INTERNATIONAL STANDARD

ISO 80601-2-72

First edition
2015-09-01

Medical electrical equipment

Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

Appareils électromédicaux

Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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

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

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

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This first edition of ISO 80601-2-72 cancels and replaces the second edition of ISO 10651-2:2004. This edition of ISO 80601-2-72 constitutes a major technical revision of ISO 10651-2:2004 and includes an alignment with the third edition of IEC 60601-1 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

— extending the scope to include the VENTILATOR and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the VENTILATOR, and thus, not only the VENTILATOR itself;

— identification of ESSENTIAL PERFORMANCE for a VENTILATOR and its ACCESSORIES;

— modification of the obstruction of the expiratory limb (continuing AIRWAY PRESSURE) ALARM CONDITION requirement;

and the following additions:

— tests for ventilation performance;

— tests for mechanical strength (via IEC 60601-1-11);

— new symbols;

— requirements for a VENTILATOR as a component of an ME SYSTEM;

— tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);

— tests for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);

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

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

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

— *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

— *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

— *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

— *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use*

— *Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment*

— *Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

— *Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

— *Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

IEC 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*

— *Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

— *Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

— *Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*

— *Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

The ISO and IEC 80601 family of standards are also parts of the IEC 60601 family of standards.

Introduction

This part of ISO 80601 specifies requirements for lung ventilators that are intended for use in the HOME HEALTHCARE ENVIRONMENT for PATIENTS who are dependent for ventilation for their life support. These VENTILATORS are frequently used in locations where the power driving the VENTILATOR is not reliable. These VENTILATORS are often supervised by non-healthcare personnel (LAY OPERATORS) with varying levels of training. Lung ventilators complying with this standard can be used elsewhere (i.e. in healthcare facilities).

In referring to the structure of this part of ISO 80601,

— "clause" means one of the 17 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes 7.1, 7.2, etc.), and

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this part of ISO 80601 are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular part of ISO 80601 are by number only.

In this part of ISO 80601, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this part of ISO 80601 conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this part of ISO 80601, the auxiliary verb

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80601,

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80601, and

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations might need a transitional period following publication of a new, amended, or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this part of ISO 80601 not be adopted for mandatory implementation nationally earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

201.1 Scope, object, and related standards

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

201.1.1 *Scope

IEC 60601-1:2005+AMD1:2012, 1.1 is replaced by:

This part of ISO 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a VENTILATOR in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT:

— intended for use in the HOME HEALTHCARE ENVIRONMENT;

— intended for use by a LAY OPERATOR;

— intended for use with PATIENTS who are dependent on mechanical ventilation for their life support.

NOTE 1 Such VENTILATORS can also be used for PATIENTS who are not dependent on ventilatory support.

NOTE 2 In the HOME HEALTHCARE ENVIRONMENT, the power driving the VENTILATOR is often not reliable.

NOTE 3 Such VENTILATORS can also be used in non-critical care applications of professional health care facilities.

This part of ISO 80601 is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a VENTILATOR BREATHING SYSTEM or to a VENTILATOR where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR.

EXAMPLES Breathing tubes, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, and 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 part of ISO 80601 are not covered by specific requirements in this part of ISO 80601 except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

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

This part of ISO 80601 is not applicable to continuous positive airway pressure (CPAP) ME EQUIPMENT, high-frequency jet ventilators (HFJVs), and high-frequency oscillatory ventilators (HFOVs)[35].

This part of ISO 80601 does not specify the requirements for cuirass and “iron-lung” VENTILATORS.

This part of ISO 80601 does not specify the requirements for VENTILATORS or ACCESSORIES intended for critical care applications, which are given in ISO 80601-2-12.

This part of ISO 80601 does not specify the requirements for VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in ISO 80601-2-13.

This part of ISO 80601 does not specify the requirements for VENTILATORS or ACCESSORIES intended for emergency and transport which are given in ISO 10651-3.

NOTE 5 In the future, ISO 10651-3 is expected to be harmonized with IEC 60601-1:2005, at which time it will be replaced by ISO 80601-2-xx.

This part of ISO 80601 does not specify the requirements for VENTILATORS or ACCESSORIES intended for home-care ventilatory support equipment (intended only to augment the ventilation of spontaneously breathing PATIENTS), which are given in ISO 10651-6.

NOTE 6 In the future, ISO 10651-6 is expected to be harmonized with IEC 60601-1:2005 and IEC 60601-1-11:2015, at which time it will be replaced by ISO 80601-2-xx.

This part of ISO 80601 does not specify the requirements for obstructive sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70.[16]

This part of ISO 80601 is a particular International Standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

201.1.2 Object

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

The object of this part of ISO 80601 is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a VENTILATOR, as defined in 201.3.217, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the VENTILATOR and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of a VENTILATOR.

201.1.3 Collateral standards

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

This part of ISO 80601 refers to those applicable collateral standards that are listed in IEC 60601-1:2005+AMD1:2012, Clause 2, as well as 201.2 of this part of ISO 80601.

IEC 60601-1-3:2008 does not apply.

201.1.4 Particular standards

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

In the IEC 60601 series, particular standards can modify, replace, or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this part of ISO 80601 as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this part of ISO 80601 corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this part of ISO 80601 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 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

— "Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this part of ISO 80601.

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

— "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is amended as indicated by the text of this part of ISO 80601.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to IEC 60601-1:2005+AMD1:2012, any applicable collateral standards, and this part of ISO 80601 taken together.

Where there is no corresponding clause or subclause in this part of ISO 80601, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this part of ISO 80601.

201.2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography beginning on page 81.

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

Replacement:

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

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

IEC 60601-1-8:2006[2], *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+Amendment 1:2012

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

[1] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

[2] There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

IEC 61672-1:2002, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

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

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8185:2007[3], *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

ISO 8836:2007, *Suction catheters for use in the respiratory tract*

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 11195:1995, *Gas mixers for medical use — Stand-alone gas mixers*

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

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[3] To be replaced by ISO 80601-2-74.

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

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

ISO 80601-2-55:2011, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 17510:—[4], *Sleep apnoea breathing therapy masks and application accessories*

IEC 60601-1:2005[5], *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
+Amendment 1:2012

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

IEC 62366:2007[6], *Medical devices — Application of usability engineering to medical devices*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2007, ISO 8185:2007, ISO 9360-1:2000, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010 +AMD1:2013, IEC 60601-1-8:2006+AMD1:2012, IEC 62304:2006, IEC 62366:2007+AMD1:2014, ISO 4135:2001, and the following apply.

Addition:

201.3.201
AIRWAY PRESSURE
P_{aw}
pressure at the PATIENT-CONNECTION PORT

201.3.202
BREATHING SYSTEM FILTER
BSF
device intended to reduce transmission of particulates, including microorganisms, in breathing systems

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

201.3.203
DELIVERED VOLUME
V_{del}
volume of gas delivered through a PATIENT-CONNECTION PORT during a breath

Note 1 to entry: DELIVERED VOLUME is also referred to as tidal volume when all of the DELIVERED VOLUME enters the PATIENT'S respiratory tract. This is frequently not the case when there is significant leakage around an uncuffed (as in neonates) or otherwise unsealed tracheal tube or during non-invasive ventilation.

[SOURCE: ISO 4135:2001, 3.4.2 modified — Replaced the 'inspiratory phases' with 'a breath' and added note to entry.]

[4] To be published.

[5] There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

[6] There exists a consolidated edition 2.1(2014) including IEC 62366:2007 and its Amendment 1:2014.

201.3.204
EXHAUST PORT
port through which waste gas is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

[SOURCE: ISO 4135:2001, 4.2.1.6, modified—Deleted 'excess and/or'.]

201.3.205
FLOW-DIRECTION-SENSITIVE COMPONENT
component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

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

201.3.206
FRESH GAS
respirable gas delivered to a VENTILATOR BREATHING SYSTEM

Note 1 to entry: FRESH GAS does not include the following:

— air drawn through the emergency intake port;

— air drawn through leaks in the VENTILATOR BREATHING SYSTEM;

— gas exhaled by the PATIENT.

[SOURCE: ISO 4135:2001, 3.1.8, modified — Added 'VENTILATOR' and note to entry.]

201.3.207
GAS INTAKE PORT
port through which gas is drawn for use by the PATIENT

[SOURCE: ISO 4135:2001, 3.2.11, modified — Replaced 'a ventilator or by a patient' with 'for use by the PATIENT'.]

201.3.208
GAS OUTPUT PORT
port through which gas is delivered at respiratory pressures through the inspiratory limb to the PATIENT-CONNECTION PORT

[SOURCE: ISO 4135:2001, 3.2.8, modified — Deleted 'of a ventilator' and replaced 'through a tube' with 'through the inspiratory limb'.]

201.3.209
GAS RETURN PORT
port through which gas is returned at respiratory pressures via the expiratory limb from the PATIENT-CONNECTION PORT

[SOURCE: ISO 4135:2001, 3.2.9, modified — Deleted 'of a ventilator' and replaced 'through a tube' with 'via the expiratory limb'.]

201.3.210
HIGH-PRESSURE INPUT PORT
input port to which gas is supplied at a pressure exceeding 100 kPa

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

201.3.211
MANUAL VENTILATION PORT
port to which a manual inflating device can be connected

[SOURCE: ISO 4135:2001, 3.2.12 modified — Deleted 'of a ventilator' and replaced 'may' with 'can'.]

201.3.212
MAXIMUM LIMITED PRESSURE
$P_{LIM\ max}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

201.3.213
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and indicates the value of a variable to the OPERATOR

201.3.214
PATIENT-CONNECTION PORT
port at the PATIENT end of a VENTILATOR BREATHING SYSTEM intended for connection to an airway device

EXAMPLES Tracheal tube, tracheostomy tube, face MASK, and supralaryngeal airway are all airway devices.

Note 1 to entry: The PATIENT-CONNECTION PORT is the end of the VENTILATOR BREATHING SYSTEM proximal to the PATIENT.

[SOURCE: ISO 4135:2001, 4.2.1.2, modified — Added 'VENTILATOR' and note to entry and modernized the examples.]

201.3.215
PEEP
POSITIVE END-EXPIRATORY PRESSURE
positive AIRWAY PRESSURE at the end of an expiratory phase

[SOURCE: ISO 4135:2001, 3.3.11]

201.3.216
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

201.3.217
VENTILATOR
VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT
ME EQUIPMENT intended to augment or provide ventilation of the lungs of a PATIENT who is dependent on this ventilation in the HOME HEALTHCARE ENVIRONMENT

Note 1 to entry: For the purposes of this part of ISO 80601, dependent means needed for the majority of the day (e.g. an average need of more than 16 h of ventilation per day).

Note 2 to entry: A VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT is typically used without continuous healthcare professional supervision.

Note 3 to entry: As this VENTILATOR is intended to be applied to PATIENTS who are VENTILATOR-dependent, the VENTILATOR is considered to be a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

Note 4 to entry: A VENTILATOR complying with ISO 80601 may also be used in lower acuity settings in professional healthcare facilities.

201.3.218
VENTILATOR BREATHING SYSTEM
VBS
inspiratory or expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which FRESH GAS enters, the PATIENT-CONNECTION PORT, and the EXHAUST PORT

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+AMD1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101* Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or	[a]
generation of an ALARM CONDITION	
AIRWAY PRESSURE	201.12.4.102
continuing positive-pressure	201.12.4.110
DELIVERED VOLUME	201.12.1.104
expired $etCO_2$[b], if provided	201.12.4.104
high AIRWAY PRESSURE	201.12.4.106
hypoventilation	201.12.4.109
INTERNAL ELECTRICAL POWER SOURCE nears depletion	211.8.4.101
high leakage	201.12.4.111
low expired volume[c], if provided	201.12.4.103
obstruction	201.12.4.107
oxygen levels[d], if provided	201.12.4.101

[a] 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by ISO 80601 series.

[b] If expired volume monitoring is not provided or high leakage is not in use.

[c] If $etCO_2$ monitoring or high leakage is not in use.

[d] If a control for the setting of the inspiratory oxygen concentration is provided.

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):

The gas pathways shall be subject to the requirements for APPLIED PARTS according to this subclause. 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.

201.4.10.2* SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

The characteristics of the SUPPLY MAINS specified in 4.10.2 of the general standard apply, except for the following.

Replacement of the tenth dash as follows.

— For operation from 12 V d.c. SUPPLY MAINS

  — the RATED range shall include at least 12,4 V to 15,1 V, and

  — the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V.

— for operation from 24 V d.c. SUPPLY MAINS

— the RATED range shall include at least 24,8 V to 30,3 V, and

— the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 20 V.

— for operation from other d.c. SUPPLY MAINS

— 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

201.4.11.101.1 Overpressure requirement

If the VENTILATOR is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2007, then it shall operate and meet the requirements of this part of ISO 80601 throughout its RATED range of input pressure and shall 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 VENTILATOR is likely to be outside of its specification.

If the VENTILATOR has a maximum RATED input pressure in excess of 600 kPa, the VENTILATOR shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings, by functional testing in SINGLE FAULT CONDITION and inspection of the RISK MANAGEMENT FILE.

201.4.11.101.2 Compatibility requirement

If the VENTILATOR is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2007, then

— the RATED range of input pressure shall cover the range specified in ISO 7396-1:2007, and

— under NORMAL CONDITION,

1) the maximum 10 s average input flow required by the VENTILATOR for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port, and

2) the transient input flow 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 flow required by the VENTILATOR for each gas at a pressure of 280 kPa, measured at the gas input port;

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

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

Check compliance 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.

201.5 General requirements for testing of ME EQUIPMENT

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

Addition:

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

201.5.101.1 VENTILATOR test conditions

For testing, the VENTILATOR shall be connected to gas supplies as specified for NORMAL USE, except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated. When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

201.5.101.2* Gas flowrate and leakage specifications

In this part of ISO 80601, requirements for the flowrate, volume, and leakage are expressed at standard temperature and pressure, dry (STPD), except for those associated with the VBS, which are expressed at body temperature and pressure, saturated (BTPS).

NOTE 1 For the purposes of this part of ISO 80601, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this part of ISO 80601, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

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

201.5.101.3* VENTILATOR testing errors

For the purposes of this part of ISO 80601, declared tolerances shall include the measurement uncertainty. The MANUFACTURER shall disclose the measurement uncertainty of each disclosed tolerance in the technical description.

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking, and documents

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

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

IEC 60601-1:2005+AMD1:2012, 7.2.3 applies, except as follows.

Replacement:

The VENTILATOR shall be marked with the safety sign for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012, Table D.2, Number 10).

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101, 201.7.2.13.101, and 201.7.2.17.101 and shall be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR, if applicable. 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 VENTILATOR MANUFACTURER or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure compliance with this requirement. Additional requirements are found in 201.102.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.13.101 Additional requirements for physiological effects

Any natural rubber latex-containing components in the gas pathways or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.4.5 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 4) may be used. The instructions for use shall disclose any natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

The marking on packages shall be CLEARLY LEGIBLE and shall include the following:

a) description of the contents;

b) identification reference to the batch, type, or serial number or symbols 5.1.5, 5.1.6, or 5.1.7 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 1, symbol 2, or symbol 3);

c) for packages containing natural rubber latex, the word "LATEX" or symbol 5.4.5 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 4).

For a specific MODEL OR TYPE REFERENCE, the indication of single-use shall be consistent for the MODEL OR TYPE REFERENCE.

Check compliance by inspection.

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

The marking of ME EQUIPMENT, parts, or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

a) any special storage and/or handling instructions;

b) any particular warnings and/or precautions relevant to the immediate operation of the VENTILATOR.

If applicable, marking of OPERATOR-accessible ME EQUIPMENT parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

c) for any gas-specific inputs or outlets,

— the gas name or chemical symbol in accordance with ISO 5359:2008,

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

EXAMPLE 1 For flow controls, flexible hoses, gas cylinders.

NOTE In some countries, other colour coding is used.

d) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;

e) a warning not to obstruct the GAS INTAKE PORT.

EXAMPLE 2 WARNING: Gas Intake – Do not obstruct.

Check compliance by inspection.

201.7.4.2 Control devices

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

Amendment (add after the second dash):

The marking of the trigger sensitivity control shall be such that the minimum (least PATIENT effort) and the maximum (greatest PATIENT effort) trigger sensitivity settings are self-evident to the OPERATOR. The marking, if numeric, shall not only be numeric.

201.7.4.3 * Units of measurement

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

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

All gas volume, flow, and leakage specifications shall be expressed at standard temperature and pressure, dry (STPD) except those associated with the VBS which shall be expressed at body temperature and pressure, saturated (BTPS) absolute VBS pressure.

NOTE 1 For the purposes of this part of ISO 80601, STPD is 101.3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this part of ISO 80601, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

The unit of AIRWAY PRESSURE measurement shall be capable of being configured to be expressed in hPa.

201.7.9.1 Additional general requirements

IEC 60601-1:2005+AMD1:2012, 7.9.1 applies, except as follows.

Amendment (replace the first dash with):

— Name or trade name and address of the following:

  — the MANUFACTURER; and

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

  to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012, 7.9.2 applies, except as follows.

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

Separate instructions for use shall be provided for the following:

— LAY OPERATOR;

— supervising clinician or the healthcare professional OPERATOR.

The MANUFACTURER may choose in which instructions for use to place the information required by this part of ISO 80601 unless otherwise indicated in this part of ISO 80601 based on RISK MANAGEMENT and USABILITY considerations.

The supervising clinician or the healthcare professional OPERATOR instructions for use shall include the information contained in the LAY OPERATOR instructions for use.

Check compliance by inspection of the instructions for use, the RISK MANAGEMENT FILE, and USABILITY ENGINEERING FILE.

201.7.9.2.1.102 Additional general requirements

The instructions for use shall include the following:

a) if the VENTILATOR, its parts, or ACCESSORIES are intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the VENTILATOR, its parts, or ACCESSORIES were reused;

b) if the VENTILATOR, its parts, or ACCESSORIES are intended for single-use, information regarding the intended duration of use.

Check compliance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include the following:

a) warning statement to the effect of "WARNING: To prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions."

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

EXAMPLE 1 WARNING: Do not position next to a curtain that blocks the flow of cooling air, thereby causing the ME EQUIPMENT to overheat.

EXAMPLE 2 WARNING: Do not block the GAS INTAKE PORT or EMERGENCY INTAKE PORT, thereby interfering with PATIENT ventilation.

c) warning statement to the effect of "WARNING: Always have immediate access to an alternative means of ventilation, which is ready for use, to avoid patient death or serious injury."

EXAMPLE 3 Failure to have an alternative means of ventilation such as a second VENTILATOR of the same type or a self-inflating, manually powered resuscitator (as specified in ISO 10651-4) with MASK can result in PATIENT death if the VENTILATOR fails.

d) * a warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that are not listed in the instruction for use as the ventilator might not function correctly."

e) * 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 of "WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage."

f) warning statement to the effect of "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 affect the ventilator performance which consequently can result in patient death."

g) * warning statement to the effect of "WARNING: Do not connect the ventilator to the battery of a battery-powered wheelchair unless the connection is listed in the instruction for use of the ventilator or wheelchair as this can affect the ventilator performance which can consequently result in patient death."

h) warning statement to the effect of "WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use to prevent adverse ventilator performance which can consequently result in patient death."

i) warning statement to the effect of "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".

j) if applicable, a warning statement to the effect of "WARNING: The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser."

k) if applicable, a warning statement to the effect of "WARNING: Unintentional leaks cause indicated volume and expired CO_2 values to differ from actual patient values."

Check compliance by inspection of the instructions for use.

201.7.9.2.8.101 * Additional requirements for start-up PROCEDURE

NOTE 1 For the purposes of this part of ISO 80601, a start-up PROCEDURE is a pre-use functional test that is used to determine whether the VENTILATOR is ready for use.

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:

— the assembled breathing tubes and related ACCESSORIES;

— switchover to and operation from the INTERNAL ELECTRICAL POWER SUPPLY;

— all ALARM SIGNALS, including the ALARM SIGNALS from DISTRIBUTED ALARM SYSTEMS,

Portions of these test methods can be performed automatically by the VENTILATOR or can require OPERATOR action.

EXAMPLE 1 Combination of the power-on self-test routines and OPERATOR actions that functionally check the ALARM SIGNALS.

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 2 Additional requirements are also found in 201.15.102.

The instructions for use for the supervising clinician or the healthcare professional OPERATOR shall disclose a method by which all functions and settings necessary for NORMAL USE and can be functionally

tested to determine if they are operating correctly. Portions of this test method can be performed automatically by the VENTILATOR or can require OPERATOR action.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 * Additional requirements for operating instructions

201.7.9.2.9.101.1 * LAY OPERATOR operating instructions

The instructions for use intended for the LAY OPERATOR shall include the following:

a) the conditions under which the VENTILATOR 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) an explanation of the meaning of the IP classification marked on the ME EQUIPMENT;

c) an indication as to whether the VENTILATOR is intended for non-invasive ventilation;

EXAMPLE 3 MASK ventilation.

d) * a description of how at least the following ALARM CONDITIONS can be tested:

— high leakage;

— INTERNAL ELECTRICAL POWER SOURCE nears depletion;

— low AIRWAY PRESSURE;

— low inspiratory pressure;

— obstruction;

— power failure of external mains;

— power failure of external DC power

e) a description of how the following ALARM CONDITIONS, if provided, can be tested:

— low expired volume;

— oxygen levels

f) a description of a means to determine the operation time of the INTERNAL ELECTRICAL POWER SOURCE;

g) a description of how to connect and test the connection of a DISTRIBUTED ALARM SYSTEM.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101.2 * Supervising clinician operating instructions

The instructions for use intended for the supervising clinician or the healthcare professional OPERATOR shall include a detailed description of the function of all ventilation modes provided by the VENTILATOR, including but not limited to, the following items:

a) working principle of each of the VENTILATOR'S ventilation modes including waveforms;

b) methods for controlling the cycling;

c) parameter settings;

d) range of parameter settings;

e) any limitation of parameter settings;

f) * a description of how at least the following ALARM CONDITIONS, if included, can be tested:

- continuing positive-pressure;
- DELIVERED VOLUME;
- high AIRWAY PRESSURE;
- high expiratory volume;
- hypoventilation; and
- low expiratory volume.

The instructions for use intended for the supervising clinician or the healthcare professional OPERATOR shall include

g) 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:

- inspiratory gas pathway resistance;
- expiratory gas pathway resistance;
- compliance.

These specifications may be presented in ranges. The accuracies of set and monitored volumes may be presented as a function of these characteristics.

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

If applicable, instructions for use intended for the supervising clinician or the healthcare professional OPERATOR shall disclose

h) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER, and

EXAMPLES Dead space and resistance.

i) a statement as to whether any portion of the gas supplied to a HIGH-PRESSURE INPUT PORT is supplied to the PATIENT.

Check compliance by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection, and sterilization

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

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

The instructions for use shall identify any portions of the gas pathways through the VENTILATOR that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

201.7.9.2.13.101 Additional requirements for maintenance

The instructions for use shall disclose the following:

a) a description of periodic visual safety inspections that should be performed by the OPERATOR;

b) the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging and replacement.

Check compliance by inspection of the instructions for use.

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

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

a) any restrictions on the positioning of components within the VENTILATOR BREATHING SYSTEM;

EXAMPLE Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

b) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the VENTILATOR.

Check compliance 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

The technical description shall disclose the following:

a) summary description of the filtering and/or smoothing techniques for all measured and/or computed variables that are displayed or used for control;

b) interdependence of control functions;

c) pneumatic diagram of the VENTILATOR, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use;

d) summary description of the means of initiating and terminating the inspiratory phase while the ventilator is operating in each of its ventilatory modes;

e) means by which the continuing pressure ALARM CONDITION is detected and a summary description of the detection algorithm;

f) 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.

Check compliance by inspection of the technical description.

201.7.9.3.101 Additional requirements for the technical description

The technical description shall disclose a description of a method for checking the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this part of ISO 80601, if not performed automatically during start-up. The technical description shall disclose which checks are performed automatically.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

A TRANSIT-OPERABLE VENTILATOR shall include a means by which the VENTILATOR can be easily immobilized without the use of a TOOL to prevent unwanted movement during transport while in use.

EXAMPLES Means to attach during transport in a personal vehicle, in an ambulance, or on a wheelchair.

Compliance is checked by functional testing.

201.9.4.4 Grips and other handling devices

Replace list item b) with the following:

b) The VENTILATOR shall have a carrying handle suitably placed to enable the VENTILATOR to be carried by one hand.

Compliance is checked by carrying.

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

The A-weighted sound pressure level emitted by the VENTILATOR shall be measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2 and disclosed in the instructions for use. The A-weighted sound power level shall be calculated according to ISO 3744:2010, 8.1 and disclosed in the instructions for use.

Check compliance with the following test:

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

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

b) If a HUMIDIFIER is provided with the VENTILATOR, include the HUMIDIFIER in the test and fill to the least favourable level.

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

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

— *Connect the PATIENT-CONNECTION PORT to the test lung.*

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a VENTILATOR intended to provide DELIVERED VOLUME		
	$V_{del} \geq 300$ ml	300 ml $\geq V_{del} \geq 50$ ml	$V_{del} \leq 50$ ml
DELIVERED VOLUME, V_{del}[a]	500 ml	150 ml	30 ml
Ventilatory frequency, f	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1:2	1:2	1:2
PEEP	5 hPa	5 hPa	5 hPa
Resistance, R[b][30][42][45]	5 hPa$(l/s)^{-1}$ ± 10 %	20 hPa$(l/s)^{-1}$ ± 10 %	50 hPa$(l/s)^{-1}$ ± 10 %
Isothermal Compliance, C[b]	50 ml $(hPa)^{-1}$ ± 5 %	20 ml $(hPa)^{-1}$ ± 5 %	1 ml $(hPa)^{-1}$ ± 5 %

[a] V_{del} is measured by means of a pressure sensor on the test lung, where $V_T = C \times P_{max}$.

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

d) Set the VENTILATOR to the least favourable mode, breath type, and flow pattern, as applicable, that generates ventilation as indicated in Table 201.102.

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

e) Using the microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2002, measure the sound pressure levels at ten positions in a hemisphere with a radius from the geometric centre of the VENTILATOR as specified in ISO 3744:2010, 7.2.

f) Calculate the A-weighted sound pressure level averaged over the measurement surface according to ISO 3744:2010, 8.1.

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

h) Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.

i) Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744:2010. Average the values in accordance with ISO 3744:2010, 8.1.

j) Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+AMD1:2012, 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):

Over the RATED flowrate range and at the maximum RATED operating temperature, the temperature of the gas delivered by the VENTILATOR, both with and without a HUMIDIFIER, shall not exceed an energy

equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m³ 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	71

201.11.6.4 Leakage

Amendment (add after existing text):

The MANUFACTURER of a VENTILATOR, VBS, its parts, and ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway. Special attention shall be given to substances which are carcinogenic, mutagenic, or toxic to reproduction.

The ACCESSIBLE PARTS and gas pathways of a VENTILATOR, VBS, its parts, or ACCESSORIES that contain phthalates which are classified as carcinogenic, mutagenic, or toxic to reproduction shall be marked on the device itself or on the packaging that it contains phthalates. If the INTENDED USE of a VENTILATOR, VBS, its parts, or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The instructions for use of a VENTILATOR, VBS, its parts, or ACCESSORIES that contain such phthalates shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic, or toxic to reproduction and justification for their use.

Additional subclause:

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

Gas pathways through the VENTILATOR and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in IEC 60601-1:2005, 11.6.7 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1-11:2015, Clause 8). Dismantling or parts replacement may be performed.

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

VENTILATOR 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.

Instructions for processing and reprocessing the VENTILATOR and its ACCESSORIES shall comply with ISO 17664:2004 and ISO 14937:2009 and shall be disclosed in the instructions for use.

NOTE 1 ISO 14159 provides guidance for the design of enclosures.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this part of ISO 80601 could be affected by the cleaning or the disinfecting of the VENTILATOR or its parts or ACCESSORIES, clean and disinfect them 10 times in accordance with the methods indicated in the instruction for use, including any cooling or drying period. After these PROCEDURES, ensure that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Confirm that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

NOTE 2 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 Additional requirements are found in IEC 60601–1:2005 and IEC 60601–1:2005/AMD1:2012, 11.6.6 and IEC 60601–1-11:2015, Clause 8.

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

The VENTILATOR shall have a means of connection to an alternative SUPPLY MAINS. The instructions for use shall include the following:

a) description of the means of connection;

b) RATED voltage range;

c) NOMINAL voltage range;

d) maximum current required.

A means of connection to an automotive vehicle power source should be provided.

EXAMPLES A 12 V d.c., 100 W connector, or other MAINS CONNECTOR.

Compliance is checked 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, Clause 12 applies, except as follows.

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls and indicators of a VENTILATOR shall be CLEARLY LEGIBLE under the conditions specified in IEC 60601-1:2005+AMD1:2012, 7.1.2, but with the subtended angle increased from '30°' to '45°' and the light level extended from the range of '100 lx to 1 500 lx' to the range of '1 lx to 10 000 lx'.

The VENTILATOR may provide means to reduce the visibility of its controls and indicators either automatically or by the OPERATOR action. If provided, the VENTILATOR shall automatically resume normal visibility during an ALARM CONDITION.

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

Additional subclauses:

201.12.1.101 Breath types

A VENTILATOR shall be equipped with at least a volume-controlled or pressure-controlled breath type.

Check compliance by inspection.

201.12.1.102 Volume-controlled breath type

If a volume-controlled breath type is provided, then with a volume-controlled breath type selected and the VENTILATOR operating in NORMAL CONDITION, the accuracy as determined for the test settings and conditions specified in this part of ISO 80601 shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

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

This disclosure shall include at least the following:

— maximum error of the DELIVERED VOLUME in relation to the set value;

— maximum error of the PEEP in relation to the set value;

— if provided with a control for the setting of the inspiratory oxygen concentration, the maximum error of the inspiratory oxygen concentration (FiO_2) at the PATIENT-CONNECTION PORT in relation to the set value.

All of the errors may be separately reported for the following ranges of intended DELIVERED VOLUME:

— $V_{del} \geq 300$ ml;

— 300 ml $\geq V_{del} \geq 50$ ml;

— $V_{del} \leq 50$ ml.

The accuracy of the performance of the VENTILATOR shall be either of the following:

— determined for each VBS configuration indicated in the instructions for use;

— 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 DELIVERED VOLUME.

If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the following tests:

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

a) DELIVERED VOLUME and end-expiratory pressure errors

1) Set up the VENTILATOR as shown in Figure 201.101.

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

3) Utilize the test parameters and settings of the first applicable row (selected by intended DELIVERED VOLUME) of Table 201.104. Wait for steady-state conditions to be achieved.

NOTE 3 Intentionally, 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.

4) Determine the DELIVERED 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 lung pressure compensated, if necessary, for temperature effects due to fast compression of the gas.

NOTE 4 Additional information on the construction of an isothermal test lung is found in Reference [34].

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 accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT by comparing its reading to the DELIVERED VOLUME determined in 4). Refer to 201.12.1.104.

7) Determine the PEEP as the average of the AIRWAY PRESSURE measurements over the last 50 ms of the expiratory phase.

8) Compare the result with the PEEP setting for the test. Confirm that the resulting difference is within the tolerance indicated in the instructions for use.

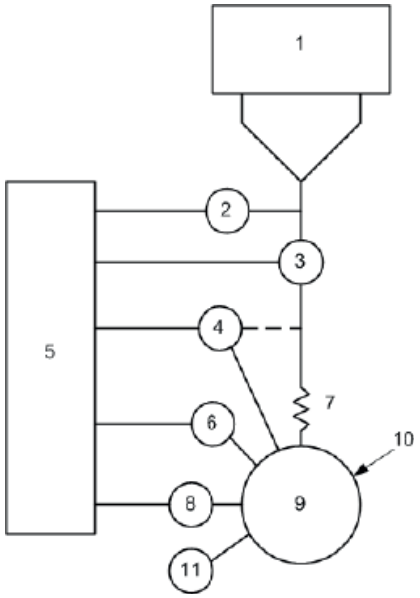
9) Repeat 3) to 8) for 30 consecutive breaths.

10) Repeat 3) to 9) for each applicable row (selected by intended DELIVERED VOLUME) of Table 201.104.

11) If a HUMIDIFIER is included in the VBS, repeat the DELIVERED VOLUME tests with the minimum HUMIDIFIER water level without re-determining the VBS compliance.

12) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat 2) to 11) for each flow pattern available on the VENTILATOR.

13) If the VENTILATOR permits operation without compliance correction, repeat 2) to 12) without compliance correction.



Key

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

NOTE The oxygen sensor may be placed in the VBS.

Figure 201.101 — Typical test setup for volume-control and pressure-control breath type accuracy

Table 201.104 — Volume-controlled breath TYPE TEST settings

Test number	Test lung parameters		VENTILATOR settings				
	Compliance (ml(hPa)$^{-1}$) ± 10 %	**Linear**[30][42][45] **resistance** (hPa(l/s)$^{-1}$) ± 10 %	**Volume** (ml)	**Ventilatory frequency** (breaths/min)	**INSPIRATORY TIME** (s)	**FiO_2**[a] (%)	**PEEP** (hPa)
1	50	5	500	20	1	28	5
2	50	20	500	20	1	35	10
3	20	5	500	20	1	35	5
4	20	20	500	20	1	28	10

Table 201.104 (*continued*)

Test number	Test lung parameters		VENTILATOR settings				
	Compliance (ml(hPa)$^{-1}$) ± 10 %	**Linear**[30][42][45] **resistance** (hPa(l/s)$^{-1}$) ± 10 %	**Volume** (ml)	**Ventilatory frequency** (breaths/min)	**INSPIRATORY TIME** (s)	**FiO$_2$**[a] (%)	**PEEP** (hPa)
5	20	20	300	20	1	28	5
6	20	50	300	20	1	35	10
7	10	50	300	20	1	28	10
8	10	20	200	20	1	35	5
9	3	20	50	30	0,6	28	5
10	3	50	50	30	0,6	28	10
11	3	200	50	30	0,6	35	5

[a] If the VENTILATOR is not provided with a control for the setting of the inspiratory oxygen concentration, room air is used.

b) FiO_2 error

14) If provided with a control for the setting of the inspiratory oxygen concentration, the accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration-measuring device at the PATIENT-CONNECTION PORT or inside the test lung. If the sensor is located at the PATIENT-CONNECTION PORT, the value of the concentration is the flow-weighted average concentration during the inspiratory phase.

15) Compare the measured O_2 concentration with the FiO_2 setting. Confirm that the difference is within the tolerance indicated in the instructions for use.

NOTE 5 If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration.

NOTE 6 If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inspiratory phase.

NOTE 7 If the O_2 concentration-measuring device has pressure dependencies, compensate for these dependencies.

16) Obtain the FiO_2 error by comparing the FiO_2 setting to the measured value for each test in a) above.

17) Confirm that each result is within the tolerance indicated in the instructions for use.

201.12.1.103 Pressure-controlled breath type

If a pressure-controlled breath type is provided, then with a pressure-controlled breath type selected and the VENTILATOR operating in NORMAL CONDITION, the accuracy as determined for the test settings and conditions specified in this part of ISO 80601 shall be disclosed in the instructions for use as the maximum bias error and maximum linearity error.

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

This disclosure shall include at least the following:

— the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the inspiratory phase in relation to the set value;

— the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the inspiratory phase in relation to the set value under leak condition;

— the maximum error of PEEP in relation to the set value;

— if provided with a control for the setting of the inspiratory oxygen concentration, the maximum error of the inspiratory oxygen concentration (FiO_2) at the PATIENT-CONNECTION PORT in relation to the set value.

All of the errors may be separately reported for the following ranges of intended DELIVERED VOLUME:

— $V_{del} \geq 300$ ml;

— 300 ml $\geq V_{del} \geq 50$ ml;

— $V_{del} \leq 50$ ml.

The accuracy of the performance of the VENTILATOR shall be either of the following:

— determined for each VBS configuration indicated in the instructions for use;

— 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 DELIVERED VOLUME range.

If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the following tests:

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

a) End-inspiratory and end-expiratory pressure errors

1) Set up the VENTILATOR as shown in Figure 201.101.

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

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

NOTE 3 Intentionally, 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.

4) Determine the AIRWAY PRESSURE at the end of the inspiratory 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 DELIVERED VOLUME, for example, by integration of the flow signal provided by a calibrated flow sensor located at the PATIENT-CONNECTION PORT or for a VENTILATOR that indicates a leakage-compensated DELIVERED VOLUME by the product of the test lung compliance and the measured change of lung pressure, if necessary, compensated for temperature effects due to fast compression of the gas.*

NOTE 4 Additional information on the construction of an isothermal test lung is found in Reference [34].

7) *Determine the accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT by comparing its reading to the DELIVERED VOLUME determined in 6). Refer to 201.12.1.104.*

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

9) *Compare the result with the PEEP setting for the test. Confirm that the resulting difference is within the tolerance indicated in the instructions for use.*

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

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

12) *If a HUMIDIFIER is included in the VBS, repeat the AIRWAY PRESSURE tests with the minimum HUMIDIFIER water level without re-determining the VBS compliance.*

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

b) *FiO_2 error*

14) *If provided with a control for the setting of the inspiratory oxygen concentration, the accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration measuring device at the PATIENT-CONNECTION PORT or inside the test lung. If the sensor is located at the PATIENT-CONNECTION PORT, the value of the concentration is the flow-weighted average concentration as a function of flow during the inspiratory phase.*

15) *Compare the measured O_2 concentration with the FiO_2 setting. Confirm that the difference is within the tolerance indicated in the instructions for use.*

NOTE 5 If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration.

NOTE 6 If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inspiratory phase.

NOTE 7 If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.

16) *Obtain the FiO_2 error by comparing the FiO_2 setting to the measured value for each test in a) above.*

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

Table 201.105 — Pressure-controlled breath TYPE TEST settings

Test number	Intended DELIVERED VOLUME[a] (ml)	Test lung parameters			VENTILATOR settings				
		Compliance (ml(hPa)$^{-1}$) ± 10 %	Linear[30] [42][45] Resistance (hPa(l/s)$^{-1}$) ± 10 %	Leakage[b] (ml/min) ±10 %	Ventilatory frequency (breaths/min)	INSPIRATORY TIME[c] (s)	Pressure[d] (hPa)	FiO_2[e] (%)	PEEP (hPa)
1	500	50	5	0	20	1	10	28	5
2	500	50	20	0	20	1	15	35	10
3	500	20	5	0	20	1	25	35	5
4	500	20	20	0	20	1	25	28	10
5	500	50	5	5 000	20	1	25	28	5
6	500	50	20	10 000	20	1	25	35	10
7	300	20	20	0	20	1	15	28	5
8	300	20	50	0	20	1	25	35	10
9	300	10	50	0	20	1	30	35	5
10	300	20	20	3 000	20	1	25	28	5
11	300	20	50	6 000	20	1	25	35	10
12	200	10	20	0	20	1	25	28	10
13	50	3	20	0	30	0,6	15	28	5
14	50	3	50	0	30	0,6	15	28	10
15	50	3	200	0	30	0,6	25	35	5

[a] The volume in this column is intended to be used for the selection of the test conditions and parameters based on the intended DELIVERED VOLUME of the VENTILATOR.

[b] For the purpose of this test, the VBS under test is set up with the leakage at a constant pressure of 20 hPa.

[c] The rise time of the VENTILATOR should be set to a value that ensures that the set pressure can be reached within the INSPIRATORY TIME.

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

[e] If the VENTILATOR is not provided with a control for the setting of the inspiratory oxygen concentration, room air is used.

201.12.1.104 * DELIVERED VOLUME MONITORING EQUIPMENT

The VENTILATOR shall be equipped with DELIVERED VOLUME MONITORING EQUIPMENT. The indication of the value of the DELIVERED VOLUME MONITORING EQUIPMENT and associated ALARM CONDITIONS may be disabled when the expired volume MONITORING EQUIPMENT is in use. The accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT shall be disclosed in the instructions for use. The indicated value of DELIVERED VOLUME may be displayed on OPERATOR demand.

The DELIVERED VOLUME MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects at least a MEDIUM PRIORITY ALARM CONDITION to indicate when the low DELIVERED VOLUME ALARM LIMIT is reached. The DELIVERED VOLUME MONITORING EQUIPMENT may be equipped with an ALARM SYSTEM that starts with a LOW PRIORITY ALARM CONDITION to indicate when the DELIVERED VOLUME reaches the ALARM LIMIT and, if this state continues, escalates to a MEDIUM PRIORITY ALARM CONDITION.

The DELIVERED VOLUME ALARM LIMIT may be pre-adjusted, RESPONSIBLE ORGANIZATION-adjustable, OPERATOR-adjustable, VENTILATOR-adjustable, or a combination of OPERATOR-adjustable and VENTILATOR-adjustable.

If the ALARM LIMIT is adjustable by the VENTILATOR, a summary description of the algorithm that determines the ALARM LIMIT value shall be disclosed in the instructions for use.

NOTE Depending on the type of ventilation mode being utilized, there can be more than one active ALARM LIMIT.

Check compliance with functional testing and the following.

Select and set up the worst-case VBS configuration indicated in the instructions for use.

EXAMPLE Minimum and maximum VBS compliance.

Confirm that the DELIVERED VOLUME MONITORING EQUIPMENT accuracy as measured in 201.12.1.102 a) 6) and 201.12.1.103 a) 7), as applicable, is within the accuracy disclosed in the instructions for use.

For a VBS that includes a HUMIDIFIER, repeat the tests at the minimum and maximum water levels (2 sets of tests for a HUMIDIFIER).

201.12.4 Protection against hazardous output

201.12.4.4 Incorrect output

IEC 60601-1:2005+AMD1:2012, 12.4.4 *applies, except as follows.*

Amendment (replace the compliance check with):

Any pressure setting change and its relation to any other pressure settings shall be displayed while the setting is performed.

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.

The VENTILATOR shall provide the RESPONSIBLE ORGANIZATION a means to allow the supervising clinician or the healthcare professional OPERATOR to have direct access to the ventilation settings and ALARM LIMITS (see 201.109).

The VENTILATOR shall provide the RESPONSIBLE ORGANIZATION or the supervising clinician or the healthcare professional OPERATOR a means to restrict the LAY OPERATOR from adjusting the ventilation settings and ALARM SETTINGS (see 201.109).

EXAMPLES Settings needing protection include ventilatory frequency, I:E ratio, INSPIRATORY TIME, adjustable pressure limitation, high inspiratory pressure ALARM LIMIT, and mode breath type.

Compliance is checked by functional testing and inspection of the RISK MANAGEMENT FILE.

Additional subclauses:

201.12.4.101 Oxygen monitor

If provided with a control for the setting of the inspiratory oxygen concentration, the VENTILATOR shall either

— be equipped with O_2 MONITORING EQUIPMENT for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the PATIENT-CONNECTION PORT), or

— if not so equipped, the instructions for use shall contain a statement to the effect that the VENTILATOR is to be equipped with O_2 MONITORING EQUIPMENT for measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the PATIENT-CONNECTION PORT) that complies with ISO 80601-2-55:2011 before being put into service.

Unless the O_2 MONITORING EQUIPMENT is an integral part of the VENTILATOR, information on where to connect the O_2 MONITORING EQUIPMENT shall be disclosed in the instructions for use.

The O_2 MONITORING EQUIPMENT shall

— comply with ISO 80601-2-55:2011, and

— be equipped with an ALARM SYSTEM that detects a high oxygen level ALARM CONDITION.

NOTE A low oxygen level ALARM CONDITION is required by ISO 80601-2-55.

Check compliance by application of the tests of ISO 80601-2-55:2011 and, if appropriate, inspection of the instructions for use.

201.12.4.102 * Measurement of AIRWAY PRESSURE

The VENTILATOR shall be equipped with MONITORING EQUIPMENT to indicate the AIRWAY PRESSURE. The site of actual measurement can be anywhere in the VENTILATOR BREATHING SYSTEM, but the indicated value shall be referenced to the PATIENT-CONNECTION PORT. Under steady-state conditions, the indicated AIRWAY PRESSURE shall be accurate to within ± (2 hPa (2 cmH_2O) + 4 %) of the actual reading.

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. The AIRWAY PRESSURE MONITORING EQUIPMENT may be equipped with an ALARM SYSTEM that starts with a LOW PRIORITY ALARM CONDITION to indicate when the AIRWAY PRESSURE reaches the ALARM LIMIT and, if this state continues, escalates to a MEDIUM PRIORITY ALARM CONDITION.

The AIRWAY PRESSURE ALARM LIMIT may be pre-adjusted, RESPONSIBLE ORGANIZATION-adjustable, OPERATOR-adjustable, VENTILATOR-adjustable, or a combination of OPERATOR-adjustable and VENTILATOR-adjustable. If the ALARM LIMIT is adjustable by the VENTILATOR, a summary description of the algorithm that determines the ALARM LIMIT value shall be disclosed in the instructions for use.

NOTE Depending on the type of ventilation mode being utilized, there can be more than one active ALARM LIMIT.

Check compliance by functional testing.

201.12.4.103 * Measurement of expired volume and low-volume ALARM CONDITIONS

A VENTILATOR intended to provide a DELIVERED VOLUME greater than 50 ml shall be equipped with MONITORING EQUIPMENT for indicating the volume expired through the PATIENT-CONNECTION PORT unless expiratory end-tidal CO_2 MONITORING EQUIPMENT (201.12.1.104) or an ALARM SYSTEM that detects a TECHNICAL ALARM CONDITION to indicate when conditions in the VBS reach the ALARM LIMIT for high leakage (201.12.4.111) is in use. The indication of the value of the expired volume MONITORING EQUIPMENT and associated ALARM CONDITIONS may be disabled when the DELIVERED VOLUME MONITORING EQUIPMENT is in use. The accuracy of expired volume MONITORING EQUIPMENT shall be disclosed in the instructions for use. The MONITORING EQUIPMENT for indicating the volume expired through the PATIENT-CONNECTION PORT may be provided by an option.

The expired volume MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects at least MEDIUM PRIORITY ALARM CONDITIONS to indicate when the low-expired volume ALARM LIMIT and the high-expired volume ALARM LIMIT are reached. The expired volume MONITORING EQUIPMENT may be equipped with an ALARM SYSTEM that starts with LOW PRIORITY ALARM CONDITIONS to indicate when the expired volume reaches either ALARM LIMIT and, if this state continues, escalates to MEDIUM PRIORITY ALARM CONDITIONS.

The expired volume ALARM LIMITS may be pre-adjusted, RESPONSIBLE ORGANIZATION-adjustable, OPERATOR-adjustable, VENTILATOR-adjustable, or a combination of OPERATOR-adjustable and VENTILATOR-adjustable. If the ALARM LIMITS are adjustable by the VENTILATOR, a summary description of the algorithm that determines the ALARM LIMIT values shall be disclosed in the instructions for use.

NOTE Depending on the type of ventilation mode being utilized, there can be more than one active ALARM LIMIT.

Check compliance by functional testing using the test conditions described in Table 201.103 and Table 201.104 and inspection of the instructions for use. Select and set up the worst-case VBS configuration indicated in the instructions for use.

EXAMPLE Minimum and maximum VBS compliance.

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

201.12.4.104 * Expiratory end-tidal CO_2 MONITORING EQUIPMENT

Notwithstanding the requirements of 201.12.4.103 as an alternative to 201.12.4.103, a VENTILATOR may either

— be equipped with CO_2 MONITORING EQUIPMENT for the measurement of expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the PATIENT-CONNECTION PORT) that is integral to the VENTILATOR, or

— be equipped with a FUNCTIONAL CONNECTION to CO_2 MONITORING EQUIPMENT that permits the VENTILATOR to determine of when the CO_2 MONITORING EQUIPMENT is in use.

CO_2 MONITORING EQUIPMENT shall comply with ISO 80601-2-55:2011.

Where the CO_2 MONITORING EQUIPMENT is not an integral part of the VENTILATOR, the instructions for use shall include the following:

— statement to the effect that the VENTILATOR is to be provided with CO_2 MONITORING EQUIPMENT that complies with ISO 80601-2-55:2011 before being put into service;

— information on where to connect the CO_2 MONITORING EQUIPMENT.

Check compliance by inspection.

201.12.4.105 * MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

A PROTECTION DEVICE shall be provided to prevent the AIRWAY PRESSURE from exceeding the MAXIMUM LIMITED PRESSURE under both NORMAL CONDITION and SINGLE FAULT CONDITION. The MAXIMUM LIMITED PRESSURE shall not exceed 90 hPa (90 cmH_2O).

Check compliance by functional testing.

201.12.4.106 High-pressure ALARM CONDITION and PROTECTION DEVICE

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects a high-AIRWAY PRESSURE ALARM CONDITION to indicate when the high-pressure limit for AIRWAY PRESSURE is reached. The ALARM LIMIT may be independently adjustable, connected to an adjustable pressure limitation or may be related to the set pressure of the VENTILATOR. If the ALARM LIMIT is independently adjustable, it shall not be possible to set the ALARM LIMIT to a value less than that of the adjustable pressure limitation. The maximum ALARM CONDITION DELAY of the high-AIRWAY PRESSURE ALARM CONDITION shall not exceed three consecutive breaths.

The high-AIRWAY PRESSURE ALARM CONDITION shall either be HIGH PRIORITY or MEDIUM PRIORITY and escalate to HIGH PRIORITY if the high-AIRWAY PRESSURE ALARM CONDITION exists for longer than ten consecutive breaths or 30 s, whichever is less. The priority can escalate sooner than ten consecutive breaths or 30 s.

PATIENT-generated transient pressure increases should not cause the high-pressure limit ALARM CONDITION.

EXAMPLE Transient pressure increase caused by the PATIENT coughing.

Each time the HIGH PRIORITY high-pressure ALARM LIMIT for AIRWAY PRESSURE is reached, the VENTILATOR shall act to reduce the pressure at the PATIENT-CONNECTION PORT to the level of the set PEEP. The interval from the moment that the AIRWAY PRESSURE equals the high-pressure ALARM LIMIT to the moment that the pressure starts to decline shall not exceed 200 ms. During SINGLE FAULT CONDITION, the AIRWAY PRESSURE may go below the set PEEP level.

Check compliance by functional testing.

201.12.4.107 * Obstruction ALARM CONDITION

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects a TECHNICAL ALARM CONDITION to indicate when conditions in the VBS reach the ALARM LIMIT for obstruction.

EXAMPLES ALARM CONDITION to warn of the following:

— obstructed inspiratory breathing tube or expiratory gas pathway;

— blocked exhalation valve;

— blocked expiratory BREATHING SYSTEM FILTER.

The obstruction TECHNICAL ALARM CONDITION shall be HIGH PRIORITY. The maximum ALARM CONDITION DELAY shall be no more than two breath cycles or 5 s, whichever is greater.

Whenever the obstruction ALARM CONDITION occurs, the VENTILATOR shall, within no more than one breath cycle, reduce the AIRWAY PRESSURE to either atmospheric pressure or the set PEEP level. The VENTILATOR should be equipped with a PROTECTION DEVICE to allow spontaneous breathing when obstruction occurs. If equipped with the PROTECTION DEVICE, the pressure drop measured at the PATIENT-CONNECTION PORT, with all recommended ACCESSORIES in place, shall not exceed 6,0 hPa (6,0 cmH_2O) at the following flowrates:

— 30 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, $\boldsymbol{V}_{del} \geq 300$ ml;

— 15 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, 300 ml ≥ $\boldsymbol{V}_{del} \geq 50$ ml;

— 2,5 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, $\boldsymbol{V}_{del} \leq 50$ ml.

The means by which the obstruction ALARM CONDITION is determined and a means to test it shall be described in the ACCOMPANYING DOCUMENT.

Check compliance by functional testing with each VBS indicated in the instructions for use, according to the test method described in the ACCOMPANYING DOCUMENT.

201.12.4.108 * Partial-occlusion ALARM CONDITION

The VENTILATOR should be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects a TECHNICAL ALARM CONDITION to indicate when the expiratory gas pathway is partially occluded.

A summary description of the means by which the expiratory-gas-pathway-partial-occlusion ALARM CONDITION is determined shall be described in the ACCOMPANYING DOCUMENT.

Check compliance by functional testing with each VBS indicated in the instructions for use, according to the test method described in the ACCOMPANYING DOCUMENT.

201.12.4.109 Hypoventilation ALARM CONDITION

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects an ALARM CONDITION to indicate hypoventilation. A low respiratory breathing rate may be used for the hypoventilation ALARM CONDITION.

NOTE The hypoventilation ALARM CONDITION can be determined, *inter alia*, by the measurement of the variations of AIRWAY PRESSURE (201.12.4.102), expiratory volume (201.12.4.103), DELIVERED VOLUME (201.12.1.103), or CO_2 (201.12.4.104) or by an INTELLIGENT ALARM SYSTEM utilizing one or more variables.

Compliance is checked by functional testing.

201.12.4.110 Continuing positive-pressure ALARM CONDITION

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects an ALARM CONDITION to indicate an unintended continuing positive pressure lasting for more than 17 s. The continuing positive pressure ALARM CONDITION shall be at least MEDIUM PRIORITY.

The technical description shall disclose a summary of the algorithm used to determine the continuing positive-pressure ALARM CONDITION.

Compliance is checked by functional testing.

201.12.4.111 * High leakage ALARM CONDITION

The VENTILATOR shall be equipped with an ALARM SYSTEM that detects a TECHNICAL ALARM CONDITION to indicate when conditions in the VBS reach the ALARM LIMIT for high leakage. The high leakage TECHNICAL ALARM CONDITION shall be at least MEDIUM PRIORITY. The high leakage TECHNICAL ALARM CONDITION may be disabled when the DELIVERED VOLUME MONITORING EQUIPMENT is in use.

201.12.101 * Protection against accidental adjustments

Means of protection against accidental adjustment of controls that can create a HAZARDOUS SITUATION, including against accidently turning the VENTILATOR off, shall be provided. Turning off the ventilation shall require at least a sequence of two very deliberate actions.

NOTE 1 This can be accomplished by means of hardware or software or a combination of both.

NOTE 2 This can be accomplished by two dedicated confirmation actions.

It shall be possible to set all VENTILATOR parameters prior to starting any ventilation mode.

To switch on the VENTILATOR and to start the ventilation shall require two different actions.

The USABILITY of these means of protection shall be evaluated in the USABILITY ENGINEERING PROCESS.

NOTE 3 The requirements for the USABILITY ENGINEERING PROCESS are found in IEC 60601–1:2005+AMD1:2012, 12.2 and IEC 60601–1-6:2010+AMD1:2013.

Check compliance by functional testing and inspection of USABILITY ENGINEERING FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions

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

Additional subclauses:

201.13.2.101 * Additional specific SINGLE FAULT CONDITIONS

A VENTILATOR shall be so constructed that the following SINGLE FAULT CONDITIONS shall not cause an unacceptable RISK:

— a disruption of the gas delivery to the VENTILATOR support equipment, or

— removal or failure of an OPERATOR-detachable BREATHING SYSTEM FILTER.

Check compliance by functional testing and inspection of RISK MANAGEMENT FILE.

201.13.101 Failure of one gas supply to a VENTILATOR

Following the failure of one external gas supply, a VENTILATOR equipped with a means to deliver inspired oxygen concentrations greater than ambient shall automatically use the remaining gas supply, and otherwise maintain normal operation.

NOTE For the purpose of this part of ISO 80601, the failure of the blower is not considered as the failure of a gas supply.

Check compliance by functional testing.

201.13.102 * Independence of ventilation control function and related RISK CONTROL measures

A SINGLE FAULT CONDITION shall not cause the ventilation-control function and the corresponding PROTECTION DEVICE to fail simultaneously.

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:

— the ventilation-control function and the corresponding MONITORING EQUIPMENT;

— the ventilation-control function and the corresponding ALARM SYSTEM.

Check compliance by inspection and functional testing.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

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

201.14.1 General

Amendment (extend the last paragraph prior to the compliance check with):

The ventilation control SOFTWARE ITEMS of the VENTILATOR PESS without an independent hardware RISK CONTROL measure shall be considered as software safety Class C as defined in IEC 62304:2006.

201.15 Construction of ME EQUIPMENT

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

Additional subclauses:

201.15.101 Mode of operation

A VENTILATOR shall be suitable for continuous operation.

Check compliance by inspection.

201.15.102 ACCESSORY pre-use check

A VENTILATOR shall be equipped with means that allow the determination of whether or not the VBS is suitable for use. Additional requirements are also found in 201.7.9.2.8.101. This means might require OPERATOR action.

Check compliance by functional testing.

201.15.103 Integrated dual-limb VBS

A VENTILATOR should be designed in such a way as to allow the use of an integrated VBS, which allows the continuous monitoring of expired volume (201.12.4.103) or the expiratory end-tidal CO_2 monitoring (201.12.4.104), while in use.

EXAMPLE A VENTILATOR designed for use of a coaxial breathing system or a single limb breathing system which includes or provides connect ability to expiratory expired volume or expiratory end-tidal CO_2 in the close vicinity of the PATIENT-CONNECTION PORT.

201.16 ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, 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 form an ME SYSTEM with the VENTILATOR.

Check compliance by application of the relevant tests of IEC 60601-1:2005+AMD1:2012.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

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

New clauses:

201.101 Gas connections

201.101.1 Connection to the MEDICAL GAS PIPELINE SYSTEM

If an OPERATOR-detachable hose assembly is provided for connection between the VENTILATOR and a MEDICAL GAS PIPELINE SYSTEM, it shall comply with ISO 5359:2008.

Check compliance by application of the tests of ISO 5359:2008.

201.101.2 VBS connectors

201.101.2.1* General

A conical VBS connector shall be either a 15 mm or a 22 mm connector complying with ISO 5356-1:2004 or not engage with those connectors.

A non-conical connector shall not engage with a conical connector complying with ISO 5356-1:2004 unless it complies with the engagement, disengagement, and leakage requirements of that standard.

The VBS, its parts, or ACCESSORIES, shall not be equipped with connectors that permit a FUNCTIONAL CONNECTION with a connector complying with ISO 594-1:1986 or ISO 594-2:1998[7].

Check compliance by application of the tests of ISO 5356-1:2004 and functional testing.

201.101.2.2 Other named ports

201.101.2.2.1 PATIENT-CONNECTION PORT

The PATIENT-CONNECTION PORT shall be one either of the following:

a) female 15 mm conical connector complying with ISO 5356-1:2004;

b) coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2004.

Check compliance by application of the tests of ISO 5356-1:2004.

201.101.2.2.2 GAS OUTPUT PORT and GAS RETURN PORT

The GAS OUTPUT PORT and the GAS RETURN PORT shall be one of the following or not engage with those connectors:

a) male 22 mm conical connector complying with ISO 5356-1:2004;

b) male 15 mm conical connector complying with ISO 5356-1:2004;

[7] To be replaced by ISO 80369-7.

c) coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2004.

Check compliance by application of the tests of ISO 5356-1:2004.

201.101.2.2.3 * Manual ventilation port

The VENTILATOR shall not be equipped with a MANUAL VENTILATION PORT.

Check compliance by inspection.

201.101.2.2.4 FLOW-DIRECTION-SENSITIVE COMPONENTS

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 compliance by inspection of OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENTS and inspection of the RISK MANAGEMENT FILE.

201.101.2.2.5 ACCESSORY port

If provided, each ACCESSORY port shall comply with ISO 80369-1:2010 and shall be provided with a means to secure the ACCESSORY in position and a means to secure closure after removal of the ACCESSORY.

NOTE 1 It is expected that the RESP-125 connector of ISO 80369-2 will meet this criterion.

NOTE 2 This port is generally used for measuring pressure, sampling of gases, or for introduction of therapeutic aerosols.

Check compliance by inspection and application of the tests of ISO 80369-1:2010.

201.101.2.2.6 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall not be compatible with connectors specified in ISO 5356-1:2004 and shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.

Check compliance by inspection and application of the tests of ISO 5356-1:2004.

201.101.2.2.7 Gas EXHAUST PORT

If a connector is provided for the gas EXHAUST PORT, it shall be a 30 mm connector complying with ISO 5356-1:2004.

NOTE A 30-mm connector complying with ISO 5356-1:2004 is suitable for connection to ANAESTHESIA GAS SCAVENGING SYSTEM (AGSS) that complies with ISO 80601-2-13:2011.

A VENTILATOR shall be designed so that any provided gas EXHAUST PORT is not obstructed during use.

Check compliance by inspection and application of the tests of ISO 5356-1:2004.

201.101.2.2.8 Oxygen inlet port

An oxygen inlet connector of the VENTILATOR, which is not intended for direct connection to the MEDICAL GAS PIPELINE SYSTEM (201.101.1) and is OPERATOR-accessible without the use of a TOOL, shall comply with ISO 80369-1:2010. A VENTILATOR with this inlet connector shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with oxygen supply systems up to 600 kPa, in NORMAL CONDITION.

NOTE It is expected that the RESP-6000 connector of ISO 80369-2 will meet this criterion.

Check compliance by functional testing and application of the tests of ISO 80369-1:2010.

201.102 Requirements for the VBS and ACCESSORIES

201.102.1 * General

All VENTILATOR BREATHING SYSTEMS, their parts, and ACCESSORIES shall comply with the requirements of this part of ISO 80601, whether they are produced by the MANUFACTURER of the VENTILATOR or by another entity ("third-party manufacturer" or healthcare provider).

Check compliance by the tests of this part of ISO 80601.

201.102.2 Labelling

The MODEL OR TYPE REFERENCE of at least one compatible VENTILATOR shall be disclosed in the ACCOMPANYING DOCUMENT provided with each VBS or ACCESSORY, compliant with 201.102.1.

Statements shall be included in the ACCOMPANYING DOCUMENT of each VENTILATOR BREATHING SYSTEM, part, or ACCESSORY to the effect that

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

b) incompatible parts can result in degraded performance, and

c) 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 compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 Breathing tubes

Breathing tubes, other than heated breathing tubes, intended for use in the VBS shall comply with ISO 5367:2000.

NOTE Heated breathing tubes are covered by ISO 8185.

Check compliance by application of the tests of ISO 5367:2000.

201.102.4 * Humidification

201.102.4.1 HUMIDIFIER

Any HUMIDIFIER, including heated breathing tubes, either incorporated into the VENTILATOR or recommended for use with the VENTILATOR, shall comply with ISO 8185:2007.[8]

Check compliance by application of the tests of ISO 8185:2007.

201.102.4.2 HEAT AND MOISTURE EXCHANGER (HME)

Any HME, either incorporated into the VBS or recommended for use with the VBS, shall comply with ISO 9360-1:2000 or ISO 9360-2:2001.

Check compliance 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 VENTILATOR or recommended for use with the VENTILATOR, shall comply with the relevant requirements of ISO 23328-1:2003 and ISO 23328-2:2002.

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

[8] To be replaced by ISO 80601-2-74.

201.102.6 VENTILATOR BREATHING SYSTEMS

201.102.6.1 Leakage from VBS

The unintended leakage from the VBS external to the VENTILATOR shall not exceed the following and at a continuous pressure of (60 ± 3) hPa ((60 ± 3) cmH_2O):

— 70 ml/min if specified for a VENTILATOR with an intended DELIVERED VOLUME ≥300 ml;

— 40 ml/min if specified for a VENTILATOR with an intended DELIVERED VOLUME between 50 ml and 300 ml;

— 30 ml/min if specified for a VENTILATOR with an intended DELIVERED VOLUME ≤50 ml.

Check compliance by the following test.

a) Set up the VBS for the intended application as indicated in the instructions for use.

b) Seal all ports.

c) Connect a pressure-measuring device and introduce the air into the VBS until a pressure of 60 hPa (60 cmH_2O) is reached.

d) Adjust the flow of air to stabilize the pressure and record the leakage flow.

201.102.6.2* Non-invasive ventilation

The instructions for use for a VENTILATOR intended for non-invasive ventilation shall include a warning statement to the effect that the exhaled volume of the PATIENT can differ from the indicated exhaled volume due to leaks around the MASK.

Check compliance by inspection of the instructions for use.

201.103 * Spontaneous breathing during loss of power supply

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.

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 of the following flowrates:

— 30 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, $\boldsymbol{V}_{del}$ ≥ 300 ml;

— 15 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, 300 ml ≥ $\boldsymbol{V}_{del}$ ≥ 50 ml;

— 2,5 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, $\boldsymbol{V}_{del}$ ≤ 50 ml.

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

Check compliance by functional testing and measurement of flow, pressure, and resistance at the PATIENT-CONNECTION PORT with that combination of ACCESSORIES indicated in the instructions for use which produces the greatest pressure drop.

201.104 * Training

In the application of the requirements of IEC 62366:2007, Clause 7, training shall be considered necessary for both the LAY OPERATOR and the designee of the RESPONSIBLE ORGANIZATION.

NOTE Requirements for training are found in IEC 62366:2007, Clause 7.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.105 * Indication of duration of operation

The VENTILATOR shall have means to indicate visually, either automatically or by OPERATOR action, the cumulative hours of operation of the VENTILATOR. The VENTILATOR should also have means by OPERATOR action to indicate visually the time until the next recommended preventive maintenance.

Check compliance by inspection.

201.106 FUNCTIONAL CONNECTION

201.106.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained if the FUNCTIONAL CONNECTION of a VENTILATOR is disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.106.2 * Connection to an electronic health record

A VENTILATOR should be equipped with a FUNCTIONAL CONNECTION that permits data transmission from the VENTILATOR to, for example, an electronic health record.

201.106.3 * Connection to a DISTRIBUTED ALARM SYSTEM

A VENTILATOR shall be equipped with a FUNCTIONAL CONNECTION that permits connection to a DISTRIBUTED ALARM SYSTEM.

Check compliance by inspection.

201.106.4 Connection for remote control

A VENTILATOR may be equipped with a FUNCTIONAL CONNECTION for connection for external control of the VENTILATOR.

201.107 Display loops

201.107.1 Pressure-volume loops

If a VENTILATOR is provided with the display of pressure-volume loops, the graph shall use the following:

— DELIVERED VOLUME on the vertical axis;

— AIRWAY PRESSURE on the horizontal axis.

Positive values shall be on the top and the right of the display. Increases in DELIVERED VOLUME shall be positive values. The volume shall be reset to the origin at the beginning of each breath.

Check compliance by inspection.

201.107.2 Flow-volume loops

If a VENTILATOR is provided with the display of flow-volume loops, the graph shall use the following:

— flowrate on the vertical axis;

— DELIVERED VOLUME on the horizontal axis.

Positive values shall be on the top and the right of the display. Gas flow to the PATIENT (inspiratory flow) and increases in DELIVERED VOLUME shall be positive values. The volume shall be reset to the origin at the beginning of each breath.

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

Check compliance by inspection.

201.108 POWER SUPPLY CORDS

Any DETACHABLE POWER SUPPLY CORD or DETACHABLE D.C. POWER CORD of an electrically-powered VENTILATOR shall be protected against accidental disconnection from the VENTILATOR under a force of 30 N.

Compliance is checked by inspection and, for a VENTILATOR when provided with an APPLIANCE COUPLER or detachable d.c. power cord, by the following test.

Subject the detachable cord for one min to an axial pull of force of 30 N.

During the test, the MAINS CONNECTOR becoming disconnected from the APPLIANCE INLET or the detachable d.c. power cord becoming disconnected from the d.c. input connector of the VENTILATOR is considered a failure.

201.109 VENTILATOR security

Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 201.12.4.4).

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).

Compliance is checked by inspection of the technical description.

202 Electromagnetic disturbances — Requirements and tests

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

202.4.3.1 * Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

— the VENTILATOR operated using the conditions and test configuration of 201.12.1.102 or 201.12.1.103.

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 part of ISO 80601 are not considered deviations or allowances.

Addition:

202.8.1.101 Additional general requirements

The VENTILATOR shall be tested according to the requirements for the HOME HEALTHCARE ENVIRONMENT.

The following degradations, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:

— component failures;

— changes in programmable parameters or settings;

— reset to default settings;

— change of operating mode;

EXAMPLES Change of breath type, ventilation mode, ventilatory frequency, I:E ratio.

— initiation of an unintended operation;

— error of DELIVERED VOLUME of individual breaths greater than 35 % and error of the DELIVERED VOLUME averaged over a one-minute interval greater than 25 %.

The VENTILATOR can exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

206 Usability

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

For a VENTILATOR, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) setting the OPERATOR-adjustable controls;

— setting ALARM LIMITS;

— inactivating ALARM SIGNALS;

— switching between different ventilation modes and breath types;

— setting ventilation control parameters;

EXAMPLES 1 Ventilatory frequency, DELIVERED VOLUME, PEEP, pressure support.

b) observing monitored ventilation parameters;

EXAMPLES 2 AIRWAY PRESSURE and expired volume.

c) configuring the VBS, including connection of the detachable parts of the VBS to the VENTILATOR;

EXAMPLES 3 HUMIDIFIER, nebulizer, water-trap, tubing, BREATHING SYSTEM FILTER, MONITORING EQUIPMENT.

d) connecting or disconnecting the PATIENT-CONNECTION PORT of the VBS to the PATIENT-interface;

e) reprocessing the VBS components;

f) starting the VENTILATOR from power off;

g) turning off the VENTILATOR;

h) performing a basic pre-use functional check of the VENTILATOR including the ALARM SYSTEM;

i) switching between power sources;

j) testing power sources;

k) connecting and disconnecting the DISTRIBUTED ALARM SYSTEM.

The following functions, if available, shall also be considered PRIMARY OPERATING FUNCTIONS:

l) starting ventilation from standby;

m) activating standby.

The following actions associated with ventilation shall also be considered PRIMARY OPERATING FUNCTIONS:

NOTE For the purposes of this part of ISO 80601, the following functions are considered PRIMARY OPERATING FUNCTIONS even though they are not performed on the VENTILATOR'S OPERATOR-EQUIPMENT INTERFACE.

n) humidifying/conditioning gases delivered through the VBS;

o) adding medication to the gas flowing into the PATIENT;

EXAMPLES 4 Nebulisation or injecting fluids into the ancillary port connection of the VBS.

p) suctioning the PATIENT'S airway;

q) providing alternative means of ventilation;

EXAMPLE 5 Use of a manual resuscitator.

r) for a TRANSIT OPERABLE VENTILATOR, positioning the PATIENT and the VENTILATOR on the wheelchair.

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

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

Additional subclauses:

208.6.8.3.101 Additional requirements for global indefinite ALARM SIGNAL inactivation states

A VENTILATOR shall not be equipped with a means to initiate a global ALARM OFF while connected to a PATIENT.

Check compliance by functional testing.

208.6.8.4.101 * Additional requirements for termination of ALARM SIGNAL inactivation

The duration of AUDIO PAUSED or ACKNOWLEDGED for the ALARM CONDITIONS required by this part of ISO 80601 shall not exceed 120 s without OPERATOR intervention.

NOTE This permits an OPERATOR to deliberately extend the duration of AUDIO PAUSED by direct action.

Check compliance by functional testing.

208.6.12.101 * Additional requirements for ALARM SYSTEM logging

Notwithstanding the requirements of IEC 60601-1-8:2006+AMD1:2012, the VENTILATOR shall

— be equipped with an ALARM SYSTEM log for all ALARM CONDITIONS and all ALARM SIGNAL inactivation states with a capacity of at least 1 000 events,

— not lose the contents of the ALARM SYSTEM log during a loss of power for less than 365 d unless deleted by RESPONSIBLE ORGANIZATION action, and

— not permit the LAY OPERATOR to erase the contents of the ALARM SYSTEM log.

This log shall also include at least the following events:

— change of ventilation settings;

— change of ALARM SETTINGS;

— power supply source change;

— access mode;

— result of the last pre-use check.

Check compliance 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 *applies except as follows:*

Additional subclauses:

211.8.4.101* Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

Notwithstanding the requirements of IEC 60601-1-11:2015, 8.4, the VENTILATOR shall be equipped with the following:

— an INTERNAL ELECTRICAL POWER SOURCE capable of powering the VENTILATOR for at least 2 h when the SUPPLY MAINS falls outside the values necessary to maintain normal operation;

— a means of determining the state of this INTERNAL ELECTRICAL POWER SOURCE.

As the INTERNAL ELECTRICAL POWER SOURCE depletes, but at least 15 min prior to the loss of all power, the VENTILATOR shall be equipped with a means to detect an impending INTERNAL ELECTRICAL POWER SOURCE failure ALARM CONDITION. It shall be of at least MEDIUM PRIORITY. The impending INTERNAL ELECTRICAL POWER SOURCE failure ALARM CONDITION priority shall escalate to HIGH PRIORITY at least 5 min prior to the depletion of the INTERNAL ELECTRICAL POWER SOURCE. There shall be at least 5 min between the beginnings of these two ALARM CONDITIONS. The instructions for use shall state the time between loss of all power and the generation of ALARM SIGNALS for the impending INTERNAL ELECTRICAL POWER SOURCE failure warning ALARM CONDITION.

NOTE 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 life-supporting function of the VENTILATOR.

The instructions for use shall disclose the following:

a) the operational time of the VENTILATOR when powered from each power source under the following conditions:

   — fully charged power source;

— DELIVERED VOLUME, V_{del} = 800 ml or the largest RATED DELIVERED VOLUME, whichever is smaller;

— ventilatory frequency, f = 20 min^{-1};

— I:E ratio = 1:2;

— resistance, R = 5 $hPa(l/s)^{-1}$ ± 10 %;

— compliance, C = 50 ml $(hPa)^{-1}$ ± 5 %;

b) how the alternative SUPPLY MAINS can be tested;

c) the behaviour of the VENTILATOR after a switch-over to the INTERNAL ELECTRICAL POWER SOURCE or alternative SUPPLY MAINS;

d) the behaviour of the VENTILATOR while the INTERNAL ELECTRICAL POWER SOURCE or alternative SUPPLY MAINS is recharging.

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

211.10.1.1 General requirements for mechanical strength

Amendment (add as the first paragraph):

The tests of IEC 60601-1-11:2015, Clause 10 and IEC 60601-1:2005+AMD1:2012, 15.3 shall be performed on the same test VENTILATOR after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this part of ISO 80601 have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use. If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate VENTILATOR may be used for each specified PROCEDURE.

Annexes of the general standard apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS, or their parts

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

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

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Any particular warnings and/or precautions relevant to the immediate operation of the VENTILATOR	201.7.2.101 b)
Arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS, if applicable	201.7.2.101 d)
Containing natural rubber latex, if applicable	201.7.2.13.101
For ACCESSORIES supplied separately, indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR, if applicable	201.7.2.4.101
For ACCESSORIES supplied separately, the requirements of 201.7.2.101, 201.7.2.13.101, and 201.7.2.17.101	201.7.2.4.101
For each VBS part and ACCESSORY, contains phthalates, if applicable	201.11.6.4
For packaging, containing natural rubber latex, if applicable	201.7.2.17.101 c)
For packaging, description of the contents	201.7.2.17.101 a)
For packaging, identification reference to the batch, type, or serial number	201.7.2.17.101 b)
Gas name or chemical symbol for any gas-specific inputs and outlets, if applicable	201.7.2.101 c)
Gas-specific colour coding for any gas-specific inputs and outlets, if applicable	201.7.2.101 c)
Legibility of controls or indicators	201.12.1
Mandatory action safety sign: follow instructions for use	201.7.2.3
Trigger sensitivity control minimum and maximum settings self-evident, if applicable	201.7.4.2
Trigger sensitivity control not only numeric, if applicable	201.7.4.2
Warning not to obstruct the GAS INTAKE PORT, if applicable	201.7.2.101 e)

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of a VENTILATOR or its parts are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general

Description of requirement	Subclause
Description of the means by which the obstruction ALARM CONDITION is determined	201.12.4.107
Description of the means by which the partial-occlusion ALARM CONDITION is determined, if provided	201.12.4.108
Description of the means to test the obstruction ALARM CONDITION	201.12.4.107
For each VBS and ACCESSORY, the MODEL OR TYPE REFERENCE of at least one compatible VENTILATOR	201.102.2
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 a)
For each VBS part and ACCESSORY, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b)
For each VBS part and ACCESSORY, 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 c)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 3) ii)
Name or trade name and address of the MANUFACTURER and where the MANUFACTURER does not have an address within the locale an authorized representative	201.7.9.1
Units of measure for AIRWAY PRESSURE capable of being in hPa	201.7.4.3
Units of measure for volumes, flows, and leakages expressed as STPD or BTPS, as appropriate	201.7.4.3
Warning that the VENTILATOR is a high flow device warning, if applicable	201.4.11.101.2 3) iii)

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

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

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Accuracy of expired volume MONITORING EQUIPMENT, if so equipped	201.12.4.103
Accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT	201.12.1.104
Alternative SUPPLY MAINS, maximum current required	201.11.8.101 d)
Alternative SUPPLY MAINS, means of connection	201.11.8.101 a)
Alternative SUPPLY MAINS, NOMINAL voltage range	201.11.8.101 c)
Alternative SUPPLY MAINS, RATED voltage range	201.11.8.101 b)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101
Any adverse effect of any recommended ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR, if applicable	201.7.9.2.14.101 b)
A-weighted sound power level emitted by the VENTILATOR	201.9.6.2.101

Table 201.C.103 (*continued*)

Description of requirement	Subclause
A-weighted sound pressure level emitted by the VENTILATOR	201.9.6.2.101
Behaviour of the VENTILATOR after a switchover to the INTERNAL ELECTRICAL POWER SOURCE or alternative SUPPLY MAINS	211.8.4.101 c)
Behaviour of the VENTILATOR while the INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source is recharging	211.8.4.101 d)
Description of the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging or replacement, if applicable	201.7.9.2.13 b)
Description of the periodic visual safety inspections that should be performed by the OPERATOR	201.7.9.2.13 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 a VENTILATOR intended for non-invasive ventilation, a warning statement to the effect that the exhaled volume of the PATIENT can differ from the measured exhaled volume due to leaks around the MASK	201.102.6.2
For a VENTILATOR, an explanation of the meaning of the IP classification marked on the ME EQUIPMENT	201.7.9.2.9.101 b)
For a VENTILATOR, its parts or ACCESSORIES intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the VENTILATOR, its parts or ACCESSORIES would be re-used	201.7.9.2.1.102 a)
For a VENTILATOR, its parts or ACCESSORIES intended for single-use, intended duration of use	201.7.9.2.1.102 b)
For ACCESSORIES supplied separately where marking the ACCESSORY is not practicable, the requirements of 201.7.2.4.101, 201.7.2.13.101, and 201.7.2.17.101	201.7.2.4.101
For each VBS, part and ACCESSORY, information on RESIDUAL RISKS for children or treatment of pregnant or nursing women and, if applicable, on appropriate precautionary measures for devices that contain phthalates	201.11.6.4
For the LAY OPERATOR instructions, a description of a means to determine the operation time of the INTERNAL ELECTRICAL POWER SOURCE	201.7.9.2.9.101.1 f)
For the LAY OPERATOR instructions, a description of how the listed ALARM CONDITIONS can be tested	201.7.9.2.9.101.1 d)
For the LAY OPERATOR instructions, a description of how the low oxygen ALARM CONDITION can be tested, if provided	201.7.9.2.9.101.1 e)
For the LAY OPERATOR instructions, a description of how to connect a DISTRIBUTED ALARM SYSTEM	201.7.9.2.9.101.1 g)
For the LAY OPERATOR instructions, an explanation of the meaning of the IP classification	201.7.9.2.9.101.1 b)
For the LAY OPERATOR instructions, an indication as to whether the VENTILATOR is intended for non-invasive ventilation	201.7.9.2.9.101.1 c)
For the LAY OPERATOR instructions, conditions under which the VENTILATOR maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)

Table 201.C.103 (*continued*)

Description of requirement	Subclause
For the LAY OPERATOR instructions, method by which 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
For the LAY OPERATOR instructions, method by which all 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
For the LAY OPERATOR instructions, 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
For the LAY OPERATOR instructions, the specifications of any ACCESSORIES or equipment required to perform the tests described in 201.7.9.2.8.101	201.7.9.2.8.101
For the supervising clinician or the healthcare professional OPERATOR instructions, a description of how the listed ALARM CONDITIONS can be tested	201.7.9.2.9.101.2 f)
For the supervising clinician or the healthcare professional OPERATOR instructions, a statement as to whether any portion of the gas supplied to a HIGH-PRESSURE INPUT PORT is supplied to the PATIENT, if applicable	201.7.9.2.9.101.2 i)
For the supervising clinician or the healthcare professional OPERATOR instructions, any limitation of parameter settings	201.7.9.2.9.101.2 e)
For the supervising clinician or the healthcare professional OPERATOR instructions, 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
For the supervising clinician or the healthcare professional OPERATOR instructions, the essential technical characteristics of each recommended BREATHING SYSTEM FILTER, if applicable	201.7.9.2.9.101.2 g)
For the supervising clinician or the healthcare professional OPERATOR instructions for use, the information contained in the instructions for use for the LAY OPERATOR	201.7.9.2.1.101
For the supervising clinician or the healthcare professional OPERATOR instructions, the methods for controlling the cycling	201.7.9.2.9.101.2 b)
For the supervising clinician or the healthcare professional OPERATOR instructions, the parameter settings	201.7.9.2.9.101.2 c)
For the supervising clinician or the healthcare professional OPERATOR instructions, the range of parameter settings	201.7.9.2.9.101.2 d)
For the supervising clinician or the healthcare professional OPERATOR instructions, 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 g)
For the supervising clinician or the healthcare professional OPERATOR instructions, 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 g)
For the supervising clinician or the healthcare professional OPERATOR instructions, the working principle of each of the VENTILATOR'S ventilation modes including waveforms	201.7.9.2.9.101.2 a)

Table 201.C.103 (*continued*)

Description of requirement	Subclause
Information on how to connect CO_2 MONITORING EQUIPMENT, if not so equipped, if applicable	201.12.4.104
Information on how to connect O_2 MONITORING EQUIPMENT, unless such equipment is an integral part of the VENTILATOR	201.12.4.101
Length of time between the loss of power and impending INTERNAL ELECTRICAL POWER SOURCE failure warning ALARM CONDITION	211.8.4.101
Maximum error of the AIRWAY PRESSURE at the end of the inspiratory phase in relation to the set value for a pressure-controlled breath in NORMAL CONDITION	201.12.1.103
Maximum error of the AIRWAY PRESSURE at the end of the inspiratory phase in relation to the set value for a pressure-controlled breath in NORMAL CONDITION under leak condition	201.12.1.103
Maximum error of the DELIVERED VOLUME in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.102
Maximum error of the inspiratory oxygen concentration (FiO_2) at the PATIENT-CONNECTION PORT in relation to the set value for a pressure-controlled breath in NORMAL CONDITION, if provided	201.12.1.103
Maximum error of the inspiratory oxygen concentration (FiO_2) at the PATIENT-CONNECTION PORT in relation to the set value for a volume-controlled breath in NORMAL CONDITION, if provided	201.12.1.102
Maximum error of the PEEP in relation to the set value for a pressure-controlled breath in NORMAL CONDITION	201.12.1.103
Maximum error of the PEEP in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.102
Means by which the alternative SUPPLY MAINS can be tested	211.8.4.101
Operational time of the power sources when fully charged	211.8.4.101 a)
Processing or reprocessing instructions for the VENTILATOR and its ACCESSORIES	201.11.6.6
Separate instructions for use for LAY OPERATOR	201.7.9.2.1.101
Separate instructions for use for supervising clinician or the healthcare professional OPERATOR	201.7.9.2.1.101
Statement to the effect that the VENTILATOR is to be equipped with CO_2 MONITORING EQUIPMENT before being put into service, if not so equipped, if applicable	201.12.4.104
Statement to the effect that the VENTILATOR is to be equipped with O_2 MONITORING EQUIPMENT for the measurement of inspiratory oxygen concentration before being put into service, if not so equipped	201.12.4.101
Summary description of the VENTILATOR algorithm for determining the AIRWAY PRESSURE ALARM LIMIT, if provided	201.12.4.102
Summary description of the VENTILATOR algorithm for determining the DELIVERED VOLUME ALARM LIMIT, if provided	201.12.1.104
Summary description of the VENTILATOR algorithm for determining the expired volume ALARM LIMIT, if provided	201.12.4.103

Table 201.C.103 (*continued*)

Description of requirement	Subclause
Warning statement to the effect to always have immediate access to an alternative means of ventilation to avoid patient death or serious injury	201.7.9.2.2.101 c)
Warning statement to the effect to not add any attachments or accessories to the ventilator that are not listed in the instruction for use or the ventilator might not function correctly	201.7.9.2.2.101 d)
Warning statement to the effect to 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 patient death	201.7.9.2.2.101 g)
Warning statement to the effect to not cover the ventilator or place in a position that affects proper operation, including applicable examples	201.7.9.2.2.101 b)
Warning statement to the effect to 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 can consequently result in patient death	201.7.9.2.2.101 f)
Warning statement to the effect that the ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 j)
Warning statement to the effect that to prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions	201.7.9.2.2.101 a)
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 i)
Warning statement to the effect that unintentional leaks cause indicated volume and expired CO_2 values to differ from actual patient values, if applicable	201.7.9.2.2.101 k)
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 e)
Warning statement to the effect that when using the ventilator in a carrying case, only use a carrying case that is listed in the instruction for use to prevent adverse ventilator performance which can consequently result in patient death	201.7.9.2.2.101 h)
Which portions of the gas pathways through the VENTILATOR can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION	201.7.9.2.12

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of a VENTILATOR or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of a method for checking the function of ALARM SYSTEM for ALARM CONDITIONS of this part of ISO 80601, if not performed automatically at start-up	201.7.9.3.101
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
Listing of which ALARM CONDITIONS are checked automatically at start-up	201.7.9.3.101
Means of restricting access	201.109
Pneumatic diagram of the VENTILATOR, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use	201.7.9.3.1.101 c)
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 f)
Summary description of the detection algorithm for the continuing positive-pressure ALARM CONDITION	201.12.4.110
Summary description of the filtering and/or smoothing techniques for all measured and/or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means by which the continuing pressure ALARM CONDITION is detected and a summary description of the detection algorithm	201.7.9.3.1.101 e)
Summary description of the means of initiating and terminating the inspiratory phase while the VENTILATOR is operating in each of its ventilatory modes	201.7.9.3.1.101 d)

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005 *and* IEC 60601-1:2005/AMD1:2012, Annex D *applies, except as follows:*

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title
1		ISO 7000-2492 Symbol 5.1.5 ISO 15223-1:2012	Batch code
2		ISO 7000-2493 Symbol 5.1.6 ISO 15223-1:2012	Catalogue number
3		ISO 7000-2498 Symbol 5.1.7 ISO 15223-1:2012	Serial number
4		ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:2012	Contains or presence of natural rubber latex
NOTE EN 15986:2011 provides additional information for phthalate symbols.			

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of this part of ISO 80601 and is intended for those who are familiar with the subject of this part of ISO 80601 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 part of ISO 80601 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 in this part of ISO 80601. The numbering is, therefore, not consecutive.

201.1.1 Scope

There are key contextual differences between a home VENTILATOR and a critical care VENTILATOR, even 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 (1) knowledge and certainty of ventilation against (2) the PATIENT'S autonomy and lifestyle.

The definition of dependent PATIENT provided in this part of ISO 80601 correctly identifies that dependent PATIENTS do not necessarily rely on the VENTILATOR for every breath. So for many home PATIENTS, the support offered by a VENTILATOR can be intermittent or episodic and even when support is provided, the degree of support can be highly variable. For example, for the chronically tracheotomised PATIENT, the act of speech requires a deflated cuff and a variable leak to atmosphere. The cuff often remains deflated throughout the day, and, in the case of volume target ventilation, the tidal volume is arbitrarily increased to account for the variable lost volume. In this situation, monitoring of both inspiratory and expiratory volume is likely to be an inaccurate representation of the respired volume. However, it's unlikely that the monitoring of expiratory flow is available anyway, because any benefit of an expiratory limb is outweighed by its encumbrance. The monitoring of end-tidal CO_2 ($etCO_2$) can also be unreliable, particularly if there is any PEEP configured (PEEP in the presence of leak dilutes the measurement and introduces variability). At night, the cuff can be inflated, requiring the tidal volume setting to be altered to avoid over-ventilation. An alternate example is intermittent mouthpiece ventilation, where the VENTILATOR might not routinely sample the expired volume at all.

These very typical situations do not benefit from the expensive instrumentation essential for a traditional VENTILATOR to comply with standards. For the tracheotomised PATIENT, relative accuracy can be equally effective as absolute accuracy because the volume is adjusted arbitrarily more than half the day. In fact, one 'ideal' strategy can be a robust leak estimation scheme that perfectly compensated for the leak while present, and then decompensated once the leak is resolved. Which is the best home VENTILATOR? Is the expense imposed by extra instrumentation justified? The answer is, it depends on the PATIENT, the clinical adjustments, the VENTILATOR, and the quality of its labelling. Absolute accuracy can be critical. Or it can be that the most robust safety measure is a simple apnoea ALARM CONDITION, or independent monitoring, or a PATIENT prepared to take responsibility in return for autonomy.

Despite this nuanced reality involving a broad range of PATIENTS, this part of ISO 80601 draws heavily from the traditional hospital VENTILATOR standards. It currently mandates the monitoring of inspiratory

volume expiratory volume, and/or $etCO_2$, and places great emphasis on accuracy of ventilation target (pressure or volume) and how this accuracy is maintained in the face of different circuit ACCESSORIES. It mandates the same monitoring accuracy target as the critical care VENTILATOR standard, across all VBS circuit configurations.

Does mandating the traditional VENTILATOR requirements serve the ventilated individual well? By doing so, the choice of circuits and ACCESSORIES available to the supervising clinician and PATIENT can be unnecessarily constrained. Does loosening the requirements serve the supervising clinician/PATIENT/carer any better? It depends on the situation, and so it is a topic better managed by RISK MANAGEMENT than mandatory requirements. For an autonomous dependent PATIENT, a life-support VENTILATOR with good relative volume accuracy can be entirely appropriate, with judicious configuration of ALARM SETTINGS enabled by well written clinical instructions. The monitoring of expiratory volume and $etCO_2$ is unnecessary. By contrast, an extremely dependent PATIENT or one of poor mentation can be routinely reliant on accurate monitoring, possibly independent from the VENTILATOR. In short, the monitoring requirements should be commensurate with the fragility of the PATIENT and their environment, and the labelling should advise accordingly.

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 that 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.

For example, the modern life-supporting VENTILATOR has differing modes of ventilation that can consist of multiple breath types. This is necessary as PATIENT response to ventilation is unpredictable. PATIENT-initiated breaths or breaths where the inspiration is terminated by the PATIENT can have characteristics that are different from those that have been set by the OPERATOR.

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 VENTILATOR need to be investigated regarding biocompatibility and compatibility with substances that might pass into 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.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For d.c. SUPPLY MAINS, the requirements support operation from lead-acid batteries and automobiles. A typical 12 V lead-acid battery has an open circuit voltage of approximately 12,65 V when fully charged. This voltage drops to approximately 12,06 V when 25 % charged. Furthermore, while cranking the engine, automotive lead-acid batteries are RATED for their ampacity while maintaining 7,2 V. MANUFACTURERS need to consider whether or not their equipment needs to operate under this condition. While the engine is running, the battery charging system typically maintains the .d.c. voltage between 12,8 V and 14,8 V.[20][22] The values for d.c. operation are also consistent with the European standard medical devices carried in an air ambulance as described in EN 13718-1:2008.[23]

201.4.11.101 Additional requirements for pressurized gas input

A VENTILATOR 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 VENTILATOR in NORMAL CONDITION does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these VENTILATORS 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 VENTILATORS 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 VENTILATORS 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.

VENTILATORS with maximum RATED input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum RATED input pressure.

Under the SINGLE FAULT CONDITION that the supply pressure of any one gas drops below 280 kPa, under steady-state conditions, it is understood that a VENTILATOR cannot be expected to continue to operate on this gas. However, it is required that in this case, the VENTILATOR should detect the unacceptable low pressure, produce an ALARM SIGNAL and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the VENTILATOR. This requirement is stated in 201.13.101.

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

The MEDICAL GAS PIPELINE SYSTEM is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the MEDICAL GAS PIPELINE SYSTEM by the application of a 'diversity factor'; a factor agreed 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 flow of 60 l/min to the required proportion of terminal outlets. However, if the flow demand from many adjacent VENTILATORS exceeds 60 l/min, there is an increased possibility that the VENTILATOR input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

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

VENTILATORS that can draw greater average or transient flows during INTENDED USE are permitted, but their ACCOMPANYING DOCUMENTS are required to disclose those flows and warn of the need for a different diversity factor.

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

MANUFACTURERS should be aware that other 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 committee decided that where this part of ISO 80601 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 VENTILATOR to have a declared range DELIVERED VOLUME of 300 ml to 1 000 ml and another 100 ml to 300 ml, with each VENTILATOR only being required to be tested for the conditions specified for ≥300 ml or ≤300 ml, respectively.

201.5.101.2 Gas flow rate and leakage specifications

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

Gas delivery systems supplying pressurized gas to medical equipment, including VENTILATORS, follow engineering conventions and specify gas quantities and flow rates at STPD conditions. This practice is followed in this part of ISO 80601 for all requirements concerning gas input.

However, VENTILATORS complying with this part of ISO 80601 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 VENTILATOR. With a standard temperature of 0 °C, 1 l of gas referenced to standard temperature pressure dry (STPD) can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different VENTILATORS, it is essential that the information for all VENTILATORS is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

In VENTILATORS, a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

The necessary corrections also depend on the location of the flow transducer in the VBS. The humidity of the gas can be zero when the transducer measures the inspiratory flow inside the VENTILATOR. However, when 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 VENTILATOR that uses ambient air, the humidity of the drawn-in air can be unknown to the VENTILATOR. 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 201.12.1, 201.12.4.102, and 201.12.4.103 are met.

201.5.101.3 VENTILATOR testing errors

When testing VENTILATOR performance, several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that MANUFACTURERS allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognize the significance of the uncertainty in their own measurements when testing to this part of ISO 80601.

In practice, this means that, for example, if a MANUFACTURER determines that a parameter has a tolerance of ±7 % but that the measurement uncertainty is ±3 %, then a parameter tolerance of ±10 % is declared. If a third-party tester subsequently obtains an error of the measured value for that parameter of ±15 % with a measurement uncertainty of ±5 %, then the third-party tester has to accept the MANUFACTURER'S claim.

Furthermore, the MANUFACTURER is required to disclose the measurement uncertainty for each declared value in order to provide both information to the RESPONSIBLE ORGANIZATION and guidance for a third-party tester as to the needed measurement accuracy when testing to this part of ISO 80601.

201.7.2.3 Consult ACCOMPANYING DOCUMENTS

The committee agreed that following the instructions for use is a mandatory action for the safe operation of a VENTILATOR.

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

d)

The OPERATOR should be aware that only the parts or ACCESSORIES listed in the instruction for use have been validated by the MANUFACTURER. The use of non-validated parts can represent an unacceptable RISK.

EXAMPLE 1 A power supply unit other than the one recommended by the MANUFACTURER might be designed and manufactured with poor quality (bad reliability), might affect the electromagnetic compatibility of the VENTILATOR, etc.

EXAMPLE 2 The connection of parts to the VBS that are not listed in the instruction 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 will affect the BASIC SAFETY and ESSENTIAL PERFORMANCE.

e)

The functionality of BREATHING SYSTEM FILTERS is affected by a number of aspects of structure, properties, and local environment.

At the most basic, a BSF is designed to be a filter that removes particles suspended in gas, i.e. a "dry aerosol". The particles primarily targeted in the VBS are bacteria or virus particles (although other particles would be subject to retention). The filtering material ("medium") is composed of a matrix of

solid material with open passageways to allow gas flow. The passageways in such gas filters are relatively large compared to the bacteria and virus particles that are to be removed. The spatial arrangement of the solid part of the filter medium versus the open spaces in the medium brings the particles in proximity to the surfaces of the medium, where physical forces (electrostatic attraction and Van der Waals forces) attract and bind the particles within the matrix, removing them from the gas flow.

In the practical situation of anaesthesia or respiratory care therapy, environmental factors related to the PATIENT or the therapy can alter the performance of the BSF from that which would occur in the simple flow of air with suspended microorganisms though the BSF.

One major factor is the presence, phase, and amount of moisture present in the 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 BSFs can adsorb or absorb part of this humidity.

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

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

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

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

In addition, there can be a temporal aspect to the properties of relative hydrophilicity or hydrophobicity; whereby prolonged exposure to water alters these properties during the EXPECTED SERVICE LIFE of the BSF. A BSF is typically labelled with an EXPECTED SERVICE LIFE, in hours or days, that reflects its ability to perform to its labelled specifications in the clinical environment.

It should be obvious that the potential influence of water on performance differs in anaesthesia and respiratory care applications, although many, if not most, BSFs are indicated for use in both applications.

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

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at VENTILATOR or physiologic pressures. In the case of nebulised medications, the type of nebuliser and its operating parameters are variables that affect the likelihood or magnitude of significantly increased BSF flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during OPERATOR or PATIENT manipulation of the VBS has been implicated as a source of acute BSF blockage.

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

The OPERATOR needs to be aware that the effects of such substances can be manifested as increases in the amount of positive AIRWAY PRESSURE required for a VENTILATOR-provided breath, or as an increase in expiratory flow resistance, resulting in a step-wise increase in intrapulmonary pressure that, if not detected, can lead to pneumothorax.

Awareness of the possibility, albeit infrequent or rare, of such significant increases in BSF flow resistance and inclusion in a trouble-shooting scheme for this and other causes of impaired ventilation can reduce or eliminate adverse events occurring secondary to BSF flow occlusion.

Direct PATIENT monitoring and usage of the appropriate settings for, and prompt attention to, VENTILATOR ALARM CONDITIONS are essential to provide maximum PATIENT safety.

Once a BSF is recognized to be a source of impaired ventilation, simply removing the occluded BSF and replacing it with another BSF returns ventilation to a normal state.

g)

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 VENTILATOR 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 VENTILATOR. These might adversely affect the performance of the VENTILATOR or, in the extreme, these voltage fluctuations might lead to a stoppage of ventilation. In addition, these SUPPLY MAINS variations can also affect the electromagnetic compatibility of the VENTILATOR.

The OPERATOR needs to be aware that only wheelchairs listed in the instruction 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 VENTILATOR, as well as the measuring sensors and the ALARM SIGNAL generation.

201.7.9.2.9.101 Additional requirements for operating instructions

Some VENTILATORS are designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. Thus, knowledge of these VBS characteristics is important for the OPERATOR to be aware of the VENTILATOR capability. Also, knowledge of the maximum VBS resistance (at NOMINAL and maximum flowrates) is important because an occlusion FALSE POSITIVE ALARM CONDITION can be caused by the use of high resistance components in the VBS. These characteristics of the VBS need to be inclusive of any inhalation and exhalation particle/bacteria filters, HUMIDIFIER, nebuliser, water collection vessels, and connectors needed for operation.

201.7.9.2.9.101.1 LAY OPERATOR operating instructions

d)

This part of ISO 80601 requires that instructions for use for both the LAY OPERATOR and the supervising clinician or healthcare professional describe methods of testing VENTILATOR 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 VENTILATOR 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 VENTILATOR settings, it is vitally important that they learn how to test a VENTILATOR 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 healthcare professional 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 VENTILATOR ALARM SYSTEMS are fully functional.

201.7.9.2.9.101.1 Supervising clinician operating instructions

f)

See rationale for 201.7.9.2.9.101.1 d).

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The use of antistatic and/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 VENTILATOR in general terms so the reader can understand the important behaviour of the VENTILATOR (e.g. mean values and their time specifications, number of breaths, and delays etc.). Some items (e.g. pressures) that one would find in the instructions for use of a professional use VENTILATOR are placed in the technical description for this home use VENTILATOR as that information is not expected to be meaningful to the LAY OPERATOR, but is necessary for the supervising clinician or the healthcare professional OPERATOR.

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 track.[37] Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.[28] 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[32].

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/ m^3 of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,9786 m^3/kg of dry air and an enthalpy content of 197 kJ/m^3 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/m^3 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.[43] This is confirmed by studies conducted by the U.S. Navy Medical Research and Development Command[28] 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/TR 16142 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the PATIENT on whom they are being used or the employees or third parties interacting with them.

This means that VENTILATORS, their ACCESSORIES, and parts cannot be used if there is a potential RISK of the PATIENT, OPERATOR, or other person being infected as a result of contact with the VENTILATOR, ACCESSORY, or part.

Therefore, VENTILATORS, their ACCESSORIES, and parts require an appropriate level of disinfection depending on their use, but rarely need to be sterile.

Recommendations for hygienic reprocessing of VENTILATORS, their ACCESSORIES, and parts are based on the general hygiene requirements for the reprocessing of medical devices and need to take into consideration the special requirements and needs of PATIENT care in the clinical environment.[9] The requirements for hygienic reprocessing of this part of ISO 80601 are intended to

— make the RESPONSIBLE ORGANIZATION for reprocessing the VENTILATOR aware of how to implement these tasks in a responsible manner through appropriate delegation, and

— help all parties involved in the reprocessing of VENTILATORS, their ACCESSORIES, and parts to comply with the MANUFACTURER'S instructions.

The cleaning and disinfection PROCEDURES of the MANUFACTURER are also intended to provide practical support to all those involved in PATIENT care in the clinical environment with regards to implementing the hygiene measures required for the PATIENT'S safety.

It should be noted that VENTILATORS, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any VENTILATOR that has already been used on another PATIENT is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and reprocessing PROCEDURES are essential to protect the next person handling the device or the next PATIENT on whom the device is used. Hence, VENTILATORS, their re-usable ACCESSORIES and parts that have been used are required to undergo a reprocessing PROCESS, following the MANUFACTURER'S instructions, prior to reuse by another PATIENT.

The following basic considerations need to be addressed by the MANUFACTURER when specifying the reprocessing instructions of a VENTILATOR, its ACCESSORIES or parts:

— protecting the PATIENT, the OPERATOR, and the RESPONSIBLE ORGANIZATION (including personnel involved in performing the reprocessing PROCESS);

— the limits of the PROCEDURES used for reprocessing (such as the number of reprocessing 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 reprocessing PROCESS should be determined by the following:

— the potential degree and type of contamination of the VENTILATOR, ACCESSORIES or parts;

— the RISK of infecting another PATIENT resulting from their reuse and the type of application of the VENTILATOR.

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S re-breathing under SINGLE FAULT CONDITION should be considered.

On the basis of the above, a VERIFIED and VALIDATED documented reprocessing 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 following conditions have been fulfilled:

— documented reprocessing PROCEDURE'S effectiveness has been VERIFIED through appropriate scientific methods by the MANUFACTURER;

— reliability of the documented reprocessing PROCEDURES has been VERIFIED in practice through appropriate quality assurance measures by the RESPONSIBLE ORGANIZATION carrying out the reprocessing PROCEDURES.

When selecting and evaluating the reprocessing PROCEDURES, the MANUFACTURER should consider the following:

— the amount and type of pathogenic microorganisms expected to contaminate the VENTILATOR, ACCESSORIES, or parts;

— the RISK for the pathogenic microorganisms to be transmitted to the PATIENT, OPERATOR, or other persons;

— the microorganism's resistance to the recommended reprocessing PROCEDURES.

The RISKS posed by a reprocessed VENTILATOR, ACCESSORIES, or parts are determined by the following factors:

a) undesired effects, which can result from the following:

   — previous use;

   — previous reprocessing PROCESSES;

   — 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 reprocessing 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 reprocessing PROCESS and the feasibility of the reprocessing PROCESS for the VENTILATOR, ACCESSORIES, or parts, the MANUFACTURER should consider the following points:

— RISKS involved in the reprocessing PROCESS;

— cost effectiveness of the reprocessing PROCESS;

— practicability of the reprocessing PROCESS;

— availability of the cleaning equipment and the cleaning agents specified in the reprocessing PROCESS;

— efficiency of the reprocessing PROCESS;

— reproducibility of the reprocessing PROCESS;

— quality management requirements of the reprocessing PROCESS;

— environmental impact of the reprocessing PROCESS and the disposal of the VENTILATOR, ACCESSORIES, or parts.

The MANUFACTURER should VERIFY all cleaning agents and reprocessing PROCEDURES used with regard to their suitability and repeatability with the VENTILATOR, ACCESSORIES, or parts, depending on the type of use.

The RESPONSIBLE ORGANIZATION should VERIFY that manual cleaning and disinfection of the VENTILATOR, ACCESSORIES, or parts are always carried out in accordance with the PROCEDURES specified in the ACCOMPANYING DOCUMENT.

The MANUFACTURER should specify VALIDATED automated cleaning and disinfection PROCEDURES. If they are not followed, the effectiveness of the cleaning and disinfection cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of cleaning agents and disinfectants, and residence time.

To ensure the reproducibility of automated reprocessing PROCEDURES, tests should be carried out on a regular basis.

The MANUFACTURER should ensure that the specified disinfection PROCEDURES are VERIFIED to be bactericidal, fungicidal, and virucidal so that the cleaned and disinfected VENTILATOR, ACCESSORIES, or parts do not pose an unacceptable RISK of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next PATIENT, OPERATOR, or person.

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

Following any reprocessing PROCEDURE, a safety and functional testing of the VENTILATOR (as specified by the MANUFACTURER'S instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the VENTILATOR.

The extent and type of the tests depends on the VENTILATOR, ACCESSORY, or part and these need to be defined in the ACCOMPANYING DOCUMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

The committee considered that the accuracy of set and displayed values is a key component of the ESSENTIAL PERFORMANCE of a VENTILATOR (i.e. the delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION). The general standard requires MANUFACTURERS to declare accuracies and to address the associated RISKS in the RISK MANAGEMENT PROCESS. One of the associated RISKS is lack of consistency between MANUFACTURERS in their declarations of accuracy, both in terms of the reference settings used and the conditions of test. Consistency in these situations can only be achieved by means of internationally agreed standards and these requirements have been formulated in order to fulfil this objective.

The test settings and conditions and, for certain parameters, minimum requirements, specified in this subclause have been selected by the committee as those necessary to demonstrate adequate ESSENTIAL PERFORMANCE of a VENTILATOR with regards to the parameters specified. The test PROCEDURES have been written as TYPE TESTS (additional information is found in 3.135 and Clause 5), with the expectation that MANUFACTURERS design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified encompass any results obtained by a TYPE TEST performed in accordance with the test PROCEDURES specified in this subclause.

201.12.1.104 DELIVERED VOLUME MONITORING EQUIPMENT

Evidence is accumulating that both volutrauma and barotrauma can result in respiratory morbidity and affect long-term respiratory outcome. Overstretching of the lung results in a decrease of the compliance in the respiratory system, an increase in the water content of the lungs, and microscopic evidence of alveolar and interstitial oedema, alveolar haemorrhage, and neutrophil infiltration.[41] The immature lung is especially vulnerable to injury due to overstretching of the lungs.[43] Volutrauma has been characterized by airway modelling and airway hyper-responsiveness in infant rats.[42] In addition, the early onset of airway hyper-responsiveness is a predictor of bronchopulmonary dysplasia in human infants,[43] a condition resulting in permanent lung injury.[45] As a result, the OPERATOR needs to know both the DELIVERED VOLUME and AIRWAY PRESSURE to be able to assess the adequacy of the PATIENT'S ventilation.

As with the measurement of AIRWAY PRESSURE, the site of the volume measurement is not specified, but the value is required to be referenced to the PATIENT-CONNECTION PORT (additional information is also found in the rationale for 201.12.4.102). The permissible errors in both setting and measurement of AIRWAY PRESSURE and DELIVERED VOLUME are reasonable for PATIENTS that require more than 50 ml DELIVERED VOLUME, i.e. there is little RISK of over-ventilating or under-ventilating such PATIENTS. This is less true for smaller PATIENTS, particularly those requiring tidal volumes of less than 50 ml, with stiff lungs in volume-control modes. As a result, MANUFACTURERS of VENTILATORS intended to deliver tidal volumes of less than 50 ml should recommend the initial use of a pressure-control ventilation mode until such time as the cardiorespiratory status of the PATIENT has stabilized. Whether volume-control ventilation or pressure-control ventilation is chosen is less the issue than is the maintenance of non-injurious tidal volumes as a function of body weight (usually predicted body weight or ideal body weight). Although slightly lower than the range for paediatric and adult PATIENTS, the clinically accepted value for infants lies in the range of 4 ml/kg to 6 ml/kg.

With a non-leaking airway interface such as a cuffed tracheostomy tube, the monitoring of expired volume is preferred as this provides a more accurate estimate of the pulmonary tidal volume. It is confusing to the OPERATOR to have multiple ALARM CONDITIONS based on both DELIVERED VOLUME and expired volume, and it is therefore appropriate that the monitoring of DELIVERED VOLUME and its associated ALARM CONDITIONS be capable of being disabled when the monitoring of expired volume is in use.

Airway interfaces which allow considerable gas leak are in common use. These include tracheostomy tubes used without, or with an under-inflated, cuff; tracheostomy tubes that incorporate a speech valve (such as Passy-Muir valve); and non-invasive MASKS. In these use situations, the monitoring of expired volume is impracticable and the committee believes that it is imperative that the DELIVERED VOLUME

monitor remain in use for maintaining PATIENT safety when the monitoring of expired volume is not in use.

201.12.4.102 Measurement of AIRWAY PRESSURE

Additional information is also found in the rationale for 201.12.1.103.

The site in the VBS at which pressure is sensed varies from VENTILATOR to VENTILATOR. Generally, the MANUFACTURER chooses one of the following 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 VENTILATOR: on the inspiratory side of the VBS (at the "to PATIENT" port) and on the expiratory side of the VBS (at the "from PATIENT" port), and, after mathematical manipulation, averaging the two values.

201.12.4.103 Measurement of expired volume and low-volume ALARM CONDITIONS

It is desirable to have a fast-responding measurement of volume and narrow ALARM LIMITS. However, as there is often considerable variation in a PATIENT'S ventilatory pressures and volumes, narrow ALARM LIMITS inevitably lead to clinically insignificant ALARM CONDITIONS. As a result, OPERATORS choose to set wide ALARM LIMITS to reduce the number of insignificant ALARM CONDITIONS despite the fact that this can compromise PATIENT care when there is a prolonged small change in ventilation. Therefore, it is recommended that a VENTILATOR be designed to use initially a lower priority ALARM CONDITION, which escalates to a higher priority if the ALARM LIMIT violation persists. The initial ALARM CONDITION priority and the priorities and timing of the escalation should be determined by the severity of the potential HARM to the PATIENT in combination with the length of time that the OPERATOR has to prevent the HARM from occurring.

When the tracheostomy tube cuff is deflated during mechanical ventilation exhaled volume monitoring is unreliable at best and likely impossible, especially when a speaking valve [9] is used in conjunction with the deflated cuff. In spite of the impact on exhaled volume monitoring and the associated ALARM CONDITIONS, there are several reasons why it can be preferable to deflate the tracheostomy tube cuff in stable, mechanically ventilated PATIENTS. These quality-of-life reasons to deflate a tracheostomy tube cuff of a ventilated PATIENT are outlined below.

Speech: When the tracheostomy tube cuff is deflated, it allows the PATIENT to exhale through the vocal cords and communicate through speech. This is particularly important for children. Introducing the speaking valve as soon as possible after tracheotomy offers more normal speech/language development as the child is able to vocalize (e.g. cry, laugh, coo, and babble) which is an important precursor to speech and is important to the parent/child bonding process.

Swallowing food and liquids (including secretions): Deflating the cuff allows the larynx to elevate and move with anterior, natural mechanical motion each time one swallows that keeps the airway safe from food and drink. The larynx is an organ of swallow and closed position speaking valves restore positive subglottic pressure generated during the swallow. That positive pressure happens as the lungs recoil during the apnoeic phase of the swallow against closed cords. The pressure builds as high as 10 cmH_2O, and is responsible for preventing food or drink from entering the trachea, and stimulating vocal cord closure. When the larynx pulls forward during the swallow, it pulls open the oesophagus; as the oesophagus opens, pressure falls (Boyle's law) and a vacuum environment is created to pull food or drink into the oesophagus, not through cords that have positive pressure under them.

[9] An example speaking valve is commercially available from Passy-Muir, Inc., http://www.passy-muir.com/. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of this product.

Sensation/protection from aspiration: Redirecting exhaled air through the oropharynx restores sensation and allows the PATIENT to feel the back of his throat. If a cuff is inflated, sensation is dulled and the PATIENT is at a higher RISK of aspiration because the cuff is inflated. Oral secretions do not pool in the back of the throat because sensation is restored and the PATIENT coughs, clears, and/or swallows those secretions away.

Cough/airway clearance: PATIENTS who are able to close the glottis and build subglottic pressure can have natural cough strength restored and thereby need less invasive suction PROCEDURES.

Smell and taste: Tracheotomised PATIENTS usually lose the ability to smell and taste due to a lack of airflow through the nasal and oral cavities. Use of a speaking valve re-establishes this airflow during exhalation and as a result, olfaction is stimulated.[40] Restoration of olfaction can also facilitate the sense of taste. In turn, PATIENTS can experience improvement in appetite, which can lead to increased oral intake and improved nutritional status.

Toileting: A closed glottis makes a Valsalva manoeuvre possible. This manoeuvre is used for toileting, upper body strength (e.g. grunting to push yourself out of a chair or lift a heavy object) and to help balance for safer ambulation.

Overall quality of life: A tracheostomy can raise many psychological/quality of life issues for PATIENTS. Difficulty with communication, as well as secretion management and swallowing problems, can discourage PATIENTS from attempting to socialize or interact with others. When using a speaking valve, PATIENTS can breathe, speak, and use their hands more normally without drawing attention to the tracheostomy. PATIENTS can use an ascot or scarf to cover the tracheostomy tube from sight if they wish to do so. Restoration of normal speech, reduced suctioning requirements, and improved swallowing facilitate return to a more normal lifestyle. PATIENTS can function without feeling disabled and conspicuous because of their tracheostomy. Increased communicative ability can enable PATIENTS to regain control over their environment and facilitate an improvement in self-esteem and well-being.

Alternative monitoring and ALARM CONDITIONS: For all of the above quality of life reasons, it can be preferable to deflate the tracheostomy tube cuff in stable, mechanically ventilated PATIENTS. In such cases, it is important to provide alternative monitoring and associated ALARM CONDITIONS that can aid in detecting significant increases in leak or circuit disconnect and then alert the caregiver to those situations. None of these methods can provide direct replacement of exhaled volume monitoring and the associated ALARM CONDITIONS, but this part of ISO 80601 permits the monitoring of expiratory end-tidal CO_2 (201.12.1.104) or the detection of high leakage (201.12.4.111).

201.12.4.104 Expiratory end-tidal CO_2 MONITORING EQUIPMENT

The monitoring of expiratory end-tidal CO_2 is employed clinically as a surrogate for arterial CO_2 tension. It therefore provides an alternative to monitoring expired tidal volume in assessing the adequacy of ventilation of the lungs. However, in the event of an occlusion or leak within the VBS, minute ventilation can be significantly reduced, while arterial CO_2 rises. This can result in end-tidal CO_2 monitored values that remain within the clinically acceptable range as the PATIENT tidal volume is reduced below the level of physiologic dead space. The committee did not believe that safety could be ensured through use of monitoring of end-tidal CO_2 unless either monitoring DELIVERED VOLUME or expired volume was also in use.

It is not intended that this constrain a MANUFACTURER to integrate the CO_2 MONITORING EQUIPMENT into the VENTILATOR. However, when it is not integrated, a FUNCTIONAL CONNECTION between the CO_2 MONITORING EQUIPMENT and the VENTILATOR is required in order to ensure that the CO_2 MONITORING EQUIPMENT is in use. For the purpose of the TYPE TEST, the MANUFACTURER is expected to demonstrate that there is a FUNCTIONAL CONNECTION between the VENTILATOR and end-tidal CO_2 MONITORING EQUIPMENT, such that the resulting ME SYSTEM complies with the requirements of this part of ISO 80601. This allows for cases such

as when the end-tidal CO_2 MONITORING EQUIPMENT is integrated within a vital signs monitor from a separate MANUFACTURER.

201.12.4.105 MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

The value chosen for the MAXIMUM LIMITED PRESSURE[26][33] 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 paediatric PATIENTS. 90 hPa is required to permit a PATIENT to perform breathe stacking thereby avoiding the need for frequent suctioning.

201.12.4.107 Obstruction ALARM CONDITION

Sustained elevated AIRWAY PRESSURE levels can cause hazardous increases in intra-thoracic pressure. Such pressure increases can result in decreased venous return, reduced cardiac output, and a subsequent drop in arterial blood pressure. Obstruction of the expiratory limb is the most common obstruction in a VENTILATOR. The obstruction of expiratory limb ALARM CONDITION should be designed to detect promptly a reduced expiratory flow due to an increased resistance in the expiratory limb.

The nature or duration of an occlusion in the expiratory limb of the VBS cannot be predicted. Assuming that the occlusion is severe and the safety valve opens quickly, the PATIENT is not exposed to potentially injurious high pressures, although at the likely expense of the loss of PEEP. Further inspirations, whether or not assisted by the VENTILATOR, necessitate REBREATHING the previously exhaled gas trapped in the inspiratory limb. Given these considerations and their consequences, the associated ALARM CONDITION is required to be at least MEDIUM PRIORITY. Even if the VENTILATOR is highly sophisticated, the presence of an occlusion in the expiratory limb of the VBS can compromise the VENTILATOR'S ability to provide essential respiratory support to the PATIENT, which requires prompt action by the OPERATOR.

Causes of continuing AIRWAY PRESSURE include a malfunctioning expiratory valve, kinked tubing, and expiratory filter blockage. Nebulised drugs can block expiratory filters within a short time.

Other consequences of incomplete expiration (increased peak AIRWAY PRESSURE or decreased ventilation) can be detected and indicated by other ALARM CONDITIONS required by this part of ISO 80601. Practice shows that clinically used ALARM LIMITS are not always sensitive enough to provide early and specific detection of this potentially HAZARDOUS SITUATION.

201.12.4.108 Partial-occlusion ALARM CONDITION

Total obstruction of the expiratory gas pathway that immediately leads to an increased end-expiratory pressure is detected and acted on as indicated in 201.12.4.107. In this circumstance, the opening of an inspiratory safety valve is also required. More commonly, the underlying causes responsible for total obstruction can also cause a partial obstruction (e.g. minor kinking of the expiratory hose) or a slowly increasing resistance (e.g. due to slow build-up of nebulised aerosols on an expiratory BREATHING SYSTEM FILTER, dependent on the filter material and the composition of the nebulised drug).

Partial obstruction not only leads to PATIENT discomfort (increased expiratory work of breathing, missing triggers), but can develop into total obstruction. It is therefore desirable to detect and alert the OPERATOR to increased resistance of the expiratory limb as early as possible to give the OPERATOR sufficient time for remedy without interrupting ventilation.

This part of ISO 80601 does not specify the degree of obstruction that should be detected or the priority of the partial obstruction ALARM CONDITION. The sensitivity that can be achieved without generating FALSE POSITIVE ALARM CONDITIONS not only depends on the design of the VENTILATOR, but also on the characteristics of the individual PATIENT. Therefore, the committee came to the conclusion that it is not desirable to be more specific.

201.12.4.111 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 flow, time, and pressure monitoring along with pattern recognition be utilized to determine if high leakage has occurred.

201.12.101 Protection against accidental adjustments

Unacceptable RISKS to the PATIENT can occur as a result of accidental adjustments of operating controls or turning off the VENTILATOR. To control this RISK, the OPERATOR-EQUIPMENT INTERFACE should be designed to prevent accidental adjustments. The USABILITY ENGINEERING PROCESS is used to ensure that these RISKS are reduced to acceptable levels. Example methods could include mechanical RISK CONTROL techniques such as locks, shielding, friction loading and detents; pressure-sensitive finger pads; capacitive finger switches; and microprocessor-oriented "soft" RISK CONTROLS or a specific sequence of key or switch operations.

201.13.2.101 Additional specific SINGLE FAULT CONDITIONS

Operation of a VENTILATOR without an OPERATOR-detachable BREATHING SYSTEM FILTER in place is considered reasonably foreseeable when considering those parts of the VBS that might become contaminated with body fluids or expired gases. If a VENTILATOR can operate without the BREATHING SYSTEM FILTER, then one should assume that it has been operated without the BREATHING SYSTEM FILTER and therefore, those parts of the VBS have been contaminated. Additional information is also found in the rationale for 201.11.6.6.

201.13.102 Independence of ventilation control functions and related RISK CONTROL measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

201.101.2.1 General

Non-standard VBS connectors can represent an unacceptable RISK as attempts are made to fit a standard VBS to a VENTILATOR in an emergency situation. Non-standard VBS connectors can cause leaks if used with similar but not compatible connectors.

The use of Luer taper or Luer-lock connectors complying with ISO 594-1 or ISO 594-2 are not permitted for use in a VBS as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

201.101.2.2.3 MANUAL VENTILATION PORT

Although provision for the manual ventilation of the PATIENT in cases of emergency is strongly encouraged, the committee decided that this should be by means of a connection into the detachable part of the VENTILATOR BREATHING SYSTEM or at the PATIENT CONNECTION PORT. It was decided that the use of a connection port on the VENTILATOR could lead to misuse or confusion, with no compensating advantage.

201.102.1 General

It is the responsibility of the MANUFACTURER of a VENTILATOR BREATHING SYSTEM, its parts, or ACCESSORIES to VERIFY that their product complies with the requirements of this part of ISO 80601 by testing their product, in combination with the other items for which compatibility is claimed, to the requirements of this part of ISO 80601.

201.102.4 Humidification

Water management refers to the complete PROCESS by which moisture, in the form of water vapour, is added to the breathing gas delivered to the PATIENT'S lungs and the PROCESS by which humidified breathing gas is conducted back to the VENTILATOR'S expiratory system and exhausted to the room. Intrinsic to this PROCESS is the necessity to remove bulk water due to condensation of moisture attributable to pressure and temperature changes in the VBS. Even if breathing gas reaches the PATIENT-CONNECTION PORT without any added moisture, the expired breathing gas directed back to the VENTILATOR