International Standard

ISO 80601-2-80

Second edition
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Medical electrical equipment —

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

Appareils électromédicaux —

Partie 2-80: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas d'insuffisance ventilatoire

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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).

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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 80601-2-80:2018), 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, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements;
- added requirements for *ventilatory support equipment system recovery*; 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.

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 for *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).

Varying levels of ventilatory support is often used for *patients* who have stable ventilatory needs and in some cases, changing needs as their disease worsens. This document addresses *patients* who typically have severe enough respiratory function 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. This is best characterised by *lung* functions worse than[36]

— FEV_1/FVC[1] < 70 %, or

— FEV_1 < 50 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilatory support are:

— moderate to severe Chronic Obstructive Pulmonary Disease (COPD);

— moderate Amyotrophic Lateral Sclerosis (ALS)[44];

— severe bronchopulmonary dysplasia; and

— muscular dystrophy.

Ventilatory support equipment intended for this group of *patients* typically can require *technical alarm conditions* in the event that *essential performance* is absent. The most fragile of these *patients* would likely experience injury, but not serious injury or death, with the loss of this *artificial ventilation*. For these *patients*, it is likely that ventilatory support is needed during waking hours while *patients* are moving inside or outside the home in order to facilitate mobility and functional independence in the activities of daily living.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *terms defined in Clause 3 of the general standard*[2]*, in this document or as noted: italic type*; and

— 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:

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

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.*

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

Medical electrical equipment

Part 2-80:
Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

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 insufficiency*, as defined in 201.3.302, 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 insufficiency* or failure, the most fragile of which would likely experience injury with the loss of this *artificial ventilation*;

— intended for *transit-operable* use; and

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

EXAMPLE 1 *Patients* with moderate to severe chronic obstructive pulmonary disease (COPD), moderate amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy.

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

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 impairment*, which are given in ISO 80601-2-79;

— sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;

— high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87;

— high-frequency oscillatory *ventilators* (HFOVs)[20];

— 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 insufficiency,* as defined in 201.3.302, 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*[31] and labelling[32] 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 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[33].

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, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3:2008, 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 define *basic safety* and *essential performance* requirements, and 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 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 5359:2014+Amd 1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

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+AMD2:2020[4], *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 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*

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*.

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.

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

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

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

201.3.202
acknowledged
state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

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

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

201.3.203
airway pressure
$\boldsymbol{P_{aw}}$
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 indicates 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

Note 1 to entry: The *gas pathway* is bounded by the 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.

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

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

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

[SOURCE: ISO 18562-1:2024, 3.11]

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 80601-2-12:2023, 201.3.247, modified — added note.]

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, 3.13.4, 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, 3.1.16, 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 continuously 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
system recovery
method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

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

[SOURCE: ISO 80601-2-12:2023, 201.3.298]

201.3.289
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]

201.3.290
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.]

201.3.291
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.]

201.3.292
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.]

201.3.293
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]

201.3.294
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*".]

201.3.295
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]

201.3.296
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.]

201.3.297
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.]

201.3.298
ventilator
medical device or medical electrical equipment intended to provide artificial ventilation

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

201.3.299
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.]

201.3.300
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]

201.3.301
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*).

[SOURCE: ISO 80601-2-79:2024, 201.3.300]

201.3.302
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 *ventilatory 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*.

201.3.303
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 intended for a *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.

201.3.304
volume-control
inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

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

201.4 General requirements

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

Addition:

201.4.3.101 Additional requirements for *essential performance*

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

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

Table 201.101— Distributed *essential performance* requirements

Requirement	Subclause
Providing *ventilation* at the *patient-connection port* within the *alarm limits* set by the *operator* or	[a]
generation of an *alarm condition*	
Functional connection failure	201.13.2.103
Low *airway pressure*	201.12.4.101
High *airway pressure*, if provided	201.12.4.101.3
Hypoventilation	201.12.4.104
Internal electrical power source nears depletion	201.11.8.101
System recovery	201.4.3.102
Power supply failure	201.11.8.101
High leakage, if provided	201.12.4.105

[a] 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of *ventilation* as acceptance criteria following specific tests required by this document.

201.4.3.102 *System recovery*

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

a) Following a malfunction, the *ventilatory support equipment* shall attempt to perform a *system recovery* to restore *essential performance* of the *ventilatory support equipment*.

NOTE 2 *Ventilatory support equipment* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *ventilatory support equipment*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of *ventilation*. *Ventilation* would thus be interrupted until an alternative means of *ventilation* is connected. *System recovery,* as specified

in this subclause, attempts to automatically re-establish *ventilation* in a shorter period. If necessary, the *ventilatory support equipment* can be replaced later when it is less consequential for the *patient's* therapy.

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

1) cessation in the *ventilation* of the *patient*; or

2) reduction in the function of *ventilatory support equipment* subassemblies without impacting the *ventilation* of the *patient.*

EXAMPLE The temporary blanking of the display.

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

1) the *ventilatory support equipment* shall allow spontaneous *patient* breathing in accordance with 201.103; and

2) the *ventilatory support equipment* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of *ventilation*.

i) The *system recovery* with a cessation of *ventilation alarm condition* shall be *high priority*.

d) During a *system recovery* without a cessation of *ventilation*, the *ventilatory support equipment* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of *ventilation*.

1) The *alarm condition* for *system recovery* without a cessation of *ventilation* shall be at least *low priority.*

2) A *low priority system recovery* without a cessation of *ventilation alarm condition* need not have an auditory *alarm signal*.

e) Following a *system recovery* without *operator* intervention, the *ventilatory support equipment* shall attempt to operate with the same system configuration settings, *ventilation* settings and *alarm settings* as before the *system recovery*.

1) If the system configuration settings, ventilation settings or *alarm settings* are different after the *system recovery*, the *ventilatory support equipment* shall be equipped with an *alarm system* to indicate any change in settings.

2) The change in settings *alarm condition* shall be at least *medium priority*.

f) The duration of a *system recovery* with a cessation of *ventilation* should be as short as practicable to avoid an unacceptable *risk* to the *patient*.

g) The maximum duration of a *system recovery* shall be disclosed in the *instructions for use*.

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

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

The *manufacturer* shall:

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

bb) summarize the methodology used to determine this probability.

Replacement (replace the compliance check):

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

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

Amendment (add prior to the compliance check):

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

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

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).

201.4.10.2 *Supply mains* for *ME equipment* and *ME systems*

Replacement of the tenth dash as follows.

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

— For operation from:

1) 12 V d.c. *supply mains*

   i) the *rated* range shall include at least 12,4 V to 15,1 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 10 V.

2) 24 V d.c. *supply mains*

   i) the *rated* range shall include at least 24,8 V to 30,3 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 20 V.

3) other d.c. *supply mains*

   i) a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

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 needed 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 7396-1:2016+AMD1:2017, then

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

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

b) under *normal condition*,

1) the maximum 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*;

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 flowrate at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flowrate, 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 80601-2-80 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 ~ 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 ±(10 ml +10 % of set volume) then the uncertainty of the measurement cannot exceed ±(3 ml +3 % 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 *technical description*.

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6, applies, except as follows:

Additional subclause:

201.6.101 Additional requirements for classification of *ME equipment* and *ME systems*

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

Ventilatory support equipment shall be *transit-operable*.

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);

2) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* 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*-accessible *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 on or adjacent to the following items:

1) for a *gas intake port*, 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 the following.

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 or in-use bag, only use a carrying case or in-use bag 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 of health of the patient."

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: 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 which consequently can result in degradation of the health of the patient."

e) A warning statement to the effect that "WARNING: Do not connect the ventilator to the battery of a battery-powered wheelchair unless the connection is listed in the instructions for use of the ventilator or wheelchair as this can compromise the ventilator performance which consequently can result in degradation of the health of the patient."

NOTE 4 There is guidance or rationale for this list item contained in Clause AA.2.

f) A warning statement to the effect that "WARNING: 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".

g) 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.

h) If applicable, a warning statement to the effect that “WARNING: The ventilation supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebuliser.”

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) the switchover to and operation from the *internal electrical power source;* and

3) all of the *alarm signals*, including 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 functions and settings necessary for *normal use* can be 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*.

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

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

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 description of a means to determine the operation time of the *internal electrical power source*; and

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

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

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

201.7.9.2.9.101.2 Supervising clinician or *healthcare professional operator* operating instructions

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

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;

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:

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

i) high *airway pressure*, if provided;

ii) high leakage (circuit disconnect), if provided; and

iii) 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 3 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 and the 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) 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 all measured and 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*; and

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*.

201.7.9.3.101 Additional requirements for the *technical description*

a) The *technical description* shall include a description of a method for checking the proper functioning of the *alarm system* for each of the *alarm conditions* specified in this Table 201.101, except *system recovery*, if not performed automatically during the start-up *procedure*.

b) The *technical description* shall disclose which checks are performed automatically.

Check conformity by inspection of the *technical description*.

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

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

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

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

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) *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 1 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* so as 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.[46]

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) *Ventilatory support equipment* shall be designed to include 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 in- 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 the sound-reflecting plane and attach the least favourable *VBS* from those indicated in the *instructions for use*.

NOTE 1 The least favourable *VBS* configuration can vary by *ventilation-mode*, *inflation-type* and flow pattern, as applicable.

2) If a *humidifier* is provided with 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) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.

i) Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the *ventilatory support equipment*.

ii) Connect the *patient-connection port* to the test lung.

4) Select the test case from Table 201.102 that is the least favourable *ventilation mode*, *inflation-type* and flow pattern.

NOTE 2 The least favourable *ventilation mode*, *inflation-type* and flow pattern can vary by *VBS* configuration.

5) Using a microphone of the sound level meter, conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{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 3 There is guidance or rationale for this list item contained in Clause AA.2.

6) Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with 8.2.2 of ISO 3744:2010.

7) Calculate the A-weighted sound power level in accordance with 8.6 of ISO 3744:2010.

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

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

10) Ensure that the sound power level is less than or equal to that disclosed in the *instructions for use.*

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition	
	For *ventilatory support equipment* intended to provide *tidal volume*	
	$V_T \geq 300$ ml	$V_T \leq 300$ ml
Tidal volume, V_T[a]	500 ml	150 ml
Set rate	10 breaths/min	20 breaths/min
I:E ratio	1:2	1:2
BAP	5 hPa (5 cmH_2O)	5 hPa (5 cmH_2O)
Resistance, R[a][30][41][43]	5 hPa·$(l/s)^{-1}$ ± 10 %	20 hPa·$(l/s)^{-1}$ ± 10 %
Compliance, C[a,b]	50 ml·$(hPa)^{-1}$ ± 10 %	20 ml·$(hPa)^{-1}$ ± 10 %

[a] V_T is measured by means of a pressure sensor on the test lung, where $V_T = C \cdot (P_{max} - P_{min})$;
V_T is the volume delivered to the test lung;
C is the isothermal compliance of the test lung;
P_{min} is the minimum pressure measured in the test lung;
P_{max} is the maximum pressure measured in the test lung.

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

201.10 Protection against unwanted and excessive radiation *hazards*

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 kJ/kg dry air) when averaged over 120 s.

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

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

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

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

Amendment (add additional requirement as new first paragraph):

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 for:

1) *cleaning* and *disinfection;* or

2) *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 *gas pathways* of 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*.

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

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*.

Check conformity by inspection of the *risk management file*. When conformity with this document can be affected by the *cleaning* or the *disinfection* 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 pathway*.

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 subclauses:

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*

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

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

b) *Ventilatory support equipment* shall 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.

c) A fully charged *internal electrical power source* shall be capable of powering the *ventilatory support equipment* for at least 2 h.

d) A means shall be provided for determining the state of this *internal electrical power source.*

e) A means shall be provided to indicate that the *ventilatory support equipment* is powered from the *internal electrical power source.*

f) The *ventilatory support equipment* shall either:

1) be equipped with an *alarm system* that:

i) detects an *alarm condition* of at least a *low priority* to indicate the switchover to the *internal electrical power source*;

ii) detects an *alarm condition* of at least a *low priority* to indicate there is at least 15 min of remaining power available in the *internal electrical power source;*

iii) detects an *alarm condition* of at least a *medium priority* to indicate there is at least 5 min of remaining power available in the *internal electrical power source;*

iv) provides at least 5 min between the start of these two *internal electrical power source* failure *alarm conditions;*

2) or be equipped with an *intelligent alarm system*, based on additional information, determines that the impending *internal electrical power source* failure *alarm condition* is suppressed or its priority is changed.

NOTE 2 The *operator* needs sufficient time "prior to the loss of all power" to take action to ensure that alternative arrangements can be made to continue the function of the *ventilatory support equipment*.

g) 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

i) the *internal electrical power source*, or

ii) an alternative *supply mains*.

3) the behaviour of the *ventilatory support equipment* during the recharging of

i) the *internal electrical power source*, or

ii) an alternative *supply mains*.

4) the minimum time between complete loss of *internal electrical power source* and

i) the start of the *low priority* impending *internal electrical power source* failure *alarm condition*, and

ii) the *medium priority* impending *internal electrical power source* failure *alarm condition*.

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

201.11.8.101.2 Alternative power supply/*supply mains*

a) The *ventilatory support equipment* shall have a means of connection to an alternative *supply mains*.

EXAMPLE 1 A 12 V d.c., 100 W *connector* for connection to an automotive vehicle power source.

EXAMPLE 2 A connection to alternative d.c. power source.

b) The *instructions for use* shall include:

1) a description of the means of connection;

2) the *rated* voltage range;

3) the *nominal* voltage; and

4) the maximum current required.

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:

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, but with the light level extended from the range of '100 lx to 1 500 lx' to the range of '100 lx to 10 000 lx'.

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 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.

Additional subclauses:

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 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 ±(5 ml+ 10 % 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) $V_T \geq 300$ ml; and

2) 300 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

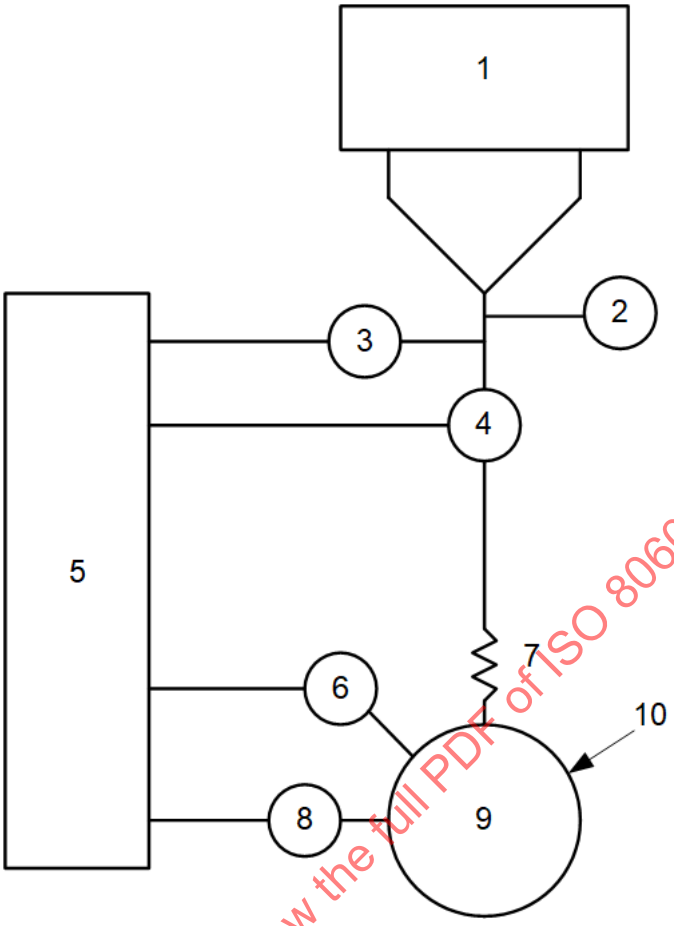
2) determined for the worst-case *VBS* configurations indicated in the *instructions for use*.

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 201.101.



Key

1 *ventilatory support equipment* under test (single or dual limb)
2 artificial leakage (applies for *pressure-control inflation-type* only), see Table 201.105, 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 201.101 — Typical test setup for *volume-control* and *pressure-control inflation-type* accuracy

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 201.104. Wait for steady-state conditions to be achieved.

NOTE 2 Potentially, for some of these tests (i.e. those utilizing a *VBS* with a large compliance and a high resistance) the *end-expiratory flow* will not reach zero.

Table 201.104 — *Type test* settings *for volume-control inflation-type type*

Test number	Test lung parameters		*Ventilatory support equipment* settings			
	Compliance (ml·(hPa)$^{-1}$) ± 10 %	**Linear**[30][41][43] **resistance** (hPa·(l/s)$^{-1}$) ± 10 %	***Tidal volume*** ml	***Set rate***[a] breaths/min	***Inspiratory time*** s	***BAP*** hPa (cmH_2O)
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	10	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.

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 3 Additional information on the construction of an isothermal test lung is found in Reference [38].

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* setting 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.

9) Repeat 3) to 8) for each applicable row (selected by intended *tidal volume*) of Table 201.104.

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.

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

2) 300 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 201.101.

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

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

NOTE 2 Potentially, for some of these tests (i.e. those utilizing a *VBS* with a large compliance and a high resistance) the *end-expiratory flow* will not reach zero.

Table 201.105 — *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 [30][41][43] (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_2O)	*BAP* hPa (cmH_2O)
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	10	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 201.101) at a constant pressure of 20 hPa.

[c] In the case that *end-expiratory flow* does not reach zero, reduce the *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 *BAP*.

[f] The *instructions for use* shall indicate this value.

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 *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 2) to 7) for 30 consecutive breaths.

9) Repeat 2) to 8) for each applicable row (selected by intended *tidal volume*) of Table 201.105.

10) 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.

11) If the *ventilatory support equipment* permits operation without compliance correction, repeat 2) to 10) without compliance correction.

12) Compare each result to the tolerance indicated in the *instructions for use*.

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 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 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 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 and *alarm limits* (see 201.108).

dd) The *ventilatory support equipment* shall provide the *responsible organization* or the *healthcare professional operator* with a means to restrict the *lay operator* from adjusting the *ventilation* settings and *alarm settings* (see 201.108).

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.

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 ± (2 hPa + 4 % of the actual reading) (± (2 cmH_2O + 4 % of the actual reading)).

d) The *airway pressure monitoring equipment* shall be equipped with an *alarm system* that detects at least a *medium priority alarm condition* to indicate when the low-*airway pressure alarm limit* is reached.

1) The *airway pressure monitoring equipment* may be equipped with an *alarm system*

i) that starts with a *low priority alarm condition* to indicate when the *airway pressure* reaches the *alarm limit* and,

ii) if this state continues, escalates to a *medium priority alarm condition.*

e) The low *airway pressure alarm signal* may be inactivated with *alarm off*.

f) *Alarm off* may be activated by the *ventilatory support equipment*.

g) 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.

h) 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 2 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 *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 cmH_2O) more than the high-pressure *alarm limit; or*

b) 90 hPa (90 cmH_2O).

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

NOTE 3 See also 201.12.4.103.

Check conformity by functional testing.

201.12.4.103 High-pressure *alarm condition*

a) If the *maximum limited pressure* is greater than 40 hPa (40 cmH_2O), 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 cmH_2O) more than the highest of the current *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 cmH_2O).

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.

h) 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.

i) 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.

j) 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.

k) In *normal condition*, whenever the high-*airway pressure alarm condition* occurs, the *ventilatory support equipment* shall reduce the *airway pressure* to the set *BAP* level within the lessor of:

1) one *respiratory cycle*; or

2) 5 s.

l) 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.

201.12.4.104 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*.

201.12.4.105 Hypoventilation *alarm condition*

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

b) The hypoventilation *alarm condition* shall include the detection of a lack of connection or disruption of the gas delivery to the *airway device* from the *ventilatory support equipment.*

EXAMPLE 1 A lack of connection of the *breathing system* to the *gas output port.*

EXAMPLE 2 The incorrect configuration of the *breathing system*.

EXAMPLE 3 The inadvertent disconnection of *breathing system* components.

EXAMPLE 4 A lack of connection between the *patient-connection port* and *airway device*.

NOTE The hypoventilation *alarm condition* can be determined, amongst other things, by the measurement of the variations of *airway pressure*, expiratory volume, tidal volume or low respiratory rate or by an *intelligent alarm system* utilizing one or more variables.

Check conformity by functional testing.

201.12.4.106 High leakage *alarm condition*

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

a) The *ventilatory support equipment* may be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for high leakage.

b) If provided, the high leakage *technical alarm condition*

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

2) an *intelligent alarm system*, based on additional information, determines that the high leakage *technical alarm condition:*

i) is suppressed; or

ii) its priority is changed.

c) The high leakage *technical alarm condition* may be disabled when the *tidal volume monitoring equipment* is in use.

Check conformity by inspection.

201.12.4.107 CO_2 *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

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 cmH_2O). See also 201.12.4.103 e) 2) and 206 b) 8).

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 expiratory valve control tubing to a gas sampling port.

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*.

201.13.102 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*.

b) The *ventilatory support equipment* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this communication failure.

c) The communication failure *technical alarm condition:*

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

2) an *intelligent alarm system*, based on additional information, determines that the communication failure *technical alarm condition:*

i) is suppressed; or

ii) the priority is changed.

Check conformity by functional testing.

201.14 *Programmable electrical medical systems* (*PEMS*)

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

201.14.1 General

Amendment (add prior to the compliance check):

aa) The *programmable electronic subsystems* (*PESS*) of *ventilatory support equipment* shall be developed with a design *process* conforming with:

1) IEC 62304:2006+AMD1:2015; and

2) IEC 81001-5-1:2021.

bb) The *ventilation* control *software items* of the *ventilatory support equipment PESS* without an independent *risk control* measure external to the *PESS* shall be considered as software safety Class C.

201.14.101 *Cybersecurity* capabilities

a) 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 those related to 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 the *internal electrical power supply*;

3) all *alarm signals*, including, if provided, the *alarm signals* from a *distributed alarm system;*

4) if provided, high leakage (circuit disconnect) *alarm condition.*

b) This test method

1) shall 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 this document and 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 Blower-based *ventilatory support equipment* operating with 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;

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* or 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 generally used e.g. for measuring gas concentrations 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 an accessory port.

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

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

1) be *marked* with either:

i) the *symbol* ISO 7000-1641 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, *symbol* 11); or

ii) if the *marking* is the primary *risk control* measure, the *safety sign* ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.2, *safety sign* 10).

2) include in its *instructions for use* a warning to the effect that "Warning: As this [insert name of medical device here] uses a Luer connector for other than intravascular or hypodermic access, there is a possibility that an inadvertent connection can occur between this [insert name of medical device here] and another medical device or accessory using a Luer connector, which

can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks."

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

201.101.1.2.6 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 80601-2-13:2022.

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 the *ventilatory support equipment* or *ventilator 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) *Ventilatory support 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").

Check conformity by the tests of this standard.

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 Humidification system

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 or

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 cmH_2O) 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 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 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;

   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;

      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.

201.107 *Ventilatory support equipment* security

Means of restricting access to changing or to the storage of changes shall be described in the *technical description* [see 201.12.4 dd) and 208.6.12.2 b)].

EXAMPLE 1 Access controlled by a *tool*.

EXAMPLE 2 Access controlled by *responsible organization* password and a *technical description* that is separate from the *instructions for use*.

EXAMPLE 3 Access controlled by individual *operator* password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed (e.g. one for the *responsible organization* and one for each *operator*).

Check conformity by inspection of the *technical description*.

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 201.12.1.102 or 201.12.1.103, selected by intended *tidal volume*, as appropriate. During this testing, set the volume and pressure *alarm condition alarm limits* to their least sensitive levels.

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

Amendment (add note to list element b)):

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

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;

ii) the *inspiratory volume* averaged over a one-minute interval deviating by more than 25 % of the *inspiratory volume* measured prior to the test;

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) observing and identifying:

i) the *alarm signals*; and

ii) the *alarm signal* inactivation states;

3) 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*.

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

5) *processing* the *VBS* components;

6) starting the *ventilatory support equipment* from power off including performing the start-up *procedure*;

7) turning off the *ventilatory support equipment;*

8) carrying the *ventilatory support equipment* with one hand:

i) either directly, or

ii) by use of a carrying case or in-use bag;

9) 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*;

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

   iv) setting *ventilation* control parameters;

   EXAMPLE 3 *Set rate*, set *BAP*, pressure support, *inspiratory time* or *I:E ratio*

3) switching between power sources;

4) connecting and disconnecting the *distributed alarm system*;

5) testing power sources;

6) starting *ventilation* from standby; and

7) activating standby.

8) setting of the adjustable high-pressure *alarm limit* to values exceeding 40 hPa (40 cmH_2O);

9) setting of the adjustable high-pressure *alarm limit* to values exceeding 20 hPa (20 cmH_2O) more than the maximum set *airway pressure*; and

10) setting of the *airway pressure* to values exceeding 40 hPa (40 cmH_2O).

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

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

1) humidifying/conditioning gases delivered through the *VBS*; and

2) positioning the *patient* and the *ventilatory support equipment* on a wheelchair.

206.101 Training

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

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

a) the *healthcare professional operator;*

b) the *lay operator*; and

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

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*.

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

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

Replacement:

208.6.5.4.2 Selection of *default alarm preset*

a) Whenever the *ventilatory support equipment*

1) is in *healthcare professional operator*-mode,

2) the *healthcare professional operator* indicates to the *ventilatory support equipment*, preferably through a function, that a different *patient* has been connected to the *ventilatory support equipment*, then:

3) the default *ventilatory support equipment* settings, including the *default alarm preset,* shall be automatically selected, or

4) means shall be provided for the *healthcare professional operator* to select the *ventilatory support equipment* settings, including the *alarm settings.*

b) Whenever the *ventilatory support equipment*:

1) is in *lay operator* mode,

2) the *operator* switches the *ventilatory support equipment* on, then:

3) the *ventilatory support equipment* shall assume the retained *ventilatory support equipment* settings from previous use, or

4) means shall be provided for the *operator* to select *ventilatory support equipment* preset, including the *alarm settings*.

c) Means shall be provided to ensure that the *ventilatory support equipment* settings are retained.

Check conformity by functional testing and inspection.

Additional subclause:

208.6.12.3.101 Additional requirements for *operator alarm system* logging

Ventilatory support equipment shall be provided with an *operator* log with a capacity of at least 1 000 events in total.

Check conformity by inspection and functional testing.

208.6.12.3 *Responsible organization alarm system* logging

Replacement:

a) *Ventilatory support equipment* shall be provided with a *responsible organization* log with a capacity of at least 1 000 events in total.

b) Viewing the *responsible organization alarm system* log shall be restricted to the *responsible organization* in accordance with IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7.

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

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

1) the *ventilatory support equipment* settings; and

2) each change of those settings.

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

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

1) the *alarm settings*; and

2) each change of those settings.

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

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

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

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

i) The *technical description* shall indicate:

1) the *responsible organization alarm system* log capacity; and

2) what happens to the contents of the *alarm system* log as it reaches capacity.

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

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

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

Check conformity by inspection and functional testing.

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.*

Additional subclause:

211.10.1.1 General requirements for mechanical strength

Amendment (add before 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 *marking*	Subclause
Adjacent to each input connector, for oxygen gas inputs, the *rated* range of oxygen concentration	201.7.2.18 cc)
Adjacent to each input connector, gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used	201.7.2.18 dd)
Adjacent to each input connector, the gas name or chemical *symbol*	201.7.2.18 aa)
Adjacent to each input connector, the *rated* range of gas pressure	201.7.2.18 bb)
All gas volume, flowrate and leakage specifications expressed at *STPD*, except those associated with the *VBS*	201.4.3 aa) 1)
For a gas pathway connection port conforming with ISO 80369-7, *symbol* ISO 7000-1641 or *safety sign* ISO 7010-M002, as appropriate	201.101.1.2.5 c) 1)
For *accessories* supplied separately, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilatory support equipment*, if applicable	201.7.2.4.101 a) 2)
For *accessories* supplied separately where *marking* the *accessory* is not practicable, the requirements of ISO 20417:2021, 6.1.1 c)	201.7.2.4.101 a) 1)
For *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool,* an arrow indicating the direction of the flow	201.7.1.101 a) 3)
For *ventilatory support equipment* intended to be used in the magnetic resonance (MR) environment, MR safe, if appropriate	201.7.2.101 a) 1) i)
For *ventilatory support equipment* intended to be used in the magnetic resonance (MR) environment, MR conditional, if appropriate	201.7.2.101 a) 1) ii)
For *ventilatory support equipment* intended to be used in the magnetic resonance (MR) environment, MR unsafe, if appropriate	201.7.2.101 a) 2)
Requirements of ISO 20417	201.7.2.4.101 a)
Trigger sensitivity control lowest number to represent the setting for the least *patient* 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)
Trigger sensitivity control not only numeric, if applicable	201.7.4.2 bb) 2)

Description of *marking*	Subclause
Unit of *airway pressure* 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 *BTPS*	201.4.3 aa) 2)
Warning not to obstruct the *gas intake port*, 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 *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, if applicable	201.16.2 100)
For each *VBS* and *accessory*, the *model* or *type reference* of at least one compatible *ventilatory support equipment*	201.102.2 a)
For each *VBS*, its parts or accessories, 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 *accessory*, a statement to the effect that ventilator breathing systems, their parts and accessories are validated for use with specific ventilators	201.102.2 b) 1)
For each *VBS*, part and *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
List of designated *masks* or *accessories* required to control rebreathing or the information to locate the list, if required	201.12.4.107 d) 1) iii) 201.12.4.107 d) 1) iv)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 b) 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 b) 3) ii)
Units of measure for volumes, flows and leakages expressed as *STPD* or *BTPS*, as appropriate	201.7.4.3 aa)
Ventilatory support equipment is a high flow device warning, if applicable	201.4.11.101.2 b) 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	201.12.4.107 d) 1) i)
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	201.12.4.107 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	201.12.4.107 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
Accuracy of expired volume *monitoring equipment*, if so equipped	201.12.4.102
Alternative *supply mains*, maximum current required	201.11.8.101.2 b) 4)
Alternative *supply mains*, means of connection	201.11.8.101.2 b) 1)
Alternative *supply mains*, *nominal* voltage range	201.11.8.101.2 b) 3)
Alternative *supply mains*, *rated* voltage range	201.11.8.101.2 b) 2)
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *ventilatory support equipment*, if applicable	201.7.9.2.14.101 b)
Any known unacceptable *risk* associated with using the *ME equipment*, its parts or *accessories* for longer than the *expected service life*	211.7.4.8 100)
A-weighted sound power level emitted by the *ventilatory support equipment*	201.9.6.2.1.101 b)
A-weighted sound pressure level emitted by the *ventilatory support equipment*	201.9.6.2.1.101 a)
Behaviour of the *ventilatory support equipment* after a switchover to the *internal electrical power source* or alternative *supply mains*	201.11.8.101.1 g) 2)
Behaviour of the *ventilatory support equipment* while the *internal electrical power source* or external reserve electrical power source is recharging	201.11.8.101.1 g) 3)
Description of the *internal electrical power source* care and maintenance *procedures*, 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 *operator*	201.7.9.2.13.101 a)
Disclosure of any restrictions on the placing of components within the *ventilator breathing system*, if applicable	201.7.9.2.14.101 a)
For the *healthcare professional operator instructions for use*, the information contained in instructions for use for *lay operator*	201.7.9.2.1.101 c)
For the *healthcare professional operator instructions for use*, a cross reference between the *manufacturer*-specific naming of the *ventilatory support equipment's ventilation-modes* and the *ventilation-mode* systematic coding scheme	201.7.9.2.9.101.2 b) 5)
For the *healthcare professional operator instructions for use*, a description of how the listed *alarm conditions* can be tested	201.7.9.2.9.101.2 b) 1)
For the *healthcare professional operator instructions for use*, any limitation of parameter settings	201.7.9.2.9.101.2 a) 5)
For the *healthcare professional operator instructions for use*, method by which all functions and settings necessary for *normal use* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 d)
For the *healthcare professional operator instructions for use*, the essential technical characteristics of each recommended *breathing system filter*, if applicable	201.7.9.2.9.101.2 c) 1)
For the *healthcare professional operator instructions for use*, the methods for controlling the cycling	201.7.9.2.9.101.2 a) 2)

Description of requirement	Subclause
For the *healthcare professional operator instructions for use*, the parameter settings	201.7.9.2.9.101.2 a) 3)
For the *healthcare professional operator instructions for use*, the range of parameter settings	201.7.9.2.9.101.2 a) 4)
For the *healthcare professional operator instructions for use*, the *rated* range of inspiratory and expiratory *gas pathway* resistances of the assembled *operator*-detachable 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 *healthcare professional operator instructions for use*, the *rated* range of compliance of the assembled *operator*-detachable 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)
For the *healthcare professional operator instructions for use*, the working principle of each of the *ventilatory support equipment's* ventilation modes including waveforms	201.7.9.2.9.101.2 a) 1)
For the *lay operator instructions for use*, a description of a means to determine the operation time of the *internal electrical power source*, if provided	201.7.9.2.9.101.1 b)
For the *lay operator instructions for use*, a description of how to connect a *distributed alarm system*, of provided	201.7.9.2.9.101.1 c)
For the *lay operator instructions for use*, conditions under which the *ventilatory support equipment* maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)
For the *lay operator instructions for use*, method by which the all of the *alarm signals*, including the *alarm signals* from *distributed alarm systems* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 3)
For the *lay operator instructions for use*, method by which the assembled breathing tubes and related *accessories* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 1)
For the *lay operator instructions for use*, method by which the switchover to and operation from the *internal electrical power supply* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 2)
For the *lay operator instructions for use*, the *model or type reference* needed to perform the pre-use check can be performed	201.15.102 c)
For the *lay operator instructions for use*, the *procedure* by which pre-use check can be performed	201.15.102 d)
Intended range of *tidal volume*	201.7.9.2.1.101 d)
Maximum duration of a *system recovery* of ventilation	201.4.3.102 g)
Maximum error of the *airway pressure* at the end of the *expiratory phase* in relation to the set value for a *pressure-control inflation-type* in *normal condition*	201.12.1.103 b) 3)
Maximum error of the *airway pressure* at the end of the *expiratory phase* in relation to the set value under leak for a *pressure-control inflation-type* in *normal condition* under leak condition	201.12.1.103 b) 4)

Description of requirement	Subclause
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value for a *pressure-control inflation-type* in *normal condition*	201.12.1.103 b) 1)
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value under leak for a *pressure-control inflation-type* in *normal condition* under leak condition	201.12.1.103 b) 2)
Maximum error of the *PEEP* in relation to the set *BAP* value for a *volume-control inflation-type* in *normal condition*	201.12.1.102 b) 2)
Maximum error of the *tidal volume* in relation to the set value for a *volume-control inflation-type* in *normal condition*	201.12.1.102 b) 1)
Minimum time between complete loss of *internal electrical power source* and the start of the *low priority* impending *internal electrical power source* failure *alarm condition*	201.11.8.101.1 g) 4) i)
Minimum time between complete loss of *internal electrical power source* and the *medium priority* impending *internal electrical power source* failure *alarm condition*	201.11.8.101.1 g) 4) ii)
Operational time of the power source when fully charged	201.11.8.101.1 g) 1)
Performance and pass-fail criteria for other *inflation-types* in *normal condition*	201.12.1.104 a)
Processing instructions for the *gas pathways* of the *ventilatory support equipment* and its *accessories*	201.11.6.6 cc) 2)
Processing instructions for the *ventilatory support equipment enclosure*	201.11.6.6 ee) 2)
Requirements of ISO 20417	201.7.1.101 a)
Separate *instructions for use* for *healthcare professional operator*	201.7.9.2.1.101 a) 2)
Separate *instructions for use* for *lay operator*	201.7.9.2.1.101 a) 1)
Specifications of any required *accessories* 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 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)
Summary description of the *ventilatory support equipment* algorithm for determining the *airway pressure alarm limit*, if provided	201.12.4.101 h)
Warning regarding Luer connection to the *gas pathway*, 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 as the ventilator might not function correctly leading to the risk of degradation of health of the patient	201.7.9.2.2.101 b)
Warning statement to the effect that do not connect the ventilator to the battery of a wheelchair battery-powered wheelchair unless the connection is listed in the instructions for use of the ventilator or wheelchair as this can affect the ventilator performance which consequently can result in degradation of health of the patient	201.7.9.2.2.101 e)
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 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 affect the ventilator performance which consequently can result in degradation of health of the patient	201.7.9.2.2.101 d)
Warning statement to the effect that the ventilation supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 h)
Warning statement to the effect that this ventilator is not suitable for a ventilator-dependent patient	201.7.9.2.2.101 g)
Warning 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	201.7.9.2.2.101 f)
Warning statement to the effect that when using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage, if applicable	201.7.9.2.2.101 c)
Which portions of the *gas pathways* through the *ventilatory support equipment* can become contaminated with body fluids or expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12 aa)

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

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

Table 201.C.104 — *Technical description*

Description of requirement	Subclause
Description of a method for checking the function of *alarm system* for *alarm conditions* of this document, if not performed automatically at start-up	201.7.9.3.101 a)
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 *operator*	201.7.9.3.1.101 f)
Listing of which *alarm conditions* that are checked automatically at start-up	201.7.9.3.101 b)
Means of restricting access	201.108
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*	201.7.9.3.1.101 c)
Requirements of ISO 20417	201.7.1.101
Responsible organization alarm system log capacity	208.6.12.3 i) 1)
Statement to the effect that the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories intended to be used to connect to the patient prior to use	201.7.9.3.1.101 e)

Description of requirement	Subclause
Summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means of initiating and terminating the *inflation phase* while the ventilator is operating in each of its ventilatory modes	201.7.9.3.1.101 d)
Summary description of the test method and *procedure* to test other *inflation-types*, if provided	201.12.1.104 e)
What happens to the contents of the *alarm system* log as it reaches capacity	208.6.12.3 i) 2)
What happens to the contents of the log after the *alarm system* has experienced a total loss of power (*supply mains* and *internal electrical power source*) for a finite duration	208.6.12.3 h)

Annex D
(informative)

Symbols on *marking*

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

Addition:

Table 201.D.1.101 — Additional *symbols* on *marking*

No	*Symbol*	Reference	Title and description
1		IEC 60878:2022 Symbol 7.3.1-1 of IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
2		IEC 60878:2022 Symbol 7.3.1-2 of IEC 62570:2014	MR Safe Alternative graphical *symbol* representation. Same meaning as IEC 62570:2014, 7.3.1-1.
3		IEC 60878:2022 *Symbol* 7.3.2 of IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. The MR Conditional *symbol* may be supplemented by supplementary *marking* that describes the conditions for which the item has been demonstrated to be MR Conditional.

No	*Symbol*	Reference	Title and description
4		IEC 60878:2022 Symbol 7.3.3 of IEC 62570:2014	MR Unsafe To identify an item which poses unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. Note – When color reproduction is not practical, the *symbol* 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:

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 a 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 80601-2-80 conforming *ventilatory support equipment* are used by *patients* who require minimal to moderate level of support to provide adequate gas exchange. 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 daily living. The most fragile of these *patients* would likely experience injury with the loss of this *artificial ventilation*.

Additional information is contained in ISO 21954.

ISO 80601-2-80 *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*.

— **201.3.288 *System recovery***

The concept of recovery is mentioned in IEC 62304:2006+AMD1:2015, 5.5.4 d). See also rationale for 201.4.3.102.

— **201.4.3.101 — Additional requirements for *essential performance***

Essential performance as "*ventilation* within the *alarm limits* set by the *operator* or generation of an *alarm condition*" is inclusive of those breaths that the *patient* modifies outside of the ventilatory parameters set by the *operator*, but still within the *alarm limits,* which are considered safe by the *operator*. It is expected that the *operator* sets appropriate *alarm limits,* which thereby define the *essential performance* for a particular *patient*.

The distributed *essential performance* criteria captured within Table 201.101 have been identified by the committees as the minimum clinical performance necessary to reduce the possibility of exposing the *patient* to unacceptable *risk*. Compliance criteria for some of the clauses within IEC 60601-1, ISO 80601-2-12 and the other applicable collateral standards includes "maintain *essential performance*". The committees have recognized the difficulty in confirming that all aspects of *essential performance* are maintained when completing longer duration testing.

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

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

— **201.4.3.102 — *System recovery***

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

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

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

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

— **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 *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 201.13.2.101.

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 flowrate 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 *ventilators* 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 flowrates 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 CO_2) 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 (~ 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 pressurised 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 flowrates.

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 recognise the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 % then 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 ±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 ±3 %.

Note that 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.

— **201.6.101 — Additional requirements for classification of *ME equipment* and *ME systems***

Patients who suffer from *ventilatory impairment* or *ventilatory insufficiency* get short of breath more easily because the work to breathe is increased. Even with supplemental oxygen usage, the feeling of shortness of breath and the fatigue caused by the increased work to breathe is likely to lead to a more sedentary lifestyle. A sedentary lifestyle causes a *patient's* body to lose oxygen usage efficiency and this leads to increasing shortness of breath with mobility (movement of skeletal muscles). This phenomenon is likely to cause a *patient* who suffers from *ventilatory impairment* or *ventilatory insufficiency* to get progressively weaker and less able to be mobile and participate in the activities of daily living (ADL). This also means that the *patient* is likely to get progressively more dependent on functional assistance from outside help.

Initially, the application of ventilatory support to reduce the work to breathe was limited to times when the *patient* with *ventilatory impairment* or *ventilatory insufficiency* was admitted to a healthcare facility due to an exacerbation or decompensation (cold, flu, or other contributing factor).

However, we have known for decades that providing *patients* with ventilatory support at home can reduce the work to breathe and ventilatory fatigue and therefore improve the ventilatory impaired/insufficient *patient's* ability to move about, exercise and participate in ADL.

This was demonstrated in a 1994 study that examined exercise tolerance and breathlessness in *patients* with severe Chronic Obstructive Pulmonary Disease (COPD). The study found that "IPS [inspiratory pressure support] improved median walking distance by 62 % compared with the control walk (sham circuit). There was no change in walking distance with either *CPAP* or oxygen at 2 l/min"[39].

When *ventilation* challenges and the retention of CO_2 first present in mild to moderate COPD (or other disease states), the *patient* 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 *patient* with *ventilatory-impairment* to continue to move about and participate in ADL. *Stationary ventilatory support equipment* (not *transit-operable*) that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

When the *ventilation* challenge reaches a more significant level, such as in severe COPD, it is more likely that ventilatory support is needed during waking and moving hours in order to facilitate mobility and functional independence in ADL. For this *ventilatory insufficiency patient* profile, it is important that the *ventilatory support equipment* be *transit-operable* so that it can accompany the *patient* while moving about and participating in ADL.

In conclusion, there is no doubt that exercise and maintaining an active social life with participation in ADL improves not only life expectancy but also life satisfaction. The ability to move and maintain independence that is more functional can also cut down on the need for a home health attendant. *Ventilatory support equipment* that is only *stationary* while in use can be adequate for use by a *patient* with *ventilatory impairment* but the *patient* with *ventilatory insufficiency* needs ventilatory support from *transit-operable ventilatory support equipment* that facilitates mobility, including doctor visits, and participation in ADL.

— **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 though 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 though the filter medium without effect. If there is a sufficiently high relative humidity, some *BSF*s can adsorb or absorb part of this humidity.

If the moisture exists as a liquid aerosol, the water droplets can also be retained by the filter.

The properties of a filter medium that govern the degree to which this interaction with water takes place is its relative affinity for water. A medium which readily attracts water is termed "hydrophilic" and a medium which repels water is termed "hydrophobic". These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

Another example of liquid phase water can be termed "bulk water". An example of this is the collected condensate that occurs in the expiratory limb of the *VBS*. Depending on the management of the circuit, and the positioning of the *BSF*, this bulk water can actually completely cover and occlude the filter. If a sufficient pressure is applied, the liquid water can be forced though the pores of the filter medium. This requires relatively low pressure for a hydrophilic filter and relatively high pressure for a hydrophobic filter.

The practical consequences of the latter scenario is that if liquid is forced though a hydrophilic *BSF*, gas flow blockage can be relieved, but any microorganisms removed by the filter can be carried past the filter with the liquid stream. In the case of a hydrophobic filter, the pressure in the *VBS* is usually not sufficient to force liquid though the medium, so the microbial retention is not compromised. Airflow occlusion persists, however, until steps are taking 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, *BSF*s are indicated for use in both applications.

Additional effects on *BSF* functionality can be caused by the introduction of substances other than water or gas into the device. Such substances can originate from the *patient* (e.g. sputum, exudates, blood, vomitus) or substances introduced by the *operator* into the *VBS* (e.g. gross amounts of medications intended to be nebulised for administration though the *VBS*).

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at 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 *BSF*s.

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.

— ***e)***

Wheelchair batteries, even though they mostly convey the appearance that they supply standard voltages for auxiliary battery-powered equipment, often provide neither the appropriate *connector* nor an adequate voltage range to safely supply the *ventilatory support equipment* for normal operation. Depending on the battery load condition required for the movement of the wheelchair, the voltages supplied at the auxiliary *connector* often show major voltage drops and simultaneous current limitations. It is reasonably foreseeable that these variations are often outside the external *supply mains* ratings of the *ventilatory support equipment*. These might adversely affect the performance of the *ventilatory support equipment* or in the extreme these voltage fluctuations might lead to a stoppage of *ventilation*. In addition, these *supply mains* variations can also adversely affect the electromagnetic compatibility of the *ventilatory support equipment*.

The *operator* needs to be aware that only wheelchairs listed in the *instructions for use* have been *validated* by the *manufacturer*. The use of non-*validated* wheelchairs can represent an unacceptable *risk* for the *patient*.

— **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.

— **201.7.9.2.9.101.1 *Lay operator* operating instructions**

— **c)**

This document requires that *instructions for use* for both the *lay operator* and the supervising clinician or *healthcare professional operator* describe methods of testing *ventilatory support*

equipment alarm conditions. It is useless to require these tests unless the tests serve the intended purpose of ensuring that *operators* are alerted to potentially *hazardous situations* while ventilating in the environment of use.

Alarm condition testing instructions for the *lay operator* need to provide simple tasks that create *alarm limit* violations without changing any *ventilatory support equipment* settings.

Lay operators have a need to know that the *alarm limits* are likely to be violated when common but potentially harmful situations occur. Since *lay operators* might not be allowed to change *ventilatory support equipment* settings, it is vitally important that they learn how to test a *ventilatory support equipment* while it is set up with prescribed settings to determine that *alarm limits* are violated during interruption of *ventilation* (due to disconnection, occlusion, etc.) and other potentially *hazardous situations*.

Alarm condition testing instructions for *lay operators* are similar to reverse troubleshooting. A series of simple tasks simulate problems and the *operator* verifies that the *alarm limits* intended to alert for each problem are violated. It is best if these simulations can be performed without a test lung. For improved *lay operator* confidence, the supervising clinician or *healthcare professional operator* might find it beneficial to demonstrate these tests for the *lay operator*.

For this type of *ventilator*, *alarm condition* testing instructions for *healthcare professional operators* should be as simple as possible, since it is intended that these *ventilators* are used outside of a hospital setting. These tests can require that the *operator* make settings changes and use a test lung in order to test whether the *ventilatory support equipment alarm systems* are fully functional.

— **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 *normal* 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.

— **201.7.9.2.9.101.2 — *Healthcare professional operator* operating instructions**

— ***b) 1)***

See rationale for 201.7.9.2.9.101.1 c).

— **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) 5)***

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[39]. 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[40].

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/kg 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 0,978 6 m^3/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[41]. This is confirmed by studies conducted by the U.S.

Navy Medical Research and Development Command[39], 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 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 document 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;

— 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 equipment or the next *patient* on whom the equipment 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);

— 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;

— 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*;

— 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;

— 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*;

   — 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;

— 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*;

— 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 use* 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*.

— **201.11.8.101.1 — *Internal electrical power source* and *alarm conditions***

Two hours was chosen as the minimum acceptable time necessary to ensure that alternative arrangements could be made to continue the function. Climatic, traffic and other conditions require at least this period before restoration of power or arrangement for other supplies.

— **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*;

— 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.

— **201.12.4.102 — *Maximum limited pressure protection device***

The value chosen for the *maximum limited pressure*[37][47] 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 .

— **201.12.4.106 — High leakage *alarm condition***

The high leakage *technical alarm condition* is permitted to be used as a surrogate for expired volume monitoring and its associated *alarm conditions*. The *manufacturer* needs to ensure that the high leakage *technical alarm condition* is robust and thereby proven to provide a reasonably safe alternative. It is suggested that a combination of flowrate, time, and pressure monitoring along with pattern recognition be used to determine that high leakage has occurred.

— **201.12.4.107 — CO_2 *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 CO_2 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 CO_2 *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*;