (Table 201.D.2.101, *symbol 5*) for an 'MR Conditional' ventilator.
- 2) for a ventilator not intended for use in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014 *symbol 7.3.3* (Table 201.D.2.101, *symbol 6*) for an 'MR Unsafe' ventilator.
- 3) for *flow-direction-sensitive components* that are operator-removable without the use of a tool, an arrow indicating the direction:
- i) of the flow; or
 - ii) of inspiratory flow if exposed to inspiratory and expiratory flow.
- b) If applicable, operator-accessible ME equipment, parts or accessories shall have clearly legible markings of the following on or adjacent to the following items:
- 1) a warning not to obstruct the *gas intake port*; and
- EXAMPLE 1 WARNING: Gas intake – Do not obstruct
- i) A symbol or safety sign evaluated in accordance with to IEC 62366-1 as information for safety may be used.
- 2) an arrow indicating the intended direction of gas flow:
- i) for the *gas output port*; and
 - 1) *Symbol 0795* of ISO 7000 (Table 201.D.2.101, *symbol 2*) may be used for *gas output port*.
 - ii) for the *gas return port*.
 - 1) *Symbol 0794* of ISO 7000 (Table 201.D.2.101, *symbol 1*) may be used for the *gas return port*.
- 3) for a sampling gas inlet, either with the text "Gas sample" or the *Symbol ISO 7000-0794*, (Table 201.D.2.101, *symbol 1*).

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

Check conformity by inspection.

201.7.4.3 Units of measurement

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 for those associated with the VBS which
- bb) shall be expressed at BTPS.

201.7.9.2.1 General

Amendment (add as the fifth bullet following the first paragraph):

- the intended position of the *operator*;

Addition:

201.7.9.2.1.101 Additional general requirements

The *instructions for use* shall disclose the following:

- a) the intended range of *tidal volume*.

Check conformity by inspection.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *instructions for use* shall include:

- 1) 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, thereby interfering with patient ventilation.

- 2) 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 10651-4:2023) with mask can result in patient death if the ventilator fails.

- 3) 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.”

- b) If applicable, the *instructions for use* shall include the following:

- 1) 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.”

- 2) 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.”

- 3) 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.”

- 4) 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.

- 5) 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.”
- 6) 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 1 There is guidance or rationale for this subclause contained in Clause AA.2.

NOTE 2 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

The *instructions for use* shall disclose

- a) a listing of the following pressures:
 - 1) the range of *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) 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 identify:
- 1) at least one set of *accessories*; and
 - 2) if applicable, the *ME equipment* necessary for the *ventilator's intended use*.
- 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 reasonably foreseeable 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 of the *instructions for use* 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *technical description* shall disclose:
- 1) 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*;
 - 2) 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
 - 3) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*.
- b) If applicable, the *technical description* shall disclose
- 1) 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*, other than *system recovery*, 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*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies.

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies, except as follows:

Addition:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- 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 in accordance with 8.2.5 and 8.6 of ISO 3744:2010; and
 - 2) disclosed in the *instructions for use*.
- c) Check conformity with the following test:
 - 1) 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.

- 2) If a *humidifier* is provided with the *ventilator*, include the *humidifier* filled to the least favourable level in the test.

- 3) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.
 - i) 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*.
 - ii) Connect the *patient-connection port* to the test lung.
- 4) 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.

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a <i>ventilator</i> intended to provide <i>tidal volume</i>		
	$V_T \geq 300 \text{ ml}$	$300 \text{ ml} \geq V_T \geq 50 \text{ ml}$	$V_T \leq 50 \text{ ml}$
<i>Tidal volume</i> , V_T^a	500 ml	150 ml	30 ml
<i>Set rate</i>	10 breaths/min	20 breaths/min	30 breaths/min
<i>I:E ratio</i>	1:2	1:2	1:2
<i>BAP</i>	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)
Linear resistance, $R^{b[49][66][69]}$	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 ± 10 %	20 ml·hPa ⁻¹ ± 10 %	1 ml·hPa ⁻¹ ± 10 %
<p>^a V_T is measured by means of a pressure sensor at the test lung, where $V_T = C (P_{\max} - P_{\min})$, and</p> <p>$V_T$ is the volume delivered to the test lung</p> <p>C is the isothermal compliance of the test lung</p> <p>P_{\max} is the maximum pressure measured in the test lung</p> <p>P_{\min} is the minimum pressure measured in the test lung.</p> <p>^b The accuracy for C and R applies over the ranges of the measured parameters.</p> <p>NOTE There is guidance or rationale for this table contained in Clause AA.2.</p>			

- 5) 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. $L_{AF\max}$) 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 conformity with 8.2.2 of ISO 3744:2010.
- 6) Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with 8.2.2 of ISO 3744:2010.
- 7) Calculate the A-weighted sound power level in accordance with 8.6 of ISO 3744:2010.
- 8) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.
- 9) Ensure that the average measured sound pressure level is less than that disclosed in the *instructions for use*.
- 10) Ensure that the sound power level is less than that disclosed in the *instructions for use*.

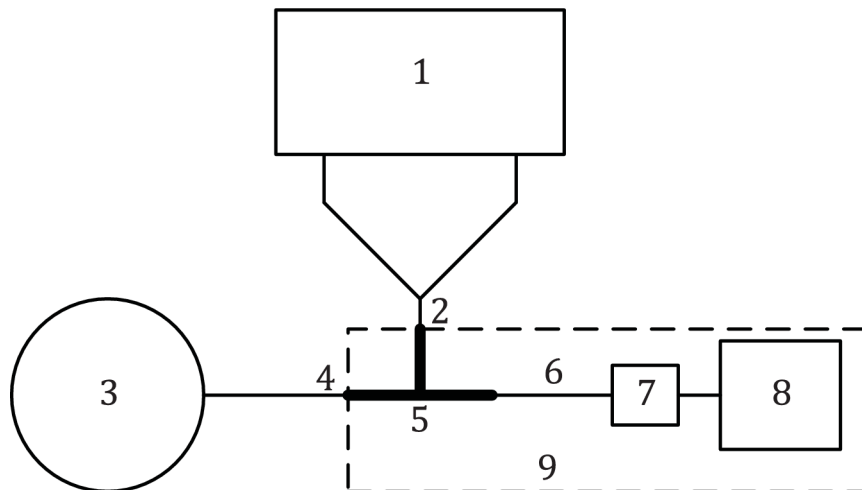
201.9.101 Additional requirements for suction procedures

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- 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*.

- c) Check conformity by inspection of the *instructions for use* and with the following test:
 - 1) 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. Use a closed *suction catheter* of minimum inside diameter of 2,95 mm (French (Charriere) equivalent size 14 F).
 - 2) Adjust the suction equipment as follows:
 - i) 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.
 - ii) 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*, $V_T \geq 300$ ml;
 - II) 15 l/min, for a *ventilator* intended to provide *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml; and
 - III) 5 l/min, for a *ventilator* intended to provide *tidal volume*, $V_T \leq 50$ ml.
 - 3) Disable the suction flow without affecting the flow control valve setting.
 - 4) Connect the *ventilator* as shown in Figure 201.101 using the lowest compliance *VBS* indicated in the *instructions for use* for the intended *tidal volume* range.
 - 5) Connect a test lung to the *patient-connection port* of the closed *suction catheter* adaptor. Use a test lung with compliance:
 - i) 10 ml/hPa ± 10 %, for a *ventilator* intended to provide *tidal volume*, $V_T \geq 300$ ml;
 - ii) 3 ml/hPa ± 10 %, for a *ventilator* intended to provide *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml; and



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 8836:2019
- 7 flow control valve (can be incorporated in 8)
- 8 suction equipment conforming with ISO 10079-1:2022 or ISO 10079-3:2022
- 9 suction system

Figure 201.101 — Typical closed suctioning test setup

- iii) 0,5 ml/hPa \pm 10 %, for a ventilator intended to provide tidal volume, $V_T \leq 50$ ml.
- 6) Do not enable any special suction procedure ventilator operational mode and retract the closed suction catheter.
- 7) Perform any compliance correction as indicated in the instructions for use.
- 8) Select a volume-control inflation-type with the following settings:
 - i) minimum tidal volume for the intended tidal volume range;
 - ii) set rate: 10 breaths/min; and
 - iii) trigger: off or, if not so equipped, at the most insensitive method and setting.
- 9) Wait until stability is achieved.
- 10) Advance the closed suction catheter between 1 cm and 2 cm beyond the patient-connection port.
- 11) 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.

- 12) 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.

- 13) Wait until stability is achieved.
- 14) Confirm that the *ventilator* continues to function as intended.

EXAMPLE The *tidal volume* is within specification.

- 15) Repeat 1) to 14) for each intended *tidal volume* range.
- 16) Repeat 1) to 15) using a *pressure-control inflation-type* with the following parameters in lieu of 1):
 - i) ventilation pressure of 5 cmH₂O or, if the *ventilator* cannot be set that low, the lowest setting;
 - ii) *set rate*: 10 breaths/min; and
 - iii) trigger: off or, if not so equipped, at the most insensitive setting.
- 17) Repeat 1) to 15) using the recommended *ventilation-mode* and settings for use with a closed *suction catheter* in lieu of 1) unless the recommended *ventilation-mode* and settings have already been tested.

201.10 Protection against unwanted and excessive radiation hazards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies.

201.11 Protection against excessive temperatures and other hazards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows:

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (add before the last paragraph):

In *normal use* and *single fault conditions* and 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 not exceed:

- aa) 70 °C; and
- 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (add additional requirement as new first paragraph):

- aa) *Gas pathways* through the *ventilator* and its *accessories* not intended for *single use* 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 for:
 - 1) *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+AMD2:2020.

- bb) *Processing* instructions for the *gas pathways* that can become contaminated of the *ventilator* and its *accessories* shall:
 - 1) conform with ISO 17664-1:2021;

- 2) conform with ISO 14937:2009, if applicable; and
- 3) be disclosed in the *instructions for use*.

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

- cc) *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 provides guidance for the design of *enclosures*.

dd) *Processing* instructions for the *ventilator enclosure* shall

- 1) conform with ISO 17664-2:2021; and
- 2) be disclosed in the *instructions for use*.

Check conformity by inspection of the *risk management file* to determine the *gas pathways* that can become contaminated in *normal condition* and *single fault condition* and conformity with ISO 17664-1:2021 and ISO 17664-2:2021, as appropriate. 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 *processing* 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+AMD2:2020.

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 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* in accordance with ISO 18562-1:2023.

Addition:

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall be equipped with
 - 1) 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.

- 2) a means of determining the remaining capacity or operation time provided by the *internal electrical power source*.
 - i) This indication may be qualitative.
 - 3) a means to determine the power source that is currently powering the *ventilator*.
- b) A *ventilator* shall
- 1) be equipped with an *alarm system* that detects a *technical alarm condition* or
 - i) The *alarm condition* for switchover to an *internal electrical power source* shall be at least a *low priority*.
 - 2) generates an *information signal* to indicate a switchover to an *internal electrical power source*.
 - 3) 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.
 - i) The *internal electrical power source* nears depletion *alarm condition* shall be at least a *medium priority*.
 - ii) 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*.
- c) The *instructions for use* shall disclose
- 1) for each intended *tidal volume* under the conditions of Table 201.102, the operational time of the *ventilator* when powered from
 - i) an aged (see d) 1), fully charged *internal electrical power source* and
 - ii) 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*.
 - 2) the means by which the secondary *supply mains*, if provided, can be tested.
 - 3) the behaviour of the *ventilator* after a switchover:
 - i) to the *internal electrical power source*; or
 - ii) 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.
 - 4) the behaviour of the *ventilator* while:
 - i) the *internal electrical power source* is recharging; and
 - ii) the external reserve electrical power source is recharging, if provided.
- d) Check conformity by inspection of the *instructions for use*, functional testing and the following test.
- 1) Age a previously unused *internal electrical power source* by operating the *ventilator* from the *internal electrical power source* using the test parameters from the column of Table 201.102 representing the largest intended *tidal volume* and *inflation-type*:

- i) until the *high priority internal electrical power source* nears depletion *technical alarm condition* becomes active;
 - ii) recharge the *internal electrical power source* by connecting the *ventilator* to *supply mains*;
 - I) A dwell time may be inserted following recharging to permit the *ventilator* to reach thermal equilibrium.
 - iii) repeat i) and ii) 10 times; and
 - iv) for a *transit-operable ventilator*, repeat i) and ii) an additional 40 times.
 - v) Instead of using the *ventilator*, discharging and charging circuits may be used with an equivalent profile simulating worst-case conditions:
 - I) temperature of the *internal electrical power source* while in use;
 - II) over the discharging time; and
 - III) over the charging time.
- 2) Operate the *ventilator* using an intended *tidal volume* and *inflation-type* under the conditions of Table 201.102.
 - 3) Confirm that the *medium priority alarm condition* occurs at least 10 min prior to the loss of ventilation.
 - 4) Confirm that the *high priority alarm condition* occurs at least 5 min prior to the loss of ventilation.
 - 5) Repeat 2) to 4) for each remaining range of intended *tidal volume*.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (add after existing sentence):

- aa) The controls and display of a *ventilator* necessary to perform the *primary operating functions* indicated in 206.101 a) 2) and 206.101 a) 3) shall be *clearly legible* under the conditions specified in 7.1.2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 with the intended position of the *operator* for the purpose evaluating the legibility of *markings* is at least 2 m from the *ventilator*.

Check conformity by application of the tests in 7.1.2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020.

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

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 (FiO_2) concentration at the *patient-connection port* in relation to the set value.
 - i) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

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

- 1) $V_T \geq 300$ ml;
- 2) $300 \text{ ml} \geq V_T \geq 50$ ml; and
- 3) $V_T \leq 50$ 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* configurations indicated in the *instructions for use*. In determining the worst-case configuration, consider use with active and passive humidification.

NOTE 2 The worst-case *VBS* configuration can be different for each error or *nominal tidal volume*.

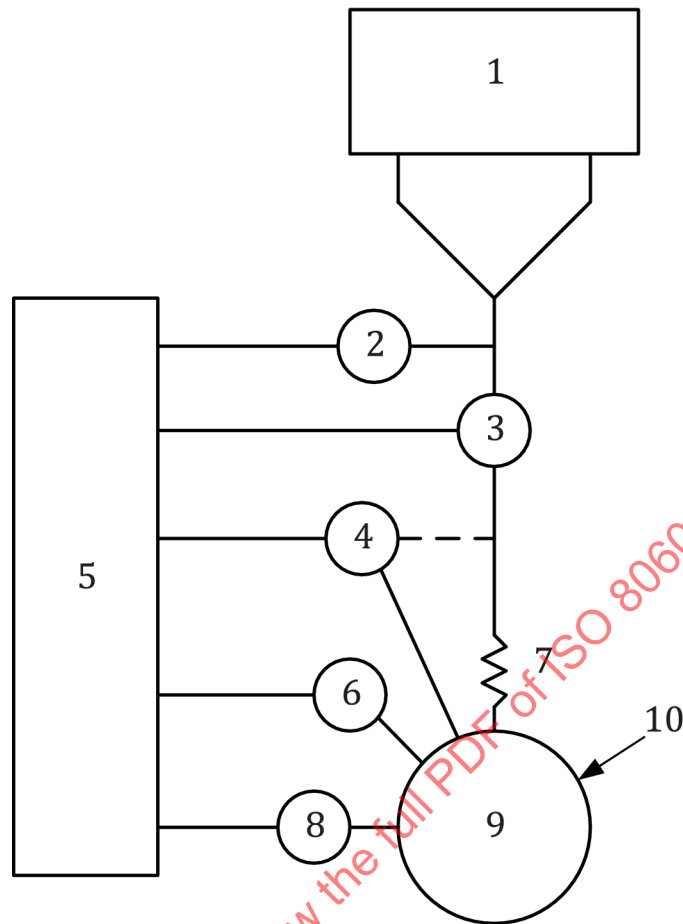
e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the design documentation.

f) Check conformity by inspection of the design documentation for the rationale, if applicable, and with the following tests:

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

- 1) *Tidal volume* and end-expiratory pressure errors
 - i) Set up the *ventilator* as shown in Figure 201.102.
 - ii) 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.
 - iii) Use the test parameters and settings of the first applicable row (selected by intended *tidal volume*) of Table 201.104.
 - iv) Wait for steady-state conditions to be achieved.
 - v) 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 [59].

**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

- vi) Compare the result with the acceptance criteria derived from the volume setting for the test and the tolerance indicated in the *instructions for use*.
- vii) If the 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 v). Refer to Table 201.104.
- viii) 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 ^{[49][66][69]} hPa·(l/s) ⁻¹ ±10 %	Tidal volume ml	Set rate ^a breaths/min	Inspiratory time s	FiO ₂ %	BAP hPa (cmH ₂ O)
1	— ^b	— ^b	Maximum settable tidal volume	— ^b	— ^b	— ^b	— ^b
2	50	5	500	20	1	30	5
3	50	20	500	12	1	90	10
4	20	5	500	20	1	90	5
5	20	20	500	20	1	30	10
6	20	20	300	20	1	30	5
7	20	50	300	12	1	90	10
8	10	50	300	20	1	30	10
9	10	10	200	20	1	90	5
10	3	10	50	30	0,6	30	5
11	3	20	50	30	0,6	30	10
12	3	50	50	20	0,6	60	5
13	3	20	30	30	0,6	30	5
14	3	50	30	20	0,6	90	10
15	1	20	30	30	0,6	90	5
16	1	100	30	30	0,6	30	10
17	1	200	20	50	0,4	30	5
18	1	200	15	50	0,4	60	10
19	1	50	10	60	0,4	60	5
20	0,5	50	5	60	0,4	60	10
21	0,5	200	5	30	0,4	30	5
22	0,5	200	5	60	0,4	30	10
23	— ^b	— ^b	Minimum settable tidal volume	— ^b	— ^b	— ^b	— ^b

^a If the *end-expiratory flow* does not reach zero, reduce the *set rate* until it does.

^b The *instructions for use* shall indicate this value.

NOTE There is guidance or rationale for this table contained in Clause AA.2.

- ix) Compare the result with the acceptance criteria derived from the *BAP* setting for the test and the resulting difference with the tolerance indicated in the *instructions for use*.
- x) Repeat iii) to ix) for 30 consecutive *inflations*.

- xi) Repeat iv) to x) for each applicable row (selected by intended *tidal volume*) of Table 201.104.
- xii) 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.
- xiii) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat ii) to xii) for each flow pattern available on the *ventilator*.
- xiv) If the *ventilator* permits operation without compliance correction, repeat ii) to x) without compliance correction.

2) Oxygen (O_2) error

- i) The accuracy of the inspiratory oxygen concentration of the gas delivered is assessed by placing the sensor of an oxygen 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*.
- ii) Evaluate the measured oxygen concentration with the acceptance criteria derived from the oxygen setting for the test and the disclosed tolerance.
- iii) 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 oxygen concentration measuring device has pressure dependencies, compensate for these dependencies.
- iv) Compare each result with the acceptance criteria derived from the oxygen setting for the test in f) 1) 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 $\pm(3,0 \text{ hPa} + 5 \% \text{ of the set pressure})$; $(\pm(3,0 \text{ cmH}_2\text{O} + 5 \% \text{ of the set pressure}))$

- 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 (FiO_2) concentration at the *patient-connection port* in relation to the set value.
 - i) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

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

- 1) $V_T \geq 300 \text{ ml}$;
- 2) $300 \text{ ml} \geq V_T \geq 50 \text{ ml}$; and

3) $V_T \leq 50$ 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*. In determining the worst-case configuration consider use with active and passive humidification.

NOTE 2 The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.

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

1) End-inspiratory and end-expiratory pressure errors

- i) Set up the *ventilator* as shown in Figure 201.102.
- ii) 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.
- iii) Use 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.
- iv) Determine the *airway pressure* at the end of the *inflation phase* as the average over the preceding 50 ms.
- v) Compare the result with the acceptance criteria derived from the pressure setting for the test and the tolerance indicated in the *instructions for use*.
- vi) 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 test 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 [59].

- vii) If the *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 vi). Refer to Table 201.105.
- viii) Determine the *PEEP* as the average of the *airway pressure* measurements over the last 50 ms of the *expiratory phase*.
- ix) Compare the result with the acceptance criteria derived from the *BAP* setting for the test and the tolerance indicated in the *instructions for use*.
- x) Repeat ii) to ix) for 30 consecutive *inflations*.
- xi) Repeat ii) to x) for each applicable row (selected by intended *tidal volume*) of Table 201.105.
- xii) 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.

Table 201.105 — Pressure-control inflation-type testing

Test number	Intended tidal volume ^a ml	Test lung parameters		Ventilator settings				
		Compliance ml/hPa ±10 %	Linear Resistance [49][66][69] hPa·(l/s) ⁻¹ ±10 %	Set rate ^b breaths/min	Inspiratory time ^c s	Δ inspiratory pressure ^d hPa	FiO ₂ %	BAP hPa (cmH ₂ O)
1	— ^e	— ^e	— ^e	— ^e	— ^e	Maximum settable pressure	— ^e	— ^e
2	500	50	5	20	1	10	30	5
3	500	50	20	12	1	15	90	10
4	500	20	5	20	1	25	90	5
5	500	20	20	20	1	25	30	10
6	300	20	20	20	1	15	30	5
7	300	20	50	12	1	25	90	10
8	300	10	50	20	1	30	90	5
9	200	10	10	20	1	25	30	10
10	50	3	10	30	0,6	15	30	5
11	50	3	20	30	0,6	15	30	10
12	50	3	50	20	0,6	25	60	5
13	30	3	20	30	0,6	10	30	5
14	30	3	50	20	0,6	15	90	10
15	30	1	20	30	0,6	30	90	5
16	30	1	100	30	0,6	30	30	10
17	20	1	200	50	0,4	20	30	5
18	15	1	200	50	0,4	15	60	10
19	10	1	50	60	0,4	10	60	5
20	5	0,5	50	60	0,4	15	60	10
21	5	0,5	50	30	0,4	10	30	5
22	5	0,5	200	60	0,4	15	30	10
23	— ^e	— ^e	— ^e	— ^e	— ^e	Minimum settable pressure	— ^e	— ^e

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

^b If the *end-expiratory flow* does not reach zero, reduce the *set rate* until it does.

^c The rise time of the *ventilator* should be set to a value that ensures that 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 The *instructions for use* shall indicate this value.

NOTE There is guidance or rationale for this table contained in Clause AA.2.

- xiii) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat ii) to xii) for each flow pattern available on the *ventilator*.
- xiv) If the *ventilator* permits operation without compliance correction, repeat ii) to xiii) without compliance correction.

2) Oxygen (FiO_2) error

- i) The accuracy of the inspiratory oxygen concentration of the gas delivered is assessed by placing the sensor of an oxygen 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*.
- ii) Evaluate the measured oxygen concentration with the acceptance criteria derived from the oxygen setting for the test and the disclosed tolerance.
- iii) 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 oxygen concentration measuring device has pressure dependencies, compensate for these dependencies.
- iv) Compare each result with the acceptance criteria derived from the oxygen setting for the test in f) 1) 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 performance and acceptance criteria may be reported separately for the following ranges of intended *tidal volume*:
 - 1) $V_T \geq 300$ ml;
 - 2) $300 \text{ ml} \geq V_T \geq 50$ ml; and
 - 3) $V_T \leq 50$ 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*. In determining the worst-case configuration consider use with active and passive humidification.

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

- d) 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 *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*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) If the *ventilator* is equipped with *inspiratory volume monitoring equipment*, the accuracy of the *inspiratory volume monitoring equipment* shall be disclosed in the *instructions for use*.
- b) For actual *tidal volumes* greater than 50 ml, the accuracy of the *inspiratory volume monitoring equipment* shall be within $\pm(4,0 \text{ ml} + 15 \% \text{ of the actual inspiratory volume})$.

Check conformity with the following.

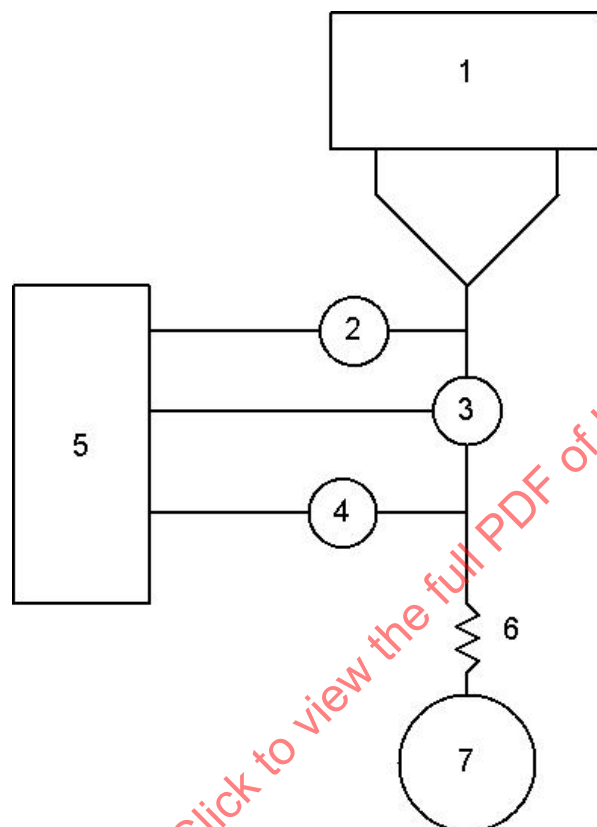
Confirm that the *inspiratory volume monitoring equipment* accuracy as measured in 201.12.1.101 f) 1) vii) and 201.12.1.102 f) 1) vii) is within the accuracy disclosed in the *instructions for use*. For *tidal volumes* greater than 50 ml ensure that the accuracy disclosed in the *instructions for use* is $\pm(4,0 + (15 \% \text{ of the actual inspiratory volume}))$ ml or better.

201.12.1.105 *Response of the ventilator to an increase in set oxygen (O₂) concentration*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The length of time required for the oxygen concentration in the *tidal volume* to change from an oxygen concentration of 21 % to an oxygen concentration of 90 % of the maximum achievable delivered oxygen concentration shall be disclosed in the *instructions for use*.
- b) The worst-case input oxygen concentration within the *rated* range shall be used for this test.
- c) The time shall be reported separately, as appropriate, at *tidal volumes* for each intended *tidal volume* under the conditions of Table 201.106, using:
- 1) the worst-case *VBS*; or
 - 2) the maximum internal volume *VBS* and
 - 3) if *bias flow* or *continuous flow* controls are provided, at:
 - i) the minimum *bias flow*, or
 - ii) the minimum *continuous flow*.
- d) The time may be reported separately for:
- 1) each *VBS*; or
 - 2) as a maximum (for the worst-case *VBS* and minimum *tidal volume*).
- e) Check conformity with the following tests.

- 1) Set up the *ventilator* as shown in Figure 201.103 using the worst-case *VBS* or using the maximum internal volume *VBS*. If the *VBS* includes a *humidifier*, use the minimum *humidifier* water level indicated in the *instructions for use*.
- 2) Use the test conditions for the first applicable column available on the *ventilator* (selected by intended *tidal volume range*) in Table 201.106.



Key

- | | | | |
|---|------------------------------|---|-------------------------|
| 1 | <i>ventilator</i> under test | 5 | data acquisition system |
| 2 | pressure sensor | 6 | resistance |
| 3 | flow sensor | 7 | test lung |
| 4 | oxygen sensor | | |

Figure 201.103 — Oxygen concentration change test setup

Table 201.106 — Test conditions for oxygen concentration change tests

Adjustable parameter	Test condition		
	For a ventilator intended to provide <i>tidal volume</i>		
	$V_T \geq 300 \text{ ml}$	$300 \text{ ml} \geq V_T \geq 50 \text{ ml}$	$V_T \leq 50 \text{ ml}$
<i>Tidal volume, V_T^a</i>	500 ml	150 ml	30 ml
<i>Set rate</i>	10 <i>breaths/min</i>	20 <i>breaths/min</i>	30 <i>breaths/min</i>
<i>I:E ratio</i>	1:2	1:2	1:2
Resistance, $R^{b[49][66][69]}$	$5 \text{ hPa} \cdot (\text{l/s})^{-1} \pm 10 \%$	$20 \text{ hPa} \cdot (\text{l/s})^{-1} \pm 10 \%$	$50 \text{ hPa} \cdot (\text{l/s})^{-1} \pm 10 \%$
^a V_T is determined by using the settings of the <i>ventilator</i> .			
^b The accuracy for R applies over the ranges of the measured parameters.			

- 3) Ventilate the test lung with a set oxygen concentration of 21 %.
- 4) Wait until equilibrium is reached in the inspired oxygen concentration at the *patient-connection port*.
- 5) Change the set oxygen concentration to the maximum delivered oxygen concentration that the *ventilator* permits.
- 6) Measure the time delay between setting the new concentration and achieving 90 % of the final oxygen concentration during inspiration at the *patient-connection port*. 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*.
- 7) Ensure that the measured time delay is less than or equal to that indicated in the *instructions for use*.
- 8) Repeat 3) to 7) for each applicable column (selected by intended *tidal volume* range) in Table 201.106.
- 9) If the *ventilator* is provided with *bias flow* during the *expiratory phase*, repeat 3) to 8) at the minimum *bias flow* setting available on the *ventilator*.
- 10) If the *ventilator* is provided with *continuous flow* throughout the *respiratory cycle*, repeat 3) to 8) at the minimum continuous flowrate setting available on the *ventilator*.

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 Oxygen monitor

- a) The *ventilator* shall either:
 - 1) be equipped with oxygen *monitoring equipment* for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port*) that is integral to the *ventilator*; or

- 2) the *instructions for use* shall contain a statement to the effect that the *ventilator* is to be equipped with *oxygen monitoring equipment* for measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port*) before being put into service.
- b) Integrated *oxygen 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;
 - i) None of the display of the *ventilator* shall be blanked when fulfilling the requirement of ISO 80601-2-55:2018, 201.12.1.101.4.1 c).
 - 4) 201.12.1.102;
 - 5) 201.12.1.103; and
 - 6) 208.6.1.2.
- c) Where the *oxygen monitoring equipment* is not an integral part of the *ventilator*, the *instructions for use* shall include information on where to connect the *oxygen monitoring equipment*.
- d) The *oxygen 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 conformity 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*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall be equipped with *monitoring equipment* to measure the *airway pressure*.
- b) The site of actual measurement:
- 1) may be anywhere in the *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 $\pm(2 \text{ hPa} + 4 \% \text{ of the actual reading})$ ($\pm(2 \text{ cmH}_2\text{O} + 4 \% \text{ of the actual reading})$).

Check conformity by functional testing.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.12.4.103.1 Ventilators intended to provide a *tidal volume* >50 ml

a) A *ventilator* intended to provide a *tidal volume* greater than 50 ml shall 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* shall include a statement to the effect that the *ventilator* is to be equipped with *monitoring equipment* that conforms with this document before being put into service.
 - i) Information on where to connect the expired volume *monitoring equipment* shall be disclosed in the *instructions for use*.

b) If equipped,

- 1) the accuracy of measurement of expired volumes greater than 50 ml shall be within $\pm(4,0 \text{ ml} + 15 \% \text{ of the actual volume expired through the } \textit{patient-connection port})$.
- 2) the accuracy of expired volume *monitoring equipment* shall be disclosed in the *instructions for use*.
 - i) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

NOTE The use of Oxygen 93 % can reduce the accuracy of measurement due to influence of other gases such as argon on flow measurement.
- 3) the expired volume *monitoring equipment* shall be equipped with an *alarm system* to indicate when:
 - i) the low expired volume *alarm limit* is reached; and
 - ii) the high expired volume *alarm limit* is reached.
- 4) the low expired volume and the high expired volume *alarm conditions*:
 - i) shall be at least *medium priority*; unless
 - ii) an *intelligent alarm system*, based on additional information, determines that
 - I) the low expired volume *alarm condition* or
 - II) the high expired volume *alarm condition*
 is suppressed or its priority is changed.

5) the expired volume *monitoring equipment* may be equipped with an *alarm system* that:

- i) starts with *low priority alarm conditions* to indicate when the expired volume reaches either *alarm limit*; and
- ii) if this state continues, escalates to *medium priority alarm conditions*.

6) the expired volume *alarm limits* may be:

- i) pre-adjusted;
- ii) *responsible organization*-configurable;

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

- iii) *healthcare professional operator*-adjustable;
 - iv) *ventilator*-adjustable; or
 - v) a combination of *healthcare professional operator*-adjustable and *ventilator*-adjustable.
- 7) if the *alarm limits* are adjustable by the *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 used, there can be more than one active *alarm limit*.

Check conformity 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*).

201.12.4.103.2 Ventilators intended to provide a *tidal volume* ≤50 ml

- a) If a *ventilator* is intended to provide a *tidal volume* ≤50 ml, it may be equipped with expired volume monitoring equipment.
- b) The accuracy of the expired volume monitoring equipment at an expired volume ≤50 ml shall be disclosed in the *instructions for use*.
 - 1) 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.

- c) The expired volume monitoring equipment may be equipped with an *alarm system* to indicate when the expired volume reaches the low expired volume *alarm limit*.
- d) The low expired volume *alarm condition*:
 - 1) shall be at least *low priority*; unless
 - 2) an *intelligent alarm system*, based on additional information, determines that:
 - i) the low expired volume *alarm condition* is suppressed; or
 - ii) its priority is changed.
- e) If provided, the expired volume *alarm limit* may be:
 - 1) pre-adjusted;
 - 2) *responsible organization*-configurable;

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

- 3) *healthcare professional operator*-adjustable;

- 4) *ventilator*-adjustable; or
- 5) a combination of *healthcare professional operator*-adjustable and *ventilator*-adjustable.
- f) If the *alarm limit* is adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the *instructions for use*.

NOTE 3 Depending on the type of *ventilation-mode* being used, there can be more than one active *alarm limit*.

Check conformity 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 and maximum *VBS* compliance.

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

201.12.4.104 Expiratory end-tidal CO₂ monitoring equipment

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) If a *ventilator* intended to provide a *tidal volume* ≤50 ml is not equipped with expired volume monitoring equipment (see 201.12.4.103.2), the *ventilator* shall either:
 - 1) be equipped with CO₂ monitoring equipment for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port*) that is integral to the *ventilator*; or
 - 2) the *instructions for use* shall contain a statement to the effect that the *ventilator* is to be equipped with CO₂ monitoring equipment for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port*) before being put into service.
 - i) The *instructions for use* shall include information on where to connect the CO₂ monitoring equipment.
- b) Integrated CO₂ 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;
 - i) None of the display of the *ventilator* shall be blanked when fulfilling the requirement of ISO 80601-2-55:2018, 201.12.1.101.4.1 c).
 - 4) 201.12.1.102;
 - 5) 201.12.1.103; and
 - 6) for expired CO₂ concentration, 208.6.1.2.

Check conformity by inspection.

201.12.4.105 *Maximum limited pressure protection device*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

A *protection device* shall be provided to prevent the *airway pressure* from exceeding for more than 200 ms the lower of:

- a) 20 hPa (20 cmH₂O) more than the high *airway pressure alarm limit*; or
- b) 125 hPa (125 cmH₂O).

NOTE 2 This requirement applies in both *normal condition* and *single fault condition*. See 201.3.265.

NOTE 3 See also 201.12.4.106 and 201.12.4.110.

Check conformity by functional testing.

201.12.4.106 *High airway pressure alarm condition and protection device*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* to indicate when the high-pressure limit for *airway pressure* is reached during the entire *respiratory cycle*.
- 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; or
 - 2) related to the set pressure of the *ventilator*.
- d) It shall not be possible to set the high *airway pressure alarm limit* to a value greater than the *maximum limited pressure*.
- e) Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm the setting of the high *airway pressure alarm limit* to values exceeding the lower of:
 - 1) 20 hPa (20 cmH₂O) more than the maximum set *airway pressure*; or

NOTE 2 An example of the maximum set pressure is the sum of the set *BAP* and the set Δ *inspiratory pressure*.

NOTE 3 An example for a bi-level positive *airway pressure ventilation-mode*, is the sum of the set *BAP_H* and the set Δ *H inspiratory pressure*. See ISO 19223:2019, Figure C.33.

NOTE 4 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 cmH₂O).

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

EXAMPLE A 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) In *normal condition*, whenever the high *airway pressure alarm condition* occurs, the *ventilator* shall reduce the *airway pressure* to the set *BAP* level within the lesser of:

- 1) two *respiratory cycles*; or
- 2) 15 s.

- i) During *single fault condition*, the *ventilator* shall reduce the *airway pressure* to the set *BAP* level or below within no more 30 s.

Check conformity by functional testing.

201.12.4.107 *PEEP alarm conditions*

- a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate when the end-expiratory pressure is above the high *PEEP alarm limit*.
- b) The *ventilator* may be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate when the end-expiratory pressure is below the low *PEEP alarm limit*.
- c) Both the high and low *PEEP alarm conditions*:
 - 1) shall be of at least *medium priority*; unless
 - 2) an *intelligent alarm system*, based on additional information determines that the high or low *PEEP alarm condition*:
 - i) is suppressed; or
 - ii) the priority is changed.
- d) The *alarm condition delay* for high *PEEP alarm condition* shall not exceed the duration of three *inflations*.

Check conformity by functional testing with every *VBS* indicated in the *instructions for use*.

NOTE To perform this test, modification of the *ventilator* to disable the *BAP* control can be required.

201.12.4.108 *Obstruction alarm condition*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects a *technical alarm condition* to indicate when the *alarm limit* for obstruction is reached.

EXAMPLE *Alarm condition* to warn of:
— an obstructed inspiratory or expiratory breathing tube;
— a blocked exhalation valve; and
— a blocked expiratory *breathing system filter*.

- b) The obstruction *technical alarm condition*:
- 1) shall be *high priority*, unless
 - 2) an *intelligent alarm system*, based on additional information, determines that the obstruction *technical alarm condition*:
 - i) is suppressed; or
 - ii) its priority is changed.
- c) The *alarm condition delay* shall not exceed more than
- 1) two *respiratory cycles* or
 - 2) 5 s,
- whichever is greater.
- d) Whenever the obstruction *alarm condition* occurs, the *ventilator* shall, within no more than one *respiratory cycle*, reduce the *airway pressure* to either:
- 1) atmospheric pressure; or
 - 2) the set *BAP* level.
- e) The *ventilator* should be equipped with a *protection device* to allow spontaneous breathing when obstruction occurs.
- f) If equipped with the *protection device*, the pressure drop measured at the *patient-connection port*, with all recommended *accessories* in place, shall not exceed 6,0 hPa (6,0 cmH₂O) at a flowrate of:
- 1) 30 l/min for a *ventilator* intended to provide *tidal volume*, $V_T \geq 300$ ml;
 - 2) 15 l/min for a *ventilator* intended to provide *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml; and
 - 3) 2,5 l/min for a *ventilator* intended to provide *tidal volume*, $V_T \leq 50$ ml.
- g) The *accompanying document* shall describe:
- 1) the means by which the obstruction *alarm condition* is determined; and
 - 2) a means to test the obstruction *alarm condition*.

Check conformity by functional testing with each VBS indicated in the *instructions for use*, in accordance with the test method described in the *accompanying document*.

201.12.4.109 Disconnection *alarm condition*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for disconnection.

NOTE 2 Disconnection can be detected using one or more means, for example measurement of pressure at the *ventilator gas output port*, measurement of flow at the exhalation valve or measurement of expired flow or end-tidal CO₂ at the *patient-connection port*.

- b) The disconnection *technical alarm condition* shall be at least *medium priority*.
- c) Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm the setting of *alarm off* or *audio off* for the disconnection *technical alarm condition*.
- d) The *instructions for use* shall disclose the maximum *alarm condition delay* of the disconnection *technical alarm condition*.
- e) The *instructions for use* shall disclose any *use scenarios* in which decannulation might not be detected as a *VBS* disconnection.

EXAMPLE For a neonatal *ventilator* normally intended to be used with a flow sensor placed between the *patient-connection port* and the tracheal tube, use of the *ventilator* with the flow sensor disconnected.

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

201.12.4.110 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 cmH₂O). See also 201.12.4.106 e) and 206.101 a) 6).

Check conformity by functional testing.

201.12.101 Protection against accidental or unintentional adjustments

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall include a means for the *healthcare professional operator* to confirm the *ventilation-mode* and settings:
- 1) during the start-up *procedure*; and
 - 2) when the *ventilation-mode* is changed during use.
- b) Means of protection shall be provided against accidental or unintentional adjustment of controls that can create a *hazardous situation*, including against accidentally turning the *ventilator* off.
- c) The *usability* of these means of protection shall be evaluated in the *usability engineering process*.

NOTE 2 The requirements for the *usability engineering process* are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 12.2 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020.

Check conformity by functional testing and inspection of *usability engineering file*.

201.13 Hazardous situations and fault conditions for ME equipment

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 13 applies, except as follows:

Addition:

201.13.2.101 Additional specific *single fault conditions*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

- a) disconnection or blockage of the gas delivery to the *patient-connection port* from the *ventilator*;
- b) when present, disconnection or blockage of the gas flow pathway from the *patient-connection port* to the *ventilator*;
- c) failure to install, removal or failure of a *healthcare professional operator-detachable breathing system filter*; and
- d) interruption 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*.

Check conformity by functional testing and inspection of *risk management file*.

201.13.2.102 Failure of one gas supply to a *ventilator*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) For a *ventilator* with multiple high-pressure gas supplies, following the failure of one gas supply the *ventilator* shall:
 - 1) continue ventilation using the other gas supply;
 - 2) maintain *basic safety*; and
 - 3) maintain *essential performance*.
- b) The *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*; unless
 - 2) an *intelligent alarm system*, based on additional information, determines that the gas supply failure *technical alarm condition* is suppressed.

Check conformity by functional testing.

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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- 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 of the following to fail in such a way that the loss of the ventilation control function is not detected:
 - 1) a ventilation control function and the corresponding *monitoring equipment*; or
 - 2) a ventilation control function and the corresponding *alarm system*

Check conformity by inspection and functional testing.

201.13.2.104 Failure of *functional connection* to a ventilator control or monitoring means

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) Following the failure of a *functional connection* to a ventilator control or monitoring means, the ventilator shall continue to ventilate the patient.
- b) The ventilator shall be equipped with an alarm system that detects a *technical alarm condition* to indicate this communication failure.
- c) The communication failure *technical alarm condition*:
 - 1) shall be at least *medium priority*; unless
 - 2) an *intelligent alarm system*, based on additional information, determines that the communication failure *technical alarm condition*:
 - i) is suppressed; or
 - ii) the priority is changed.

Check conformity by functional testing.

201.14 Programmable electrical medical systems (PEMS)

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 applies, except as follows:

Addition:

201.14.1 General

- aa) The *programmable electronic subsystems (PESS)* of a ventilator shall be developed with a design process conforming with:
 - 1) IEC 62304:2006+AMD1:2015; and
 - 2) IEC 81001-5-1:2021.

- bb) The ventilation control *software items* of the *ventilator PESS* without an independent hardware *risk control* measure shall be considered as software safety Class C.

Check conformity 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).

201.14.102 Cybersecurity capabilities of critical care ventilators

- a) The design and manufacture of a critical care *ventilator* should contribute to safe operation related to *cybersecurity* threats.
- b) *Risk control* measures as specified in IEC/TR 60601-4-5:2021, Clauses 4 to 7, should be implemented, as appropriate, with the following additions to IEC/TR 60601-4-5:2021, 4.6.3.
- 1) *Essential function*: After disconnection of all data interfaces to *IT-network* connections possibly subject to *attack* (via physical or logical disconnection), if necessary, after restarting the critical care *ventilator* once, all clinical functions except those related to the affected remote functionality should be in place and operate as intended.
 - 2) *Firecall* functions: As a critical care *ventilator* is used with *healthcare professional operator* supervision, the user interface need not require authentication for *operators* and thus need not require *firecall* functions. If authentication for *operators* to *operator* accessible settings is in place also for the user interface, a *firecall* function should be able to overrule that *operator* authentication combined with a log entry protected against modifications by the *operator* (i.e. *responsible organization* log). *IT-network* interfaces including those for remote access typically require authentication but should not include *firecall* functions.
 - 3) Target *security level* SL-T: For user interfaces and for remote setting of clinical functions, the expected *security level* of SL-T, as specified in IEC/TR 60601-4-5:2021, is 1 or better. However, authentication of *operators* is not required for the user interface, only for access via data interfaces. The expected *security level* of SL-T, as specified in IEC/TR 60601-4-5:2021, is 2 or better for secure updates or restorage of software, remotely or locally.

201.15 Construction of ME equipment

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 15 applies, except as follows:

Addition:

201.15.3.5.101 Additional requirements for rough handling

201.15.3.5.101.1 Shock and vibration (robustness)

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) A *ventilator* and its parts, including applicable *accessories* shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling.
- b) *Stationary ME equipment* is exempt from the requirements of this subclause.
- c) After the following tests, the *ventilator* shall:
- 1) maintain *basic safety* and *essential performance*; and

- 2) conform with the requirements of 201.12.1 and 201.12.4.

NOTE 1 A *ventilator* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

- d) Check conformity by performing the following tests:

- 1) Shock test in conformity with IEC 60068-2-27:2008, using the following conditions:

NOTE 2 This represents IEC/TR 60721-4-7:2001, Class 7M2.

- i) test type: Type 1:

- I) peak acceleration: 150 m/s² (15 g);
- II) duration: 11 ms;
- III) pulse shape: half-sine; and
- IV) number of shocks: 3 shocks per direction per axis (18 total);

or

- ii) test type: Type 2:

- I) peak acceleration: 300 m/s² (30 g);
- II) duration: 6 ms;
- III) pulse shape: half-sine; and
- IV) number of shocks: 3 shocks per direction per axis (18 total).

- 2) Broadband random vibration test in conformity with IEC 60068-2-64:2008+AMD1:2019, using the following conditions:

NOTE 3 This represents IEC/TR 60721-4-7:2001, Classes 7M1 and 7M2, modified.

- i) acceleration amplitude:

- I) 10 Hz to 100 Hz: 1,0 (m/s²)²·Hz⁻¹; and
- II) 100 Hz to 500 Hz: -6 db per octave;

- ii) duration: 10 min per perpendicular axis (3 total).

- e) Confirm that *basic safety* and *essential performance* and the requirements of 201.12.1 and 201.12.4 are maintained following the tests.

201.15.3.5.101.2 Shock and vibration for a *transit-operable ventilator* during operation

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) A *ventilator* and its parts, including applicable *accessories*, intended for *transit-operable* use (during *patient* transport inside a healthcare facility) shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling while operating.
- b) For this test, the *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 A *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, a *ventilator* shall maintain *basic safety* and *essential performance* while ventilating a test lung using the worst-case conditions and parameters of Table 201.102, selected by intended *tidal volume*, as appropriate.
- d) Perform the tests with a *volume-control inflation-type* or a *pressure-control inflation-type*, as applicable.
- e) During the testing, the error of:
 - 1) the *inspiratory volume* of individual *inflations* shall not deviate by more than 35 % of the *inspiratory volume* measured prior to the test;
 - 2) the *inspiratory volume* averaged over a one min interval shall not deviate by more than 25 % of the *inspiratory volume* measured prior to the test;
 - i) One-minute averaged testing need not be performed if the *inspiratory volume* of individual *inflations* does not deviate by more than 25 %.
 - 3) the *PEEP* of individual *inflations* shall not deviate by more than 5,0 hPa (5,0 cmH₂O) from the *PEEP* measured prior to the test; and
 - 4) the delivered FiO₂ (inspiratory oxygen concentration) averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the *instructions for use*.
 - i) One-minute averaged testing need not be performed if the FiO₂ of individual *inflations* does not deviate by more than the deviation disclosed by the *manufacturer* in the *instructions for use*.
- f) During this testing, the *alarm limits* for volume and pressure *alarm conditions* shall be set to their least sensitive levels.
- g) Check conformity by performing the following tests:
 - 1) Shock test in conformity with IEC 60068-2-27:2008, using the following conditions:
 - i) test type: Type 1:
 - I) peak acceleration: 50 m/s² (5 g);
 - II) duration: 6 ms;
 - III) pulse shape: half-sine; and
 - IV) number of shocks: 3 shocks per direction per axis (18 total).
 - 2) Broadband random vibration test in conformity with IEC 60068-2-64:2008+AMD1:2019, using the following conditions:
 - i) acceleration amplitude:
 - I) 10 Hz to 100 Hz: 0,33 (m/s²)²·Hz⁻¹; and
 - II) 100 Hz to 500 Hz: –6 db per octave;
 - ii) duration: 30 min per perpendicular axis (3 total).
 - 3) Free fall in conformity with IEC 60068-2-31:2008, using Procedure 1 and the following conditions:
 - i) fall height:

- I) for mass ≤ 1 kg, 0,25 m;
- II) for mass > 1 kg and ≤ 10 kg, 0,1 m;
- III) for mass > 10 kg and ≤ 50 kg, 0,05 m; and
- IV) for mass > 50 kg, 0,01 m
- ii) number of falls: 2 in each specified attitude.
- 4) Confirm that during these tests:
 - i) *basic safety* is maintained; and
 - ii) the *inspiratory volume*, *PEEP* and delivered FiO_2 are within the indicated limits during the tests.

201.15.4.1 Construction of connectors

Amendment (add as the first paragraph):

- aa) *Healthcare professional operator-detachable gas pathway connectors* in the VBS are exempt from this requirement.

201.15.101 Mode of operation

A ventilator shall be suitable for *continuous operation*.

Check conformity by inspection.

201.15.102 Delivered oxygen concentration

- a) A ventilator shall be capable of supplying gas with an oxygen concentration over the range from ambient to at least 95 % of the input oxygen concentration at the *patient-connection port*.
- b) The oxygen concentration shall include the effects of:
 - 1) the range of the *rated* input oxygen concentration;
 - 2) the available flow from the oxygen source; and
 - 3) the delivered flowrate to the *patient-connection port*.

Check conformity by functional testing.

201.15.103 Accessory self-check

- a) A ventilator shall be equipped with means that allow the determination of whether or not the VBS resistance and compliance characteristics fall 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 conformity by functional testing.

201.16 *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 16 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 *ventilator*; or
- b) form an *ME system* with the *ventilator*.

For *accessories* as part of the *ventilator*, check conformity in combination with the *ventilator*.

The testing need not to be repeated for each combination for a family of *accessories* with a family of *ventilators*. See 201.5 for worst case combinations.

For *accessories* forming an *ME system* with the *ventilator*, apply the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.1. Check conformity by application of the relevant tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.1, and by application of the relevant tests.

201.16.2 Accompanying documents of an *ME system*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (add after element c)):

- 100) if applicable, a description of the *use scenarios* and ranges of ventilation settings over which elevated temperature of the gas at the *ventilator gas output port* can lead to the failure of a respiratory gas *humidifier* to function according to its specification.

EXAMPLE 100 A blower/turbine-based *ventilator* operating with *ventilator* settings that result in the delivered breathing gas temperature exceeding 27 °C can cause the *humidifier* to reduce humidity output below the lower limit allowed by ISO 80601-2-74.

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 17 applies.

Addition:

201.101 Gas connections

201.101.1 Protection against reverse gas leakage

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

For a *ventilator* with two or more *high-pressure inlets*,

- a) means shall be provided to limit reverse gas flowrate (leakage) 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 inlet* into the supply system of a different gas to less than 100 ml/h in *normal condition* or *single fault condition*.

Check conformity by functional testing.

201.101.2 Connection to an inlet

201.101.2.1 Low-pressure hose assembly

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

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

201.101.2.2 Filter

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

NOTE 1 The need for particle filtration in oxygen-enriched environments including the proper choice of filter materials is discussed in ISO 15001:2010.

NOTE 2 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 conformity by inspection.

201.101.3 VBS connectors

201.101.3.1 General

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) *Operator-detachable VBS connections* through which the main flow of gas to or from the *patient* passes in *normal condition*, excluding the *patient-connection port*:
 - 1) shall be:
 - i) a 15 mm *connector* conforming with ISO 5356-1:2015;
 - ii) a 22 mm *connector* conforming with ISO 5356-1:2015; or
 - iii) for a *ventilator* only intended for *tidal volumes* of ≤300 ml, a 11,5 mm *connector* conforming with ISO 5356-1:2015; or
 - 2) may be a non-conical *connector* that does not engage with a conical *connector* conforming with ISO 5356-1:2015.

Check conformity 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 15 mm conical socket *connector* conforming with ISO 5356-1:2015;
- b) a 22 mm conical cone *connector* conforming with ISO 5356-1:2015; or
- c) a coaxial 15 mm/22 mm conical *connector* conforming with ISO 5356-1:2015.

Check conformity 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 22 mm conical cone *connector* conforming with ISO 5356-1:2015.
 - 2) a 15 mm conical cone *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, a *ventilator* only intended for *tidal volumes* of ≤ 300 ml, may be equipped with a *gas output port* and a *gas return port* using a 11,5 mm conical cone *connector* conforming with ISO 5356-1:2015.

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

201.101.3.2.3 Emergency intake

- a) An *emergency intake* shall not be equipped with an *operator-accessible connector*.
- b) An *emergency intake* shall be designed to prevent obstruction when the *ventilator* is in use.

Check conformity by inspection.

201.101.3.2.4 Flow-direction-sensitive components

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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 conformity by inspection of detachable *flow-direction-sensitive components* and inspection of the *risk management file*.

201.101.3.2.5 Gas pathway connection port

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) If provided, the *gas pathway* connection port of a *ventilator*, *VBS* or *accessory* shall:

- 1) be provided with a means to secure the *accessory* in position; and
- 2) be provided with a means to secure closure after removal of the *accessory*.

NOTE 2 This port directly connects to the *gas pathway* and is used e.g. for measuring gas concentrations or for the introduction of liquids.

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

b) The *gas pathway* connection port of a *ventilator*, *VBS* or *accessory* may conform with ISO 80369-7:2021.

c) A *gas pathway* connection port that conforms with ISO 80369-7:2021 shall:

- 1) be *marked* with either:
 - i) the *symbol* ISO 7000-1641 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, *symbol* 11); or
 - ii) if the *marking* is the primary *risk control* measure, the *safety sign* ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.2, *safety sign* 10).
- 2) include in its *instructions for use* a warning to the effect that “Warning: As this [insert name of medical device here] uses a Luer connector for other than intravascular or hypodermic access, there is a possibility that an inadvertent connection can occur between this [insert name of medical device here] and another medical device or accessory using a Luer connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks.”

Check conformity by inspection and, if applicable, by application of the tests of ISO 80369-7:2021.

201.101.3.2.6 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 *anaesthesia gas scavenging system* (AGSS) that conforms with ISO 80601-2-13.

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

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

201.101.3.2.7 Temperature sensor port

The *VBS* may be equipped with a temperature sensor port conforming with 201.101.8 of ISO 80601-2-74:2021.

201.101.3.2.8 *Gas intake port*

A *ventilator* that incorporates a *gas intake port* shall be designed such that the *gas intake port* cannot be blocked by a flat surface.

EXAMPLE A *gas intake port* incorporating a protective cage, or with multiple intake orifices arranged in a non-planar geometry.

Check conformity by functional testing.

201.102 Requirements for the *VBS* and *accessories*

201.102.1 General

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

Check conformity 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 the *model or type reference* of at least one compatible *ventilator*.
- b) Statements shall be included in the *accompanying document* of each *ventilator breathing system*, its parts or *accessories* 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 conformity by inspection of the *accompanying document*.

201.102.3 Breathing sets

Breathing sets intended for use in the *VBS* shall conform with ISO 5367:2014, 5.3.4.

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

201.102.4 Water vapour management

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.102.4.1 Humidification system

Any *humidifier*, including heated breathing tubes, either incorporated into the *ventilator* or recommended for use with the *ventilator*, shall conform with ISO 80601-2-74:2021.

Check conformity by application of the tests of ISO 80601-2-74:2021.

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

201.102.6 Breathing system filters

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

- a) ISO 23328-1:2003; and
- b) ISO 23328-2:2002.

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

201.102.7 Ventilator breathing systems

201.102.7.1 Leakage from complete VBS

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Unintended leakage from the *VBS* should not exceed:

- a) 200 ml/min at 50 hPa (50 cmH₂O) for a *ventilator* intended to provide a *tidal volume* greater than 300 ml;
- b) 100 ml/min at 40 hPa (40 cmH₂O) for a *ventilator* intended to provide a *tidal volume* between 300 ml and 50 ml; and
- c) 50 ml/min at 20 hPa (20 cmH₂O) for a *ventilator* intended to provide a *tidal volume* less than 50 ml.

201.102.7.2 Non-invasive ventilation

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *instructions for use* for a *ventilator* intended for non-invasive ventilation shall include a warning statement to the effect that the exhaled volume and exhaled CO₂ of the *patient* can differ from the measured exhaled volume and exhaled CO₂ due to leaks around the *mask*.

- b) A *ventilator* intended for non-invasive ventilation should either:
- 1) be equipped with *CO₂ monitoring equipment* for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the *patient-connection port*) in accordance with ISO 80601-2-55; or
 - 2) if not so equipped, the *instructions for use* should contain a statement to the effect that the *ventilator* is to be provided with *CO₂ monitoring equipment* for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the *patient-connection port*) in accordance with ISO 80601-2-55 before being put into service.

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

201.103 Spontaneous breathing during loss of ventilation

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) A *protection device* shall be provided to allow spontaneous breathing when normal ventilation is compromised as a result of *system recovery* or 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 cmH₂O) at a flowrate of:
- 1) 30 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \geq 300$ ml;
 - 2) 15 l/min for a *ventilator* intended to provide a *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml;
 - 3) 2,5 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \leq 50$ ml.

NOTE These requirements are intended to allow the *patient* to breathe spontaneously under compromised conditions.

Check conformity by functional testing and measurement of flowrate, 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) The *ventilator* shall have means to indicate visually the cumulative hours of operation of the *ventilator*, either:
- 1) automatically; or
 - 2) by *operator* action.
- b) The *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 conformity by inspection.

201.105 *Functional connection*

201.105.1 General

Basic safety and essential performance shall be maintained if connections to the *functional connections* of 201.105 of a *ventilator* are:

- a) disrupted; or
- b) if the equipment connected to those parts fails.

Check conformity by functional testing.

201.105.2 Connection to an electronic health record

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

Check conformity by inspection.

201.105.3 Connection to a *distributed alarm system* or *distributed information system about alarm conditions*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) A *ventilator* shall be equipped with a *functional connection* that permits connection to:
 - 1) a *distributed alarm system*; or
 - 2) a *distributed information system about alarm conditions*.
 - i) A *ventilator* should not be equipped with a *functional connection* that only permits connection to a *distributed information system about alarm conditions*.

201.105.4 Connection for remote control

A *ventilator* may be equipped with a *functional connection* for external control of the *ventilator*.

NOTE AAMI 2700-1:2019^[41] is an example of a suitable standard for providing such a *functional connection*.

201.106 Display loops

201.106.1 Pressure-volume loops

- a) If a *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 conformity by inspection.

201.106.2 Flow-volume loops

- a) If a *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 *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 conformity by inspection.

201.107 Timed ventilatory pause

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.107.1 Expiratory pause

- a) A *ventilator* may be equipped with a *healthcare professional operator*-controlled means to pause the *ventilator* in expiration.
- b) If a *ventilator* is equipped with a means to pause the *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:
 - i) *responsible organization*-configurable; or

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

- ii) *operator*-adjustable.
- 2) during the *expiratory pause*, any apnoea-related ventilatory *alarm condition* that would be caused by this *expiratory pause* shall be:
 - i) *audio paused*; or
 - ii) *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+AMD2:2020, the *ventilator* shall indicate the presence of the *expiratory pause* with at least:
 - i) an *information signal*; or
 - ii) a *low priority alarm condition*.

NOTE 2 An *expiratory pause* can be equivalent to placing the *ventilator* into standby mode or *CPAP* and automatically resuming ventilation after a pre-determined duration.

NOTE 3 The *expiratory pause* can be used to synchronize radiographic imaging with deflated *lungs*.

Check conformity by inspection and functional testing.

201.107.2 *Inspiratory pause*

- a) A *ventilator* may be equipped with a *healthcare professional operator*-controlled means to pause automatic ventilation at end-inspiration.
- b) If a *ventilator* is equipped with a means to pause the *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; and
 - 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:
 - i) non-adjustable;
 - ii) *responsible organization*-configurable; or

NOTE 1 There is guidance or rationale for this list item contained in Clause AA.2.

- iii) *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*.

d) In addition to the requirements for *alarm signal* inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, the *ventilator* shall indicate the presence of the *inspiratory pause* with

1) at least an *information signal*; or

2) a *low priority alarm condition*.

NOTE 2 The *inspiratory pause* can be used to synchronize radiographic imaging with *lung inflation* or used for a recruitment manoeuvre (a temporary increase in pressure intended to expand the *lung*).

Check conformity by inspection and functional testing.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 applies except as follows:

202.4.3.1 Compliance criteria

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (replace the second dash of 4.3.1 with):

— the *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 condition 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

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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*, *set rate*, *I:E ratio*.

5) initiation of an unintended operation;

6) during the testing, the error of the:

- i) *inspiratory volume* of individual *inflations* shall not deviate by more than 35 % of the *inspiratory volume* measured prior to the test;
 - ii) *inspiratory volume* averaged over a one min interval shall not deviate by more than 25 % of the *inspiratory volume* measured prior to the test;
 - l) One-minute averaged testing need not be performed if the *inspiratory volume* of individual *inflations* does not deviate by more than 25 %.
 - iii) *PEEP* of individual *inflations* shall not deviate by more than 5 hPa (5,0 cmH₂O) from the *PEEP* measured prior to the test; and
 - iv) delivered *FiO₂* averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the *instructions for use*.
 - l) One-minute averaged testing need not be performed if the *FiO₂* of individual *inflations* does not deviate by more than the deviation disclosed by the *manufacturer* in the *instructions for use*.
- b) The *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+AMD2:2020 applies except as follows:

Addition:

206.101 Primary operating functions

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

- 1) setting the *healthcare professional operator*-adjustable controls:
 - i) setting *alarm limits*;
 - ii) inactivating *alarm signals*;
 - iii) switching between different *ventilation-modes* and *inflation-types*; and
 - iv) setting ventilation control parameters;

EXAMPLE 1 *Tidal volume*, *set rate*, *BAP*, pressure support

2) observing and identifying the monitored ventilation parameters;

EXAMPLE 2 *Airway pressure* and expired volume

EXAMPLE 3 *FiO₂* (inspiratory oxygen concentration) or *etCO₂* (end-tidal carbon dioxide concentration)

3) observing and identifying:

- i) the *alarm signals*; and
 - ii) the *alarm signal* inactivation states;
- 4) configuring the *VBS* including:

- i) connection of the detachable parts of the *VBS* to the *ventilator*;

EXAMPLE 4 *Humidifier, nebuliser^[18], water-trap, tubing, breathing system filter*

- 5) connecting or disconnecting the *patient-connection port* of the *VBS* to the *patient-interface*;
- 6) starting the *ventilator* from power off;
- 7) performing a basic pre-use functional check of the *ventilator* including the *alarm system*;
- 8) identifying any limitation of the *ventilator's* ability to detect decannulation or extubation based on the intended *patient* profile and the *VBS* configuration;
- 9) turning off the *ventilator*; and
- 10) *processing* the *ventilator* between *patient* uses.

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

- 1) starting ventilation from standby;
- 2) activating standby;
- 3) activating manoeuvres that help assess *lung* function or the effectiveness of *ventilator* parameter settings;

EXAMPLE 5 *Inspiratory pause, expiratory pause, slow inflation*

- 4) activating a closed suctioning function;
- 5) attaching the *ventilator* and, where applicable the *VBS*, to a trolley;
- 6) setting of the adjustable high-pressure *alarm limit* to values exceeding 60 hPa (60 cmH₂O); and
- 7) setting of the *airway pressure* to values exceeding 60 hPa (60 cmH₂O).

- 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 *ventilator's operator interface*.

- 1) humidifying/conditioning gases delivered through the *VBS*;
- 2) adding medication to the gas flowing into the *patient*;

EXAMPLE 6 *Nebulisation^[18] or injecting fluids into the ancillary port connection of the *VBS**

- 3) suctioning the *patient's* airway;
- 4) X-raying the *patient*;
- 5) understanding the need for alternative means of ventilation with a manual resuscitator;

- 6) positioning the *patient*; and
- 7) connecting and disconnecting a *distributed alarm system*.

206.102 Training

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

In the application of the requirements in 5.6 and 5.8 of IEC 62366-1:2015, training shall be considered necessary for both:

- a) the *healthcare professional operator*; and
- b) the designee of the *responsible organization* (e.g. *service personnel* or *processing personnel*).

NOTE Requirements for training are found in 5.6 and 5.8 of IEC 62366-1:2015.

Check conformity by inspection of the *accompanying document*.

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

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies except as follows:

Addition:

208.6.3.2.2.101 Additional requirements for 1 m (*operator's position*) visual alarm signals and information signals

High priority alarm signals should be accompanied by information describing possible causes of the *alarm condition* and appropriate actions to take in response. *Operator* action may be required to display this information.

EXAMPLE The obstruction alarm limit has been reached. Check the breathing system tubing for blockages or crimping. Check breathing system filters for blockage.

208.6.8.3.101 Additional requirements for global indefinite alarm signal inactivation states

- a) A *ventilator* shall not be equipped with a means to initiate a global *alarm off* while connected to a *patient*.
- b) A *ventilator* shall not be equipped with a means to initiate a global *audio off* unless the *ventilator* is connected to a *distributed alarm system*.

Check conformity by functional testing.

208.6.8.4.101 Additional requirements for termination of alarm signal inactivation

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

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

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

Check conformity by functional testing.

208.6.12.2 Operator alarm system logging

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Replacement:

- a) A *ventilator* shall be provided with an *operator alarm system log*.
- b) The *operator alarm system log* shall:
 - 1) be equipped with a capacity of at least 1 000 events in total for:
 - i) *high priority alarm conditions*;
 - ii) *medium priority alarm conditions*;
 - iii) *low priority alarm conditions*; and
 - iv) *alarm signal inactivation states*
 - 2) time stamp all events in accordance with IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.12.2 a).
 - 3) 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.
 - 4) not permit the *healthcare professional operator* to erase the contents of the *alarm system log*.
- c) In addition, the *operator alarm system log* should include at least the following events:
 - 1) any change of *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 being used; and
 - 5) results of the pre-use check.

Check conformity by inspection and functional testing.

208.6.12.3 Responsible organization alarm system logging

Replacement:

- a) A *ventilator* shall be provided with a *responsible organization log* with a capacity of at least 1 000 events in total.
- b) Viewing the *responsible organization alarm system log* shall be restricted to the *responsible organization* in accordance with IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7.

c) The *responsible organization alarm system* log shall include all of the information contained in the *operator alarm system* log.

d) The *responsible organization alarm system* log shall contain:

- 1) the *ventilator* settings; and
- 2) each change of those settings.

EXAMPLE 1 The name of the *ventilator* preset in use and any changes made to it.

e) The *responsible organization alarm system* log shall contain:

- 1) the *alarm settings*; and
- 2) each change of those settings.

EXAMPLE 2 The name of the *alarm preset* in use and any changes made to it.

f) Means shall not be provided for the *operator* or *responsible organization* to edit or delete entries in the *responsible organization alarm system* log.

g) The *responsible organization alarm system* log shall be retained when the *alarm system* is powered down.

h) The *technical description* shall indicate what happens to the contents of the log after the *alarm system* has experienced an unexpected total loss of power (*supply mains* and *internal electrical power source*).

i) The *technical description* shall indicate:

- 1) the *responsible organization alarm system* log capacity; and
- 2) what happens to the contents of the log as it reaches capacity.

EXAMPLE 3 The *alarm system* discards the oldest data when the log becomes full.

j) The *alarm system* should log *technical alarm conditions* for servicing and maintenance purposes. This log should not be resettable or editable by *operator* action.

k) The log may be provided either within the equipment or remotely through a communications interface.

Check conformity by inspection and functional testing.

The annexes of IEC 60601-1:2005+AMD1:2012+AMD2:2020, apply, except as follows:

Annex C (informative)

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Annex C applies, except as follows:

Addition:

201.C.101 **Marking on the outside of ME equipment, ME systems or their parts**

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

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

Description of marking	Subclause
For a <i>gas output port</i> , an arrow indicating the direction of gas flow	201.7.2.101 b) 2) i)
For a <i>gas return port</i> , an arrow indicating the direction of gas flow	201.7.2.101 b) 2) ii)
For a gas sampling inlet, 'gas sample' or <i>Symbol</i> ISO 7000-0794	201.7.2.101 b) 3)
For a <i>ventilator</i> intended for the magnetic resonance (MR) environment, MR safe, if applicable	201.7.2.101 a) 1) i)
For a <i>ventilator</i> intended for the magnetic resonance (MR) environment, MR conditional, if applicable	201.7.2.101 a) 1) ii)
For a <i>ventilator</i> not intended for the magnetic resonance (MR) environment, MR unsafe, if applicable	201.7.2.101 a) 2)
For <i>accessories</i> supplied separately, indication of any limitations or adverse effects of the <i>accessory</i> on the <i>basic safety</i> or <i>essential performance</i> of the <i>ventilator</i> , if applicable	201.7.2.4.101 a) 2)
For <i>accessories</i> supplied separately, the requirements of ISO 20417:2021, 6.1.1 c)	201.7.2.4.101 a) 1)
For oxygen inputs, the <i>rated</i> range of oxygen concentration	201.7.2.18 cc)
For the <i>flow-direction-sensitive components</i> removable without the use of a <i>tool</i> , an arrow indicating the direction of the flow	201.7.2.101 a) 3)
Gas name or chemical <i>symbol</i>	201.7.2.18 aa)
Gas-specific colour coding, if applicable	201.7.2.18 dd)
Mandatory action <i>safety sign</i> : follow <i>instructions for use</i>	201.7.2.3
<i>Rated</i> range of gas pressure	201.7.2.18 bb)
Requirements of ISO 20417	201.7.1.101
<i>Symbol</i> or <i>safety sign</i> , as appropriate, for ISO 80369-7 connections to the <i>gas pathway</i>	201.101.3.2.5 c) 1)
Warning not to obstruct the <i>gas intake port</i> , if applicable	201.7.2.101 b) 1)

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

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

Table 201.C.102 — Accompanying documents, general

Description of requirement	Subclause
Description of the <i>use scenarios</i> and ranges of ventilation settings over which elevated temperature of the gas at the <i>ventilator gas output port</i> can lead to the failure of a respiratory gas <i>humidifier</i> to function according to its specification	201.16.2
For each <i>VBS</i> and <i>accessory</i> , the <i>model or type reference</i> of at least one compatible <i>ventilator</i>	201.102.2 a)
For each <i>VBS</i> , part and <i>accessory</i> , 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 <i>VBS</i> , part and <i>accessory</i> , a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
For each <i>VBS</i> , part and <i>accessory</i> , 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)
Intended position of the <i>operator</i>	201.7.9.2.1
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 b) 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 b) 3) ii)
Means by which the obstruction <i>alarm condition</i> is determined	201.12.4.108 g) 1)
Means to test the obstruction <i>alarm condition</i>	201.12.4.108 g) 2)
Requirements of ISO 20417	201.7.1.101
Units of measure for volumes, flows and leakages, for other than the <i>VBS</i> in <i>STPD</i>	201.7.4.3 aa)
Units of measure for volumes, flows and leakages, for the <i>VBS</i> in <i>BTPS</i>	201.7.4.3 bb)
<i>Ventilator</i> is a high-flow device warning, if applicable	201.4.11.101.2 b) 3) iii)

201.C.103 — Accompanying documents, instructions for use

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

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Acceptance criteria for other <i>inflation-types</i>	201.12.1.103 a) 2)
Accuracy of expired volume <i>monitoring equipment</i> , <i>tidal volume</i> >50 ml, including the effects of the <i>rated</i> oxygen concentration	201.12.4.103.1 b) 2) 201.12.4.103.1 b) 2) i)
Accuracy of expired volume <i>monitoring equipment</i> , <i>tidal volume</i> ≤50 ml, including the effects of the <i>rated</i> oxygen concentration	201.12.4.103.2 b) 201.12.4.103.2 b) 1)
Accuracy of the <i>inspiratory volume monitoring equipment</i> , if so equipped	201.12.1.104 a)
Any reasonably foreseeable adverse effect of any recommended <i>accessory</i> on the <i>basic safety</i> or <i>essential performance</i> of the <i>ventilator</i> , if applicable	201.7.9.2.14.101 b) 2)
A-weighted sound power level emitted by the <i>ventilator</i>	201.9.6.2.1.101 b) 2)
A-weighted sound pressure level emitted by the <i>ventilator</i>	201.9.6.2.1.101 a) 2)
Behaviour of the <i>ventilator</i> after a switchover to the external reserve electrical power source, if provided	201.11.8.101 c) 3) ii)
Behaviour of the <i>ventilator</i> after a switchover to the <i>internal electrical power source</i>	201.11.8.101 c) 3) i)
Behaviour of the <i>ventilator</i> while the external reserve electrical power source is recharging	201.11.8.101 c) 4) ii)

Description of requirement	Subclause
Behaviour of the <i>ventilator</i> while the <i>internal electrical power source</i> is recharging	201.11.8.101 c) 4) i)
Conditions under which the <i>ventilator</i> maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101 c)
Cross reference between the <i>manufacturer-specific</i> naming of the <i>ventilator's ventilation-modes</i> and the <i>ventilation-mode</i> systematic coding scheme of ISO 19223	201.7.9.2.9.101 f)
Cross reference to the additional information in the <i>technical description</i> , if the <i>technical description</i> is separable	201.7.9.2.16.101 b)
Description of the algorithm that determines the <i>alarm limit</i> values of expired volume <i>monitoring equipment</i> , if so equipped	201.12.4.103.1 b) 7) 201.12.4.103.2 g)
Disclosure of any restrictions on the placing of components within the <i>ventilator breathing system</i> , if applicable	201.7.9.2.14.101 b) 1)
Equipment necessary for <i>intended use</i>	201.7.9.2.14.101 a) 2)
FiO ₂ accuracy includes effects of <i>rated</i> input oxygen concentration	201.12.1.101 b) 3) i) 201.12.1.102 b) 3) i)
For a <i>ventilator</i> intended for non-invasive ventilation not equipped with a CO ₂ monitor, a statement to the effect that the <i>ventilator</i> is to be provided with CO ₂ <i>monitoring equipment</i> for the measurement of expiratory carbon dioxide concentration before being put into service	201.102.7.2 a)
For a <i>ventilator</i> intended for non-invasive ventilation, a warning statement to the effect that the exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask	201.102.7.2 a)
For a <i>ventilator</i> not equipped with expired volume <i>monitoring equipment</i> and intended to deliver a <i>tidal volume</i> ≤50 ml, information on how to connect CO ₂ <i>monitoring equipment</i> to the <i>VBS</i> shall be disclosed in the <i>instructions for use</i> unless such equipment is an integral part of the <i>VBS</i>	201.12.4.104 a) 2)
For a <i>ventilator</i> , an explanation of the meaning of the IP classification <i>marked</i> on the <i>ME equipment</i>	201.7.9.2.9.101 d)
For <i>accessories</i> supplied separately where <i>marking</i> the <i>accessory</i> is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101 b)
Indication as to whether the <i>ventilator</i> is intended for non-invasive ventilation	201.7.9.2.9.101 e)
Information on how to connect CO ₂ <i>monitoring equipment</i> , unless such equipment is an integral part of the <i>ventilator</i>	201.12.4.104 a) 2) i)
Information on how to connect oxygen <i>monitoring equipment</i> , unless such equipment is an integral part of the <i>ventilator</i>	201.12.4.101 c)
Information on how to connect the expired volume <i>monitoring equipment</i> , if not so equipped	201.12.4.103.1 a) 2) i)
Intended range of <i>tidal volume</i>	201.7.9.2.1.101 a)
Length of time required for the oxygen concentration in the <i>tidal volume</i> to change from a concentration of 21 % to 90 % of the maximum settable oxygen concentration	201.12.1.105 a)
List of contents of <i>technical description</i> , if the <i>technical description</i> is separable	201.7.9.2.16.101 a)
Maximum disconnection <i>alarm condition delay</i>	201.12.4.109 d)
Maximum duration of <i>system recovery</i>	201.4.3.102 g)
Maximum error of the <i>airway pressure</i> at the end of the <i>inflation phase</i> in relation to the set value for a <i>pressure-control inflation</i> in <i>normal condition</i>	201.12.1.102 b) 1)
Maximum error of the inspiratory oxygen concentration (FiO ₂) at the <i>patient-connection port</i> in relation to the set value for a <i>volume-control inflation</i> in <i>normal condition</i>	201.12.1.101 b) 3)
Maximum error of the inspiratory oxygen concentration (FiO ₂) at the <i>patient-connection port</i> in relation to the set value for a <i>pressure-control inflation</i> in <i>normal condition</i>	201.12.1.102 b) 3)

Description of requirement	Subclause
Maximum error of the <i>inspiratory volume</i> in relation to the set <i>tidal volume</i> for a <i>volume-control inflation</i> in <i>normal condition</i>	201.12.1.101 b) 1)
Maximum error of the <i>PEEP</i> in relation to the set value for <i>BAP</i> for a <i>volume-control inflation</i> in <i>normal condition</i>	201.12.1.101 b) 2)
Maximum error of the <i>PEEP</i> in relation to the set value for <i>BAP</i> for a <i>pressure-control inflation</i> in <i>normal condition</i>	201.12.1.102 b) 2)
Means by which the <i>maximum working pressure</i> is accomplished	201.7.9.2.9.101 a) 3)
Means by which the secondary <i>supply mains</i> can be tested, if provided	201.11.8.101 c) 2)
Method by which all of the <i>alarm signals</i> can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 3)
Method by which switchover to and operation from the <i>internal electrical power source</i> can be functionally tested to determine if the <i>ventilator</i> is operating correctly	201.7.9.2.8.101 a) 2)
Method by which the assembled <i>VBS</i> can be functionally tested to determine if it is operating correctly	201.7.9.2.8.101 a) 1)
Operational time of the <i>ventilator</i> when powered from a fully charged, aged <i>internal electrical power source</i>	201.11.8.101 c) 1) i)
Operational time of the <i>ventilator</i> when powered from fully charged, external reserve power source, if provided	201.11.8.101 c) 1) ii)
Performance of other <i>inflation-types</i> in <i>normal condition</i> , including effects <i>rated oxygen concentration</i>	201.12.1.103 a) 1) 201.12.1.103 a) 3)
<i>Processing</i> instructions for the <i>enclosure</i> of the <i>ventilator</i>	201.11.6.6 dd) 2)
<i>Processing</i> instructions for the <i>gas pathways</i> of the <i>ventilator</i> and its <i>accessories</i>	201.11.6.6 bb) 3)
<i>Range</i> of the <i>maximum limited pressure</i>	201.7.9.2.9.101 a) 1)
<i>Rated</i> range of expiratory <i>gas pathway</i> resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 2)
<i>Rated</i> range of inspiratory <i>gas pathway</i> resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 1)
<i>Rated</i> range of <i>VBS</i> compliance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 3)
<i>Rated</i> range to which the <i>maximum working pressure</i> can be set, if adjustable	201.7.9.2.9.101 a) 2)
Recommended <i>ventilation-mode</i> and settings for closed suctioning	201.9.101 a)
Requirements of ISO 20417	201.7.1.101
Set of <i>accessories</i>	201.7.9.2.14.101 a) 1)
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) 4)
Statement to the effect that the <i>ventilator</i> is to be equipped with <i>oxygen monitoring equipment</i> 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 <i>ventilator</i> is to be equipped with <i>monitoring equipment</i> for indicating expired volume at the <i>patient-connection port</i> before being put into service, if not so equipped	201.12.4.103.1 a) 2)
Subatmospheric pressure limit at the <i>patient-connection port</i> , for <i>ventilators</i> that can generate subatmospheric pressure in the <i>expiratory phase</i>	201.7.9.2.9.101 a) 5)
Summary description of the algorithm that determines the <i>alarm limit</i> values	201.12.4.103.1 f)
<i>Use scenarios</i> in which decannulation might not be detected as a <i>VBS</i> disconnection	201.12.4.109 e)

Description of requirement	Subclause
Ventilation accuracy expressed as bias error and linearity error	201.12.1.101 a) 201.12.1.102 a)
Warning regarding ISO 80369-7 connections to the <i>gas pathway</i> , if equipped	201.101.3.2.5 c) 2)
Warning statement to the effect that 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	201.7.9.2.2.101 a) 3)
Warning statement to the effect that do not cover the ventilator or place in a position that affects proper operation, including applicable examples	201.7.9.2.2.101 a) 1)
Warning statement to the effect that the responsible organization needs to ensure that the oxygen source is compatible with the ventilator	201.7.9.2.2.101 b) 5)
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 b) 4)
Warning statement to the effect that the <i>ventilator</i> shall not be used in a hyperbaric chamber, if applicable	201.7.9.2.2.101 b) 1)
Warning statement to the effect that the <i>ventilator</i> shall not be used with nitric oxide, if applicable	201.7.9.2.2.101 b) 2)
Warning statement to the effect that the <i>ventilator</i> shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium), if applicable	201.7.9.2.2.101 b) 3)
Warning statement to the effect that to always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of <i>patient</i> death or serious deterioration of health	201.7.9.2.2.101 a) 2)
Warning statement to the effect that when using nebulisation or humidification breathings system filters and heat and moisture exchangers can require more frequent replacement	201.7.9.2.2.101 b) 6)
Which portions of the <i>gas pathways</i> through the <i>ventilator</i> can become contaminated with body fluids or by contaminates carried by expired gases during both <i>normal condition</i> and <i>single fault condition</i>	201.7.9.2.12 aa)

201.C.104 Accompanying documents, technical description

Additional requirements for information to be included in the *technical description* of a *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 <i>alarm system</i> for each of the <i>alarm conditions</i> specified in this document	201.7.9.3.101 a)
Description of what happens to the contents of the log after the <i>alarm system</i> has experienced an unexpected total loss of power (<i>supply mains</i> and <i>internal electrical power source</i>) for a finite duration	208.6.12.3 h)
Description of what happens to the contents of the <i>responsible organization alarm system</i> log as it reaches capacity	208.6.12.3 i) 2)
Description of which checks are performed automatically for checking the function of the <i>alarm system</i> for each of the <i>alarm conditions</i> specified in this document	201.7.9.3.101 b)
Disclosure of the essential technical characteristics of each recommended <i>breathing system filter</i> , if applicable	201.7.9.3.1.101 b) 1)
Disclosure of the measurement uncertainty for each disclosed tolerance	201.5.101.3 c)
Pneumatic diagram of the <i>ventilator</i> , including a diagram for <i>operator-detachable</i> parts of the <i>ventilator breathing system</i> either supplied or recommended in the <i>instructions for use</i>	201.7.9.3.1.101 a) 2)
Requirements of ISO 20417	201.7.1.101
<i>Responsible organization alarm system</i> log capacity	208.6.12.3 i) 1)
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) 1)
Summary description of the means of initiating and terminating the <i>inflation phase</i> in each <i>ventilation-mode</i> of the <i>ventilator</i>	201.7.9.3.1.101 a) 3)

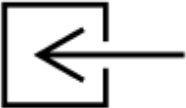
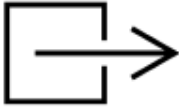


Annex D (informative)



Symbols on marking

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Annex D applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1		ISO 7000-0794 IEC 60878:2022	Input; entrance To identify an entrance, for example exhaust gas entry for measurement (for example of CO- value). For electrical (signal) input use <i>symbol</i> IEC 60417-5034.
2		ISO 7000-0795 IEC 60878:2022	Output; exit To identify an exit, for example of a hydraulic pump. For electrical (signal) output use <i>symbol</i> IEC 60417-5035.
3		IEC 60878:2022 <i>Symbol</i> 7.3.1-1 of IEC 62570:2014	MR Safe To identify an item which poses no unacceptable <i>risks</i> to the <i>patient</i> , medical staff or other persons within the MR environment. When color reproduction is not practical, the <i>symbol</i> 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.
4		IEC 60878:2022 <i>Symbol</i> 7.3.1-2 of IEC 62570:2014	MR Safe Alternative graphical <i>symbol</i> representation. Same meaning as IEC 62570-7.3.1-1.

No	Symbol	Reference	Title and description
5		IEC 60878:2022 <i>Symbol 7.3.2 of IEC 62570:2014</i>	<p>MR Conditional</p> <p>To identify an item which poses no unacceptable <i>risks</i> within defined conditions to the <i>patient</i>, medical staff or other persons within the MR environment.</p> <p>When color reproduction is not practical, the <i>symbol</i> 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.</p> <p>The MR Conditional <i>symbol</i> may be supplemented by supplementary <i>marking</i> that describes the conditions for which the item has been demonstrated to be MR Conditional.</p>
6		IEC 60878:2022 <i>Symbol 7.3.3 of IEC 62570:2014</i>	<p>MR Unsafe</p> <p>To identify an item which poses unacceptable <i>risks</i> to the <i>patient</i>, medical staff or other persons within the MR environment.</p> <p>Note – When color reproduction is not practical, the <i>symbol</i> may be printed in black and white. The use of the colored version is strongly encouraged for the added visibility and information provided by the color.</p>

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

The numbering of the following rationales corresponds to the numbering of the clauses and subclauses in this document. The numbering is, therefore, not consecutive.

— 201.1.1 — Scope

ISO 80601-2-12 *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-control 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 delivery to the *patient* based on the measured physiological parameter. A *ventilator* will not titrate but will either stop ventilation or generate an *alarm condition*.

— 201.3.285 — *Professional healthcare facility*

Unlike the *home healthcare environment*, the environment in a *professional healthcare facility* is considered to be a controlled environment. That is, *supply mains* is reliable with minimum variations and sometimes with backup power. The protective earth connection is robust. Temperature, humidity and altitude conditions are stable, and disruptions from electromagnetic disturbances are controlled.

— 201.3.298 — *System recovery*

The concept of recovery is mentioned in IEC 62304:2015+AMD1:2015, 5.5.4 d).

— 201.4.3.101 — *Additional requirements for essential performance*

The modern critical care *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 *healthcare professional operator*. *Essential performance* as “ventilation within the *alarm limits* set by the *healthcare professional operator*” is inclusive of those *inflations* that the *patient* modifies outside of the ventilatory parameters set by the *healthcare professional operator*, but still within the *alarm limits* which are considered safe by the *healthcare professional operator*.

It is expected that the *healthcare professional 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 probability of exposing the *patient* to unacceptable *risk*. Conformity 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 confirm that *essential performance* has been maintained. Although the degradations detailed in 202.8.1.101 are associated with *immunity* testing, the same criteria are intended to be used when the conformity 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 conformity 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.

— 201.4.3.102 **System recovery**

IEC 62304:2006+A1:2015, 5.5.4 d), identifies fault handling as potentially including recovery. In previous standards applicable to *ventilators*, the management of *risk* associated with *single fault conditions* is limited to specifying that a *single fault condition* not causing the simultaneous failure of both a ventilation-control function, and the corresponding *protection device*. It is commonplace that a *ventilator* experiencing *single fault condition* shuts down while providing *alarm signals*. While this is appropriate for some fault modes, for example when a critical hardware component has failed, there are other fault modes where it can be possible for a *system recovery process* to allow ventilation to continue.

Many *ventilators* use one or more microprocessors to control ventilation and to provide monitoring and *alarm system* functions. Software controlled equipment is inherently susceptible to *single fault conditions* that can be transient in nature. For example, a processing element might stop responding correctly as a result of a software defect, such as a buffer over-run or domain error; memory corruption such as can occur due to ionising radiation; or in input error such as from electromagnetic interference on a *functional connection*.

The *risk of harm* to the *patient* is reduced if, in addition to the *ventilator* providing *alarm signals* to indicate the loss of ventilation due to a *single fault condition*, it can reset and resume ventilation. This might be implemented by having a watchdog processor that can detect the failure of a ventilation-control software process and restart the ventilation-control processor into a known state.

In some cases, this *procedure* can also be applicable to *single-fault conditions* that result in non-functional hardware components. An example would be a blower motor that stalls as a result of mechanical shock during operation. If the *ventilator* control system is able to restart the blower, and hence resume ventilation, this reduces the *risk of harm* to the *patient* further below that level that would pertain if the *ventilator* were to remain inoperable, albeit with *alarm signals* active.

The *manufacturer* determines the appropriate system response to a *system recovery process* that fails to restore full functioning. This could occur either because the *single fault condition* is permanent in nature, or because of an ongoing but essentially temporary phenomenon such as continued electromagnetic interference. It is confusing to the *operator* for the system to continually repeat a *system recovery process* that has failed. In this instance it can be more appropriate to enter a *fail-safe state* with an informative *alarm signal*.

— 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.

— 201.4.11.101 — **Additional requirements for pressurized gas input**

A critical care *ventilator* designed to be connected to a pressurized 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 *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 a *ventilator* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurized gas supply.

Pressurized medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant standards, supply medical gases 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 critical care *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 but in the case of critical care *ventilators* it is considered that, because all the *ventilators* in a critical care unit could be affected simultaneously, it is not acceptable that such *ventilators* should just generate an *alarm signal* and shut down under these overpressure conditions. For this reason, there is a specific requirement that *ventilators* should continue operation with acceptable performance so that *patients* can continue to be ventilated until such time as normal operation can be restored or that alternative means of ventilation can be used.

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 a *ventilator* cannot be expected to continue to operate on this gas. However, it is required that in this case the *ventilator* should detect the unacceptable low pressure, produce an *alarm signal* and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the *ventilator*. This requirement is stated in 201.13.2.102.

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 across the terminal unit and the hose assembly connecting the device to the pipeline at 60 l/min.

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 flowrate of 60 l/min to the required proportion of terminal *outlets*. However, if the flowrate 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 minimize 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 *ventilators* 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 10524-1:2018.

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 flowrate of 60 l/min is greater than the test flowrate 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 flowrate 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*.

— 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 *ventilator* to have a declared *tidal volume* range of 300 ml to 1 000 ml and another 100 ml to 300 ml, with each *ventilator* only being required to be tested for the conditions specified for ≥ 300 ml or ≤ 300 ml respectively.

— 201.5.101.1 — Ventilator test conditions

— a) 2)

Test laboratories do not routinely have access to compressed air and oxygen supplies that are certified to medical pipeline standards. In many jurisdictions, medical grade oxygen is a drug and access is controlled. Enforcing a requirement for type testing to use gases that are approved to medical gas standards would add significant cost, and potentially prevent some test laboratories from being able to perform the *type tests* of this document.

For purposes of testing to this document, there is no significant difference between industrial compressed gases and medical compressed gases.

In practice, the oxygen concentration in industrial grade oxygen is no less than that in medical grade oxygen, although the permitted contaminant profile is different. Similarly, industrial compressed air is typically provided from a compressor that entrains ambient air, with principal components (nitrogen, oxygen, argon and CO₂) at concentrations that align with the requirements for medical air.

A *ventilator* controls, and measures, flows of gas from air and oxygen *inlets*. The control and measurement technologies are potentially susceptible to gas composition, however the critical parameters for flow measurement and control are density, viscosity, thermal capacity and oxygen

concentration. The differences in trace contaminant gases between industrial and medical gases supplies do not result in significant differences in flow measurement and control, and therefore will not change the results of *type test*.

The only likely contaminants in industrial compressed gases that could impact test results would be oil or water in droplet form, as these could potentially damage the *ventilator* parts. Industrial compressed air is usually provided from a compressor that entrains ambient air, which will include water vapour. Dryers and water traps are required to reduce the humidity to prevent condensation in the compressed gas.

Provided the dew point of the industrial gas supplies is below the temperatures of equipment parts during testing, condensation should not occur, and the results of *type tests* remain valid.

— 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 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 a *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 pressurized gas to medical equipment, including *ventilators*, follow engineering conventions and specify gas quantities and flowrates at *STPD* conditions. This practice is followed in this document for all requirements concerning gas input.

However, *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 a *ventilator*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* (*standard temperature pressure dry*) can expand the *lungs* to 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *ventilators*, it is essential that the information for all *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 *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 *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 *ventilator* that uses ambient air, the humidity of the drawn-in air can be unknown to the *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 *tidal volumes* greater than 50 ml, the committees came to the conclusion that the permitted inaccuracy of the measurement of $\pm(4 + (15 \%))$ 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.

— 201.5.101.3 — *Ventilator testing errors*

When testing *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 recognize 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 $\pm 10\%$, but the measurement uncertainty is $\pm 3\%$, then the test results are acceptable if, given the uncertainty band for the measured value, the probability of the measured values being within the limit is at least 50 %. In almost all cases, measurement uncertainty has a symmetrical distribution, and the 50 % likelihood criterion is met if the measured value is within the disclosed limit, in this example, within $\pm 10\%$ of the setting. If a third-party is testing to this document, they also need to include measurement uncertainty in their testing. The third-party testing organization needs to control measurement uncertainty to the same level as that disclosed for type testing, in this example $\pm 3\%$.

Note that a third party testing organization obtaining a measured value outside the limit does not necessarily invalidate the claim – the deviation from the limit is required to be compared to the uncertainty of the measurement to establish the probability of the data representing a true deviation from specification.

See IEC Guide 115 for more information regarding measurement uncertainty.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

— 201.7.2.3 — *Consult accompanying documents*

The committees agreed that following the *instructions for use* is a mandatory action for the safe operation of a *ventilator*.

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

Essential principle, 21.5, of ISO 16142-1:2016 and the European Medical Devices Regulation 2017/745 General Safety and Performance Requirement, 23.2, places requirements on the *manufacturer* of a medical device to include information on the medical device or *accessory* label that includes “any special storage and/or handling conditions” and “any special operating instructions”. These requirements provide information to the *operators* of the medical device intended to ensure that it is stored and handled in a manner that does not adversely affect medical device performance or safety.

It is not expected that this would include storage conditions common to most similar medical devices, such as a storage temperature range (unless this is more restrictive than the operational temperature range). This subclause requires labelling for information that is necessary to prevent a *hazard*, and that might not be evident to *operators* of other medical devices.

One example would be for a medical device with an internal battery that is required to be functional even when connected to the *supply mains* (for example to provide for surge current for a

medical device with a very variable power consumption or to maintain a real-time clock during periods of storage). For this medical device it would be appropriate to include labelling to leave the *ventilator* connected to wall power when not in use; the *operator* of the equipment cannot be assumed to recognize that such equipment with an internal battery might nonetheless become unusable even when connected to wall power if the battery is left to discharge while not in use.

A further example would be for a medical device with an internal fluid reservoir, which could leak externally, or cause a component failure, if the medical device were to be stored upside down. It is very common for *ME equipment* to be stored in orientation that is distinct from the operating position, so for this medical device it would be appropriate to include labelling to show permissible orientation.

— 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

— 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

a) 1)

A cover (e.g. a curtain or an unfavourable position of the *ventilator*) could cause the air intakes or openings of the *enclosure* to be partly or fully blocked. Air intakes are ports for ambient air for blower-driven *ventilators* or *emergency intakes*.

Openings in the *ventilator* housing are required for circulation of air for cooling and removal of leaked medical gases of the *ventilator*.

a) 2)

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*.

a) 3)

Additional attachments or other components or subassemblies increase the resistance and compliance of the *VBS*. The additional flow of a pneumatic nebuliser^[18] 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.

b) 1)

Components of critical care *ventilators* are typically not designed for the high ambient pressures in a hyperbaric chamber (e.g. 2 000 hPa). Ambient pressure sensors might not be calibrated for high ambient pressures resulting in severe failure of the *ventilator*. The high ambient pressure also can cause an incorrect measurement of the flowrate and oxygen concentration.

The much higher partial pressure of oxygen in a hyperbaric chamber would increase the *risk* of fire in the *ventilator*. A *ventilator* intended for use in a hyperbaric chamber requires special design considerations beyond the requirements of this document.

b) 2)

Nitric oxide can cause significant material compatibility issues with the components of some *VBS* (e.g. flow sensors).

b) 3)

Helium and gas mixtures with helium have characteristics that are significantly different from those of air or air-oxygen mixtures. This decreases the accuracy of the flowrate measurement and impairs the ventilation function.

Because of the changed oxygen concentration caused by helium or mixtures of helium the delivered oxygen concentration for the *patient* would be incorrect. *False positive alarm conditions* for both level and low oxygen concentrations can result.

Because of the very low density of helium, the gas leakage in the *VBS* is also increased. The low density also has an impact on the measurement of the resistance in the *VBS*.

b) 4)

The additional gas flow in gas volume reduces the accuracy of the flowrate measurement with a subsequent impairment of the ventilation function.

b) 5)

Ventilators need for their proper function a specific range of pressure, flowrate and gas concentration at the *high-pressure inlets*. Deviations of the *inlet* gas concentration for oxygen can influence the calibration of the oxygen sensor. Significant inaccuracies of the measurement of inspiratory oxygen concentration can occur.

In case the pressure or the deliverable flow of the central gas supply is too low, the *ventilator* would switch over to the remaining gas, e.g. from oxygen to air, with impact on the delivered oxygen concentration.

b) 6)

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 through 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 through 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 through 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 through 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 through 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^[18] for administration through 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^[18], 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 the effects of such substances can be manifested as increases in the amount of positive *airway pressure* required for a *ventilator*-provided breath, or as an

increase in expiratory flow resistance, resulting 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, *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.

— **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 *ventilator*, as well the measuring sensors and the *alarm signal* generation.

— **201.7.9.2.9.101 — Additional requirements for operating instructions**

b)

Some *ventilators* are designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. This can be required to provide the greater length needed during MRI procedures, for example. Thus, knowledge of these *VBS* characteristics is important for the *healthcare professional operator* to be aware of the *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^[18], water collection vessels and *connectors* needed for operation.

— **201.7.9.2.16.101 — Additional requirements for reference to the technical description**

Instructions for use are often kept as simple as possible so that the *healthcare professional operator* can easily find and follow important information. Therefore, more technical information, such as required by this subclause, is better placed in the *technical description*. However, without adequate cross-referencing, a *healthcare professional operator* facing a problem might not be aware that additional information is readily available in a separate document.

— **201.7.9.3.1.101 — Additional general requirements**

1)

The *manufacturer* is expected to express the description of the *ventilator* in general terms so the reader can understand the important behaviour of the *ventilator*, e.g. mean values and their time specifications, number of *inflations* and delays, etc.

— **201.9.6.2.1.101 — Additional requirements for audible acoustic energy**

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

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 *ventilator* to have a declared *tidal volume* range of 300 ml to 1 000 ml and another 100 ml to 300 ml, with each *ventilator* only being required to be tested for the conditions specified for ≥ 300 ml or ≤ 300 ml respectively.

— 201.9.101 — Additional requirements for suction procedures

It is now common practice in critical care areas to use a closed *suction catheter* during *artificial ventilation* of a *patient*. Use of a closed *suction catheter* allows uninterrupted *artificial ventilation* without disconnection of the *VBS* from the tracheal tube, tracheostomy tube or other *airway device*. This is in contrast to the use of a traditional open *suction catheter* which requires the opening or disconnection of the *VBS* before application of subatmospheric pressure to the respiratory tract.

A closed *suction catheter* is provided with an adaptor that permits its connection at the *patient-connection port*. When used as intended, an in-line or closed *suction catheter* and related suction equipment become an *accessory* to the *ventilator* and an extension of the *VBS*. When a *VBS* is equipped with a *suction catheter* adaptor, the *patient* end of the closed *suction catheter* adaptor becomes the 'new' *patient-connection port*.

While use of closed *suction catheters* is regarded as expected *normal use* by a *healthcare professional operator*, the related subatmospheric pressures within the *VBS* have been known to damage some *ventilators*^{[50][74]}.

The purpose of this requirement and test method is to replicate these worst-case in-use conditions caused by a closed *suction catheter* and to demonstrate that a *ventilator* resumes intended function after (but not during) the use of a *suction catheter*.

— 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^[61]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract^[71]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (256 kJ/kg) for 45 min^[57].

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 0,978 6 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*.

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. This allows a safety margin of approximately 25 % relative to the enthalpy figure of 197 kJ/m³ confirmed to be safe^[71].

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 for a long time been in use to limit the energy transfer of humidified breathing air to the respiratory tract of a *patient* with bypassed upper airways and no negative feedback with regard to this limitation was known at the time of the consideration of this document. Even in the vulnerable neonatal *patient* population, the committees are aware of no reports of injury resulting from excessive thermal output from a respiratory gas *humidifier* when operating to specification. 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^{[57][61][71]}:

- 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/m³ and add a maximum temperature limitation of 70 °C, whichever is lower. The committees agreed and confirmed this proposal.

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

Critical care *ventilators* are life-sustaining. Fluids commonly found in the critical care environment include saline, blood and other body fluids.

The committees agreed that the IP22 designation provided the most appropriate requirements to ensure that the *ventilator*, its *accessories* and parts maintain *basic safety* and *essential performance* during *normal use*.

— 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 an 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 conform 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*:

- the external *enclosure* of the *ventilator*;
- the *ventilator's* removable breathing circuit, including *accessories* and parts (e.g. *humidifier*, removable flow sensor, *connectors*, water traps, *breathing system filters*);
- 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
- 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 committees suggest 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 to be 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* could be 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 the *gas pathways* of *ventilators*, their reusable *accessories* and parts that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* and have been used should, when required for appropriate infection control, undergo a *processing procedure* following the *manufacturer's* instructions, prior to reuse by 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 that standardised *procedures* have consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedure* 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* rebreathing 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 so 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:

- undesired effects, which can result from:
 - the previous use,
 - the previous *processing procedures*, and
 - transportation and storage;
- 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);
- the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing procedure* 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 procedure*;
- 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*.

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

The operating time of a battery depends significantly on the number of charging and discharging cycles. Therefore, the committees decided that the *manufacturer* has to disclose the operating time in the *instructions for use* with both fresh and with aged batteries.

For aging a battery, the number of charging and discharging cycles was defined by the committees as 10 cycles for a *stationary ventilator* and an additional 40 cycles for a *transit-operable ventilator*, which means in total 50 cycles.

The assumption for the 10 cycles for a *stationary ventilator* was that every month there would typically be a single power breakdown in the hospital.

The assumption for the 50 cycles for a *transit-operable ventilator* was that 40 times per year the *ventilator* would be used for *patient* transport within the hospital and that every month there would typically be a single power breakdown in the hospital.

— 201.12.1 — Accuracy of controls and instruments

aa)

The committees considered that the accuracy of set and displayed values is a key component of the *essential performance* of a *ventilator* (i.e., the delivery of ventilation at the *patient-connection port* within the *alarm limits* set by the *healthcare professional operator* or generation of an *alarm condition*). The general standard requires *manufacturers* to declare accuracies and to address the associated *risks* in the *risk management process*. One of the associated *risks* is lack of consistency between *manufacturers* in their declarations of accuracy, both in terms of the reference settings used and the conditions of testing. Consistency in these situations can only be achieved by means of internationally agreed standards and these requirements have been formulated in order to fulfil this objective.

The test settings and conditions and, for certain parameters, minimum requirements, specified in this subclause have been selected by the committees as those necessary to demonstrate adequate *essential performance* of a critical care *ventilator* with regard to the parameters specified. The test *procedures* have been written as *type tests* (additional information is found in 3.135 and Clause 5 of the general standard), with the expectation that *manufacturers* will design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified will encompass any results obtained by a *type test* performed in accordance with the test *procedures* specified in this subclause.

In situations where the *ventilator* is being used to treat highly infectious diseases (e.g., SARS, COVID-19), the *operators* are wearing a substantial amount of personal protective equipment (e.g., multiple layers of protective clothing and gloves as well as goggles that might be blurred due to aerosol)^[46]. To ensure that the *operator* can both clearly see and adjust the *ventilator*, the minimum intended position of the *operator* was extended to 2 m for the purpose of legibility testing. Extending the position of the *operator* to 2 m was meant as an easier testing method than changing the testers visual acuity at 1 m. The conformity instruction for this test being changed to a 2 m distance was not meant to represent any real-world scenario. Additionally, this change permits the *operator* to clearly see the important information from the foot of the bed in situations where the *operator's* vision is not impacted by personal protective equipment.

— 201.12.1.101 – *Volume-control inflation-type*

b) 3)

A *ventilator* that is intended for use with a *medical gas pipeline system* driven from 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* driven from 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* driven by Oxygen 93, the *rated* concentration could be as wide as “90 % to 100 % O₂” 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 % O₂” 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, 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 test 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^[40]. The only difference has been the addition of five further infant test cases to extend downwards the range of *tidal volume*.

ASTM F1100^[40] 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 an endotracheal tube (ETT). 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 ETT) 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)⁻¹ to 25 hPa·(l/s)⁻¹ in neonates, to less than 5 hPa·(l/s)⁻¹ in adults^[70]. 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 ETT.

Measurements of pressure drop versus flowrate for seven sizes of ETTs have been published^[60]. A 7,0 mm ETT has a resistance at 1 l/s that is close to R10 (10 hPa·(l/s)⁻¹), 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)⁻¹).

For smaller sizes of ETT, the resistance changes significantly as flow increases above a critical value, which represents the onset of turbulence. Figure AA.1 demonstrates this effect.

The critical flow ranges from 0,25 l/s for a 3,5 mm ETT, to 0,63 l/s for a 7,0 mm ETT. 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 Table 201.103 in the previous edition of this document, i.e. ISO 80601-2-12:2011. 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.

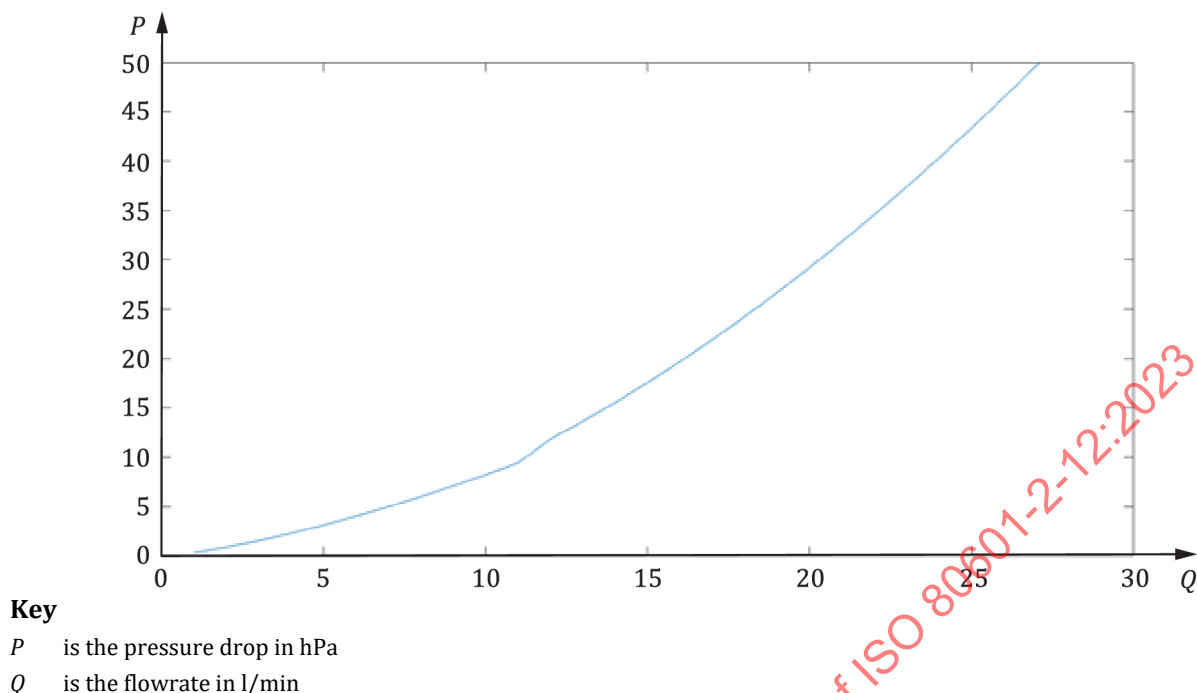


Figure AA.1 — Pressure drop calculation for 3,0 mm ETT, 100 % RH room air at sea level, 37°C, using approach specified in Reference [60]

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 a *tidal 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 ETT tube 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 $\text{hPa} \cdot (\text{l/s})^{-1}$).

The test cases need to account for both the resistance of the endotracheal 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 - #21) resistance values of $50 \text{ hPa} \cdot (\text{l/s})^{-1}$ to $200 \text{ hPa} \cdot (\text{l/s})^{-1}$ remain appropriate. For test cases with *tidal volumes* of 30 ml to 50 ml, representing term neonates or infants, resistance values of $20 \text{ hPa} \cdot (\text{l/s})^{-1}$ to $100 \text{ hPa} \cdot (\text{l/s})^{-1}$ would be appropriate. For test cases of 50 ml or greater, resistance values should be $5 \text{ hPa} \cdot (\text{l/s})^{-1}$ to $50 \text{ hPa} \cdot (\text{l/s})^{-1}$. Based on this, the resistance values in Table 201.104 and Table 201.105 have been adjusted from the values contained in previous standards.

Table AA.1 — Flow and pressure drop for linear and parabolic resistors

Test #	C ml/hPa	R hPa·(l/s) ⁻¹	V _T ml	Inspiratory time s	Mean flow, l/min	Peak flow, l/min	Parabolic ΔP hPa	Linear ΔP hPa
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

ETT diameter mm	Test case flow l/min	Pressure drop hPa	Resistance hPa·(l/s) ⁻¹
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

— **201.12.1.102 — Pressure-control inflation-type**

b) 3)

See rationale for 201.12.1.101 b) 3).

Table 201.105 — Pressure-control inflation-type testing

See rationale for Table 201.104.

— **201.12.1.104 — Inspiratory volume monitoring**

Evidence is accumulating that both volutrauma and barotrauma can result in respiratory morbidity and affect long-term respiratory outcome. Overstretching of the *lung* results in a decrease of the compliance in the respiratory system. A continual overstretching results in an increase in the water content of the *lungs* and microscopic evidence of alveolar and interstitial oedema, alveolar haemorrhage and neutrophil infiltration^[65]. The immature *lung* is especially vulnerable to injury due to overstretching^[68]. Volutrauma has been characterized by airway modelling and airway hyper-responsiveness in infant rats^[56]. In addition the early onset of airway hyper-responsiveness is a predictor of bronchopulmonary dysplasia in human infants^[68], a condition resulting in permanent *lung* injury^[69]. As a result, the *healthcare professional operator* needs to know both the *inspiratory volume* and *airway pressure* to be able to assess the adequacy of the *patient's* ventilation.

As with the measurement of *airway pressure*, the site of the volume measurement is not specified, but the value is required to be referenced to the *patient-connection port* (additional information is found in the rationale for 201.12.1.102). The permissible errors in measurement of *airway pressure* and *inspiratory volume* are reasonable for *patients* that require more than 50 ml *inspiratory volume*, i.e. there is little *risk* associated with under-ventilating such *patients*. This is less true for smaller *patients*, particularly those requiring *tidal volumes* of less than 50 ml, with stiff *lungs* in a *volume-control inflation-type*.

For neonatal and infant *patients*, it is not practicable to mandate an accuracy specification for volume monitoring. In *ventilator* use-cases that do not include a flow sensor at the *patient-connection port*, this can only be estimated by subtracting the *tidal volume* estimated as lost to the compliance of the *VBS* from the *tidal volume* as measured by flow sensors in the *ventilator*. For those *patients* requiring *tidal volumes* of less than 50 ml, this circuit compliance volume can significantly exceed the tolerance mandated in this subclause.

There can be clinical reasons why it is not appropriate to use a flow sensor at the *patient-connection port* for some *patients*. Such a flow sensor would add a dead space to the *VBS*, which increases rebreathing, and imposes an additional ventilatory burden. In addition, the mass of the flow sensor can contribute to unintended extubation, which can contraindicate use in some infants.

As a consequence, the accuracy specification for volume monitoring with *tidal volumes* of less than 50 ml has been left as a *manufacturer disclosure*.

— **201.12.1.105 — Response of the ventilator to an increase in oxygen concentration**

It is important that changes in the delivered oxygen concentration can be made without major delay. This is especially relevant in cases where a rapid increase of the inspired oxygen concentration is necessary for *patient* care. For instance, it is common practice to preload the *patient* with high concentrations of oxygen for a brief period prior to open suctioning. Depending on the design of the *ventilator* and depending on the settings, significant delays can occur.

The committees could not develop a maximum delay as there are too many possible clinical scenarios. However, the *healthcare professional operator* needs to know how a *ventilator* will respond, particularly to a request for a sudden increase in oxygen concentration delivery.

As a result, a test method has been developed. The results of this test are required to be disclosed in the *instructions for use* so that an *healthcare professional operator* can effectively care for the *patient*.

— 201.12.4.102 — Measurement of *airway pressure*

Additional information is found in the rationale for subclause 201.12.1.104.

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 the *airway pressure*, $\bar{P}_Y(t)$.

$$\bar{P}_Y(t) = \frac{P_Y^I(t) + P_Y^E(t)}{2} \quad (\text{AA.3})$$

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.

— 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, *healthcare professional 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 a *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 *healthcare professional operator* has to prevent the *harm* from occurring.

— 201.12.4.103.1 — Ventilators intended to provide a tidal volume >50 ml

— b) 6) ii)

In this document the phrase '*responsible organization-configurable*' is used to describe *ventilator* settings that are prearranged either to a specific value or a range of values by the *responsible organization* for a particular setting. *Responsible organization-configurable* settings are normally protected from change by the normal clinical *operator*. When the *responsible organization-configurable* parameter is constrained to a range, the *operator* typically can then adjust the parameter value within the constrained range.

— 201.12.4.103.2 — Ventilators intended to provide a tidal volume ≤50 ml

— b) 6) ii)

See the rationale for 201.12.4.103.1 b) 6) ii).

— 201.12.4.104 — Expiratory end-tidal CO₂ monitoring equipment

The monitoring of expiratory end-tidal CO₂ is employed clinically as a surrogate for arterial CO₂ 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 CO₂ rises. This can result in monitored end-tidal CO₂ values that remain within the clinically acceptable range as the *patient tidal volume* is reduced below the level of physiologic dead space. The committees did not believe that safety could be ensured through use of monitoring of end-tidal CO₂ unless either monitoring *inspiratory volume* or expired volume was also in use.

It is not intended that this constrain a *manufacturer* to integrate the CO₂ *monitoring equipment* into the *ventilator*. This allows for cases such as when the end-tidal CO₂ *monitoring equipment* is integrated within a vital signs monitor from a separate *manufacturer*.

— 201.12.4.105 — *Maximum limited pressure protection device*

When developing this edition of the document the committees carried out a re-evaluation of the current level of *maximum limited pressure*.

For several decades, international standards have specified the *maximum limited pressure* under *single fault conditions* of 125 hPa (125 cmH₂O). However, limiting the *lung* pressure to 125 hPa (125 cmH₂O) is not considered as *lung* protective. Therefore, it has been suggested that the *maximum limited pressure* should be reduced.

In a general population, the *lung* protective ventilation strategy involves keeping *tidal volumes* at 4 ml/kg to 6 ml/kg of predicted body weight (PBW) and preventing *lung* pressure from exceeding ~28 hPa (28 cmH₂O) and “driving” pressures from exceeding 15 hPa (15 cmH₂O). However even while applying this *lung* protective strategy as described above a limited number of *patients* need extremely high pressures at the *patient-connection port* (i.e. >80 hPa (80 cmH₂O)) due to the extremely high resistance of their airways (e.g. *patients* suffering from an acute severe asthma).

Another clinical strategy considered is the use of a high *set rate* in order to minimize *lung* delta pressure while maintaining adequate CO₂ removal. This requires a short inspiratory duration which in turn requires a high flowrate that requires a pressure at the *patient-connection point* that is significantly higher than the pressure in the *patient lung*.

High peak pressure at the *patient-connection port* can also be necessary for short periods for *lung* recruitment manoeuvres in obese *patients*.

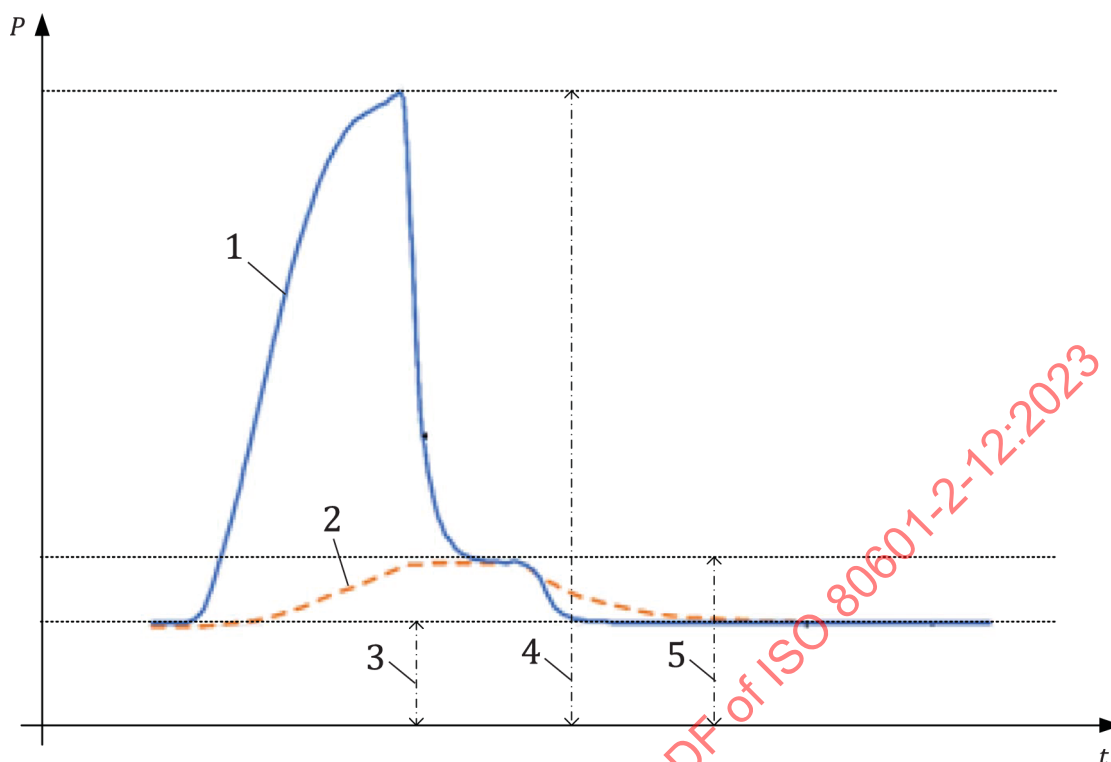
The Figure AA.2 illustrates a pressure waveform during *volume-control* breath delivery to a *patient* with acute severe asthma. This shows a high peak pressure at the *patient-connection port* but a much lower pressure to which the *lung* of the *patient* is exposed. The high peak *airway pressure* at the *patient-connection port* is not injurious to the *lung*, as it does not reach the *patient's lung*. However, if *lung* would be exposed to these non-acceptable pressures, the *lung* would be injured.

Considering the need to control the *risk* of a potential barotrauma (i.e. to reduce the *maximum limited pressure* the *patient* will be exposed to under *single fault conditions* as far as possible) but also considering the need to provide higher pressures under specific clinical conditions, the committees have developed a new concept which accommodates both the safe pressure limitation under *single fault conditions* for each individual *patient* and the clinical needs of higher pressures for a specific group of *patients*.

A review of incident databases did not identify any data demonstrating enhanced safety with a general pressure limitation lower than 125 hPa (125 cmH₂O). Therefore increased *patient* safety would not be achieved by reducing the *maximum limited pressure* below 125 hPa (125 cmH₂O), and such a reduction would prevent required treatment of certain *patients* and diagnoses.

This document defines a high-pressure *alarm condition*, with an *alarm limit* that is adjustable by the *operator*. Standard clinical practice is to set the high-pressure *alarm limit* to a value that is a safe maximum peak *airway pressure* for the *patient*.

The *maximum limited pressure* is a secondary means of protection which becomes effective under *single fault condition*. In order to apply an appropriate level of *maximum limited pressure*, while not preventing effective ventilation with pressures necessary for the specific case, the committees decided to link the *maximum limited pressure* to the *operator-configured high-pressure alarm limit*.

**Key**

- | | | | |
|---|---------------------------|---|---------------------------------------|
| 1 | airway pressure, P_{aw} | 4 | maximum airway pressure, $P_{aw,max}$ |
| 2 | lung pressure, P_{lung} | 5 | maximum lung pressure, $P_{lung,max}$ |
| 3 | BAP | | |

Figure AA.2 — Pressure waveforms as a function of time during volume-control breath delivery to a patient with acute severe asthma

It is very common to use active controlled valves for limiting the maximum pressure. These valves open with a certain response time, which could result in a short pressure overshoot. When open the flow results in a pressure differential. Both effects together with the tolerance of the pressure control requires there to be a margin between the high-pressure *alarm limit* and *maximum limited pressure*. Taking account of the technology available the committees determined that a margin of 20 hPa (20 cmH₂O) between the high-pressure *alarm limit* and *maximum limited pressure* would be sufficient.

In order to mitigate for unintentionally inappropriate settings, causing the high-pressure *alarm limit* to go above at 60 hPa (60 cmH₂O) or 20 hPa (20 cmH₂O) above the *operator-set* pressure, an *operator* interaction requiring a clear and deliberate action, is introduced. See rationale to 201.12.4.106.

— **201.12.4.106 — High airway pressure alarm condition and protection device**

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.

e)

Considering the reported incidents of *patient harm* associated with inappropriate setting of the high *airway pressure alarm limit*, the committees considered options to ensure that the *alarm limit* is set appropriately to reduce *risk* of barotrauma.

The great majority of *patients*, ventilated by a *ventilator* specified by this document, will not need more than a 60 hPa (60 cmH₂O) high-pressure *alarm limit* for sufficient ventilation. Therefore the committees determined that an unintentional setting in excess of 60 hPa (60 cmH₂O) would be inappropriate.

In order to control the *risk* of unintentional settings, causing the high-pressure *alarm limit* to be set above 60 hPa (60 cmH₂O) or 20 hPa (20 cmH₂O) above the *operator-set* pressure, an *operator* interaction requiring a clear and deliberate sequence of actions, was introduced to set the high-pressure *alarm limit* to values in excess of 60 hPa (60 cmH₂O) or 20 hPa (20 cmH₂O) above the *operator-set* pressure.

f)

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 expiratory flow of short duration. 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 the exhalation phase is an appropriate and sufficient response. Even in the worst case, 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*, pressure can exceed the high *airway pressure alarm limit* due to a reduced pulmonary compliance. In this scenario it would be preferable to apply a pressure limitation (with a threshold less than the high *airway 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 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*, the action defined in 201.12.4.108 (*obstruction alarm condition*) is appropriate to control the *risk*.

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 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 *gas output port* flow – either by terminating the *inflation phase*, or terminating the *bias flow* 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 set *BAP*, or atmospheric pressure level, 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 gas output port*, 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 *gas output port* flow and restore the *patient-connection port* to atmospheric pressure.

h)

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 *set 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^[46], including geriatric populations^[72], that are rarely less than 10 breaths/min, and hence would require no more than 12 s for two *respiratory cycles*.

— 201.12.4.108 – Obstruction *alarm condition*

Sustained elevated *airway pressure* levels can cause hazardous increases in intra-thoracic pressure. Such pressure increases can result in decreased venous return, reduced cardiac output and a subsequent drop in arterial blood pressure. Obstruction of the expiratory limb is the most common obstruction in a *ventilator*. The obstruction of the expiratory limb *alarm condition* should be designed to detect promptly a reduced expiratory flow due to an increased resistance in the expiratory limb.

The nature or duration of an occlusion in the expiratory limb of the *VBS* cannot be predicted. Assuming that the occlusion is severe and the safety valve opens quickly, the *patient* is not exposed to potentially injurious high pressures, although at the likely expense of the loss of *PEEP*. Further inspirations, whether or not assisted by the *ventilator*, necessitate rebreathing the previously exhaled gas trapped in the inspiratory limb. Given these considerations and their consequences, the associated *alarm condition* is required to be at least *medium priority*. Even if the *ventilator* is highly sophisticated, the presence of an occlusion in the expiratory limb of the *VBS* represents a significant corruption of the *ventilator's* ability to provide essential respiratory support to the *patient*, which requires prompt action by the *healthcare professional operator*.

Examples of causes for continuing *airway pressure* include a malfunctioning expiratory valve, kinked tubing and expiratory filter blockage. Nebulised^[18] drugs can block expiratory filters within a short time.

Other consequences of incomplete expiration (increased peak *airway pressure* or decreased ventilation) can be detected and indicated by other *alarm conditions* required by this document. Practice shows that clinically used *alarm limits* are not always sensitive enough to provide early and specific detection of this potentially hazardous situation.

— 201.12.4.109 — Disconnection *alarm condition*

Disconnection of the *ventilator breathing system* is a frequent occurrence in the critical care environment, and yet the only reference on the previous edition of this document is a reference in 201.13.2.101 to disruption of the gas delivery to the *patient-connection port* from the *ventilator*.

It is recognized that disconnection leads to a loss of gas exchange, with the possibility of significant harm or death^[64]. Many current critical care *ventilators* generate a *technical alarm condition* when this occurs. This amendment adds a mandatory requirement to provide such a disconnection *alarm condition*.

Implementation of a disconnect *alarm condition* can use a variety of technological means to detect gas flow into and out of the *lungs*, and these can differ between different groups of *patients*. Where the disconnect *alarm condition* detection mechanism uses information from one or more external sensors, such as for expired CO₂, the requirement from Clause 13 of the general standard for single fault safety applies. Loss of information from an external sensor would need to be assessed as a *single fault condition*.

Detection of disconnection of the breathing *gas pathways* between the *ventilator* and the *patient-connection port*, or disconnection at the *patient-connection port*, is mandatory.

In some *patient* groups, and particularly in neonates ventilated with a narrow lumen endotracheal tube, it might not be practicable to reliably detect decannulation without using a sensor placed

between the *patient-connection port* and the *airway device*. For example, an expiratory flow or end-tidal CO₂ sensor.

However, there can be clinical reasons why this is not appropriate. Use of either a flow sensor or a mainstream EtCO₂ sensor adds dead space to the *airway device*, which can be very significant relative to the desired *tidal volume*. This would increase rebreathing of exhaled gases and impose an additional ventilatory burden. This has been demonstrated to prolong weaning time and worsen *patient outcome*^[51].

In addition, the mass of the sensor attached to the *airway device* can increase the incidence of unintended extubation.

When using a diverting (sidestream) expired CO₂ monitor, the monitor removes a fixed flowrate of gas from the *patient-connection port*. This can exceed the spontaneous inspiratory flow for an infant *patient*, and thereby prevent use of *patient-triggered ventilation-modes*, resulting in a higher imposed work of breathing and *patient-ventilator asynchrony*.

As a consequence, the *operator* needs to retain the ability to select which monitoring devices are attached to the *VBS*, while also being aware of any limitation that the adopted configuration imposes on the operation of the *alarm system*. For this reason, this has been added to Clause 206 to ensure that the *usability process* is applied to this scenario.

Critical care *ventilators* are intended for use in the critical care environment. These settings provide specialized care for *patients* with conditions that can be life-threatening and who require constant monitoring in a *professional healthcare facility*. Not all *patients* who are cared for in the critical care environment are *ventilator-dependent*, and as a result critical care *ventilators* can be used to augment the ventilation of spontaneously breathing *patients*.

Although some *manufacturers* have chosen to provide separate *ventilation-modes* for *ventilator-dependent* and non-*ventilator-dependent patients*, this is discouraged as it leads to *operator* confusion. According to ISO 19223, *ventilation-modes* are classified by the types of *inflations* that are provided, the pattern of initiation, and independently of the intended *patient* or airway interface.

In those *patients* who are not *ventilator-dependent*, disconnection cannot require prompt attention from the *operator*. Alarm fatigue is well-documented in the clinical setting^[48], and can lead to delayed response to those *alarm signals* that really are critical, including *alarm signals* from the *ventilators* used for *ventilator-dependent patients*^[52]. It is desirable to allow the *operator* to inactivate this *alarm condition* to avoid distracting caregivers from other more critical events.

This document does not address how the *operator* confirms whether a particular *patient* is *ventilator-dependent* prior to inactivating the disconnection *alarm signals*. Many implementations are possible, for example, this information can be captured during *patient* setup; or it can be included as a prompt during the *process* of inactivation. The *manufacturer* is required to perform *usability* testing in order to validate the effectiveness of their implementation.

— 201.12.101 — Protection against accidental adjustments

Unacceptable *risks* to the *patient* can occur as a result of accidental adjustments of operating controls or turning off the *ventilator*. To control this *risk*, the *operator interface* should be designed to prevent accidental adjustments. The *usability engineering process* is used to ensure that these *risks* are reduced to acceptable levels. Example methods could include mechanical *risk control* techniques such as locks, shielding, friction-loading and detents; pressure-sensitive finger pads; capacitive finger switches; and microprocessor-oriented “soft” *risk controls*; and a specific sequence of key or switch operations.

— 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 a *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 contaminants carried by expired gases. If a *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.

Increased resistance and blockage of a *breathing system filter* when used together with nebulization^[18] or humidification is also considered as failure of an *operator-detachable breathing system filter*.

d)

Operation of a *ventilator* using an *operator-detachable remote control or monitoring module* is considered as a state of the art option of today. Independent of 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 not 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 *communicator*) also needs designed as *single fault safe*.

— 201.13.2.102 — Failure of one gas supply to a *ventilator*

This subclause addresses the *hazardous situation* created when an entire unit (e.g. the whole critical care unit or all of the operating theatres) experiences simultaneous failure of multiple *ventilators* caused by the loss of a single pressurized gas source where at least one gas source is provided by a pressurized *medical gas pipeline system*.

EXAMPLE 1 A *ventilator* is connected to both air and oxygen *medical gas pipeline systems* and one of the *medical gas pipeline systems* fails. The *ventilator* then uses the other *medical gas pipeline system* to supply gas.

EXAMPLE 2 A blower-based *ventilator* is connected is to an oxygen *medical gas pipeline system* and that *medical gas pipeline system* fails. The *ventilator* then uses the room air provided by its blower.

— **201.13.2.103 — 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.

— **201.13.2.104 — Failure of *functional connection* to a ventilator control or monitoring means**

Independent how the *functional connection* between the “ventilator module” and the remote control or monitoring module is facilitated (e.g. wired or wireless) this *functional connection* needs to be so designed and constructed that a failure or loss of the *functional connection* does not cause an unacceptable *risk* to the *patient*.

First of all this means that the safety of the *patient* is not degraded by the loss of the *functional connection*, (i.e. the “ventilator module” continues to ventilate the *patient* without any change of the ventilation parameters, without any change of setting of safety means and without any change of the setting of *alarm limits*). Further, the *healthcare professional operators* in both locations where these modules are located need to be made aware by *alarm signals* about the loss of this *functional connection* (i.e. there is a need for *alarm signals* on both sides of the *functional connection*—at the “ventilation module” and on any other remote control or monitoring module or the *distributed alarm system* or the simple remote *alarm signal* generator).

— **201.15.3.5.101.1 — Shock and vibration (robustness)**

The intention of these tests is to assess mechanical stresses on the *ventilator* in *normal use* and not to assess the suitability of the design for the *expected service life* or fatigue.

ME equipment, including *ventilators*, in *normal use*, used within a *professional healthcare facility*, or *home healthcare environment* will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, *ME equipment* intended to be used in a *professional healthcare facility* needs to be robust enough to withstand the vibration and shock testing described as level 7M1 by IEC 60721-3-7. IEC 60721-3-7 indicates that this class applies within, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

In reviewing the random vibration tests of IEC 60068-2-64:2008+AMD1:2019, the committees determined that the environment included careful handling in vehicles (including airborne vehicles). Since a critical care *ventilator* is not intended for such environments, the maximum frequency of the acceleration amplitude was limited to 500 Hz which is more reflective of non-vehicle environments.

— **201.15.3.5.101.2 — Shock and vibration for a *transit-operable ventilator* during operation**

Transit-operable ventilators (those intended to operate while the *patient* is being transported within a healthcare facility) are expected to maintain *basic safety* and *essential performance* while they are 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*.

— **201.16.2.101 — Additional general requirements for accompanying documents of an ME system**

Many respiratory gas *humidifiers* control their humidification output by servo controlling the temperature of a water bath to achieve a set gas temperature at the *humidifier* chamber *outlet*. This temperature is frequently defined to be a function of gas flowrate as measured by the *humidifier*, and is defined to target a desirable absolute humidity – the rate of evaporation of water and the rate of heat transfer from the water to the air are closely correlated. This works provided the input gas temperature is below a threshold. For example, for one leading *manufacturer of humidifiers*, the water vapour output starts to reduce when the input gas temperature exceeds 27 °C.

A *ventilator* that incorporates a blower to provide a source of breathing air drawn from an air intake inevitably increases the temperature of the air above the intake temperature. The extent of this rise in temperature will depend on the set FiO₂ (and hence the proportion of the breathing gas that has been compressed), the blower *outlet* pressure (which can significantly exceed the *ventilator gas output port* pressure), the *ventilator set rate*, *BAP*, and set Δ *inspiratory pressure* or *tidal volume*, and the efficiency of the blower technology used.

This has been confirmed in published bench study^[63]. This study confirmed that with unfavourable conditions, specifically *humidifier* chamber *inlet* gas temperatures above 37 °C, *humidifier* output could fall well below recommended minimum levels of 20 mgH₂O/l.

For a *ventilator* capable of generating an elevated gas temperature at the *gas output port*, the *responsible organization* needs to have information available to allow them to determine whether the *humidifier* is likely to remain effective.

— **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 gases, 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 system* 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.