



International
Standard

ISO 80601-2-79

**Medical electrical equipment —
Part 2-79:
Particular requirements for basic
safety and essential performance of
ventilatory support equipment for
ventilatory impairment**

Appareils électromédicaux —

*Partie 2-79: Exigences particulières pour la sécurité de base
et les performances essentielles des équipements d'assistance
ventilatoire en cas de trouble ventilatoire*

**Second edition
2024-08**

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-79:2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

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.....	iv
Introduction.....	vi
201.1 Scope, object and related standards.....	1
201.2 Normative references	4
201.3 Terms and definitions	5
201.4 General requirements	23
201.5 General requirements for testing of <i>ME equipment</i>	25
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	26
201.7 <i>ME equipment</i> identification, marking and documents.....	26
201.8 Protection against electrical hazards from <i>ME equipment</i>	33
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	33
201.10 Protection against unwanted and excessive radiation hazards.....	35
201.11 Protection against excessive temperatures and other hazards	35
201.12 Accuracy of controls and instruments and protection against hazardous outputs	38
201.13 Hazardous situations and fault conditions for <i>ME equipment</i>	49
201.14 Programmable electrical medical systems (PEMS)	50
201.15 Construction of <i>ME equipment</i>	51
201.16 <i>ME systems</i>	52
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	52
201.101 Gas connections	52
201.102 Requirements for the <i>VBS</i> and <i>accessories</i>	56
201.103 Spontaneous breathing during loss of power supply	57
201.104 Indication of duration of operation.....	57
201.105 Functional connection	58
201.106 Display loops.....	58
202 Electromagnetic disturbances — Requirements and tests.....	59
206 Usability.....	60
206.101 Training	61
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	62
Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	63
Annex D (informative) <i>Symbols on marking</i>	69
Annex AA (informative) Particular guidance and rationale	71
Annex BB (informative) Data interface requirements.....	89
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances....	95
Bibliography	100
Terminology — Alphabetized index of defined terms	103

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).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and <https://patents.iec.ch>. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

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 D, *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 second edition cancels and replaces the first edition (ISO 80601-2-79:2018), 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;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements; and
- harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO 80601 series and the 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 80601-2-79:2024

Introduction

This document specifies requirements for *ventilatory support equipment* that is intended for use in the *home healthcare environment* for *patients* who are not dependent on *ventilation* for their life support. *Ventilatory support equipment* is frequently used in locations where *supply mains* is not reliable. *Ventilatory support equipment* is often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. *Ventilatory support equipment* conforming with this document can be used elsewhere (i.e. in healthcare facilities).

Ventilatory support is often used for *patients* who have stable ventilatory needs. This document addresses *patients* who have significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the *patient*. This is best characterized by *lung* functions not worse than^[35]:

- $FEV_1/FVC^1 < 70 \%$; or
- $50 \% \leq FEV_1 < 80 \%$ predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require *ventilation* support are:

- mild to moderate Chronic Obstructive Pulmonary Disease (COPD);
- mild to moderate neuromuscular/ amyotrophic lateral sclerosis (ALS);
- obese *patients* Obese Hypoventilation Syndrome (OHS);
- Cheyne–Stokes respiration (CSR/CSA).

CSR/CSA is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnoea. The pattern repeats, with each cycle usually taking 30 s to 2 min.

Cardiac *patients* with CSR/CSA might be breathless without having significant reduction in FEV_1 . Reducing the work of breathing can help normalize their breathing.

This *ventilatory support equipment* is intended for *patients* who are spontaneously breathing and do not require *ventilation* for life support or intermittent periods of *ventilation* to maintain vital signs. *Ventilatory support equipment* intended for this group of *patients* typically does not require *physiological alarm conditions* as no *essential performance* exists. These *patients* can gain adequate relief from fatigue related to the work of breathing by using *ventilatory support equipment* during the night and while taking breaks during the day. This can enable a *patient* with *ventilatory impairment* to continue to move about and participate in the activities of daily living. Non-transit-operable *ventilatory support equipment* that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

In this document, the following print types are used:

- requirements and definitions: roman type;
- terms defined in *Clause 3* of the general standard², in this document or as noted: italic type; and

¹ This is also known as the Tiffeneau-Pinelli index.

- informative material appearing outside of tables, such as notes, examples and references: in smaller type; normative text of tables is also in a smaller type;

In referring to the structure of this document, the term:

- “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8); and
- “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

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

For the purposes of this document, the auxiliary verb:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or capability; and
- “must” is used to express an external constraint.

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

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

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

² The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-79:2024

Medical electrical equipment

Part 2-79:

Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

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 ventilatory support equipment*, as defined in 201.3.302, for *ventilatory impairment*, as defined in 201.3.300, hereafter also referred to as *ME equipment*, in combination with its *accessories*:

— intended for use in the *home healthcare environment*;

NOTE 2 In the *home healthcare environment*, the *supply mains* driving the *ventilatory support equipment* is often not reliable.

NOTE 3 Such *ventilatory support equipment* can also be used in professional health care facilities.

— intended for use by a *lay operator*;

— intended for use with *patients* who have *ventilatory impairment*, the most fragile of these *patients*, would not likely experience injury with the loss of this *artificial ventilation*; and

— not intended for *patients* who are dependent on *artificial ventilation* for their immediate life support.

EXAMPLE 1 *Patients* with mild to moderate chronic obstructive pulmonary disease (COPD).

Ventilatory support equipment 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 the *breathing system* of *ventilatory support equipment* for *ventilatory impairment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilatory support equipment* for *ventilatory impairment*.

EXAMPLE 2 Breathing sets, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system*.

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 4 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

NOTE 5 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

This document does not specify the requirements for:

- *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications, which are given in ISO 80601-2-12;
- *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;
- *ventilatory support equipment* or *accessories* intended for *ventilatory insufficiency*, which are given in ISO 80601-2-80;
- sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;
- high-frequency jet *ventilators* (HFJVs)^[33], which are given in ISO 80601-2-87;
- high-frequency oscillatory *ventilators* (HFOVs)^[22];
- respiratory high flow equipment, which are given in ISO 80601-2-90;

NOTE 6 *Ventilatory support equipment* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

- user-powered resuscitators, which are given in ISO 10651-4;
- gas-powered emergency resuscitators, which are given in ISO 10651-5;
- oxygen therapy constant flow *ME equipment*; and
- cuirass or “iron-lung” *ventilation equipment*.

201.1.2 Object

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.2 is replaced by:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *ventilatory support equipment*, for ventilatory impairment, as defined in 201.3.300, and its *accessories*.

Accessories are included because the combination of the *ventilatory support equipment* and the *accessories* need to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of the *ventilatory support equipment*.

NOTE 1 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles*^[37] and *labelling*^[38] guidances 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^[10] 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^[39].

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

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

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3, IEC 60601-1-9 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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.4 is replaced by:

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.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx”, where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 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 the general standard or 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 the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or 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, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this document” is used to make reference to the IEC 60601-1:2005+AMD1:2012+AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this particular document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or 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.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2, applies, except as follows:

Replacement:

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

Addition:

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

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

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

ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016/Amd 1:2017, *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 18562-1:2024, *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 80369-1:—³, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020⁴, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity 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.]

³ Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024.

⁴ There exists a consolidated edition 3.2(2020) including IEC 60601-1:2005, its Amendment 1:2012 and its Amendment 2:2020.

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 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]

201.3.204

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]

201.3.205

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]

201.3.206

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]

201.3.207

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]

201.3.208

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]

201.3.209

alarm signal generation delay

time from the onset of an *alarm condition* to the generation of its *alarm signal(s)*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]

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

Note 1 to entry: In addition to its direct reference, this term is only used, in context or by qualification, to designate this concept as a measured quantity.

[SOURCE: ISO 19223:2019, 3.5.2.1, modified — deleted note 2.]

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 81001-5-1:2021, 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

biocompatibility

ability of a medical device, *accessory* or material to perform with an appropriate host response in a specific application

Note 1 to entry: A medical device 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 18562-1:2024, 3.6]

201.3.217

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]

201.3.218

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.]

201.3.219

breathing system filter

BSF

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

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

201.3.220

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'.]

201.3.221

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]

201.3.222**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

Note 1 to entry: *CPAP* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of breathing to a greater extent than could be experienced during natural breathing.

Note 2 to entry: This definition excludes the use of the term to describe *ventilation-modes* where spontaneous inspirations are supported by intermittently elevated pressures other than with the intention to compensate for any actual or perceived imposed work of breathing.

Note 3 to entry: Because, as used for this *ventilation-mode*, the concept of a *CPAP* level coincides with that of a baseline *airway pressure* the setting could be designated as for either concept but as the intention of the *operator* selecting this *ventilation-mode* will be to achieve a specific *CPAP* level, this becomes an acceptable admitted term to designate the set quantity.

Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation-mode*, *CPAP* is included in this document because it is commonly made available on typical critical care *ventilators* for use as part of a continuum of a *patient's* treatment without the necessity to change to another device.

Note 5 to entry: It is possible for a *ventilation-mode* resembling *CPAP* to be realized on a *ventilator* by the use of CSV (continuous spontaneous *ventilation*) with the pressure-support (PS) *set* to 'zero' or 'none' but CSV set in this way is not equivalent to *CPAP* if its performance in response to a spontaneous inspiration is dependent on the setting of an appropriate trigger level.

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted notes 6 to 9.]

201.3.223**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 81001-5-1:2021, 3.30]

201.3.224 **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.]

201.3.225

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]

201.3.226

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]

201.3.227

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.]

201.3.228

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]

201.3.229

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]

201.3.230

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]

201.3.231

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.]

201.3.232

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]

201.3.233

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]

201.3.234

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]

201.3.235

fresh gas

respirable gas delivered to a *ventilator breathing system*

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

201.3.236

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 opposition to an *inlet*, at which gas is provided by a medical gas supply system.

[SOURCE: ISO 4135:2022, 3.1.4.21, modified — replaced "apposition" with "opposition".]

201.3.237

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]

201.3.238

gas pathway

interior surfaces, over which gases or liquids that can be inspired pass

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.

Note 1 to entry: The *gas pathway* is bounded by the fluid ports through which gases or liquids enter the medical device. This can include the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.

Note 3 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.

[SOURCE: ISO 18562-1:2024, 3.11, modified — replaced “ports” with “fluid ports”.]

201.3.239

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]

201.3.240

healthcare professional

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

Note 1 to entry: The *healthcare professional operator* is the supervising clinician or the *healthcare professional* responsible for the treatment of a *patient* on *ventilatory support equipment*.

[SOURCE: ISO 80601-2-12:—, 201.3.247, modified — added note 1 to entry.]

201.3.241

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]

201.3.242

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]

201.3.243

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: 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, modified — deleted "For the purpose of this collateral standard,".]

201.3.244

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]

201.3.245

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.]

201.3.246

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]

201.3.247

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.]

201.3.248

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.]

201.3.249

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.]

201.3.250

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.]

201.3.251

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.]

201.3.252

inspiratory pressure

airway pressure during an inspiratory or *inflation phase*

[SOURCE: ISO 19223:2019, 3.6.2, modified — deleted notes.]

201.3.253

inspiratory time

t_i

duration of an *inflation phase* or inspiratory phase

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

201.3.254

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.]

201.3.255

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.]

201.3.256

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]

201.3.257

lay

lay person

<adj> term referring to non-professional or professional without relevant specialized training

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.2]

201.3.258

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]

201.3.259

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.]

201.3.260

manual ventilation port

port to which a manual inflating device can be connected

201.3.261

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.]

201.3.262

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]

201.3.263

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.]

201.3.264

maximum working pressure

$P_{W,max}$

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

Note 1 to entry: This information is usually documented in the *instructions for use* as it is valuable in determining if a *ventilator* is suitable for use with *patients* with an impaired *lung*.

Note 2 to entry: This maximum pressure is typically determined by the *manufacturer*.

[SOURCE: ISO 19223:2019, 3.13.4, modified — deleted note 3.]

201.3.265

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]

201.3.266

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".]

201.3.267

operator interface

means by which the *operator* and the *ME equipment* interact

Note 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]

201.3.268

outlet

opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.269

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.]

201.3.270

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.]

201.3.271

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]

201.3.272

physiologic closed-loop control system

part of *ME equipment* or *ME system* used to adjust a physiologic variable relative to a command variable using a feedback variable

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

201.3.273

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.]

201.3.274

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]

201.3.275

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

201.3.276

rebreathing

inhalation of expired gas mixture from which carbon dioxide may or may not have been removed

[SOURCE: ISO 4135:2022, 3.1.5.12]

201.3.277

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.]

201.3.278

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]

201.3.279

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.]

201.3.280

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]

201.3.281

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.]

201.3.282

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.]

201.3.283

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]

201.3.284

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

201.3.285

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]

201.3.286

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]

201.3.287

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]

201.3.288

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]

201.3.289

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.]

201.3.290

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.]

201.3.291

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.]

201.3.292

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, 3.4]

201.3.293

use scenario

specific sequence of tasks performed by a specific *operator* in a specific use environment and any resulting response of the *ME equipment*

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.22, modified — replaced "user" with "*operator*" and "medical device" with "*ME equipment*".]

201.3.294

validation

confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or application 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]

201.3.295

ventilation

cyclical movement of a respirable gas into and out of the *lungs*

Note 1 to entry: This might be by external or spontaneous means, or by a combination of both.

[SOURCE: ISO 19223:2019, 3.1.9, modified — deleted note 2.]

201.3.296

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.]

201.3.297

ventilator

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

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

201.3.298

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.]

201.3.299

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]

201.3.300

ventilatory impairment

respiratory impairment

clinically significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the *patient*

Note 1 to entry: *Patients* with *ventilatory impairment* exhibit a minimal level of illness acuity, fragility, or instability. Their dependence on the *ventilatory support equipment* to maintain adequate gas exchange is minimal. Without such support as needed, these *patients* would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. Without ventilatory support as needed, these *patients* are likely to experience short periods of abnormal *lung* gas exchange which can result in them becoming more sedentary.

EXAMPLE *Patients* with mild to moderate chronic obstructive pulmonary disease (COPD).

Note 2 to entry: *Ventilatory support equipment* for *ventilatory impairment* is suitable for use where *physiological alarm condition* monitoring is usually not required because the absence or degradation of the ventilatory support is not likely to cause injury to the *patient* (i.e. *ventilatory support equipment* for *ventilatory impairment* has no *essential performance*).

201.3.301

ventilatory insufficiency

respiratory insufficiency

degradation in respiratory function severe enough to prohibit certain activities that the *patient* might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal

Note 1 to entry: *Patients* with *ventilatory insufficiency* exhibit an illness acuity, fragility or instability level up to and including a moderate to severe degradation in respiratory function. Their dependence on the *ventilatory support equipment* to maintain adequate gas exchange can range from minimal to moderate dependence. Without

such support, the most fragile of these *patients* would likely be prohibited from certain activities that they might normally pursue and this would likely interfere with their daily living. The most fragile of these *patients* would likely experience injury with the loss of this *artificial ventilation*.

EXAMPLE *Patients* with moderate to severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy.

Note 2 to entry: *Ventilatory support equipment* for *respiratory insufficiency* is suitable for use where some *physiological alarm condition* monitoring is required to prevent the absence or degradation of the ventilatory support, which in turn could cause the compromise of the health of the *patient*.

[SOURCE: ISO 80601-2-80:2024, 201.3.302]

201.3.302

ventilatory support equipment

ME equipment, suitable for domiciliary use without continuous professional supervision, intended to augment or provide *ventilation* of the *lungs* of a *patient* who is not *ventilator-dependent*

Note 1 to entry: *Ventilatory support equipment* is a type of *ventilator*, but is not a *ventilator* for *ventilator-dependent patient*.

Note 2 to entry: A *patient* suitable for *ventilatory support equipment* requires a narrow spectrum of *ventilation* modalities and monitoring for appropriate management.

[SOURCE: ISO 80601-2-80:2024, 201.3.303]

201.3.303

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

- a) For the purposes of this document, *ventilatory support equipment* for *ventilatory impairment* is considered not to have *essential performance*. Notwithstanding this fact, when this document refers to *essential performance* as acceptance criteria, the continuous pressure shall be evaluated.
- b) The method of subclauses 202.4.3.1 and 202.8.1.101 may be used to evaluate continuous pressure as an acceptance criterion following specific tests required by this document.

NOTE 2 A continuous pressure mode is often referred to as a *continuous positive airway pressure (CPAP)* mode.

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

Amendment (add at end of 4.6 prior to the compliance check):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

- aa) The VBS or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause (i.e., 4.6 of the general standard).

Additional subclauses:

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) *Ventilatory support equipment* with a *high-pressure inlet* 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.

NOTE 1 Internal pressure regulators can be necessary 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 *ventilatory support equipment* is likely to be outside of its specification.

- b) If the *ventilatory support equipment* has a maximum *rated* input pressure in excess of 600 kPa, the *ventilatory support equipment* shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

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

201.4.11.101.2 Compatibility requirement

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

- a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1+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 10 s average input flowrate required by the *ventilatory support equipment* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *high-pressure inlet*, and

- 2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s, or
- 3) the *accompanying documents* shall disclose the following:
 - i) the maximum 10 s average input flowrate required by the *ventilatory support equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*;;
 - ii) the maximum transient input flowrate averaged for 3 s required by the *ventilatory support equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*;; 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 minimizing 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 The highest driving gas consumption, the highest *fresh gas* delivery, and, if provided, the highest *rated* gas consumption at any gas power supply output under worst-case settings for *set rate* and *tidal volume* and worst-case *medical gas pipeline system* conditions within the *rated* range for *inlet* pressure.

201.5 General requirements for testing of *ME equipment*

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

Additional subclauses:

201.5.101 Additional requirements for the 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 *Ventilatory support equipment* test conditions

- a) For testing, the *ventilatory support equipment*:
 - 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 1 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.

NOTE 2 This subclause is only applicable to *ventilatory support equipment* intended to be connected to a gas supply in *normal use* (e.g. *medical gas pipeline system* or medical gas cylinder).

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 the 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 Ventilatory support equipment 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) evaluation of uncertainty of measurement from IEC Guide 115:2023, 4.1.1 and 4.1.2; and
- 2) simple acceptance method from IEC Guide 115:2023, 4.3.

NOTE 2 Previous revisions of ISO 80601-2-79 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 measurement 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 *tidal 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 of each disclosed tolerance in the *technical description*.

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

201.6 Classification of ME equipment and ME systems

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:

Additional subclauses:

201.7.1.101 Information to be supplied by the manufacturer

- a) The *information supplied by the manufacturer of ventilatory support equipment 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.

201.7.2.4.101 Additional requirements for accessories

a) *Accessories* supplied separately shall

- 1) fulfil the 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* of the *ventilatory support equipment*, if applicable.

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

NOTE The *manufacturer* of the *accessory* can be the *ventilatory support equipment manufacturer* or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure conformity with this requirement. Additional requirements are found in 201.102.

Check conformity by inspection and inspection of the *risk management file* for any limitations or adverse effects of the *accessory*.

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.

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

a) If applicable, *operator-detachable ME equipment parts* or *accessories* shall have *clearly legible markings* of the following:

- 1) for *ventilatory support equipment* 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 1*) or *symbol 7.3.1-2* (Table 201.D.2.101, *symbol 2*) of IEC 62570:2014 for 'MR Safe' *ventilatory support equipment*; or
 - ii) *symbol 7.3.2* of IEC 62570:2014 (Table 201.D.2.101, *symbol 3*) for 'MR Conditional' *ventilatory support equipment*.
- 2) for *ventilatory support equipment* 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 4*) for 'MR Unsafe' *ventilatory support equipment*.
- 3) for *flow-direction-sensitive components* that are *operator-removable* without the use of a *tool*, an arrow indicating the direction of the flow.

b) If applicable, *operator-accessible ME equipment, parts* or *accessories* shall have *clearly legible markings* of the following adjacent to or on:

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

EXAMPLE WARNING: Gas Intake – Do not obstruct.

- i) A *symbol* or *safety sign* evaluated in accordance with IEC 62366-1 as *information for safety* may be used.

Check conformity by inspection.

201.7.4.2 Control devices

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.4.2, applies, except as follows:

Amendment (add after the second dash):

- aa) The *marking* of the trigger sensitivity control, if provided, shall be such that the minimum (least *patient effort*) and the maximum (greatest *patient effort*) settings are self-evident to the *operator*.

- bb) The *marking*, if numeric, shall:

- 1) use the lowest number to represent the setting for the least *patient effort*; and
- 2) not only be numeric.

201.7.4.3 Units of measurement

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):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

- aa) All gas volume, flowrate and leakage specifications:

- 1) shall be expressed at *STPD*; except those associated with the *VBS* which
- 2) shall be expressed at *BTPS*.

- bb) The unit of *airway pressure* measurement shall be capable of being configured to be expressed in hPa.

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

- a) Separate *instructions for use* shall be provided for:

- 1) the *lay operator*; and
- 2) the supervising clinician or the *healthcare professional operator*.

- b) Unless otherwise indicated in this document, the *manufacturer* may choose in which *instructions for use* to place the information required by this document based on *risk management* and *usability* considerations.

- c) The *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

- d) The *instructions for use* shall disclose the following:

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

Check conformity by inspection of the *instructions for use*, the *risk management file* and the *usability engineering file*.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

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

The *instructions for use* shall include:

- a) a warning statement to the effect that “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 ventilator to overheat.

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

EXAMPLE 3 WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use, to prevent the ventilator from overheating or interfering with patient ventilation.

- b) a warning statement to the effect that “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 degradation or loss of ventilatory support.”

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

- c) if the *instructions for use* include a *VBS* configuration with a *BSF* exposed to the humidity from nebulisation or humidification, a warning statement to the effect that “WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage.”

NOTE 3 There is guidance or rationale for this list item contained in Clause AA.2.

- d) a warning statement to the effect that “WARNING: This ventilator is not suitable for a ventilator-dependent patient” including descriptions as to why that is true.

EXAMPLE 4 WARNING: This ventilator is not suitable for a ventilator-dependent patient because it does not meet the safety requirements for ventilator-dependent patients.

Check conformity by inspection of the *instructions for use*.

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 For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used for the initial setup for a *patient* to determine whether the *ventilatory support equipment* is ready for use.

- a) The *instructions for use* for the *lay operator* shall disclose a method by which the following can be functionally tested to determine if they are operating correctly:

- 1) the assembled breathing tubes and related *accessories*;
- 2) if provided, the switchover to and operation from the *internal electrical power source*; and
- 3) all of the *alarm signals*, including, if provided, the *alarm signals* from *distributed alarm systems*.

NOTE 3 Additional requirements are also found in 201.15.102.

b) Portions of these test methods may:

- 1) be performed automatically by the *ventilatory support equipment*; or
- 2) require *operator* action.

EXAMPLE 1 Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

c) The specifications of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.

EXAMPLE 2 Volume, resistance, and compliance of the test lung necessary to perform the tests.

NOTE 4 Additional requirements are also found in 201.15.102.

d) The *instructions for use* for the supervising clinician or *healthcare professional operator* shall disclose a test method by which all functions and settings necessary for *normal use* can be functionally tested to determine if they are operating correctly.

e) Portions of this test method may:

- 1) be performed automatically by the *ventilatory support equipment*; or
- 2) require *operator* action.

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

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.

201.7.9.2.9.101.1 *Lay operator* operating instructions

The *instructions for use* intended for the *lay operator* shall include:

a) the conditions under which the *ventilatory support equipment* maintains the accuracy of controlled and displayed variables as disclosed in the *instructions for use*;

EXAMPLE 1 Acceptable range of water level in a *humidifier*.

EXAMPLE 2 Interval of calibration of a flow sensor.

b) a statement to the effect that “Do not use the ventilator at an altitude above [insert maximum *rated* altitude] or outside a temperature of [insert *rated* temperature range]. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance”;

c) a statement to the effect that “To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories”.

d) if applicable, a statement to the effect that “The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser.”

e) a description of a means to determine the operation time of the *internal electrical power source*, if provided,

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

Check conformity by inspection of the *instructions for use*.

201.7.9.2.9.101.2 Supervising clinician or healthcare professional operator operating instructions

- a) The *instructions for use* intended for the supervising clinician or *healthcare professional operator* shall include a detailed description of the function of all *ventilation-modes* provided by the *ventilatory support equipment* including, but not limited to, the following items:
 - 1) the working principle of each of the *ventilatory support equipment's ventilation-modes*, including waveforms;
 - 2) the methods for controlling the triggering and cycling;
 - 3) the range of parameter settings; and
 - 4) any limitation of parameter settings.
 - b) The *instructions for use* intended for the supervising clinician or *healthcare professional operator* shall include the following.
 - 1) A description of how at least the following *alarm conditions* can be functionally tested:
 - i) high *airway pressure*, if provided; and
 - ii) hypoventilation.
 - 2) 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:
 - i) inspiratory *gas pathway* resistance;
 - ii) expiratory *gas pathway* resistance;
 - iii) inspiratory *gas pathway* compliance; and
 - iv) expiratory *gas pathway* compliance.
 - 3) These specifications may be presented in ranges.
 - 4) The accuracies of set and monitored volumes may be presented as a function of these characteristics.
- NOTE Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate or the maximum pressure).
- 5) A cross reference between the *manufacturer-specific* naming of the *ventilatory support equipment's ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.
- c) If applicable, *instructions for use* intended for the supervising clinician or *healthcare professional operator* shall disclose
 - 1) the essential technical characteristics of each recommended *breathing system filter*.

EXAMPLE Dead space and resistance.

- 2) a statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories with which the ventilator is intended to be used.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.12 Cleaning, disinfection, and sterilization

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.2.12, applies, except as follows:

Amendment: (add after normal use)

and *single fault condition*

Amendment: (add after bulleted list)

aa) The *instructions for use* shall identify any portions of the *gas pathways* through the *ventilatory support equipment* that can become contaminated with body fluids or by microbial material conveyed by the expired breathing gases during both:

- 1) *normal condition*; and
- 2) *single fault condition*.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The *instructions for use* shall disclose

- a) a description of periodic safety inspections that should be performed by the *operator*.
- b) if provided, the care and maintenance *procedures* for the *internal electrical power source*, including instructions for recharging and, if applicable, replacement.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.14.101 Additional requirements for accessories, supplementary equipment, used material

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

If applicable, the *instructions for use* shall disclose:

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

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

- b) any reasonably foreseeable adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *ventilatory support equipment*.

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

201.7.9.3.1.101 Additional general requirements

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

The *technical description* shall disclose:

- a) a summary description of the filtering or smoothing (e.g. averaging) 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 *ventilatory support equipment*;

- b) the interdependence of control functions;
- c) a pneumatic diagram of the *ventilatory support equipment*, including a diagram for *operator-detachable parts of the ventilator breathing system* either supplied or recommended in the *instructions for use*;
- d) a summary description of the means of initiating and terminating the *inflation phase* while in each *ventilation-mode*;
- e) a statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories with which the ventilator is intended to be used; and
- f) the intended position of the *operator*.

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:

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

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

- a) *Transit-operable ventilatory support equipment* shall include a means by which the *ventilatory support equipment* can be secured without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE Means to restrain physically the *ventilatory support equipment* during transport in a personal vehicle, in an ambulance or on a wheelchair.

- b) The means shall secure the *ventilatory support equipment* to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 5 s in each direction.

EXAMPLE 2 Attach the *ventilatory support equipment* to an armature at a 1 m radius from an axis of horizontal rotation. When rotating through a circle every 2 s at constant speed, the lateral (centripetal) acceleration is approximately 1,0 g.^[47]

Check conformity by functional testing.

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

201.9.4.4 Grips and other handling devices

Amendment (replace list item b) with):

- b) *Transit-operable ventilatory support equipment* shall be designed either:
 - 1) to be carried by one hand; or
 - 2) to be provided with a carrying case or bag that can be carried by one hand.

Check conformity by carrying with one hand or by using the carry case or bag with one hand.

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

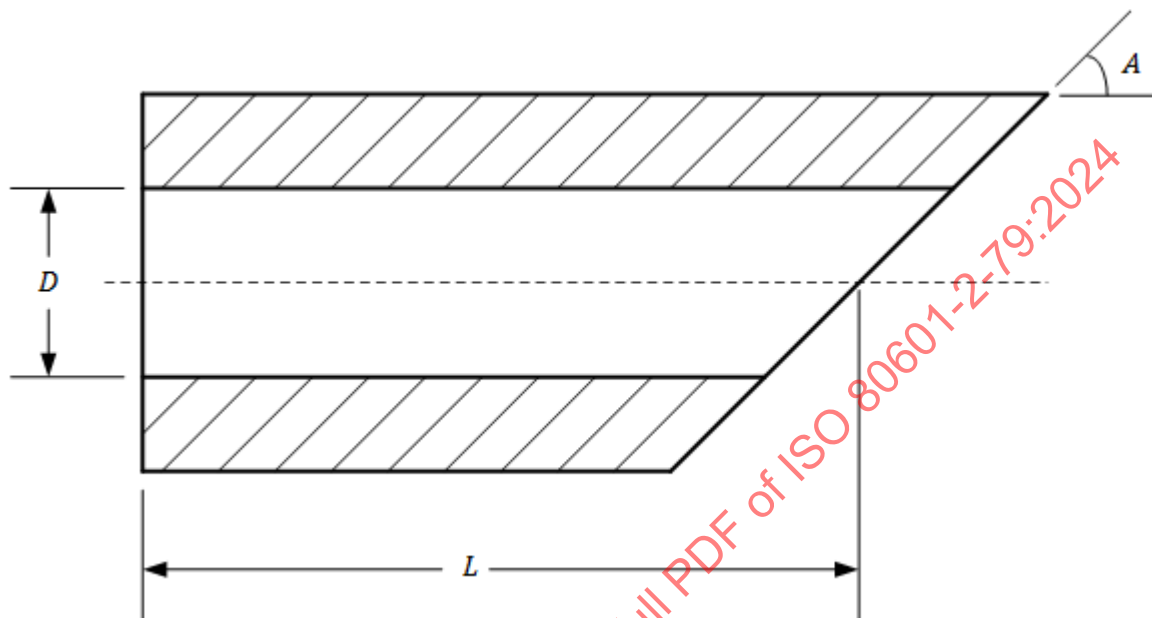
- a) The A-weighted sound pressure level emitted by the *ventilatory support equipment* shall be:
 - 1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and
 - 2) disclosed in the *instructions for use*.
- b) The A-weighted sound power level shall be:
 - 1) 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 *ventilatory support equipment* on a sound-reflecting plane and attach the least favourable VBS from those indicated in the *instructions for use*.

NOTE The least favourable VBS configuration can vary by *ventilation-mode*, *inflation-type* and flow pattern, as applicable.
 - 2) If a *humidifier* is provided with or specified in the *accompanying documents* of the *ventilatory support equipment*, include the *humidifier* in the test and fill to the least favourable level.
 - 3) Connect the standard resistance, 40 mm length and *outlet* angle of 45° (as indicated in Figure 201.101) to the *patient-connection port*.
 - i) Acoustically isolate the breathing tubes and the standard resistance out of the testing area such that the noise of the gas flowing through the breathing tubes and exiting the standard resistance does not interfere with the sound measurement of the *ventilatory support equipment*.
 - ii) Set the *ventilatory support equipment* to a mode that generates a continuous pressure of 10 hPa (10 cmH₂O) at the *patient-connection port*.
 - 4) Using a microphone of a sound level meter, conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}) at 10 positions in a hemisphere with a radius from the geometric centre of the *ventilatory support equipment* 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.

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

- 5) Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with 8.2.2 of ISO 3744:2010.
- 6) Calculate the A-weighted sound power level in accordance with 8.6 of ISO 3744:2010.
- 7) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.

- 8) Ensure that the measured sound pressure level is less than or equal to that disclosed in the *instructions for use*.
- 9) Ensure that the sound power level is less than or equal to that disclosed in the *instructions for use*.



Key

D is the internal diameter: $(4 \pm 0,1)$ mm

L is the length: (40 ± 1) mm

A is the angle $(45 \pm 1)^\circ$

Break all edges with 0,15 mm to 0,20 mm radius or 45° chamfer. Drawing not to scale.

Figure 201.101 — Standard resistance

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*

Amendment (add between the existing paragraphs):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

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 *ventilatory support equipment* at the *patient-connection port*, both with and without each *humidifier* specified for use in the *instruction 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 (a specific enthalpy not to exceed $197 \text{ kJ/kg dry air}$) when averaged over 120 s.

Table 201.101 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.101 — Examples of permissible combinations of temperature and relative humidity

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

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

Amendment (add additional requirement as new first paragraph):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

aa) *Gas pathways through the ventilatory support equipment and its accessories not intended for single use that can become contaminated with body fluids or by contaminants carried by the expired gases during normal condition or single fault condition shall be designed to allow:*

- 1) *for cleaning and disinfection; or*
- 2) *for cleaning and sterilization.*

NOTE 101 Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020, Clause 8.

bb) *Dismantling or parts replacement may be performed to accomplish these processes.*

cc) *These processing instructions for the ventilatory support equipment 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 and replace the compliance test):

dd) *Ventilatory support equipment enclosures shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the risk of infection of operators, bystanders, or the patient.*

ee) *These processing instructions for the ventilatory support equipment enclosure shall:*

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

NOTE 102 ISO 14159 provides guidance for the design of *enclosures*.

Check conformity by inspection of the *risk management file*. When conformity with this document can be affected by the *cleaning* or the *disinfecting* of the *ventilatory support equipment* 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.

NOTE 103 Additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 Sterilization of ME equipment or ME system

Amendment (add note before compliance test):

NOTE 100 Additional requirements are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.6.6 and IEC 60601-1-11:2015+AMD1:2020, Clause 8.

201.11.7 Biocompatibility of ME equipment and ME systems

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

aa) The *manufacturers* of the *ventilatory support equipment*, the *VBS*, their parts and *accessories* shall address in the *risk management process* the *risks* associated with the *biocompatibility* and potential contamination of the gas stream arising from the *gas pathways*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2024.

201.11.8 Interruption of the power supply/supply mains to ME equipment

Additional subclause:

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

201.11.8.101.1 Internal electrical power source and alarm conditions

a) *Ventilatory support equipment* may be equipped with an *internal electrical power source*.

b) If equipped, the *ventilatory support equipment* shall

- 1) be equipped with an automatic switchover to the *internal electrical power source* when the *supply mains* falls outside the values necessary to maintain normal operation;
- 2) provide a means for determining the state of this *internal electrical power source*;
- 3) provide a means to indicate that the *ventilatory support equipment* is powered from the *internal electrical power source*.

c) The *instructions for use* shall disclose

- 1) the operational time of the *ventilatory support equipment* when powered from each power source under the conditions of a fully charged *internal electrical power source* and the conditions of Table 201.102;
- 2) the behaviour of the *ventilatory support equipment* after a switch-over to the *internal electrical power source*;

- 3) the behaviour of the *ventilatory support equipment* during the recharging of the *internal electrical power source*.

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

201.11.8.101.2 Alternative power supply/supply mains

- a) If the *ventilatory support equipment* is equipped with a means of connection to an alternative *supply mains*, the *instructions for use* shall include
 - 1) a description of the means of connection;
 - 2) the *rated* voltage range;
 - 3) the *nominal* voltage;
 - 4) the maximum current required.
- b) If the *ventilatory support equipment* is *transit-operable*, a means of connection to an automotive vehicle power source should be provided.

EXAMPLE A 12 V d.c., 100 W *connector* or other *mains connector*.

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

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:

Additional subclauses:

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

- aa) The controls and indicators of *ventilatory support equipment* shall be *clearly legible* under the conditions specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2.
- bb) The *ventilatory support equipment* may provide means to reduce the visibility of its controls and indicators either automatically or by the *operator* action.
 - 1) If a means to reduce the visibility is provided, the *ventilatory support equipment* shall automatically resume normal visibility during an *alarm condition*.

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

201.12.1.101 Inflation types

Ventilatory support equipment shall be equipped with at least:

- a) a *volume-control inflation type*; or
- b) a *pressure-control inflation type*.

Check conformity by inspection.

201.12.1.102 Volume-control inflation-type

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

- 1) the maximum bias error; and
- 2) the 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 *tidal volume* in relation to the set value; and
- 2) the maximum error of the *PEEP* in relation to the set *BAP* value.

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

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

- d) The accuracy of the performance of the *ventilatory support equipment* shall either be:

- 1) determined for each *VBS* configuration indicated in the *instructions for use*; or
- 2) determined for the worst-case *VBS* configurations indicated in the *instructions for use*.

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

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

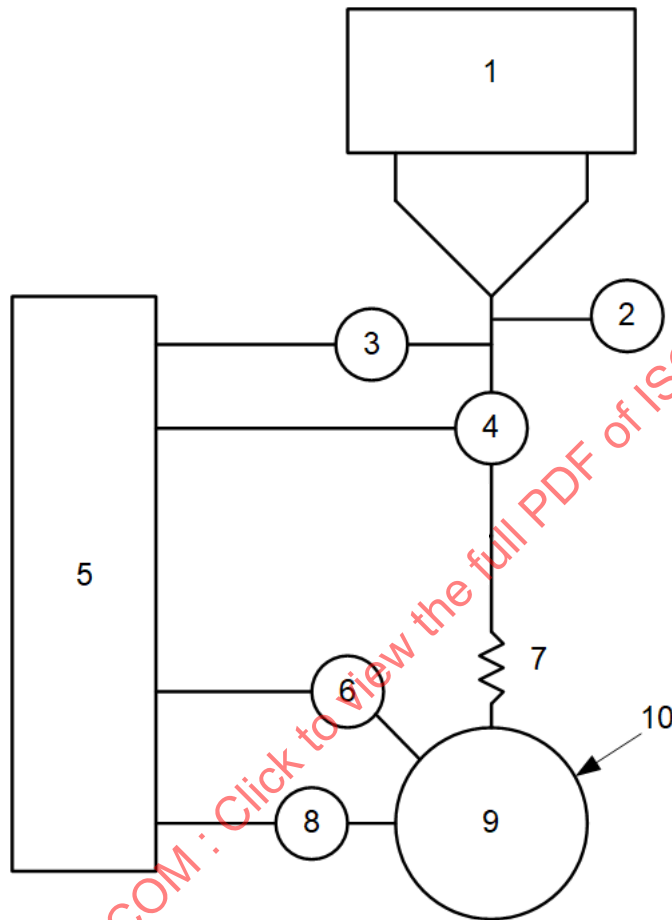
- f) Check conformity by inspection of the *risk management file* for the rationale, if applicable, and with the following tests for *tidal volume* and end-expiratory pressure errors:

- 1) Set up the *ventilatory support equipment* as shown in Figure 201.102.
- 2) If applicable, determine or input the *VBS* compliance required for compliance correction as indicated in the *instructions for use* and activate this correction. If a *humidifier* is used, fill the *humidifier* to the maximum water level prior to determining the *VBS* compliance.
- 3) Use the test parameters and settings of the first applicable row (selected by intended *tidal volume*) of Table 201.102. Wait for steady-state conditions to be achieved.
- 4) Determine the *tidal volume*, for example by 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, if necessary, for temperature effects due to fast compression of the gas, if necessary.

NOTE 2 Additional information on the construction of an isothermal test lung is found in reference^[36].

- 5) Compare the result with the volume setting for the test. Confirm that the accuracy is within the tolerance indicated in the *instructions for use*.

- 6) Determine the *PEEP* as the average of the *airway pressure* measurements over the last 50 ms of the *expiratory phase*.
- 7) Compare the result with the set *BAP* for the test. Confirm that the resulting difference is within the tolerance indicated in the *instructions for use*.
- 8) Repeat 3) to 7) for 30 consecutive breaths.



Key

- 1 ventilatory support equipment under test (single or dual limb)
- 2 artificial leakage (applies for *pressure-control inflation-type* only), see Table 201.103, note b
- 3 pressure sensor
- 4 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms (applies for *volume-control inflation-type* only)
- 5 data acquisition system, with minimum sample rate of 200 samples/s
- 6 temperature sensor
- 7 resistance in series with the test lung (R_{lung})
- 8 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
- 9 compliance of the test lung (C_{lung})
- 10 test lung

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

- 9) Repeat 6) to 8) for each applicable row (selected by intended *tidal volume*) of Table 201.102.

- 10) 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.
- 11) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, descending ramp flow) has been selected for the tests, repeat 2) to 10) for each flow pattern available on the *ventilatory support equipment*.
- 12) If the *ventilatory support equipment* permits operation without compliance correction, repeat 2) to 11) without compliance correction.

Table 201.102 — Type test settings for volume-control inflation-type

Test number	Test lung parameters		Ventilatory support equipment settings			
	Compliance (ml(hPa) ⁻¹) ±10 %	Linear ^{[32][43][44]} resistance (hPa(l/s) ⁻¹) ±10 %	Tidal volume (ml)	Set rate ^a (breaths/min)	Inspiratory time (s)	BAP hPa (cmH ₂ O)
1	— ^b	— ^b	Maximum settable tidal volume	— ^b	— ^b	— ^b
2	50	5	500	20	1	5
3	50	20	500	12	1	10
4	20	5	500	20	1	5
5	20	20	500	20	1	10
6	20	20	300	20	1	5
7	20	50	300	12	1	10
8	10	50	300	20	1	10
9	10	20	200	20	1	5
10	— ^b	— ^b	Minimum settable tidal volume	— ^b	— ^b	— ^b

^a In the case that *end-expiratory flow* does not reach zero, reduce the *set rate* until it does for at least 50 ms.

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

201.12.1.103 Pressure-control inflation-type

- a) If a *pressure-control inflation-type* is provided, then with a *pressure-control inflation-type* selected and the *ventilatory support equipment* 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 error from the set pressure, as:

- 1) the maximum bias error; and
- 2) the maximum linearity error.

EXAMPLE ± [3,0 + (5 % of the set pressure)] hPa (±(3,0 cmH₂O + 5 % 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 the *airway pressure* (P_{aw}) at the end of the *inflation* phase in relation to the set value under leak condition;
 - 3) the maximum error of the *airway pressure* (P_{aw}) at the end of the *expiratory phase* in relation to the set value; and
 - 4) the maximum error of the *airway pressure* (P_{aw}) at the end of the *expiratory phase* in relation to the set value under leak condition.
- c) All of the errors may be separately reported for the following ranges of intended *tidal volume*:
- 1) $V_T \geq 300$ ml;
 - 2) $300 \text{ ml} \geq V_T \geq 50$ ml.
- d) The accuracy of the performance of the *ventilatory support equipment* shall either be:
- 1) determined for each *VBS* configuration indicated in the *instructions for use*; or
 - 2) determined for the worst-case *VBS* configuration indicated in the *instructions for use*.
- NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.
- 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 for end-inspiratory and end-expiratory pressure errors:
- 1) Set up the *ventilatory support equipment* as shown in Figure 201.102.
 - 2) If applicable, determine or input the *VBS* compliance required for compliance correction as indicated in the *instructions for use* and activate this correction. If a *humidifier* is used, fill the *humidifier* to the maximum water level prior to determining the *VBS* compliance.
 - 3) Use the test parameters and settings of the first applicable row (selected by typical intended *tidal volume*) of Table 201.103. Wait until steady-state conditions are achieved.
 - 4) Determine the *airway pressure* at the end of the *inflation phase* as the average over the preceding 50 ms.
 - 5) Compare the result with the pressure setting for the test. Confirm that the resulting difference is within the tolerance indicated in the *instructions for use*.
 - 6) Determine the *tidal volume*, for example by integration of the flow signal provided by a calibrated flow sensor located at the *patient-connection port* or for *ventilatory support equipment* that indicates a leakage-compensated *tidal volume* by the product of the test lung compliance and the measured change of test lung pressure, if necessary, compensated for temperature effects due to fast compression of the gas.

NOTE 2 Additional information on the construction of an isothermal test lung is found in reference^[36].

- 7) Determine the *airway pressure* at the end of the *expiratory phase* as the average of the *airway pressure* measurements over the last 50 ms of the *expiratory phase*.
- 8) Compare the result with the setting for the test. Confirm that the resulting difference is within the tolerance indicated in the *instructions for use*.
- 9) Repeat 2) to 8) for 30 consecutive breaths.
- 10) Repeat 2) to 9) for each applicable row (selected by intended *tidal volume*) of Table 201.103.
- 11) 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.
- 12) If the *ventilatory support equipment* permits operation without compliance correction, repeat 2) to 11) without compliance correction.
- 13) Compare each result to the tolerance indicated in the *instructions for use*.

Table 201.103 — Test settings for pressure-control inflation-type type

Test number	Intended tidal volume ^a ml	Test lung parameters			Ventilatory support equipment settings			
		Compliance (ml(hPa) ⁻¹) ±10 %	Linear resistance [32][43][44] (hPa(l/s) ⁻¹) ±10 %	Leakage ^b (l/min) ±10 %	Set rate ^c breaths/min	Inspiratory time ^d s	Δ inspiratory pressure ^e hPa (cmH ₂ O)	BAP hPa (cmH ₂ O)
1	— ^f	— ^f	— ^f	— ^f	— ^f	— ^f	Maximum settable pressure	— ^f
2	500	50	5	0	20	1	10	5
3	500	50	20	0	12	1	15	10
4	500	20	5	0	20	1	25	5
5	500	20	20	0	20	1	25	10
6	500	50	5	5	20	1	25	5
7	500	50	20	10	12	1	25	10
8	300	20	20	0	20	1	15	5
9	300	20	50	0	12	1	25	10
10	300	10	50	0	20	1	30	5
11	300	20	20	3	20	1	25	5
12	300	20	50	6	12	1	25	10
13	200	10	20	0	20	1	25	10
14	— ^f	— ^f	— ^f	— ^f	— ^f	— ^f	Minimum settable pressure	— ^f

^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 *ventilatory support equipment*.

^b For the purpose of this test, the *VBS* under test is set up with the artificial leakage (item 4 in Figure 201.102) at a constant pressure of 20 hPa.

^c In the case that *end-expiratory flow* does not reach zero, reduce the ventilatory *set rate* until it does for at least 50 ms.

^d The rise time of the *ventilatory support equipment* should be set to a value that ensures that the set pressure can be reached within the *inspiratory time*.

^e For the purposes of this test, the set pressure is relative to set *airway pressure* at the end of the *expiratory phase*.

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

201.12.1.104 Other inflation-types

- a) If other *inflation-types* are provided, then with each other *inflation-type* selected and the *ventilatory support equipment* operating in *normal condition*,
- 1) the performance and
 - 2) their pass-fail criteria,
- as determined by the *manufacturer*, shall be disclosed in the *instructions for use*.
- b) All of the pass-fail criteria may be separately reported for the following ranges of intended *tidal volume*:
- 1) $V_T \geq 300$ ml; and
 - 2) $300 \text{ ml} \geq V_T \geq 50$ ml.
- c) The pass-fail criteria of the performance of the *ventilatory support equipment* shall either be:
- 1) determined for each *VBS* configuration indicated in the *instructions for use*; or
 - 2) determined for the worst-case *VBS* configuration indicated in the *instructions for use*.
- NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.
- d) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.
- e) The *technical description* shall disclose a summary of the test method and the details necessary to reproduce the test results used to test each other *inflation-type*.

Check conformity by inspection of the of the *accompanying documents*, inspection of the *risk management file* for the rationale, if applicable, and with the tests described in the *technical description*.

201.12.4 Protection against hazardous output

201.12.4.4 Incorrect output

- aa) Any pressure setting change and its relation to any other pressure settings shall be displayed while the setting is performed.
- bb) Any setting that affects the *I:E ratio* or *inspiratory time* shall be displayed with the *I:E ratio* and *inspiratory time* while the setting is performed.
- cc) The *ventilatory support equipment* shall provide the *responsible organization* with a means to allow the *healthcare professional operator* to have direct access to the *ventilation settings*.

EXAMPLE Settings needing protection include *set rate*, *I:E ratio*, *inspiratory time*, adjustable pressure limitation, high *inspiratory pressure alarm limit*, and *inflation-type*.

Check conformity by functional testing.

Additional subclauses:

201.12.4.101 Measurement of *airway pressure*

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

201.12.4.101.1 General

- a) The *ventilatory support equipment* shall be equipped with *monitoring equipment* to indicate 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.

201.12.4.101.2 Low *airway pressure alarm condition*

If the *ventilatory support equipment* is equipped with an *alarm system*:

- a) the *airway pressure monitoring equipment* shall be equipped with an *alarm system* that detects an *alarm condition* to indicate when the *low-airway pressure alarm limit* is reached;
- b) the *low-airway pressure alarm condition*
 - 1) shall be at least a *medium priority*, unless
 - 2) an *intelligent alarm system*, based on additional information, determines that the
 - i) *low airway pressure alarm condition* is suppressed, or
 - ii) its priority is changed, or
 - 3) may start at *low priority*, and
 - 4) if this state continues, escalates to a *medium priority alarm condition*;
- c) the *low-airway pressure alarm signal* may be inactivated with *alarm off*; and
 - 1) *Alarm off* may be activated by the *ventilatory support equipment*.
- d) the *low-airway pressure alarm limit* may be
 - 1) pre-adjusted;
 - 2) *responsible organization*-adjustable;
 - 3) *operator*-adjustable;
 - 4) *ventilatory support equipment*-adjustable; or
 - 5) a combination of *operator*-adjustable and *ventilatory support equipment*-adjustable.

- e) If the *airway pressure alarm limit* is adjustable by the *ventilatory support equipment*, a summary description of the algorithm that determines the *alarm limit* value shall be disclosed in the *instructions for use*.

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

Check conformity by functional testing.

201.12.4.102 Measurement of expired volume

If *ventilatory support equipment* is equipped with *monitoring equipment* for indicating the volume expired through the *patient-connection port*, the accuracy shall be disclosed in the *instructions for use*.

201.12.4.103 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-pressure *alarm limit*; or
- b) 60 hPa (60 cmH₂O).

NOTE 2 This requirement applies in both *normal condition* and *single fault condition*. See 201.3.263.

NOTE 3 See also 201.12.4.104.

Check conformity by functional testing.

201.12.4.104 High-pressure alarm condition

- a) If the *maximum limited pressure* is greater than 40 hPa (40 cmH₂O), the *ventilatory support equipment* shall be equipped with an *alarm system* that detects a high *airway pressure alarm condition* to indicate when the high *airway pressure alarm limit* is reached.
- b) The high *airway pressure alarm condition* shall be
 - 1) *high priority*, or
 - 2) *medium priority* and escalate to *high priority* if the high-*airway pressure alarm condition* exists for longer than ten consecutive *inflations* or 30 s, whichever is less.
 - 3) The priority may escalate sooner than ten consecutive *inflations* or 30 s.
- c) The high *airway pressure alarm limit* may be
 - 1) independently adjustable,
 - 2) connected to an adjustable pressure limitation, or
 - 3) related to the set pressure of the *ventilatory support equipment*.
- d) If the *alarm limit* is independently adjustable, it shall not be possible to set the high-*airway pressure alarm limit* to a value:
 - 1) less than that of the adjustable pressure limitation; and

2) 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-pressure *alarm limit* to values exceeding the lower of:

1) 20 hPa (20 cmH₂O) more than the highest of the *operator-set inspiratory pressures*; or

NOTE 1 An example of the *operator-set inspiratory pressure* is the sum of the set *BAP* and the set Δ *inspiratory pressure*.

NOTE 2 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 3 The *operator-set pressure* does not apply when by design the *ventilatory support equipment* adjusts the *airway pressure* on an *inflation-by-inflation* basis.

2) 40 hPa (40 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 *ventilatory support equipment* 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) The high-*airway pressure alarm condition* shall not terminate until the *airway pressure* is below the high-*airway pressure alarm limit* for more than the lesser of:

1) three consecutive *inflations*; or

2) 15 s.

i) The maximum *alarm signal generation delay* of the high-*airway pressure alarm condition* shall not exceed the lesser of:

1) three consecutive *inflations*; or

2) 15 s.

j) In *normal condition*, upon generating the high-*airway pressure alarm signals*, the *ventilatory support equipment* shall reduce the *airway pressure* to the set *BAP* level within:

1) one *respiratory cycle*; or

2) 5 s.

k) During *single fault condition*, the *ventilatory support equipment* shall reduce the *airway pressure* to the set *BAP* level or below within no more 30 s.

Check conformity by functional testing.

201.12.4.105 Hypoventilation alarm condition

- a) The *ventilatory support equipment* may be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate hypoventilation.

1) A low respiratory breathing rate may be used for the hypoventilation *alarm condition*.

- b) If equipped, the *alarm system* shall be equipped with an *alarm off* for the *alarm condition* that indicates hypoventilation.

NOTE The hypoventilation *alarm condition* can be determined, amongst other things, by the measurement of the variations of *airway pressure*, or expiratory volume, but possibly needs additional detection means. The hypoventilation *alarm condition* can also be determined by an *intelligent alarm system* utilizing one or more variables.

Check conformity by functional testing.

201.12.4.106 CO₂ rebreathing

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

- a) *Ventilatory support equipment* shall be designed so that *rebreathing* of carbon dioxide is minimised to an acceptable level as specified by ISO 17510:2015, 5.3.

NOTE 2 The design of the *ventilatory support equipment* can be such that this requirement is satisfied without a designated *mask* or *accessory*.

- b) The non-*rebreathing* performance of the *ventilatory support equipment* shall either be:

- 1) determined for each *VBS* configuration indicated in the *instructions for use*; or
- 2) determined for the worst-case *VBS* configurations indicated in the *instructions for use*.

NOTE 3 The worst-case *VBS* configuration can be different for each error or *nominal tidal volume*.

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

- d) Use of *ventilatory support equipment* with a designated *mask* or *accessory* that conforms with ISO 17510:2015, 5.3, may be used to conform with this requirement.

1) In such a case, the *accompanying documents* shall include:

- i) a warning to the effect that “Warning: To prevent asphyxia when ventilating noninvasively, use a mask or accessory that minimizes carbon dioxide rebreathing; and
- ii) if applicable, a warning to the effect that “Warning: To prevent asphyxia when ventilating noninvasively, use a mask or accessory that permits spontaneous breathing in the case that patient flow exceeds that provided by the ventilator”; and

NOTE 4 This note is only applicable for use with an open *VBS* (i.e., without a controlled exhalation valve).

iii) the list of designated *masks* or *accessories*; or

iv) alternatively the necessary information to locate such a list.

EXAMPLE The address of the list on a website.

e) Check conformity by:

- 1) inspection of the *instruction for use*; or
- 2) where the *ventilatory support equipment* provides the means of conformity, inspection of the *risk management file* and application of limits given in 5.3 of ISO 17510:2015 and the tests of Annex F of ISO 17510:2015, using the *ventilatory support equipment* as the flow source and replacing the breathing tube by the *VBS* for the test. Where a *mask* is not used, the *mask* and simulated *patient* head of Figure F.1 of ISO 17510:2015 are replaced by a direct connection.

201.12.101 Protection against accidental adjustments

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

- a) Means of protection against accidental adjustment of controls that can create a *hazardous situation* shall be provided.
- b) Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm any *airway pressure* settings exceeding 40 hPa (40 cmH₂O). See also 201.12.4.104 e) 2) and 206 b) 11).

NOTE 2 This can be accomplished by means of hardware or software or a combination of both.

NOTE 3 This can be accomplished by two dedicated confirmation actions.

- c) It shall be possible to set all *ventilatory support equipment* parameters prior to starting any *ventilation-mode*.
- d) The *usability* of these means of protection shall be evaluated in the *usability engineering process*.

NOTE 4 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:

Additional subclauses:

201.13.2.101 Additional specific single fault conditions

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

Ventilatory support equipment shall be so constructed that the following *single fault conditions* do not cause an unacceptable *risk*:

- a) misconnection of a *VBS* control connection, monitoring connection or *accessory* connection;

EXAMPLE 1 Misconnection of supplemental oxygen supply.

- b) a disconnection or blockage of the gas delivery to the *ventilatory support equipment*;
- c) a disconnection or blockage of the gas delivery to the *patient-connection port* from the *ventilatory support equipment*;

- d) when present, disconnection or blockage of the gas flow pathway from the *patient-connection port* to the *exhaust port*;
- e) failure to install, removal of or failure of an *operator-detachable breathing system filter*; and
- f) interruption of a *functional connection* between parts of the *ventilatory support equipment* or *ME system*.

EXAMPLE 2 Loss of communication between the *ventilatory support equipment* and its remote (wired or wireless) control or monitoring module.

EXAMPLE 3 Loss of communication between the *ventilatory support equipment* and its *distributed alarm system*.

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

201.13.2.102 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) the *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.

201.13.2.103 Failure of *functional connection to a ventilatory support equipment 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 *ventilatory support equipment control or monitoring means*, the *ventilatory support equipment* shall continue to ventilate the *patient*.

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.

Additional subclause:

201.14.101 Cybersecurity capabilities

- a) *Ventilatory support equipment* should contribute to safe operation related to *cybersecurity*.
- b) *Risk control measures* as specified in IEC/TR 60601-4-5:2021 Clauses 4 to 7 should be implemented as appropriate with following specific 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 *ventilatory support equipment* once, all clinical functions except of the affected remote functionality should be in place and operate as intended.
- 2) *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).
- 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. 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:

201.15.101 Mode of operation

Ventilatory support equipment shall be suitable for *continuous operation*.

Check conformity by inspection.

201.15.102 Pre-use check

- a) The *ventilatory support equipment* shall be provided with means that allow the following to be functionally tested by the *lay operator* to determine if they are operating correctly and ready for use:
 - 1) the assembled breathing tubes and related *accessories*;
 - 2) switchover to and operation from, if provided, the *internal electrical power source*; and
 - 3) all *alarm signals*, including, if provided, the *alarm signals* from a *distributed alarm system*.
- b) This test method:
 - 1) should be performed automatically by the *ventilatory support equipment*; but
 - 2) may require *operator* action.

EXAMPLE Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

NOTE Additional requirements are also found in 201.7.9.2.8.101.

- c) The *model or type reference* of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.
- d) The *instructions for use* for the *lay operator* shall disclose the *procedure* by which tests are performed.

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

201.16 *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 16, applies, except as follows:

Additional subclause:

201.16.1.101 *Additional general requirements for ME systems*

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

- a) be part of the *ventilatory support equipment*; or
- b) form an *ME system* with the *ventilatory support equipment*.

For *accessories* as part of the *ventilatory support equipment*, check conformity in combination with the *ventilatory support equipment*.

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

For *accessories* forming an *ME system* with the *ventilatory support equipment*, 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 of this document

201.16.2 *Accompanying documents of an ME system*

Amendment [add after list element c)]:

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

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

EXAMPLE 100 A blower/turbine-based *ventilatory support equipment* operating with *ventilatory support equipment* 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.

Additional clauses:

201.101 *Gas connections*

201.101.1 *VBS connectors*

201.101.1.1 *General*

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

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*

- a) shall be:

- 1) a 15 mm *connector* conforming with ISO 5356-1:2015;
 - 2) a 22 mm *connector* conforming with ISO 5356-1:2015; or
 - 3) for *ventilatory support equipment* only intended for *tidal volumes* of ≤ 300 ml, a 11,5 mm *connector* conforming with ISO 5356-1:2015; or
- b) 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.

201.101.1.2 Other named ports

201.101.1.2.1 General

Operator-detachable connectors used within the *VBS* for:

- a) control functions,
- b) monitoring functions, and
- c) other *accessory* functions

shall be non-interchangeable.

Check conformity by functional testing.

201.101.1.2.2 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 coaxial 15 mm/22 mm conical *connector* conforming with ISO 5356-1:2015; or
- c) 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.

201.101.1.2.3 Gas output port and gas return port

- a) The *gas output port* and the *gas return port*, if equipped, shall be one of the following
 - 1) 22 mm conical cone *connector* conforming with ISO 5356-1:2015.
 - 2) 15 mm conical cone *connector* conforming with ISO 5356-1:2015.
 - 3) 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, *ventilatory support equipment* 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.

201.101.1.2.4 **Manual ventilation port**

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

The *ventilatory support equipment* shall not be equipped with a *manual ventilation port*.

Check conformity by inspection.

201.101.1.2.5 **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 connects to the *gas pathway* and is used e.g. for measuring gas concentrations, for introduction of liquids or the entrainment of oxygen.

NOTE 3 For the purposes of this document, the temperature probe port specified in ISO 80601 2 74 is not considered a *gas pathway* connection 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.

201.101.1.2.6 **Monitoring probe port**

If a port is provided for introduction of a monitoring probe, it shall:

- a) not be compatible with *connectors* specified in ISO 5356-1:2015;
- b) be provided with a means to secure the probe in position; and
- c) be provided with a means to secure closure after removal of the probe.

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

201.101.1.2.7 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 80601-2-13:2011.

- b) A *ventilatory support equipment* 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.

201.101.1.2.8 Flow-direction-sensitive components

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

Any *operator-detachable flow-direction-sensitive component* of the *VBS* 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 *operator-detachable flow-direction-sensitive components* and inspection of the *risk management file*.

201.101.1.2.9 Temperature sensor port

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

201.101.2 Oxygen inlet connector

201.101.2.1 Low pressure

- a) An oxygen *inlet connector* of *respiratory high-flow therapy equipment* or *breathing system* intended for pressures less than 150 hPa that is *operator-detachable* without the use of a *tool* shall conform with ISO 80369-1:2018.

NOTE 1 It is expected that the R1 *connector* of ISO 80369-2 will meet this criterion.

NOTE 2 The R1 *connector* of ISO 80369-2 is intended for use for connections with pressures not exceeding 150 hPa.

- b) *Respiratory high-flow therapy equipment* with this oxygen *inlet connector* shall maintain *basic safety* and *essential performance* with oxygen supply systems up to 150 hPa, in *normal condition*.

Check conformity by functional testing and application of the tests of ISO 80369-1:2018.

201.101.2.2 High pressure

- a) An oxygen *inlet connector* of the *ventilatory support equipment* intended for pressures greater than 150 hPa that is *operator-detachable* without the use of a *tool*, shall:

- 1) conform with ISO 80369-1:2018; or

NOTE It is expected that the R2 *connector* of ISO 80369-2 will meet this criterion.

- 2) provide connection to a hose assembly conforming with ISO 5359:2014+AMD1:2017.

- b) *Ventilatory support equipment* with this *inlet connector* shall maintain *basic safety* and *essential performance* with oxygen supply systems up to 600 kPa, in *normal condition*.

Check conformity by functional testing and application of the tests of ISO 80369-1:2018 or ISO 5359:2014+AMD1:2017, as applicable.

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* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *ventilatory support equipment* 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 at least one *model or type reference* of *compatible ventilatory support equipment*.
- 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 accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.

Check conformity by inspection of the *accompanying document*.

201.102.3 Breathing sets

Breathing sets, other than heated breathing sets, intended for use in the VBS shall conform with ISO 5367:2023, 6.3.

NOTE Heated breathing tubes are covered by ISO 80601-2-74. See 201.102.4.1.

Check conformity by application of the tests of ISO 5367:2023, 6.3.

201.102.4 Water vapour management

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

201.102.4.1 Humidifier

Any *humidifier*, including heated breathing sets, either incorporated into the *ventilatory support equipment* or recommended for use with the *ventilatory support equipment*, 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 *HME*, 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.

201.102.5 *Breathing system filters (BSF)*

Any *BSF*, either incorporated into the *ventilatory support equipment* or recommended for use with the *ventilatory support equipment*, 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.

201.103 Spontaneous breathing during loss of power supply

NOTE 1 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 the electrical or pneumatic supply power being outside the values necessary for normal operation.
- b) The *protection device* may be provided by:
 - 1) a *mask*; or
 - 2) an *accessory*.
- c) 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 *ventilatory support equipment* intended to provide a *tidal volume*, $V_T \geq 300$ ml; and
 - 2) 15 l/min for *ventilatory support equipment* intended to provide a *tidal volume*, $V_T \leq 300$ ml.

NOTE 2 This requirement is 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 greatest 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 *ventilatory support equipment* shall have means to indicate visually the cumulative hours of operation of the *ventilatory support equipment*, either:

- 1) automatically; or
 - 2) by *operator* action.
- b) The *ventilatory support equipment* 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

NOTE See Annex BB for data interface requirements.

Basic safety and essential performance shall be maintained if connections to the *functional connection* of *ventilatory support equipment* 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.

Ventilatory support equipment should be equipped with a *functional connection* that permits data transmission from the *ventilatory support equipment* to e.g. an electronic health record.

201.105.3 Connection to a *distributed alarm system*

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

Ventilatory support equipment should be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

201.105.4 Connection for remote control

Ventilatory support equipment may be equipped with a *functional connection* for connection for remote control of the *ventilatory support equipment*.

201.106 Display loops

201.106.1 Pressure-volume loops

If *ventilatory support equipment* is provided with the display of pressure-volume loops,

- a) the graph shall use:
 - 1) *tidal 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 *tidal volume* shall be positive values;
- d) the volume shall be reset to the origin at the beginning of each *inflation*.

Check conformity by inspection.

201.106.2 Flow-volume loops

- a) If *ventilatory support equipment* is provided with the display of flow-volume loops,
 - 1) the graph shall use:
 - i) flowrate on the vertical axis; and
 - ii) *tidal volume* on the horizontal axis;
 - 2) positive values shall be on the top and the right of the display;
 - 3) gas flow to the *patient* (inspiratory flow) and increases in *tidal volume* shall be positive values;
 - 4) the volume shall be reset to the origin at the beginning of each *inflation*.
- b) The *ventilatory support equipment* 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.

202 Electromagnetic disturbances — Requirements and tests

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

202.4.3.1 Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

- the *ventilatory support equipment* operated using the conditions and test configuration of 201.9.6.2.1.101.

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.

Additional subclause:

202.8.1.101 Additional general requirements

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

- a) The *ventilatory support equipment* shall be tested according to the requirements for the *home healthcare environment*.
- b) The following degradations, if associated with *basic safety* or *essential performance*, shall not be allowed:

- 1) component failures;
- 2) changes in programmable parameters or settings;
- 3) reset to default settings;
- 4) change of operating mode;

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

- 5) initiation of an unintended operation;
- 6) during the testing, the error of:
 - i) the *inspiratory volume* of individual breaths deviating by more than 35 % of the *inspiratory volume* measured prior to the test; and
 - ii) the *inspiratory volume* averaged over a one-minute interval deviating by more than 25 % of the *inspiratory volume* measured prior to the test; and
 - I) One-minute averaged testing need not be performed if the volume of individual *inflations* does not deviate by more than 25 %.
- c) The *ventilatory support equipment* may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the *instructions for use* during *immunity testing*) that does not adversely affect *basic safety* or *essential performance*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows:

- a) For *ventilatory support equipment*, the following shall be considered *primary operating functions*:
 - 1) observing and identifying monitored *ventilation* parameters from the intended *operator's* position;

EXAMPLE 1 *Airway pressure*.
 - 2) configuring the *VBS* including connection of the detachable parts of the *VBS* to the *ventilatory support equipment*;

EXAMPLE 2 *Humidifier, nebulizer, water-trap, tubing, breathing system filter, monitoring equipment*.
 - 3) connecting or disconnecting the *patient-connection port* of the *VBS* to the *patient-interface*;
 - 4) *processing* the *VBS* components;
 - 5) starting the *ventilatory support equipment* from power off;
 - 6) turning off the *ventilatory support equipment*;
 - 7) carrying the *transit-operable ventilatory support equipment* with one hand:
 - i) either directly, or,
 - ii) by use of a carrying case or in-use bag; and

- 8) if *transit-operable*, attaching and disconnecting the *ventilatory support equipment* to prevent unwanted movement during transport while in use.
- b) The following functions, if available, also shall be considered *primary operating functions*:
 - 1) performing a basic pre-use functional check of the *ventilatory support equipment* including the *alarm system*;
 - 2) setting and inadvertent change of settings of the *operator-adjustable controls*:
 - i) setting *alarm limits*;
 - ii) inactivating *alarm signals*;
 - iii) switching between different *ventilation-modes* and *inflation-types*;
 - iv) setting *ventilation control parameters*;

EXAMPLE 3 Ventilatory set rate, set BAP, pressure support, *inspiratory time* or *I:E ratio*.
 - 3) observing and identifying:
 - i) the *alarm signals*; and
 - ii) the *alarm signal inactivation states*;
 - 4) switching between power sources;
 - 5) connecting and disconnecting the *distributed alarm system*;
 - 6) testing power sources;
 - 7) starting *ventilation* from standby; and
 - 8) activating standby.
 - 9) setting of the adjustable high-pressure *alarm limit* to values exceeding 40 hPa (40 cmH₂O);
 - 10) setting of the adjustable high-pressure *alarm limit* to values exceeding 20 hPa (20 cmH₂O) more than the maximum set *airway pressure*; and
 - 11) setting of the *airway pressure* to values exceeding 40 hPa (40 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 are not performed on the *ventilatory support equipment's operator interface*.

- 1) humidifying/conditioning gases delivered through the *VBS*.

206.101 Training

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

In the application of the requirements of IEC 62366-1:2015, 5.6, 5.7.1 b), 5.7.3 d) and 5.8 training shall be considered necessary for the following:

- a) the *healthcare professional operator*;
- b) the *lay operator* and
- c) the designee of the *responsible organization*.

NOTE 2 Requirements for training are found in 5.6 and 5.8 of IEC 62366-1:2015+AMD1:2020.

Check conformity by inspection of the *accompanying document* and the *usability engineering file*.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015+AMD1:2020 applies except as follows:

211.7.4.7 Additional requirements for *cleaning, disinfection and sterilization*

Amendment (add after 'intended use,' in the first paragraph):

in either *normal condition* or *single fault condition*,

211.7.4.8 Additional requirements for *maintenance*

Amendment (add following the second list element):

- 100) Any known unacceptable *risk* associated with using the *ME equipment*, its parts or *accessories* for longer than the *expected service life* shall be disclosed in the *instructions for use*.

211.10.1.1 General requirements for *mechanical strength*

Amendment (add as the first paragraph):

- aa) The tests of IEC 60601-1-11:2015+AMD1:2020, Clause 10, and IEC 60601-1:2005+AMD1:2012+AMD2:2020, 15.3 shall be performed on the same test *ventilatory support equipment* after the tests of 201.11.6.6 of this document are performed.
- bb) If more than one *procedure* is specified in the *instructions for use*, each *procedure* shall be so tested. A separate *ventilatory support equipment* may be used for each specified *procedure*.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, annexes, 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.1 *Marking on the outside of ME equipment, ME systems or their parts*

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

Table 201.C.101 — *Marking on the outside of ventilatory support equipment, its parts or accessories*

Description of <i>marking</i>	Subclause
Adjacent to each input <i>connector</i> , for oxygen gas inputs, the <i>rated</i> range of oxygen concentration	201.7.2.18 cc)
Adjacent to each input <i>connector</i> , gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used	201.7.2.18 dd)
Adjacent to each input <i>connector</i> , the gas name or chemical <i>symbol</i>	201.7.2.18 aa)
Adjacent to each input <i>connector</i> , the <i>rated</i> range of gas pressure	201.7.2.18 bb)
All gas volume, flowrate and leakage specifications expressed at <i>STPD</i> , except those associated with the <i>VBS</i>	201.4.3 aa) 1)
Arrow indicating the direction of the flow for <i>flow-direction-sensitive components</i> , if applicable	201.7.2.101 a) 3)
For a <i>gas pathway</i> connection port conforming with ISO 80369-7, <i>symbol</i> ISO 7000-1641 or <i>safety sign</i> ISO 7010-M002, as appropriate	201.101.1.2.5 c) 1)
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>ventilatory support equipment</i> , if applicable	201.7.2.4.101 a) 2)
For <i>accessories</i> supplied separately, the requirements ISO 20417:2021, 6.1.1 c)	201.7.2.4.101 a) 1)
For <i>ventilatory support equipment</i> intended to be used in the magnetic resonance (MR) environment, MR safe, if appropriate	201.7.2.101 a) 1) i)
For <i>ventilatory support equipment</i> intended to be used in the magnetic resonance (MR) environment, MR conditional, if appropriate	201.7.2.101 a) 1) ii)
For <i>ventilatory support equipment</i> intended to be used in the magnetic resonance (MR) environment, MR unsafe, if appropriate	201.7.2.101 a) 2)
Requirements of ISO 20417	201.7.1.101
Trigger sensitivity control lowest number to represent the setting for the least <i>patient</i> effort, if applicable	201.7.4.2 bb) 1)
Trigger sensitivity control minimum and maximum settings self-evident, if applicable	201.7.4.2 aa)

Description of <i>marking</i>	Subclause
Trigger sensitivity control not only numeric, if applicable	201.7.4.2 bb) 2)
Unit of <i>airway pressure</i> measurement shall be capable of being configured to be expressed in hPa	201.4.3 bb)
VBS gas volume, flowrate and leakage specifications expressed at <i>BTPS</i>	201.4.3 aa) 2)
Warning not to obstruct the <i>gas intake port</i> , if applicable	201.7.2.101 b) 1)

201.C.2 Accompanying documents, general

Additional requirements for general information to be included in the *accompanying documents* of *ventilatory support equipment* 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 <i>ventilation</i> settings over which elevated temperature of the gas at the <i>ventilatory support equipment gas output port</i> can lead to the failure of a respiratory gas <i>humidifier</i> to function to specification, if applicable	201.16.2 100)
For each VBS and <i>accessory</i> , the <i>model or type reference</i> of at least one compatible <i>ventilatory support equipment</i>	201.102.2 a)
For each VBS, its parts or <i>accessories</i> , a statement to the effect that the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use	201.102.2 b) 3)
For each VBS, 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 VBS, part and <i>accessory</i> , a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
List of designated <i>masks</i> or <i>accessories</i> required to control <i>rebreathing</i> or the information to locate the list, if required	201.12.4.106 d) 1) iii) 201.12.4.106 d) 1) iv)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 3) ii)
Units of measure for <i>airway pressure</i> capable of being configured in hPa	201.7.4.3 bb)
Units of measure for volumes, flows and leakages expressed as <i>STPD</i> or <i>BTPS</i> , as appropriate	201.7.4.3 aa)
<i>Ventilatory support equipment</i> is a high-flow device warning, if applicable	201.4.11.101.2 3) iii)
Warning statement to the effect that failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation, if applicable	201.12.4.106 d) 1) i)
Warning to the effect that to prevent asphyxia when ventilating noninvasively, use a mask or accessory that permits spontaneous breathing in the case that patient flow exceeds that provided by the ventilator	201.12.4.106 d) 1) ii)

201.C.3 Accompanying documents, instructions for use

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

Table 201.C.103 — *Instructions for use*

Description of requirement	Subclause
Accuracies of set and monitored volumes may be presented as a function of these characteristics	201.7.9.2.9.101.2 b) 5)
Accuracy of expired volume <i>monitoring equipment</i> , if so equipped	201.12.4.102
Alternative <i>supply mains</i> , maximum current required, if so equipped	201.11.8.101.2 a) 4)
Alternative <i>supply mains</i> , means of connection, if so equipped	201.11.8.101.2 a) 1)
Alternative <i>supply mains</i> , <i>nominal</i> voltage range, if so equipped	201.11.8.101.2 a) 3)
Alternative <i>supply mains</i> , <i>rated</i> voltage range, if so equipped	201.11.8.101.2 a) 2)
Any adverse effect of any recommended <i>accessory</i> on the <i>basic safety</i> or <i>essential performance</i> of the <i>ventilatory support equipment</i> , if applicable	201.7.9.2.14.101 b)
Any known unacceptable <i>risk</i> associated with using the <i>ME equipment</i> , its parts or <i>accessories</i> for longer than the <i>expected service life</i>	211.7.4.8 100)
A-weighted sound power level emitted by the <i>ventilatory support equipment</i>	201.9.6.2.1.101 b)
A-weighted sound pressure level emitted by the <i>ventilatory support equipment</i>	201.9.6.2.1.101 a)
Behaviour of the <i>ventilatory support equipment</i> after a switchover to the <i>internal electrical power source</i> or <i>alternative supply mains</i>	201.11.8.101.1 c) 2)
Behaviour of the <i>ventilatory support equipment</i> while the <i>internal electrical power source</i> or <i>external reserve electrical power source</i> is recharging	201.11.8.101.1 c) 3)
Description of how the high <i>airway pressure alarm condition</i> can be functionally tested, if provided	201.7.9.2.9.101.2 b) 1) i)
Description of how the hypoventilation <i>alarm condition</i> can be functionally tested	201.7.9.2.9.101.2 b) 1) ii)
Description of the <i>internal electrical power source</i> care and maintenance <i>procedures</i> , including instructions for recharging or replacement, if applicable	201.7.9.2.13.101 b)
Description of the periodic visual safety inspections that should be performed by the <i>operator</i>	201.7.9.2.13.101 a)
Disclosure of any restrictions on the placing of components within the <i>ventilator breathing system</i> , if applicable	201.7.9.2.14.101 a)
For <i>accessories</i> supplied separately where <i>marking</i> the <i>accessory</i> is not practicable, the requirements of ISO 20417:2021, 6.1.1 c)	201.7.2.4.101 b)
For the <i>healthcare professional operator instructions for use</i> , the information contained in <i>instructions for use</i> for <i>lay operator</i>	201.7.9.2.1.101 c)
For the <i>healthcare professional operator instructions for use</i> , a cross reference between the <i>manufacturer-specific</i> naming of the <i>ventilatory support equipment's ventilation-modes</i> and the <i>ventilation-mode</i> systematic coding scheme	201.7.9.2.9.101.2 b) 5)
For the <i>healthcare professional operator instructions for use</i> , any limitation of parameter settings	201.7.9.2.9.101.2 a) 4)
For the <i>healthcare professional operator instructions for use</i> , method by which all functions and settings necessary for <i>normal use</i> can be	201.7.9.2.8.101 d)

Description of requirement	Subclause
functionally tested to determine if they are operating correctly	
For the <i>healthcare professional operator instructions for use</i> , method which can determine whether or not the assembled breathing tubes and related <i>accessories</i> are suitable for use	201.7.9.2.8.101 a) 1)
For the <i>healthcare professional operator instructions for use</i> , the essential technical characteristics of each recommended <i>breathing system filter</i> , if applicable	201.7.9.2.9.101.2 c) 1)
For the <i>healthcare professional operator instructions for use</i> , the methods for controlling the triggering and cycling	201.7.9.2.9.101.2 a) 2)
For the <i>healthcare professional operator instructions for use</i> , the range of parameter settings	201.7.9.2.9.101.2 a) 3)
For the <i>healthcare professional operator instructions for use</i> , the <i>rated</i> range of inspiratory and expiratory <i>gas pathway</i> resistances of the assembled <i>operator-detachable</i> parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 2) i) 201.7.9.2.9.101.2 b) 2) ii)
For the <i>healthcare professional operator instructions for use</i> , the <i>rated</i> range of inspiratory and expiratory <i>gas pathway</i> of compliances of the assembled <i>operator-detachable</i> parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 2) iii) 201.7.9.2.9.101.2 b) 2) iv)
For the <i>healthcare professional operator instructions for use</i> , the working principle of each of the <i>ventilatory support equipment's ventilation modes</i> including waveforms	201.7.9.2.9.101.2 a) 1)
For the <i>lay operator instructions for use</i> , a description of a means to determine the operation time of the <i>internal electrical power source</i> , if provided	201.7.9.2.9.101.1 e)
For the <i>lay operator instructions for use</i> , a description of how to connect a <i>distributed alarm system</i> , if provided	201.7.9.2.9.101.1 f)
For the <i>lay operator instructions for use</i> , conditions under which the <i>ventilatory support equipment</i> maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)
For the <i>lay operator instructions for use</i> , method by which all switchover to and operation from the <i>internal electrical power supply</i> can be functionally tested to determine if they are operating correctly, if provided	201.7.9.2.8.101 a) 2)
For the <i>lay operator instructions for use</i> , method by which the all of the <i>alarm signals</i> , including the <i>alarm signals</i> from <i>distributed alarm systems</i> can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 3)
For the <i>lay operator instructions for use</i> , method by which the assembled breathing tubes and related <i>accessories</i> can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 1)
For the <i>lay operator instructions for use</i> , the <i>model or type reference</i> needed to perform the pre-use check can be performed	201.15.102 c)
For the <i>lay operator instructions for use</i> , the <i>procedure</i> by which pre-use check can be performed	201.15.102 d)
Intended range of <i>tidal volume</i>	201.7.9.2.1.101 d)
Maximum error of the <i>airway pressure</i> at the end of the <i>expiratory phase</i> in relation to the set value for a pressure-controlled breath in <i>normal condition</i>	201.12.1.103 b) 3)

Description of requirement	Subclause
Maximum error of the <i>airway pressure</i> at the end of the <i>expiratory phase</i> in relation to the set value under leak for a pressure-controlled breath in <i>normal condition</i> under leak condition	201.12.1.103 b) 4)
Maximum error of the <i>airway pressure</i> at the end of the <i>inspiratory phase</i> in relation to the set value for a pressure-controlled breath in <i>normal condition</i>	201.12.1.103 b) 1)
Maximum error of the <i>airway pressure</i> at the end of the <i>inspiratory phase</i> in relation to the set value under leak for a pressure-controlled breath in <i>normal condition</i> under leak condition	201.12.1.103 b) 2)
Maximum error of the <i>delivered volume</i> in relation to the set value for a volume-controlled breath in <i>normal condition</i>	201.12.1.102 b) 1)
Maximum error of the <i>PEEP</i> in relation to the set <i>BAP</i> for a volume-controlled breath in <i>normal condition</i>	201.12.1.102 b) 2)
Operational time of the power source when fully charged	201.11.8.101.1 c) 1)
Performance and pass-fail criteria for other breath types in <i>normal condition</i>	201.12.1.104 a)
<i>Processing</i> instructions for the <i>gas pathways</i> of <i>ventilatory support equipment</i> and its <i>accessories</i>	201.11.6.6 cc) 3)
<i>Processing</i> instructions for the <i>ventilatory support equipment enclosure</i>	201.11.6.6 ee) 2)
Requirements of ISO 20417	201.7.1.101
Separate <i>instructions for use</i> for <i>healthcare professional operator</i>	201.7.9.2.1.101 a) 2)
Separate <i>instructions for use</i> for <i>lay operator</i>	201.7.9.2.1.101 a) 1)
Specifications of any required <i>accessories</i> or test equipment needed to perform these tests of 201.7.9.2.8.101 a)	201.7.9.2.8.101 c)
Statement to the effect that do not use the ventilator at an altitude above [insert maximum <i>rated altitude</i>] or outside a temperature of [insert <i>rated temperature range</i>]. Using the ventilator outside of this temperature range or above this altitude can compromise ventilator performance	201.7.9.2.9.101.1 b)
Statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories with which the ventilator is intended to be used	201.7.9.2.9.101.2 d)
Statement to the effect that to reduce the likelihood of disconnection and to prevent adverse ventilator performance use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories	201.7.9.2.9.101.1 c)
Statement to the effect that ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.9.101.1 d)
Summary description of the <i>ventilatory support equipment</i> algorithm for determining the <i>airway pressure alarm limit</i> , if provided	201.12.4.101.2 f)
Warning regarding Luer connection to the <i>gas pathway</i> , if applicable	201.101.1.2.5 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 or the ventilator may not function correctly leading to the risk of degradation or loss of ventilatory support	201.7.9.2.2.101 b)
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)

Description of requirement	Subclause
Warning statement to the effect that the ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 c)
Warning statement to the effect that this ventilator is not suitable for a ventilator-dependent patient	201.7.9.2.2.101 d)
Which portions of the <i>gas pathways</i> through the <i>ventilatory support equipment</i> can become contaminated with body fluids or expired gases during both <i>normal condition</i> and <i>single fault condition</i>	201.7.9.2.12 aa)

201.C.4 Accompanying documents, technical description

Additional requirements for information to be included in the *technical description* of *ventilatory support equipment* or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Disclosure of the interdependence of control functions	201.7.9.3.1.101 b)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3 c)
Intended position of the <i>operator</i>	201.7.9.3.1.101 f)
Pneumatic diagram of the <i>ventilatory support equipment</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 c)
Requirements of ISO 20417	201.7.1.101
Statement to the effect that the <i>responsible organization</i> needs to ensure the compatibility of the <i>ventilator</i> and all of the parts and <i>accessories</i> intended to be used to connect to the <i>patient</i> prior to use	201.7.9.3.1.101 e)
Summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means of initiating and terminating the inspiratory phase while the <i>ventilator</i> is operating in each of its ventilatory modes	201.7.9.3.1.101 d)
Summary description of the test method and <i>procedure</i> to test other <i>inflation-types</i> , if provided	201.12.1.104 e)

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		IEC 60878:2022 <i>Symbol 7.3.1-1 of IEC 62570:2014</i>	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.
2		IEC 60878:2022 <i>Symbol 7.3.1-2 of IEC 62570:2014</i>	MR Safe Alternative graphical <i>symbol</i> representation. Same meaning as IEC 62570:2014, 7.3.1-1.
3		IEC 60878:2022 <i>Symbol 7.3.2 of IEC 62570:2014</i>	MR Conditional 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. 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. 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.

4		IEC 60878:2022 <i>Symbol 7.3.3 of</i> IEC 62570:2014	MR Unsafe To identify an item which poses unacceptable <i>risks</i> to the <i>patient</i> , medical staff or other persons within the MR environment. 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.
---	---	--	---

Additional Annexes:

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-79:2024

Annex AA (informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some 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 rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale 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

There are key contextual differences between home *ventilatory support equipment* and a *ventilator* intended for *ventilator-dependent patients*. One difference is the stability of the *patient*. Another is the balance between *ventilation* and other important lifestyle functions, such as eating, speaking, psychosocial aspects and general physical activity. When choosing and configuring modes, circuits, and *alarm conditions*, the supervising clinician and *patient* need to balance the knowledge and certainty of *ventilation* against the *patient's* autonomy and lifestyle.

ISO 80601-2-79 conforming *ventilator support equipment* are used by *patients* who require a minimal level of support to provide adequate gas exchange. Without such support, these *patients* would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. The most fragile of these *patients* would not likely experience injury with the loss of this *artificial ventilation*.

Additional information is contained in ISO 21954.

ISO 80601-2-79 *ventilatory support equipment* 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.

Pressure-control ventilatory support equipment 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 *ventilatory support equipment* does not adjust the *ventilation* therapy settings based on measurement of these *patient* parameters.

The requirements of this document do not require the *ventilatory support equipment* to adjust *ventilation* delivery parameters based on the detection in the change of physiological conditions of the *patient*. All automatic adjustments of *ventilatory support 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 *ventilatory support equipment* 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 *ventilatory support equipment's* control system that does not act to control the physiological change but continues to control the physical variable(s) to their original objectives.

Ventilatory support equipment 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 *ventilatory support equipment*.

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

- An insulin infusion pump that adjusts 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.
- An 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 *ventilatory support equipment*, these devices titrate delivery to the *patient* based on the measured physiological parameter. A *ventilatory support equipment* will not titrate but will either stop *ventilation* or generate an *alarm condition*.

— 201.4.3.101 — Additional requirements for *essential performance*

Ventilatory support equipment for *respiratory impairment* has no *essential performance*. *Patients* diagnosed with mild to moderate chronic obstructive pulmonary disease (COPD) are capable of spontaneously breathing and do not require additional *ventilation* support. In the absence of treatment (e.g. power failure or loss of therapy or other likely/foreseeable events) where performance is lost or degraded beyond the limits specified by the *manufacturer*, the *patient* does not suffer any immediate adverse effects requiring immediate medical intervention. The most fragile of these *patients* would not likely experience injury with the loss of this *artificial ventilation*. This means that a loss in performance of *ventilatory support equipment* for *respiratory impairment* does not result in an unacceptable *risk*. This is why no *alarm conditions* are required when therapy is lost or degraded.

Nonetheless, *ventilatory support equipment* for *respiratory impairment* is expected to provide effective therapy in *normal condition* even though loss of that therapy is not considered an unacceptable *risk*. This is why pressure is evaluated in lieu of *essential performance* as an acceptance criterion (i.e. pressure does not change by more than twice the *airway pressure* accuracy limit disclosed in the *instructions for use*).

— 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*. Additionally, the *gas pathways* conduct fluids into or out of the *patient*. As such, the *gas pathways* of the *VBS* and the *ventilatory support equipment* need to be investigated regarding *biocompatibility* and compatibility with substances that might pass into or out of the *patient* via the *gas pathways*. Also of concern are electrical *hazards* should

any circuitry be incorporated into the VBS. By ensuring that those items 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

Ventilatory support equipment designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures; and these pressures can only be maintained if the *ventilatory support equipment* 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 these *ventilatory support equipment* 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 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 *ventilatory support equipment* should operate to their declared specification at 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. There is a specific requirement that *ventilatory support equipment* should continue operation with acceptable performance such that *patients* can continue to be ventilated until such time as normal operation can be restored or that alternative arrangements can be made.

Ventilatory support equipment 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 *ventilatory support equipment* cannot be expected to continue to operate on this gas. However, it is required that in this case, the *ventilatory support equipment* 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 supply the *ventilatory support equipment*. This requirement is stated in 201.13.101.

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 while supplying steady-state flowrates up to 60 l/min at a single *outlet* connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the *outlet* and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a 'diversity factor'; a factor agreed upon 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 *ventilatory support equipment* exceeds 60 l/min, there is an increased possibility that the *ventilatory support equipment* input pressure could fall below 280 kPa, mainly because of the

increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal *outlet*).

In addition to steady-state flowrates of 60 l/min, the switching of the internal pneumatic subsystem and the operation of a *patient* demand subsystem can result in *ventilatory support equipment* requiring transient input flowrates 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 the pressure drop, such transient demands can generally be accommodated from the gas contained 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 *ventilatory support equipment* to below 280 kPa due to transient flowrates 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 adversely affects the performance of their *ventilatory support equipment* 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.

Ventilatory support equipment that can draw greater average or transient flows during *intended use* are permitted, but their *accompanying documents* are required to disclose those flowrates 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 conditions specified for the test do not allow a direct comparison between the two values. The subcommittee responsible for pipeline standards, agreed to the 60 l/min average flowrate value and also the 200 l/min for up to 3 s transient flowrates, 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 medical gas supply system standards permit the fitting of gas-specific terminal *outlets* to supply 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 values 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 also satisfy the test requirements of the adjacent range. This permits, for example, one *ventilatory support equipment* to have a declared range *tidal volume* of 300 ml to 1000 ml and another 100 ml to 300 ml, with each *ventilatory support equipment* only being required to be tested for the conditions specified for ≥ 300 ml or ≤ 300 ml respectively.

— 201.5.101.1 — Ventilatory support equipment 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.

Ventilatory support equipment 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 *ventilatory support equipment* 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 (70 °F) is often used in engineering. In *ventilation*, the gas in the *lungs* has a temperature identical to body temperature (approximately 37 °C) irrespective of the temperature of the gas delivered by *ventilatory support equipment*. 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 *ventilatory support equipment*, 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, *ventilatory support equipment* 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 the *ventilatory support equipment*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* (*standard temperature pressure dry*) can expand the *lungs* by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *ventilatory support equipment*, it is essential that the information for all *ventilatory support equipment* 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 *ventilatory support equipment* 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 inspiratory flow inside the *ventilatory support equipment*. When, however, the flow transducer is located at the Y-piece, the relative humidity can be anything up to 100 %. When an *HME* is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the *HME*. With a blower-based *ventilatory support equipment* that uses ambient air, the humidity of the drawn-in air can be unknown to the *ventilatory support equipment*. All these effects together 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. However, it remains the responsibility of the *manufacturer* to verify that the accuracy requirements of 201.12.4.101 and 201.12.4.102 are met throughout the *rated* range of environmental conditions.

— 201.5.101.3 — *Ventilatory support equipment testing errors*

When testing *ventilatory support equipment* 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 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 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 $\pm 3\%$.

A tester 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.

— 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*

b)

The *operator* should be aware that only the parts or *accessories* listed in the *instructions for use* have been *validated* by the *manufacturer*. The use of non-validated parts can represent an unacceptable *risk*. For example:

- a power supply unit other than the one recommended by the *manufacturer* can be designed and manufactured with poor quality (bad reliability), can adversely affect the electromagnetic compatibility of the *ventilatory support equipment*, etc.;

- the connection of parts to the *VBS* that are not listed in the *instructions for use* can increase the inspiratory or expiratory pathway resistance of the *VBS*, can increase the unintentional leakage of the *VBS*, etc. to a level that adversely affects the *basic safety* and *essential performance*.

c)

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 gas flowing through the *BSF*.

When there is low humidity in the gas (gaseous phase moisture) the gaseous water molecules 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. medications intended to be nebulised 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 the *ventilatory support equipment* or physiologic pressures. In the case of nebulised medications, the type of nebuliser, and its operating parameters are variables that affect the likelihood or magnitude of significantly increased *BSF* flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during *operator* or *patient* manipulation of the *VBS* has been implicated as a source of acute *BSF* blockage.

The cause of increased flow resistance in a *BSF* can be gross blockage of the medium passages, or the effects of surfactant properties of the substances introduced into the *BSF* upon the hydrophobicity of the filter medium. It should be noted that medications indicated for nebulisation can contain surfactant materials that are not identified in the medications' labelling with respect to their presence or their quantity, and these can change without notice for a given medication. The effect of these substances upon flow resistance differs among individual models and brands of *BSFs*.

The *operator* needs to be aware that the effects of such substances can be manifested as increases in the amount of positive *airway pressure* required for a *ventilatory support equipment*-provided *inflation*, 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, *ventilatory support equipment 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 integrity of the computer controlling the *ventilatory support equipment*, as well as the measuring sensors and the *alarm signal* generation.

— 201.7.9.2.9.101 — Additional requirements for operating instructions

Some *ventilatory support equipment* is designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. Thus knowledge of these *VBS* characteristics is important for the *operator* to be aware of the *ventilatory support equipment* 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 and exhalation

particle/bacteria filters, *humidifier*, nebuliser, water collection vessels and *connectors* needed for operation.

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

The use of antistatic or electrically conductive materials in the *VBS* is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the *risk* of electrical shock to the *patient*.

— **201.7.9.3.1.101 — Additional general requirements**

The *manufacturer* is expected to express the description of the *ventilatory support equipment* in general terms so the reader can understand the important behaviour of the *ventilatory support equipment* (e.g. mean values and their time specifications, number of breaths and delays etc.). Some items (e.g. pressures) that one would find in the *instructions for use* of a life-sustaining ventilator are placed in the *technical description* for home-use *ventilatory support equipment* as that information is not expected to be meaningful to the *lay operator*, but is necessary for the *healthcare professional operator*.

— **201.9.4.3.101 — Additional requirements for instability from unwanted lateral movement**

The intent of this subclause is to prevent *transit-operable ventilatory support equipment* from causing injury to the *patient* or other person whilst being used in transit. In a moving vehicle on a sharp bump, deceleration or corner, unrestrained equipment could be a projectile *hazard* to the *patient* or to other persons nearby. If projected to impact, the shock could damage the equipment and affect its performance. Means to restrain the equipment can employ the means typically provided in a vehicle to restrain the *patient* such as a belt, harness or grip, or the means can be provided to restrain belongings and equipment such as a pocket, basket, cup holder or portable seat anchor.

IEC 60601-1-11:2015+AMD1:2020, Clause 10.1 provides a means to ensure the *ventilatory support equipment* is not damaged in transit.

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

— **c) 4)**

8.1.1 of ISO 3744:2010 specifies that the average time-weighted sound pressure level is measured. That test method presumes that the equipment being measured has a constant sound. This is not necessarily the case for respiratory *ME equipment* that frequently has sound modulated by the breathing pattern. As a result, this document specifies that the use of the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}).

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

The objective of this requirement is to protect the *patient* from skin burns due to contact with the external surface of the *breathing tube*.

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^[40]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract^[45]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (265,6 kJ/kg) for 45 min^[34].

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 heated *humidifier* in clinical practice, the delivered gas energy limit of 197 kJ/ m³ of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen / air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,9786 m³/kg of dry air and an enthalpy content of 197 kJ/kg 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/kg of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the *patient*.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells^[42]. This is confirmed by studies conducted by the US. Navy Medical Research and Development Command^[45], which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the *patient* with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 130 kJ/kg of dry gas breathed by the *patient*.

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

The *essential principles* of ISO 16142-1:2016 require that medical devices are “not [to] compromise the clinical condition or the safety of *patients*, or the safety and health of users or, where applicable, other persons, provided that any *risks* which can be associated with their use constitute acceptable *risks* when weighed against benefits to the *patient* and are compatible with a high level of protection of health and safety.”

This means that *ventilatory support equipment*, their *accessories* and parts should not be used if there is an unacceptable *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *ventilatory support equipment*, *accessory* or part.

Therefore after long-term use in the home, *ventilatory support equipment*, their *accessories* and parts, if transferred to a new *patient*, require an appropriate level of *disinfection*, depending on their use, but rarely need to be *sterile*.

Recommendations for hygienic *processing* of *ventilatory support equipment*, 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* of this standard are intended to:

- make the *responsible organization* for *processing* the *ventilatory support equipment* aware of how to implement these tasks in a responsible manner through appropriate delegation; and
- help all parties involved in the *processing* of *ventilatory support equipment*, their *accessories* and parts to conform with the *manufacturer's instructions for use*.

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.

It should be noted that *ventilatory support equipment*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *ventilatory support equipment* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the device or the next *patient* on whom the device is used. Hence, *ventilatory support equipment*, their re-usable *accessories* and parts that have been used are required to undergo a *processing process*, following the *manufacturer's instructions for use*, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing instructions* of *ventilatory support equipment*, its *accessories* or parts:

- protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing process*);
- the limits of the *procedures* used for *processing* (such as the number of *processing cycles*); and
- the necessity to guarantee the proven standardised *procedures* to a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing process* should be determined by:

- the potential degree and type of contamination of the *ventilatory support equipment*, *accessories* or parts; and
- the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *ventilatory support equipment*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* should be considered.

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 *ventilatory support equipment*, *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 *processing ventilatory support equipment*, *accessories* or parts are determined by the following factors:

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

When considering the suitability of the *processing process* and the feasibility of the *processing process* for the *ventilatory support equipment, accessories* or parts, the *manufacturer* should consider the following points:

- the *risks* involved in the *processing process*;
- the cost effectiveness of the *processing process*;
- the practicability of the *processing process*;
- the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing process*;
- the efficiency of the *processing process*;
- the reproducibility of the *processing process*;
- quality management requirements of the *processing process*; and
- the environmental impact of the *processing process* and the disposal of the *ventilatory support equipment, accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *ventilatory support equipment, accessories* or parts, depending on the type of use.

The *responsible organization* should verify that manual *cleaning* and *disinfection* of the *ventilatory support equipment, 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 *ventilatory support equipment, 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 with the next *patient, operator* or person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, safety and functional testing of the *ventilatory support equipment* (as specified by the *manufacturer's instructions for use*) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before reuse of the *ventilatory support equipment*.

The extent and type of the tests depends on the *ventilatory support equipment, accessory* or part and these need to be defined in the *accompanying document*.

— 201.12.4.101 — Measurement of *airway pressure*

The site in the VBS at which pressure is sensed varies from *ventilatory support equipment* to *ventilatory support equipment*. 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 *ventilatory support equipment*: 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.

— 201.12.4.103 — *Maximum limited pressure protection device*

The value chosen for the *maximum limited pressure*^[46] is a compromise between the need to avoid barotrauma and the need to provide an adequate range of pressure to meet the desire of *operators* specifically to supply high insufflation pressures for *patients* with low chest wall compliance.

— 201.12.4.105 — CO₂ *rebreathing*

Masks and other *patient* interfaces intended for use with *ventilatory support equipment* without an active exhalation valve incorporate an *exhaust port*. The function of the *exhaust port* is to allow for passive removal of exhaled gases to minimize *rebreathing*.

A critical issue to be considered is whether the machine-*patient* flow through the *exhaust port* has reduced the residual exhaled CO₂ to acceptable levels.

Ventilatory support equipment can be equipped with a single-conduit *breathing gas pathway* with a dual-purpose, inspiratory/expiratory function and an *exhaust port*. The issue of CO₂ *rebreathing* will be a function of several variables, such as the following:

- the type of the breathing attachment — *face mask*, *nasal mask*, or *full face mask*;
- the size and location of the *exhaust ports*;

- the average flowrate at the minimum continuous positive *airway pressure*;
- the duration of the *patient's* exhalation.

There is the potential for clinically significant CO₂ *rebreathing* if the *exhaust ports* are not designed and located appropriately. Therefore, the design and configuration of *ventilatory support equipment* and its *masks* and *accessories* has a major impact on the potential for *rebreathing* of carbon dioxide and thereby the inspired oxygen concentration.

The maximum recommended time-weighted average for inspired CO₂ in industry is 1 %. An inspired CO₂ fraction of 1 % would add 1 013,25 Pa (7,6 mmHg) to the test model in ISO 17510:2015, Annex F, and would result in the test end-tidal CO₂ value of 1 013,25 Pa (7,6 mmHg) + 5 066,25 Pa (38 mmHg) or 6 079,5 Pa (45,6 mmHg). This represents a 20 % increase in the CO₂ level. Based on this, the committees chose a 20 % increase in the CO₂ level *normal condition* limit. Similarly, the 60 % increase in the CO₂ level *single fault condition* limit represents a time-weighted average for an inspired CO₂ of 3 %.

— 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 *ventilatory support equipment*. 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* or a specific sequence of key or switch operations.

— 201.13.2.101 — Additional specific *single fault conditions*

Operation of *ventilatory support equipment* 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 microbial material conveyed by the expired gases. If *ventilatory support equipment* 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* have been contaminated. Additional information is also found in the rationale for 201.11.6.6.

— 201.13.2.102 — 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.

For respiratory equipment, different *ventilation-control* functions can have different types of *risk control* measures. For example, *monitoring equipment* is required for some *ventilation* delivery parameters, an *alarm system* is required for loss of *ventilation* and a *protection device* is required for some faults that can create a hazardous output such as extreme over-pressure. The general standard requires the equipment to remain safe in *single fault condition*. The control function and corresponding *risk control* measure cannot both fail from the same *single fault condition* and still conform with the general standard.

— 201.13.2.103 — Failure of *functional connection to a ventilatory support equipment control or monitoring means*