BS EN ISO 80601-2-12:2011

Incorporating corrigendum October 2011

BSI Standards Publication

Medical electrical equipment

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12:2011)

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-12:2011. It is identical to ISO 80601-2-12:2011, incorporating corrigendum October 2011. It supersedes BS EN 794-1:1997+A2:2009 and BS EN 60601-2-12:2006, which are withdrawn.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by ISO corrigendum October 2011 is indicated in the text by ⟦AC1⟩ ⟨AC1⟧.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment to Subcommittee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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ICS 11.040.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2011.

Amendments/corrigenda issued since publication

Date	Text affected
31 August 2013	Implementation of ISO corrigendum October 2011

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-12

April 2011

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Supersedes EN 794-1:1997+A2:2009

English Version

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC 80601-2-12:2011)

Appareils électromédicaux - Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs (ISO/IEC 80601-2-12:2011)

Medizinische elektrische Geräte - Teil 2-12: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Beatmungsgeräten für die Intensivpflege (ISO/IEC 80601-2-12:2011)

This European Standard was approved by CEN on 5 February 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 80601-2-12:2011: E

Foreword

This document (EN ISO 80601-2-12:2011) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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

This document supersedes EN 794-1:1997+A2:2009, EN 60601-2-12:2006.

This first edition of ISO 80601-2-12 cancels and replaces the second edition of IEC 60601-2-12 (2001). This edition of ISO 80601-2-12 constitutes a major technical revision of IEC 60601-2-12:2001 and includes an alignment with third edition of IEC 60601-1.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO/IEC 80601-2-12:2011 has been approved by CEN as a EN ISO 80601-2-12:2011 without any modification.

Annex ZA
(informative)

Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
All	1, 2, 3	
201.4	1	
201.7	5, 8.6, 8.7, 10.3, 11.4.1,12.7.4, 12.8.2, 12.9, 13.1, 13.2, 13.3, 13.4, 13.5, 13.6	
201.7.2.3	13.1, 13.2	
201.7.2.101 a)	13.3 i)	
201.7.2.101 b)	13.3 j), 13.3 k)	
201.7.2.101 c), 201.7.2.101 d)	13.1	
201.7.2.101 e)	13.3 j), 13.3 k)	
201.7.2.101 f)	13.3 e)	
201.7.2.101 g)	13.3 k)	
201.7.2.101 h)	13.3 k)	
201.7.2.4.101	13.1, 13.3 e), 13.3 i), 13.3 j), 13.3 k)	
201.7.2.13.101	13.1, 13.2, 13.3 k)	
201.7.2.17.101 a)	13.2, 13.3 b), 13.3 c), 13.3 d), 13.3 f), 13.5	
201.7.2.17.101 b)	13.2, 13.3 b), 13.3 d), 13.5	
201.7.9.1	13.3 a)	
201.7.9.2.8.101	13.6 d)	
201.7.9.2.9.101	13.6 b)	
201.7.9.2.1 a)	13.6 h), 13.6 i)	
201.7.9.2.1 b)	13.6 q)	
201.7.9.2.2.101	13.1, 13.6 a)	

Table ZA.1 — (*continued*)

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.9.2.9.101	13.6 a), 13.6 b), 13.6 c), 13.6 d)	
201.7.9.2.12	13.6 h), 13.6 i)	
201.7.9.2.14.101	13.6 c)	
201.8	9.1, 9.2, 9.3, 12.6, 12.7.4	
201.9	7.1, 9.1, 9.2, 12.7.1, 12.7.2, 12.7.3	
201.10	11.1.1, 11.3	
201.11	7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 8.5, 9.1, 9.3, 12.7.5	
201.11.6.4	7.5	
201.11.8	12.2, 12.3	
201.12	9.2, 10.1, 10.2, 11.1.1, 11.3, 12.3, 12.4, 12.8.1, 12.8.2, 12.9	
201.12.1	3, 4	
201.12.4	3, 4, 12.4, 12.8	
201.13	1, 2, 4, 7.5, 7.6, 9.3	And via IEC 60601-1-6
201.14	9.1, 12.1, 12.1 a)	
201.15	4, 9.1, 9.2, 9.3, 12.6, 12.7.1, 12.7.4, 12.7.5	
201.16	9.1, 12.6, 12.7, 13.1	
201.17	11.1.1, 12.5	
201.101	9.1, 9.2, 12.7.4, 12.8.1	
201.102	3, 4, 9.1, 13.6 c)	
201.103	2, 6	
201.104	12.9	
201.105	2, 3, 4	
201.106	1, 2, 9.1, 9.2	And via IEC 60601-1-6
201.107	1, 12.9	And via IEC 60601-1-6
201.108	1, 3, 9.1, 9.2	And via IEC 60601-1-6
202	9.2, 11.1.1, 12.5	
206	1, 9.2, 12.9	And via IEC 60601-1-6
208	12.4	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this International Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
201.12.1	1.1.4	And via IEC 60601-1
–	1.1.8	
201.12.1, 201.12.101	1.2.2	And via IEC 60601-1 and IEC 60601-1-6
201.7.2.101 c), 201.7.2.101 d), 201.101.2, 201.101.3, 201.101.4	1.5.4	
–	1.6.1	Via IEC 60601-1
–	1.6.2	Via IEC 60601-1
–	1.6.3	Via IEC 60601-1
–	3.4.5	Via IEC 60601-1
201.7.2.101 i)	3.6.2	And via IEC 60601-1

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 80601-2-12 was prepared by Technical Committee 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*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-12 cancels and replaces the second edition of IEC 60601-2-12:2001. This edition of ISO 80601-2-12 constitutes a major technical revision of IEC 60601-2-12:2001 and includes an alignment with the third edition of IEC 60601-1.

The most significant changes are the following modifications:

— extending the scope to include the critical care 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 critical care VENTILATOR itself;

— identification of ESSENTIAL PERFORMANCE for a critical care 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;

— new symbols;

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

— tests for enclosure integrity (water ingress);

— tests for closed suction survivability of the VENTILATOR;

— tests for cleaning and disinfection procedures;

— 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*

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

— IEC 80601-2-30: *Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*

— IEC 80601-2-35: *Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

— IEC 80601-2-58: *Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

— IEC 80601-2-59: *Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*

— IEC 80601-2-60: *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

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN IEC 60601-1:2005, CLAUSE 3, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

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

— "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 International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular International Standard are by number only.

In this International Standard, 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 International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "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 may 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 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this International Standard not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier than 5 years from the date of publication for equipment already in production.

Medical electrical equipment —

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Subclause 1.1 of IEC 60601-1:2005, Clause 1 is replaced by:

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

— intended to be attended by a professional OPERATOR for those PATIENTS who are dependent on mechanical ventilation; and

NOTE 1 Such VENTILATORS are considered a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

— intended for use in critical care environments in a professional healthcare facility or intended for use in transport within a professional healthcare facility.

NOTE 2 A critical care VENTILATOR intended for use in transport within a professional healthcare facility is not considered an emergency and transport ventilator.

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

This International Standard is not applicable to ME EQUIPMENT or an ME SYSTEM operating in ventilation modes intended for patients who are not dependent on mechanical ventilation.

NOTE 3 A critical care VENTILATOR, when operating in such a mode, is not considered LIFE-SUPPORTING ME EQUIPMENT OR ME 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 standard are not covered by specific requirements in this standard except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

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

This International Standard is not applicable to continuous positive airway pressure (CPAP) ME EQUIPMENT, sleep apnoea therapy ME EQUIPMENT, HOME HEALTHCARE ENVIRONMENT VENTILATORS, ventilatory support ME EQUIPMENT, emergency and transport ventilators, anaesthetic ventilators, high-frequency jet ventilators (HFJVs) and high-frequency oscillatory ventilators (HFOVs).[26] This International Standard does not specify the requirements for ME EQUIPMENT that is intended solely to augment the ventilation of spontaneously breathing PATIENTS within a professional healthcare facility.

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

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for home care ventilators for ventilator-dependent PATIENTS which are given in ISO 10651-2[1)].

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for emergency and transport which are given in ISO 10651-3[2)].

This International Standard does not specify the requirements for VENTILATORS or ACCESSORIES intended for home-care ventilatory support devices which are given in ISO 10651-6[3)].

201.1.2 Object

Subclause 1.2 of IEC 60601-1:2005 is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a VENTILATOR, as defined in 201.3.222, 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

Subclause 1.3 of IEC 60601-1:2005 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, Clause 2 as well as 201.2 of this particular standard.

IEC 60601-1-3:2008 and IEC 60601-1-11:2010 do not apply.

201.1.4 Particular standards

Subclause 1.4 of IEC 60601-1:2005 is replaced by:

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

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

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1) In the future, this standard is expected to be harmonized with IEC 60601-1:2005 and IEC 60601-1-11:2010, at which time it will be replaced by ISO 80601-2-xx.

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

3) In the future, this standard is expected to be harmonized with IEC 60601-1:2005 and IEC 60601-1-11:2010, at which time it will be replaced by ISO 80601-2-xx.

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

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard is replaced completely by the text of this particular standard.

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

"Amendment" means that the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard is amended as indicated by the text of this particular standard.

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, any applicable collateral standards and this particular standard taken together.

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

201.2 Normative references

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

NOTE Informative references are listed in the bibliography beginning on page 74.

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

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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

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

IEC 61672-1:2002, *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 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7010:—[4)], *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 7010:2003, *Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas* including (Amendment 1:2006)

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

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* including (Amendment 1:2010)

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* including (Amendment 2:2010)

ISO 8185:2007, *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 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements*

ISO 10079-3:1999, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source*

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4) To be published. (Revision of ISO 7010:2003)

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

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 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.* Amendment 1:2008

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*

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

ISO 80601-2-13:—[5], *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

ISO 80601-2-55:—[5], *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60068-2-27:2008[6], *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

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

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

〚AC1〉 IEC 60529:1989 〈AC1〛, *Degrees of protection provided by enclosures (IP Code)*

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

IEC 60601-1-11:2010, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-2-2:2009, *Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

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

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

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5) To be published.

6) Cancels and replaces ISO 60068-2-29:1987.

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, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006, IEC 60601-2-2:2009, IEC 62304:2006, IEC 62366:2007, ISO 4135:2001 and the following apply.

NOTE An alphabetical index of defined terms is found beginning on page 77.

Addition:

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

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

[ISO 23328-2:2002, definition 3.1]

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

[ISO 4135:2001, definition 3.4.2 modified]

NOTE 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 tracheal tube leakage (as in neonates) or in non-invasive ventilation.

201.3.204
EMERGENCY INTAKE PORT
dedicated GAS INTAKE PORT through which gas is drawn when the supply of FRESH GAS is insufficient or absent

[ISO 4135:2001, definition 3.2.3 modified]

201.3.205
EXHAUST PORT
port through which waste gas is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

[ISO 4135:2001, definition 4.2.1.6, modified]

201.3.206
FLOW-DIRECTION-SENSITIVE COMPONENT
component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

[ISO 4135:2001, definition 3.1.7, modified]

201.3.207
FRESH GAS
respirable gas delivered to a VENTILATOR BREATHING SYSTEM

[ISO 4135:2001, definition 3.1.8, modified]

NOTE FRESH GAS does not include the following:

— air drawn through the EMERGENCY INTAKE PORT;

— air drawn through leaks in the VENTILATOR BREATHING SYSTEM; or

— gas exhaled by the PATIENT.

201.3.208
GAS INTAKE PORT
port through which gas is drawn for use by the PATIENT

[ISO 4135:2001, definition 3.2.11, modified]

201.3.209
GAS OUTPUT PORT
port through which gas is delivered at respiratory pressures via the inspiratory limb to the PATIENT-CONNECTION PORT

[ISO 4135:2001, definition 3.2.8, modified]

201.3.210
GAS RETURN PORT
port through which gas is returned at respiratory pressures via the expiratory limb from the PATIENT-CONNECTION PORT

[ISO 4135:2001, definition 3.2.9, modified]

201.3.211
HIGH-PRESSURE INPUT PORT
input port to which gas is supplied at a pressure exceeding 100 kPa

[ISO 4135:2001, definition 3.2.10.1, modified]

201.3.212
LOW-PRESSURE INPUT PORT
input port to which gas is supplied at a pressure ⟦AC1⟩ ≤ ⟨AC1⟧ 100 kPa

[ISO 4135:2001, definition 3.2.10.2, modified]

201.3.213
MANUAL VENTILATION PORT
port to which a manual inflating device is connected

[ISO 4135:2001, definition 3.2.12 modified]

201.3.214
MAXIMUM LIMITED PRESSURE
$P_{LIM\,\max}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

[ISO 4135:2001, definitions 3.3.3 and 3.3.4 modified]

201.3.215
MAXIMUM WORKING PRESSURE
$P_{W\,max}$
highest AIRWAY PRESSURE during NORMAL USE in the inspiratory phase

[ISO 4135:2001, definition 3.3.5 modified]

NOTE Even if not adjustable, this maximum is equal to or less than the MAXIMUM LIMITED PRESSURE.

201.3.216
MINIMUM LIMITED PRESSURE
$P_{LIM\,min}$
lowest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

[ISO 4135:2001, definitions 3.3.6 and 3.3.7 modified]

NOTE The MINIMUM LIMITED PRESSURE can be subatmospheric.

201.3.217
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and indicates the value of a variable to the OPERATOR

201.3.218
PATIENT-CONNECTION PORT
port of a VENTILATOR BREATHING SYSTEM intended for connection to an airway device

[ISO 4135:2001, definition 4.2.1.2, modified]

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

NOTE The PATIENT-CONNECTION PORT is the end of the VENTILATOR BREATHING SYSTEM proximal to the PATIENT.

201.3.219
PEEP
POSITIVE END-EXPIRATORY PRESSURE
positive AIRWAY PRESSURE at the end of an expiratory phase

[ISO 4135:2001, definition 3.3.11]

201.3.220
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

201.3.221
VBS
VENTILATOR BREATHING SYSTEM
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

[ISO 4135:2001, definition 4.1.1 modified]

201.3.222
VENTILATOR
ME EQUIPMENT intended to automatically augment or provide ventilation of the lungs of the PATIENT when connected to the airway of the PATIENT

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005, 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 generation of an ALARM CONDITION	[a]
oxygen level ALARM CONDITIONS	201.12.4.101
AIRWAY PRESSURE	201.12.4.106 201.12.4.107 201.12.4.108
expired volume	201.12.4.103
electrical supply failure	201.11.8.101.1
INTERNAL ELECTRICAL POWER SOURCE nears depletion	201.11.8.101.2
gas supply failure	201.13.101
gas failure cross flow	201.101.1
[a] Subclause 202.6.2.1.10 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this standard.	

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Amendment (add at end of subclause):

The gas pathways of the VBS or its parts or ACCESSORIES 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.

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

A VENTILATOR shall operate and meet the requirements of this particular standard throughout its RATED range of input pressure and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1000 kPa. A VENTILATOR with a maximum RATED input pressure in excess of 600 kPa shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

NOTE 1 Internal pressure regulators can be required to accommodate the SINGLE FAULT CONDITION of maximum input pressure as well as the RATED range of input pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure, it is desirable for gas to continue to flow to the VBS. Under this condition, the flowrate from the VENTILATOR is likely to be outside of its specification.

Check 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 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 of 200 l/min averaged for 3 s.

or:

3) the ACCOMPANYING DOCUMENTS shall disclose:

i) the 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; and

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

Check 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 Highest driving gas consumption, 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, 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

All requirements for gas flowrate, volume and leakage in this standard are expressed at STPD except for those associated with the VBS, which are expressed at BTPS.

NOTE 1 For the purposes of this standard, STPD (standard temperature and pressure dry) is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this standard, BTPS (body temperature and pressure saturated) 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 standard, declared tolerances shall be adjusted by the measurement uncertainty. The MANUFACTURER shall disclose the measurement uncertainty for each disclosed tolerance in the technical description.

Check compliance by inspection of instructions for use and 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, Clause 7 applies, except as follows:

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

IEC 60601-1:2005, 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 and Technical Corrigendum 1, Table D.2, Number 10).

Additional subclauses:

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 particular storage and/or handling instructions.

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

If applicable, OPERATOR-accessible marking of 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) for any gas inputs or outlets, the supply pressure range and the RATED flow requirements.

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

f) an indication of the date after which ME EQUIPMENT, part or ACCESSORY should not be used, expressed as the year and month. Symbol 5.12 of ISO 15223-1:2007 may be used.

g) a warning not to obstruct the EMERGENCY AIR INTAKE PORT.

EXAMPLE 2 WARNING: Emergency Air Intake – Do not obstruct

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

EXAMPLE 3 WARNING: Gas Intake – Do not obstruct

i) the mass of the most usual configuration of the VENTILATOR.

Check compliance by inspection.

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101 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.

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

All natural rubber latex-containing components in the gas pathways or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.35 from ISO 15223-1:2007 and Amendment 1:2008, (Table 201.D.2.101, symbol 10) may be used. The instructions for use shall disclose all natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages shall be CLEARLY LEGIBLY marked as follows.

a) Those containing breathing attachments intended for single-use shall be CLEARLY LEGIBLY marked with the following:

   — a description of the contents.

   — the words “SINGLE USE”, “DO NOT REUSE”, “NOT FOR REUSE” or symbol 5.2 from ISO 15223-1:2007.

   — if applicable, the word “STERILE,” or one of symbols 5.20 to 5.24 from ISO 15223-1:2007.

   — an identification reference to the batch, type or serial number or symbols 5.14, 5.15 or 5.16 from ISO 15223-1:2007.

   — the word “LATEX”, or symbol 5.35 from ISO 15223-1:2007 and Amendment 1:2008 (Table 201.D.2.101, symbol 10), if containing natural rubber latex.

b) Those containing breathing attachments intended for reuse shall be clearly marked with the following:

   — a description of the contents.

   — an identification reference to the batch, type or serial number or symbol 5.14, 5.15 or 5.16 from ISO 15223-1:2007.

   — packages containing natural rubber latex shall be clearly marked with the word “LATEX”, or symbol 5.35 from ISO 15223-1:2007 and Amendment 1:2008 (Table 201.D.2.101, symbol 10).

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.

201.7.4.3 * Unit of measure

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

〖AC1〗 *Amendment (add to the bottom as a new row in Table 1):* 〖AC1〗

All gas volume, flow and leakage specifications shall be expressed at STPD except those associated with the VBS which shall be expressed at BTPS.

NOTE 1 For the purposes of this standard, STPD (standard temperature and pressure dry) is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this standard, BTPS (body temperature and pressure saturated) is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

— Name or trade name and address of

   — the MANUFACTURER; and

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

to which the RESPONSIBLE ORGANIZATION can refer;

[AC1] *Additional subclauses:* [AC1]

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose the following:

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

b) date of issue or the revision of the instructions for use.

Check compliance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include:

a) a warning statement to the effect that the ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected, including applicable examples.

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

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

b) a warning statement to the effect that, in case of VENTILATOR failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT death.

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

c) a warning statement to the effect that adding attachments or other components or sub-assemblies to the VENTILATOR BREATHING SYSTEM can change the pressure gradient across the VENTILATOR BREATHING SYSTEM and that such changes to the VENTILATOR BREATHING SYSTEM can adversely affect the VENTILATOR performance.

d) * a warning statement to the effect that nebulisation or humidification can increase the resistance of BREATHING SYSTEM FILTERS and that the OPERATOR needs to monitor the BREATHING SYSTEM FILTER frequently for increased resistance and blockage.

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

e) a warning statement to the effect that the VENTILATOR shall not be used in a hyperbaric chamber.

f) a warning statement to the effect that the VENTILATOR shall not be used with nitric oxide.

g) a warning statement to the effect that the VENTILATOR shall not be used with helium or mixtures with helium.

h) a warning statement to the effect that the VENTILATOR accuracy can be affected by the gas added by use of a nebuliser.

Check compliance by inspection.

201.7.9.2.8.101 * Additional requirements for start-up procedure

NOTE A start-up PROCEDURE for this standard is a pre-use functional test that is used to determine that the VENTILATOR is ready for use.

The instructions for use shall disclose a method by which all of the ALARM SIGNALS can be functionally tested to determine if they are operating correctly. Portions of this test method may be automatically performed by the VENTILATOR or may require OPERATOR action.

EXAMPLE Combination of the power-on self-test routines and OPERATOR action.

Check compliance by inspection.

201.7.9.2.9.101 * Additional requirements for operating instructions

The instructions for use shall disclose:

a) a listing of the following pressures:

- MAXIMUM LIMITED PRESSURE ($P_{LIM\,max}$);
- if provided, the RATED range to which the MAXIMUM WORKING PRESSURE ($P_{W\,max}$) can be set, if adjustable;
- the means by which the MAXIMUM WORKING PRESSURE is ensured;

  EXAMPLE 1 Pressure cycling, pressure limiting, pressure generation.

- a statement that AIRWAY PRESSURE can be subatmospheric during the expiratory phase for a VENTILATOR that can generate subatmospheric pressure in the expiratory phase, if applicable**;**
- the subatmospheric pressure limit at the PATIENT-CONNECTION PORT, for VENTILATORS that can generate subatmospheric pressure in the expiratory phase.

b) the RATED range of the following characteristics of the assembled OPERATOR-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained:

- inspiratory gas pathway resistance,
- expiratory gas pathway resistance, and
- VBS 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 non-linear. 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.

c) the conditions under which the VENTILATOR maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use;

EXAMPLE 2 Acceptable range of water level in a HUMIDIFIER.

EXAMPLE 3 Interval of calibration of a flow sensor.

d) an explanation of the meaning of the IP classification marked on the ME EQUIPMENT;

e) an indication as to whether the VENTILATOR is intended for non-invasive ventilation.

EXAMPLE 4 Mask ventilation

Check compliance (to this standard) by inspection.

201.7.9.2.12 Cleaning, disinfection, and sterilization

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

The instructions for use shall identify 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.

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

The instructions for use shall include a statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the VENTILATOR BREATHING SYSTEM.

If applicable, the instructions for use shall disclose

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 (additional requirements are found in ⟦AC1⟩ 201.4.3.101 ⟨AC1⟧ and 201.16).

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

201.7.9.2.16.101 * Additional requirements for reference to the technical description

Where the technical description is supplied as a separate document from the instructions for use, then the instructions for use shall list the contents of the technical description and, wherever appropriate, provide a cross-reference to the additional information available in the technical description.

Check compliance by inspection.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose

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

c) a summary description of the means of initiating and terminating the inspiratory phase in each mode of the VENTILATOR.

If applicable, the technical description shall disclose

d) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER.

EXAMPLES Deadspace and resistance.

Check compliance by inspection.

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 standard, 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, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 9 applies, except as follows:

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 8.1 of ISO 3744:2010 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.

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.*

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 a 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 10 positions in a hemisphere with a radius from the geometric centre of the VENTILATOR as specified in 7.2 of ISO 3744:2010.

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

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

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

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a VENTILATOR intended to provide DELIVERED VOLUME		
	V_{del} [AC1] ≥ [AC1] 300 ml	300 ml [AC1] ≥ [AC1] V_{del} 50 ml	V_{del} [AC1] ≤ [AC1] 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] [22][31][33]	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.

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 8.1 of ISO 3744:2010.

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

201.9.101* Additional requirements for suction procedures

The instructions for use shall disclose a recommended ventilation mode, and settings, for use with a closed-SUCTION CATHETER.

A VENTILATOR shall continue to function as intended after the use of a closed-SUCTION CATHETER:

— for each ventilation mode with the lowest DELIVERED VOLUME of each intended DELIVERED VOLUME range indicated in the instructions for use; and

— using the VBS configuration with the lowest compliance of those indicated in the instructions for use.

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

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

a) Connect a suction system (9), as shown in Figure 201.101, leaving the PATIENT-CONNECTION PORT (4) of the closed-SUCTION CATHETER adaptor (5) open to air and the VENTILATOR disconnected. Utilize a closed-SUCTION CATHETER (6) of minimum inside diameter of 2,95 mm (French (Charriere) equivalent size 14 F).

b) Adjust the suction equipment as follows:

— *Close the flow control valve (7) and adjust the vacuum regulator of the suction equipment to an occluded vacuum of 200 hPa (204 cmH_2O) below ambient atmospheric pressure.*

— *Open and set the flow control valve (7) to give a free air flow (suction flow) of:*

i) 30 l/min, for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del} [AC1] ≥ [AC1] 300 ml;

[AC1] *ii)* [AC1] *15 l/min, for a VENTILATOR intended to provide DELIVERED VOLUME, 300 ml* [AC1] ≥ [AC1] V_{del} [AC1] ≥ [AC1] *50 ml;*

[AC1] *iii)* [AC1] *5 l/min, for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del}* [AC1] ≤ [AC1] *50 ml;*

c) Disable the suction flow without affecting the flow control valve setting.

d) Connect the VENTILATOR as shown in Figure 201.101 utilizing the lowest compliance VBS indicated in the instructions for use for the intended DELIVERED VOLUME range.

e) Connect a test lung to the PATIENT-CONNECTION PORT of the closed-SUCTION CATHETER adaptor. Utilize a test lung with compliance:

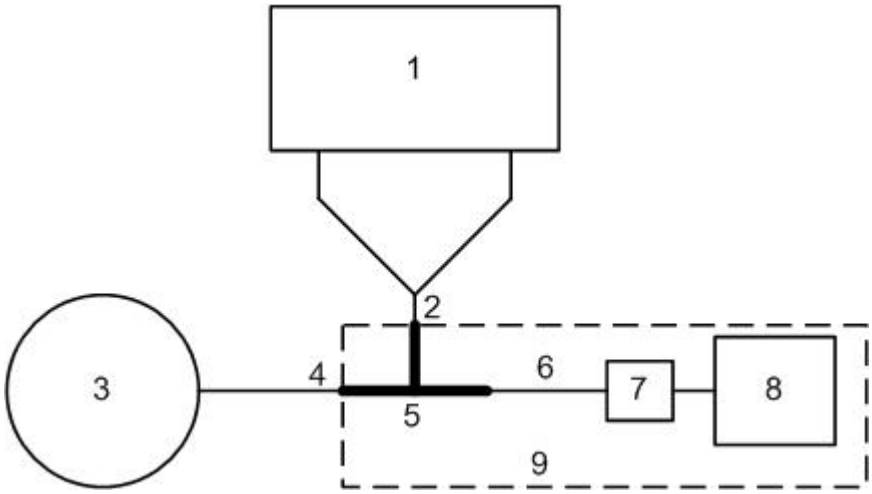
— *10 ml/hPa ± 10 %, for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del}* [AC1] ≥ [AC1] *300 ml;*

— *3 ml/hPa ± 10 %, for a VENTILATOR intended to provide DELIVERED VOLUME, 300 ml* [AC1] ≥ [AC1] V_{del} [AC1] ≥ [AC1] *50 ml;*

— *0,5 ml/hPa ± 10 %, for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del}* [AC1] ≤ [AC1] *50 ml;*

f) Do not enable any special suction procedure mode and retract the closed-SUCTION CATHETER.

g) Perform any compliance correction as indicated in the instructions for use.



Key

1 VENTILATOR under test
2 PATIENT-CONNECTION PORT of VBS before adding the closed-SUCTION CATHETER adaptor
3 test lung
4 PATIENT-CONNECTION PORT of VBS after adding the closed-SUCTION CATHETER adaptor
5 closed-SUCTION CATHETER adaptor
6 14 Fr closed-SUCTION CATHETER complying with ISO 8836:2007
7 flow control valve (can be incorporated in 8)
8 suction equipment complying with ISO 10079-1:1999 or ISO 10079-3:1999
9 suction system

Figure 201.101 — Typical closed-suctioning test setup

h) Select a volume-controlled breath type with the following settings:

- *minimum DELIVERED VOLUME for the intended DELIVERED VOLUME range;*
- *ventilatory frequency: 10 min^{-1}; and*
- *trigger: off or, if not so equipped, the most insensitive method and setting.*

i) Wait until stability is achieved.

j) Advance the closed-SUCTION CATHETER between 1 cm and 2 cm beyond the PATIENT-CONNECTION PORT (4).

k) Enable the suction flow, without affecting the flow control valve setting, and maintain for 30 s.

NOTE 2 Some ALARM CONDITIONS might become active and this is an expected possibility.

l) Terminate the suction flow by closing the suction equipment valve and retract the SUCTION CATHETER.

NOTE 3 Retracting the SUCTION CATHETER into its supplied sleeve can be important to seal the gas pathway and reduce gas leakage.

m) Wait until stability is achieved.

n) Verify that the VENTILATOR continues to function as intended.

EXAMPLE The DELIVERED VOLUME is within specification.

o) Repeat a) to n) for each intended DELIVERED VOLUME range.

p) Repeat a) to o) using a pressure-controlled breath type with the following parameters in lieu of h):

- *ventilation pressure of 5 cmH_2O or, if the VENTILATOR cannot be set that low, the lowest setting;*
- *ventilatory frequency: 10 min^{-1}; and*
- *trigger: off or, if not so equipped, the most insensitive setting.*

q) Repeat a) to o) using the recommended ventilation mode and settings for use with a closed-SUCTION CATHETER in lieu of h) unless the recommended ventilation mode and settings have already been tested.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, Clause 10 applies:

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, Clause 11 applies, except as follows:

201.11.6.4 Leakage

Amendment (add after existing text):

The MANUFACTURER of a 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.

A 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 VBS, its parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these shall be included in the RISK MANAGEMENT FILE. The instructions for use shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by inspection of the RISK MANAGEMENT FILE.

[AC1] *Additional subclause:* [AC1]

201.11.6.5.101* Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM

Enclosures of VENTILATORS shall provide at least an IP21 degree of protection to the harmful ingress of water. Enclosures of VENTILATORS should provide an IP22 degree of protection to the harmful ingress of water.

Check compliance by the tests of IEC 60529:1989 with the VENTILATOR placed in the least favourable position of NORMAL USE and by inspection. After these PROCEDURES, verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

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 dismantling for cleaning and disinfection or cleaning and sterilization (additional requirements are found in 11.6.7 of IEC 60601-1:2005).

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 cross infection of the next PATIENT.

Processing and reprocessing PROCESS instructions for 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 ISO 14159 provides guidance for the design of enclosures.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this standard could be affected by the cleaning or the disinfecting of the VENTILATOR or its parts or ACCESSORIES, they are cleaned and disinfected 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. Verify that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are found in also IEC 60601-1:2005, 11.6.6.

[AC1] *Additional subclauses:* [AC1]

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

201.11.8.101.1 TECHNICAL ALARM CONDITION for power supply failure

The VENTILATOR shall be equipped with an ALARM SYSTEM that includes a HIGH PRIORITY TECHNICAL ALARM CONDITION to indicate when the power supply falls outside the values necessary to maintain normal operation.

If the normal operation of the VENTILATOR is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the supply failure HIGH PRIORITY TECHNICAL ALARM CONDITION shall not be activated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance with the following test:

a) *Cause the power supply/SUPPLY MAINS to drop below the RATED value until either the supply failure ALARM CONDITION occurs or normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*

b) *Verify that a HIGH PRIORITY TECHNICAL ALARM CONDITION occurs at or prior to loss of normal operation, unless normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*

c) *If normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE, verify that the switchover is indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.*

d) *Return the power supply/SUPPLY MAINS to a RATED value.*

e) *Cause the power supply/SUPPLY MAINS to rise above the RATED value until either the supply failure ALARM CONDITION occurs or normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*

f) *Verify that a HIGH PRIORITY TECHNICAL ALARM CONDITION occurs at or prior to loss of normal operation, unless normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*

g) *If normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE, verify that the switchover is indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.*

201.11.8.101.2 INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source

If the VENTILATOR has an INTERNAL ELECTRICAL POWER SOURCE, the VENTILATOR shall be equipped with a means of determining the remaining capacity or operation time provided by this power source. This indication may be qualitative.

A VENTILATOR with an INTERNAL ELECTRICAL POWER SOURCE shall be equipped with an ALARM SYSTEM that includes a MEDIUM PRIORITY TECHNICAL ALARM CONDITION to indicate when the INTERNAL ELECTRICAL POWER SOURCE nears depletion, prior to the loss of all power. As the INTERNAL ELECTRICAL POWER SOURCE depletes, at least 5 min prior to depletion, the depleted INTERNAL ELECTRICAL POWER SOURCE TECHNICAL ALARM CONDITION shall escalate to HIGH PRIORITY.

The instructions for use for a VENTILATOR with an INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source shall disclose

a) the operational time of the power sources when fully charged.

b) the means by which the reserve power source can be tested.

c) the behaviour of the VENTILATOR after a switchover to the INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source.

d) the behaviour of the VENTILATOR while the INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source are recharging.

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

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, Clause 12 applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls of a VENTILATOR shall be CLEARLY LEGIBLE under the conditions specified in IEC 60601-1:2005, 7.1.2.

Check compliance by application of the tests of IEC 60601-1:2005, 7.1.2.

Additional subclauses:

201.12.1.101 Volume-controlled breath type

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

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

— 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} ⟦AC1⟩ ≥ ⟨AC1⟧ 300 ml

— 300 ml W V_{del} ⟦AC1⟩ ≥ ⟨AC1⟧ 50 ml

— V_{del} ⟦AC1⟩ ≤ ⟨AC1⟧ 50 ml

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

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

— 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.

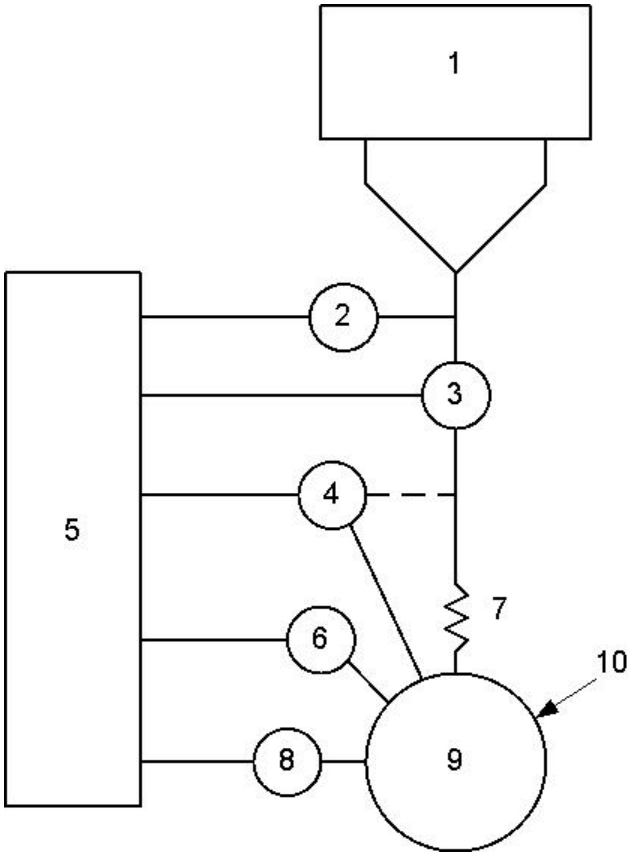
a) DELIVERED VOLUME and end expiratory pressure errors

1) Set up the VENTILATOR as shown in Figure 201.102.

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

3) Utilize the test parameters and settings of the first applicable row (selected by intended DELIVERED VOLUME) of Table 201.103. Wait for steady-state conditions to be achieved.

NOTE 3 Intentionally, for some of these tests, i.e., those with a large compliance and a large resistance, the end expiratory flow will not reach zero.



Key

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

The oxygen sensor may be placed in the VBS.

Figure 201.102 — Volume- and pressure-control breath type accuracy, typical test setup

Table 201.103 — Volume-controlled breath type testing

Test number	Test lung parameters		VENTILATOR settings				
	Compliance (ml/hPa) ± 10 %	Linear [22][31][33] resistance (hPa/l/s) ± 10 %	Volume (ml)	Ventilatory frequency (breaths/min)	INSPIRATORY TIME (s)	FiO_2 (%)	PEEP (hPa)
1	50	5	500	20	1	30	5
2	50	20	500	20	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	20	1	90	10
7	10	50	300	20	1	30	10
8	10	20	200	20	1	90	5
9	3	20	50	30	0,6	30	5
10	3	50	50	30	0,6	30	10
11	3	200	50	30	0,6	60	5
12	3	50	30	30	0,6	30	5
13	3	200	30	30	0,6	90	10
14	1	50	30	30	0,6	90	5
15	1	200	30	30	0,6	30	10
16	1	200	20	60	0,4	30	5
17	1	200	15	60	0,4	60	10
18	1	50	10	60	0,4	60	5
19	0,5	50	5	60	0,4	60	10
20	0,5	200	5	30	0,4	30	5
21	0,5	200	5	60	0,4	30	10

4) Determine the DELIVERED VOLUME, for example via integration of the flow signal provided by a calibrated flow sensor located at the PATIENT-CONNECTION PORT or by the product of the test lung compliance and the measured change of lung pressure, 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 [25].

5) Compare the result with the volume setting for the test and the resulting difference with the tolerance indicated in the instructions for use.

6) If the VENTILATOR is equipped with DELIVERED VOLUME MONITORING EQUIPMENT, 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 and the resulting difference with the tolerance indicated in the instructions for use.

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

10) Repeat 3) to 9) for each applicable row (selected by intended DELIVERED VOLUME) of Table 201.103.

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.

b) FiO_2 error

The accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration measuring device at the PATIENT-CONNECTION PORT or inside the test lung. If the sensor is located at the PATIENT-CONNECTION PORT, the value of the concentration is the flow-weighted average concentration during the inspiratory phase.

The measured O_2 concentration is compared to the FiO_2 setting and the difference is compared with 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.

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

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

201.12.1.102 Pressure-controlled breath type

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 standard 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 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 PEEP in relation to the set value;

— 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} [AC1] ≥ [AC1] 300 ml

— 300 ml W V_{del} [AC1] ≥ [AC1] 50 ml

— V_{del} [AC1] ≤ [AC1] 50 ml

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

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

— 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 201.102.

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

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

NOTE 3 Intentionally, for some of these tests, i.e., those with a large compliance and a large 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 and the resulting difference with the tolerance indicated in the instructions for use.

6) Determine the DELIVERED VOLUME, for example via integration of the flow signal provided by a calibrated flow sensor located at the PATIENT-CONNECTION PORT or by the product of the test lung compliance and the measured change of lung pressure, 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 [25].

7) If the VENTILATOR is equipped with DELIVERED VOLUME MONITORING EQUIPMENT, 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.

Table 201.104 — Pressure-controlled breath type testing

Test number	Intended DELIVERED VOLUME [a] (ml)	Test lung parameters		VENTILATOR settings				
		Compliance (ml/hPa) ± 10 %	Linear [22][31][33] Resistance (hPa/l/s) ± 10 %	Ventilatory frequency (breaths/min)	Inspiratory time [b] (s)	Pressure[c] (hPa)	FiO_2 (%)	PEEP (hPa)
1	500	50	5	20	1	10	30	5
2	500	50	20	20	1	15	90	10
3	500	20	5	20	1	25	90	5
4	500	20	20	20	1	25	30	10
5	300	20	20	20	1	15	30	5
6	300	20	50	20	1	25	90	10
7	300	10	50	20	1	30	90	5
8	200	10	20	20	1	25	30	10
9	50	3	20	30	0,6	15	30	5
10	50	3	50	30	0,6	15	30	10
11	50	3	200	30	0,6	25	60	5
12	30	3	50	30	0,6	10	30	5
13	30	3	200	30	0,6	15	90	10
14	30	1	50	30	0,6	30	90	5
15	30	1	200	30	0,6	30	30	10
16	20	1	200	60	0,4	20	30	5
17	15	1	200	60	0,4	15	60	10
18	10	1	50	60	0,4	10	60	5
19	5	0,5	50	60	0,4	15	60	10
20	5	0,5	50	30	0,4	10	30	5
21	5	0,5	200	60	0,4	15	30	10

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

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

9) Compare the result with the PEEP setting for the test and the resulting difference with the tolerance indicated in the instructions for use.

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

11) Repeat 2) to 10) for each applicable row (selected by intended DELIVERED VOLUME) of Table 201.104.

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

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.*

The measured O_2 concentration is compared to the FiO_2 setting and the difference is compared with the tolerance indicated in the instructions for use.

NOTE 3 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 4 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 5 If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.

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

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

201.12.1.103 * DELIVERED VOLUME MONITORING

If the VENTILATOR is equipped with DELIVERED VOLUME MONITORING EQUIPMENT, the accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT shall be disclosed in the instructions for use. For actual DELIVERED VOLUMES greater than 50 ml, the accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT shall be within ± (4,0 ml + 15 % of the actual DELIVERED VOLUME).

Check compliance with the following.

Verity that the DELIVERED VOLUME MONITORING EQUIPMENT *accuracy as measured in 201.12.1.101 a)6) and 201.12.1.102 a)7) is within the accuracy disclosed in the instructions for use. For* DELIVERED VOLUMES *greater than 50 ml ensure that the accuracy disclosed in the instruction for use is ± (4,0 ml + 15 % of the actual* DELIVERED VOLUME*) or better.*

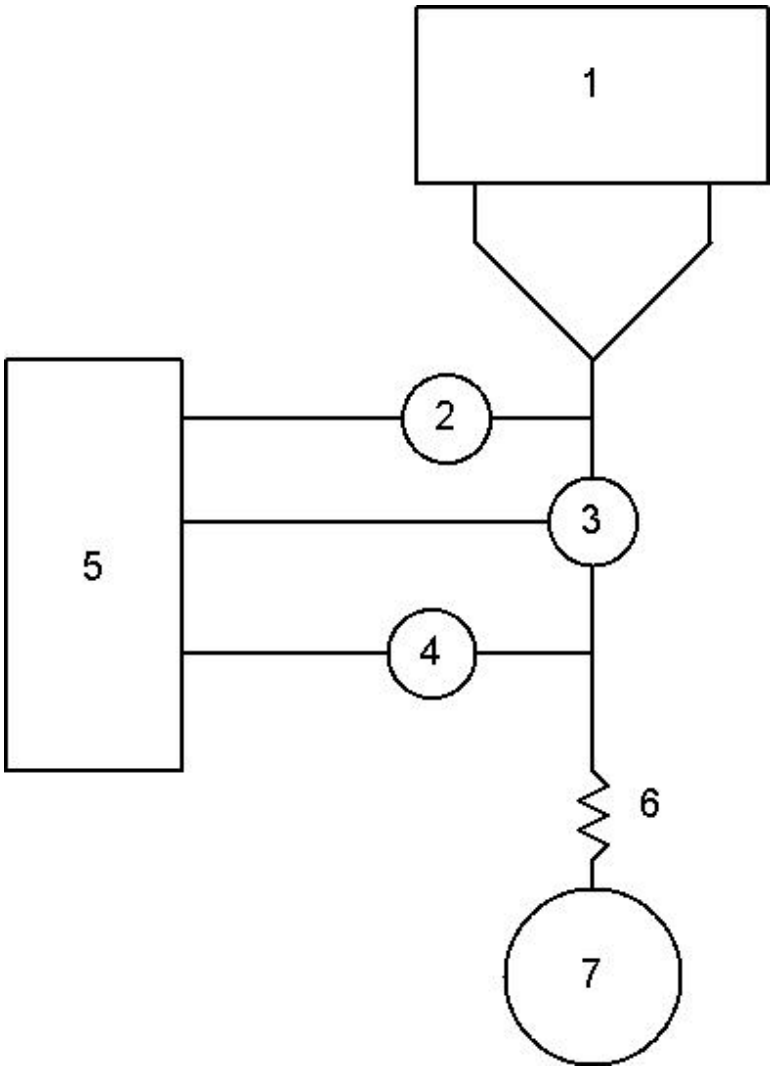
201.12.1.104 * Response of the VENTILATOR to an increase in O_2 concentration

The length of time required for the oxygen concentration in the DELIVERED VOLUME to change from a volume fraction of 21 % to 90 % of the maximum settable oxygen concentration shall be disclosed in the instructions for use. The time shall be reported separately, as appropriate, at DELIVERED VOLUMES of 500 ml, 150 ml and 30 ml using the worst case VBS or using the maximum internal volume VBS and, if provided, at the minimum base flow or continuous flow. The time may be reported separately for each VBS or as a maximum (for the worst case VBS and minimum DELIVERED VOLUME).

Check compliance with the following tests:

a) Set up the VENTILATOR *as shown in Figure 201.103 using the worst case* VBS *or using the maximum internal volume* VBS. *If the* VBS *includes a* HUMIDIFIER, *use the minimum* HUMIDIFIER *water level indicated in the instructions for use.*

b) Utilize the test conditions for the first applicable column available on the VENTILATOR *(selected by intended* DELIVERED VOLUME *range) in Table 201.105.*



Key

1 VENTILATOR under test
2 pressure sensor
3 flow sensor
4 oxygen sensor
5 data acquisition system
6 resistance
7 test lung

Figure 201.103 — O_2 concentration change test setup

c) Ventilate the test lung with a set oxygen concentration of 21 % volume fraction.

d) Wait until equilibrium is reached in the inspired oxygen concentration at the PATIENT-CONNECTION PORT.

e) Change the set oxygen concentration to the maximum volume fraction that the VENTILATOR permits.

f) Measure the time delay between setting the new concentration and achieving 90 % of the final oxygen concentration during inspiration at the PATIENT-CONNECTION PORT.

g) Ensure that the measured time delay is less than or equal to that indicated in the instructions for use.

h) Repeat c) to g) for each applicable column (selected by intended DELIVERED VOLUME range) in Table 201.105.

i) If the VENTILATOR is provided with base flow during the expiratory phase, repeat c) to h) at the minimum base flow setting available in the VENTILATOR.

j) If the VENTILATOR is provided with continuous flow throughout the respiratory cycle, repeat c) to h) at the minimum continuous flow setting available in the VENTILATOR.

Table 201.105 — Test conditions for O_2concentration change tests

Adjustable parameter	Test condition		
	For a VENTILATOR intended to provide DELIVERED VOLUME		
	V_{del} [AC1] ≥ [AC1] 300 ml	300 ml [AC1] ≥ [AC1] V_{del} 50 ml	V_{del} [AC1] ≤ [AC1] 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
Resistance, R[b] [22][31][33]	5 $hPa(l/s)^{-1}$ ± 10 %	20 $hPa(l/s)^{-1}$ ± 10 %	50 $hPa(l/s)^{-1}$ ± 10 %

[a] V_{del} is determined by using the settings of the VENTILATOR.

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

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Oxygen monitor

The VENTILATOR shall either be equipped with O_2 MONITORING EQUIPMENT for the measurement of inspiratory oxygen concentration (e.g., in the inspiratory limb or at the PATIENT-CONNECTION PORT), and complying with ISO 80601-2-55:—[7)] 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 inspiratory oxygen concentration (e.g., in the inspiratory limb or at the PATIENT-CONNECTION PORT) and complying with ISO 80601-2-55:— 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, in addition, be equipped with an ALARM SYSTEM that includes a high oxygen level ALARM CONDITION.

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

Check compliance by inspection of the instructions for use or application of the tests of ISO 80601-2-55:—.

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 may 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).

Check compliance by functional testing.

7) To be published.

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

201.12.4.103.1 VENTILATORS intended to provide a DELIVERED VOLUME > 50 ml

A VENTILATOR intended to provide a DELIVERED VOLUME greater than 50 ml shall either be equipped with MONITORING EQUIPMENT for indicating volume expired through the PATIENT-CONNECTION PORT or, if not so equipped, the instructions for use shall include a statement to the effect that the VENTILATOR is to be equipped with MONITORING EQUIPMENT that complies with this standard before being put into service. Unless the expired volume MONITORING EQUIPMENT is an integral part of the VENTILATOR, information on where to connect the expired volume MONITORING EQUIPMENT shall be disclosed in the instructions for use. The accuracy of measurement of expired volumes greater than 50 ml shall be within ± (4,0 ml + 15 % of the actual volume expired through the PATIENT-CONNECTION PORT). The accuracy of expired volume MONITORING EQUIPMENT shall be disclosed in the instructions for use.

The expired volume MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that includes 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 (2 sets of tests for a HUMIDIFIER).

201.12.4.103.2 VENTILATORS intended to provide a DELIVERED VOLUME ⌊AC1⟩ ≤ ⟨AC1⌋ 50 ml

If a VENTILATOR is intended to provide a DELIVERED VOLUME ⌊AC1⟩ ≤ ⟨AC1⌋ 50 ml, it may be equipped with expired volume MONITORING EQUIPMENT. The accuracy of expired volume MONITORING EQUIPMENT at an expired volume ⌊AC1⟩ ≤ ⟨AC1⌋ 50 ml shall be disclosed in the instructions for use. The expired volume MONITORING EQUIPMENT may be equipped with an ALARM SYSTEM that includes at least a LOW PRIORITY ALARM CONDITION to indicate when the volume reaches the low-expired volume ALARM LIMIT.

If provided, the expired 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 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 minimum and maximum water levels (2 sets of tests for a HUMIDIFIER).

201.12.4.104 * 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 125 hPa (125 cmH_2O).

Check compliance by functional testing.

201.12.4.105 High-pressure ALARM CONDITION and PROTECTION DEVICE

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that includes a HIGH PRIORITY 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 independently adjustable it shall not be possible to set the ALARM LIMIT to a value less than that of the adjustable pressure limitation. 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-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.

201.12.4.106 PEEP ALARM CONDITIONS

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that includes an ALARM CONDITION to indicate when the end-expiratory pressure is above the high PEEP ALARM LIMIT. The VENTILATOR may be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that includes an ALARM CONDITION to indicate when the end-expiratory pressure is below the low PEEP ALARM LIMIT. Both the high- and low-PEEP ALARM CONDITIONS shall be of at least MEDIUM PRIORITY. The ALARM CONDITION DELAY shall not exceed the duration of three breaths.

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

NOTE To perform this test, modification of the VENTILATOR can be required to cause failure of the PEEP control.

201.12.4.107 * Obstruction ALARM CONDITION

The VENTILATOR shall be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION to indicate when AIRWAY PRESSURE reaches the ALARM LIMIT for obstruction.

EXAMPLES ALARM CONDITION to warn of:
- an obstructed inspiratory or expiratory breathing tube
- a blocked exhalation valve
- a 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 a flowrate of:

— 30 l/min for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del} ⟦AC1⟩ ≥ ⟨AC1⟧ 300 ml;

— 15 l/min for a VENTILATOR intended to provide DELIVERED VOLUME, 300 ml ⟦AC1⟩ ≥ ⟨AC1⟧ V_{del} W 50 ml;

— 2,5 l/min for a VENTILATOR intended to provide DELIVERED VOLUME, V_{del} ⟦AC1⟩ ≤ ⟨AC1⟧ 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 includes a TECHNICAL ALARM CONDITION to indicate when the expiratory limb is partially occluded.

A summary description of the means by which the expiratory-limb-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.

⟦AC1⟩ *Additional subclause:* ⟨AC1⟧

201.12.101* Protection against accidental adjustments

Means of protection against accidental adjustment of controls that can create a hazardous output shall be provided, including against accidently turning the ventilator off. The USABILITY of these means of protection shall be evaluated in the USABILITY ENGINEERING PROCESS.

NOTE The requirements for the USABILITY ENGINEERING PROCESS are found in IEC 60601-1:2005, 12.2 and IEC 60601-1-6:2010.

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

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005, 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:

— disruption of the gas delivery to the PATIENT-CONNECTION PORT from the VENTILATOR; or

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

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

201.13.102* Failure of one gas supply to a VENTILATOR

Following the failure of one gas supply, a VENTILATOR shall automatically use the remaining gas supply, and otherwise maintain NORMAL USE. This switchover shall be accompanied by a gas-supply-failure TECHNICAL ALARM CONDITION. This gas-supply-failure TECHNICAL ALARM CONDITION shall be at least LOW PRIORITY.

When the loss of the failing gas supply changes the delivered oxygen concentration by more than 3 % volume fraction, the TECHNICAL ALARM CONDITION should be at least MEDIUM PRIORITY.

Check compliance by functional testing.

201.13.103* 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:

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

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

to fail in such a way that the loss of the ventilation-control function is not detected.

Check compliance by inspection and functional testing.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, Clause 14 applies, except as follows:

Additional subclause:

201.14.101 Software life cycle

The PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS) of a VENTILATOR shall be developed with a design PROCESS complying with IEC 62304:2006. The ventilation control SOFTWARE ITEMS of the VENTILATOR PESS without an independent hardware RISK CONTROL measure shall be considered as software safety Class C.

Check compliance by inspection of the documentation required by IEC 62304 for the software safety class (the requirements are found in 1.4 of IEC 62304:2006).

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5.101 Additional requirements for rough handling

201.15.3.5.101.1 * Shock and vibration

A VENTILATOR and its parts, including applicable ACCESSORIES, not intended for use during PATIENT transport inside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY ME EQUIPMENT is exempt from the requirements of this subclause.

After the following tests, the VENTILATOR shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE and shall comply with the requirements of 201.12.1 and 201.12.4.

Compliance is checked by performing the following tests:

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

NOTE 1 This represents IEC/TR 60721-4-7:2001, Class 7M2.

1) test type: Type 1,

- *peak acceleration: 150 m/s^2 (15 g);*
- *duration: 11 ms;*
- *pulse shape: half-sine;*
- *number of shocks: 3 shocks per direction per axis (18 total);*

or

2) test type: Type 2,

- *peak acceleration: 300 m/s^2 (30 g);*
- *duration: 6 ms;*
- *pulse shape: half-sine;*
- *number of shocks: 3 shocks per direction per axis (18 total);*

NOTE 2 A VENTILATOR tested and complying with the requirements in 15.3.4.1 of IEC 60601-1:2005, is considered to comply with this requirement.

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:

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

3) acceleration amplitude:

- *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;*
- *100 Hz to 500 Hz: –6 db per octave;*

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

c) Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE and the requirements of 201.12.1 and 201.12.4 are maintained following the tests.

201.15.3.5.101.2 * Shock and vibration for a MOBILE VENTILATOR

A VENTILATOR and its parts, including applicable ACCESSORIES, intended for MOBILE use (during PATIENT transport inside a healthcare facility) shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. For this test, the VENTILATOR and its parts, and applicable ACCESSORIES, shall be mounted using the mounting ACCESSORIES indicated in the ACCOMPANYING DOCUMENT.

NOTE If more than one mounting system is described in the ACCOMPANYING DOCUMENTS, multiple tests are required.

During the following test, a VENTILATOR shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE while ventilating a test lung using the conditions and parameters of Table 201.102, selected by intended DELIVERED VOLUME, as appropriate. Perform the tests with a volume-controlled breath type or a pressure-controlled breath type, as applicable. During the testing the error of DELIVERED VOLUME of individual breaths shall not deviate more than 35 % and the error of DELIVERED VOLUME averaged over a one minute interval shall not deviate more than 25 %. During this testing, volume and pressure ALARM CONDITIONS shall be set to their least sensitive levels.

Compliance is checked by performing the following tests:

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

1) test type: Type 1,

— *peak acceleration: 50 m/s^2 (5 g);*

— *duration: 6 ms;*

— *pulse shape: half-sine;*

— *number of shocks: 3 shocks per direction per axis (18 total);*

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:

2) acceleration amplitude:

— *10 Hz to 100 Hz: 0,33 (m/s^2)^2/Hz;*

— *100 Hz to 500 Hz: –6 db per octave;*

3) duration: 30 min per perpendicular axis (3 total).

c) Free fall in accordance with IEC 60068-2-31:2008, using Procedure 1 and the following conditions:

4) fall height:

— *for mass ⟦AC$_1$⟩ ≤ ⟨AC$_1$⟧ 1 kg, 0,25 m*

— *for mass > 1 kg and ⟦AC$_1$⟩ ≤ ⟨AC$_1$⟧ 10 kg, 0,1 m*

— *for mass > 10 kg and ⟦AC$_1$⟩ ≤ ⟨AC$_1$⟧ 50 kg, 0,05 m*

— *for mass > 50 kg, 0,01 m*

5) number of falls: 2 in each specified attitude.

d) Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained during the tests. Verify that the DELIVERED VOLUME is within the indicated limits during the tests.

201.15.101 Mode of operation

A VENTILATOR shall be suitable for continuous operation.

Check compliance by inspection.

201.15.102 Delivered oxygen concentration

A VENTILATOR shall be capable of supplying gas to the PATIENT containing an O_2 concentration over the range from ambient to at least 90 %.

When the loss of the failing gas supply changes the delivered oxygen concentration by more than 3 % volume fraction, the TECHNICAL ALARM CONDITION should be at least MEDIUM PRIORITY.

Check compliance by functional testing.

201.15.103 ACCESSORY self-check

A VENTILATOR shall be equipped with means that allow the determination of whether or not the VBS resistance and compliance characteristics are within the RATED range as indicated in 201.7.9.2.9.101 b). Additional requirements are also found in 201.7.9.2.8.101. This means may require OPERATOR action.

Check compliance by functional testing.

201.16 ME SYSTEMS

IEC 60601-1:2005, 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.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies, except as follows:

Additional subclause:

201.17.101 Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

A VENTILATOR and its ACCESSORIES shall be considered LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEMS.

Check compliance by inspection of the RISK MANAGEMENT FILE for the indication that the VENTILATOR is considered LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEMS.

New clauses:

〚AC1〛 201.101 Gas connections

201.101.1 Protection against reverse gas leakage 〈AC1〉

Means shall be provided to limit reverse gas leakage flow from gas input ports into the supply system of the same gas to less than 100 ml/min in NORMAL CONDITION.

Means shall be provided to limit cross leakage from gas supplied through one HIGH-PRESSURE INPUT PORT into the supply system of another different gas to less than 100 ml/h in NORMAL CONDITION.

If under SINGLE FAULT CONDITION the cross leakage from gas supplied through one HIGH-PRESSURE INPUT PORT into the supply system of another different gas can exceed 100 ml/h the VENTILATOR shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION to indicate this cross leakage flow. This cross flow shall not exceed 100 ml/min.

Check compliance by functional testing.

[AC1] 201.101.2 Connection to the MEDICAL GAS PIPELINE SYSTEM [AC1]

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

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

[AC1] 201.101.3 VBS connectors [AC1]

[AC1] 201.101.3.1 * General [AC1]

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 they comply 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.

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

[AC1] 201.101.3.2 Other named ports [AC1]

[AC1] 201.101.3.2.1 PATIENT-CONNECTION PORT [AC1]

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

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

b) a 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.

[AC1] 201.101.3.2.2 GAS OUTPUT PORT and GAS RETURN PORT [AC1]

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

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

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

c) a 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.

[AC1] 201.101.3.2.3 MANUAL ventilation port [AC1]

If a MANUAL VENTILATION PORT is provided, it shall be a male cylindrical connector that will accept a breathing tube complying with ISO 5367:2000.

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

[AC1] 201.101.3.2.4 EMERGENCY INTAKE PORT [AC1]

An EMERGENCY INTAKE PORT shall not be equipped with an OPERATOR-accessible connector. An EMERGENCY INTAKE PORT shall be designed to prevent obstruction when the VENTILATOR is in use.

Check compliance by inspection.

[AC1] 201.101.3.2.5 FLOW-DIRECTION-SENSITIVE COMPONENTS [AC1]

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.

[AC1] 201.101.3.2.6 ACCESSORY port [AC1]

If an ACCESSORY port is provided, it shall not be compatible with connectors specified in ISO 5356-1:2004 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 This port is generally used for sampling of gases or for introduction of therapeutic aerosols.

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

[AC1] 201.101.3.2.7 Monitoring probe port [AC1]

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.

[AC1] 201.101.3.2.8 Gas EXHAUST PORT [AC1]

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.

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.

[AC1] 201.102 Requirements for the VBS and ACCESSORIES [AC1]

[AC1] 201.102.1 * General [AC1]

All VENTILATOR BREATHING SYSTEMS, their parts and ACCESSORIES shall comply with the requirements of this International Standard, 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 International Standard.

[AC1] 201.102.2 Labelling [AC1]

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 responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

[AC1] 201.102.3 Breathing tubes [AC1]

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

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

[AC1] 201.102.4 * Water management [AC1]

[AC1] 201.102.4.1 Humidification system [AC1]

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

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

[AC1] 201.102.4.2 HEAT AND MOISTURE EXCHANGER (HME) [AC1]

Any HEAT AND MOISTURE EXCHANGER, 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.

[AC1] 201.102.5 Gas mixers [AC1]

Any gas mixer, either incorporated into the VENTILATOR or recommended for use with the VENTILATOR, shall comply with the relevant requirements of ISO 11195:1995.

Check compliance by application of the relevant tests of ISO 11195:1995.

[AC1] 201.102.6 BREATHING SYSTEM FILTERS [AC1]

Any BREATHING SYSTEM FILTER, 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.

[AC1] 201.102.7 VENTILATOR BREATHING SYSTEMS [AC1]

[AC1] 201.102.7.1 Leakage from complete VBS [AC1]

Unintended leakage from the VBS shall not exceed 200 ml/min at 50 hPa (50 cmH_2O) for a VENTILATOR intended to provide DELIVERED VOLUME greater than 300 ml, or 100 ml/min at 40 hPa (40 cmH_2O) for a VENTILATOR intended to provide DELIVERED VOLUME between 300 ml and 50 ml, or 50 ml/min at 20 hPa (20 cmH_2O) for a VENTILATOR intended to provide DELIVERED VOLUME less than 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 the pressure measuring device and introduce the air into the VBS until a pressure of:

— *50 hPa (50 cmH_2O), for a VBS intended to provide a DELIVERED VOLUME, V_{del} [AC1] ≥ [AC1] 300 ml,*

— *40 hPa (40 cmH_2O), for a VBS intended to provide a DELIVERED VOLUME, 300 ml [AC1] ≥ [AC1] V_{del} [AC1] ≥ [AC1] 50 ml, or*

— *20 hPa (20 cmH_2O), for a VBS intended to provide a DELIVERED VOLUME, V_{del} [AC1] ≤ [AC1] 50 ml,*

is reached.

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

[AC1] 201.102.7.2 * Non-invasive ventilation [AC1]

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 measured exhaled volume due to leaks around the mask.

A VENTILATOR intended for non-invasive ventilation [AC1] *text deleted* [AC1] should either be equipped with a CO_2 MONITORING EQUIPMENT for the measurement of expiratory carbon dioxide concentration, e.g., in the expiratory limb or at the PATIENT-CONNECTION PORT, in accordance with ISO 80601-2-55 (ISO 21647 replacement) or, if not so equipped, the instructions for use should contain a statement to the effect that the VENTILATOR is to be provided 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, in accordance with ISO 80601-2-55 (ISO 21647 replacement) before being put into service.

Check compliance by inspection of the instructions for use or application of the tests of ISO 80601-2-55:—.

[AC1] 201.103 * Spontaneous breathing during loss of power supply [AC1]

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 a flowrate of:

— 30 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, V_{del} [AC1] ≥ [AC1] 300 ml;

— 15 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, 300 ml [AC1] ≥ [AC1] V_{del} [AC1] ≥ [AC1] 50 ml;

— 2,5 l/min for a VENTILATOR intended to provide a DELIVERED VOLUME, V_{del} [AC1] ≤ [AC1] 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 highest pressure drop.

[AC1] 201.104 * Training [AC1]

In the application of the requirements of IEC 62366:2007, Clause 7, training shall be considered necessary for both the 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.

[AC1] 201.105 * Indication of duration of operation [AC1]

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 to indicate visually the time since the last or until the next recommended preventive maintenance.

Check compliance by inspection.

[AC1] 201.106 SIGNAL INPUT/OUTPUT PART [AC1]

[AC1] 201.106.1 General [AC1]

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained if connections to the SIGNAL INPUT/OUTPUT PARTS of a VENTILATOR are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

[AC1] 201.106.2 * Connection to an electronic health record [AC1]

A VENTILATOR shall be equipped with a SIGNAL INPUT/OUTPUT PART that permits data transmission from the VENTILATOR to an electronic health record.

Check compliance by inspection.

[AC1] 201.106.3 * Connection to a DISTRIBUTED ALARM SYSTEM [AC1]

A VENTILATOR should be equipped with a SIGNAL INPUT/OUTPUT PART that permits connection to a DISTRIBUTED ALARM SYSTEM.

[AC1] 201.106.4 * Connection for remote control [AC1]

A VENTILATOR may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for external control of the VENTILATOR.

NOTE ASTM F2761-09 is an example of a suitable standard for providing a NETWORK/DATA COUPLING.

[AC1] 201.107 Display loops [AC1]

[AC1] 201.107.1 Pressure-volume loops [AC1]

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

— DELIVERED VOLUME on the vertical axis; and

— 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.

〈AC1〉 201.107.2 Flow-volume loops 〈AC1〉

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

— flowrate on the vertical axis; and

— 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.

〈AC1〉 201.108 * Timed ventilatory pause 〈AC1〉

〈AC1〉 201.108.1 Expiratory pause 〈AC1〉

A VENTILATOR may be equipped with an OPERATOR-controlled means to pause the VENTILATOR in expiration.

If a VENTILATOR is equipped with a means to pause the VENTILATOR in expiration,

a) the duration of the expiratory pause may be OPERATOR-configurable or OPERATOR-adjustable.

b) more than one expiratory pause function may be provided.

c) during the expiratory pause, any apnoea-related ventilatory ALARM CONDITION that would be caused by this expiratory pause shall be AUDIO PAUSED or ALARM PAUSED for the duration of the expiratory pause.

d) in addition to the requirements for ALARM SIGNAL inactivation of 6.8.5 of IEC 60601-1-8:2006, the VENTILATOR shall indicate the presence of the expiratory pause with an INFORMATION SIGNAL or LOW PRIORITY ALARM CONDITION.

e) the maximum allowable duration of an expiratory pause shall be 60 s.

f) means may be provided to initiate the expiratory pause from a SIGNAL INPUT PART/SIGNAL OUTPUT PART.

NOTE 1 An expiratory pause can be equivalent to placing the VENTILATOR into standby mode or CPAP and automatically resuming ventilation after a pre-determined duration.

NOTE 2 The expiratory pause can be used to synchronize radiographic imaging with a deflated lung.

Check compliance by inspection and functional testing.

〈AC1〉 201.108.2 Inspiratory pause 〈AC1〉

A VENTILATOR may be equipped with an OPERATOR-controlled means to pause automatic ventilation at end-inspiration.

If a VENTILATOR is equipped with a means to pause the VENTILATOR in inspiration,

a) The duration of the inspiratory pause may be non-adjustable, RESPONSIBLE ORGANIZATION-configurable or OPERATOR-adjustable.

b) The high-pressure ALARM CONDITION and PROTECTION DEVICE of 201.12.4.105 shall remain active during an inspiratory pause.

c) More than one inspiratory pause function may be provided.

d) During the inspiratory pause, any apnoea or sustained AIRWAY PRESSURE ALARM CONDITION that would be caused by this inspiratory pause should be AUDIO PAUSED or ALARM PAUSED for the duration of the inspiratory pause.

e) In addition to the requirements for ALARM SIGNAL inactivation of 6.8.5 of IEC 60601-1-8:2006, the VENTILATOR shall indicate the presence of the inspiratory pause with an INFORMATION SIGNAL or LOW PRIORITY ALARM CONDITION.

f) The maximum duration of a non-adjustable inspiratory pause shall be 10 s. The maximum allowable duration of an adjustable inspiratory pause shall be 40 s.

g) Means may be provided to initiate the inspiratory pause from a SIGNAL INPUT PART/SIGNAL OUTPUT PART.

NOTE The inspiratory pause can be used to synchronize radiographic imaging with lung inflation or used for recruitment.

Check compliance by inspection and functional testing.

202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

⟦AC1⟩ 202.6.2.1.10 * Compliance criteria ⟨AC1⟩⟧

Subclause 6.2.1.10 of IEC 60601-1-2:2007 is replaced by:

Under the test conditions specified in 6.2 of IEC 60601-1-2:2007, the VENTILATOR shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE while ventilating a test lung using the conditions and parameters of Table 201.102, selected by the intended DELIVERED VOLUME, as appropriate. Perform the tests with a volume-controlled breath type or a pressure-controlled breath type, as applicable. 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; and

— 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 may exhibit temporary DEGRADATION of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 60601-1-6:2010 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

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

e) starting the VENTILATOR from power off;

f) turning off the ventilator; and

g) performing a basic pre-use functional check of the VENTILATOR including the ALARM SYSTEM.

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

h) starting ventilation from standby;

i) activating standby;

j) activating manoeuvres that help assess lung function and/or the effectiveness of VENTILATOR parameter settings;

EXAMPLES 4 Inspiratory pause, expiratory pause, slow inflation

k) activating a closed-suctioning function;

l) observing respiratory gas concentrations.

EXAMPLES 5 FiO_2 or $etCO_2$

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

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

m) humidifying/conditioning gases delivered through the VBS;

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

EXAMPLES 6 Nebulisation or injecting fluids into the ancillary port connection of the VBS

o) suctioning the PATIENT'S airway;

p) X-raying the PATIENT;

q) providing alternative means of ventilation with a manual resuscitator; and

r) positioning the PATIENT.

208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows:

Additional subclauses:

208.6.3.3.2.101 * Additional requirements for characteristics of ALARM CONDITION logging

The ALARM SYSTEM of a VENTILATOR shall be equipped with ALARM CONDITION logging according to IEC 60601-1-8:2006, 6.12, for all HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS.

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 for the ALARM CONDITIONS required by this standard 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.

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 e)
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	201.7.2.4.101
For each VBS, part and ACCESSORY, contains phthalates, if applicable	201.11.6.4
For packaging of reusable breathing attachments, containing natural rubber latex, if applicable	201.7.2.17.101 b)
For packaging of reusable breathing attachments, description of the contents	201.7.2.17.101 b)
For packaging of reusable breathing attachments, identification reference to the batch, type or serial number	201.7.2.17.101 b)
For packaging of single-use breathing attachments, “SINGLE USE”, “DO NOT REUSE”, “NOT FOR REUSE”, symbol 1051 from ISO 7000:2004 or symbol 5.2 from ISO 15223-1:2007	201.7.2.17.101 a)
For packaging of single-use breathing attachments, “STERILE,” or one of symbols 5.20 to 5.24 from ISO 15223-1:2007, if applicable	201.7.2.17.101 a)
For packaging of single-use breathing attachments, containing natural rubber latex, if applicable	201.7.2.17.101 a)
For packaging of single-use breathing attachments, description of the contents	201.7.2.17.101 a)
For packaging of single-use breathing attachments, identification reference to the batch, type or serial number	201.7.2.17.101 a)
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)
Indication of the date after which ME EQUIPMENT, part or ACCESSORY should not be used, if applicable	201.7.2.101 f)
Mandatory action safety sign: follow instructions for use	201.7.2.3
Mass of the most usual configuration of the of the most usual configuration of the VENTILATOR	201.7.2.101 i)
Supply pressure range and the RATED flow requirements for any gas inputs or outlets, if applicable	201.7.2.101 d)
Warning not to obstruct the EMERGENCY AIR INTAKE PORT, if applicable	201.7.2.101 g)
Warning not to obstruct the GAS INTAKE PORT , if applicable	201.7.2.101 h)

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
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 responsible for ensuring the compatibility of the ventilator and all of the parts 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)
Means by which the expiratory-limb-partial-occlusion ALARM CONDITION is determined and a means to test it	201.12.4.108
Means by which the obstruction ALARM CONDITION is determined and a means to test it	201.12.4.107
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 volumes, flows and leakages	201.7.4.3
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	201.12.4.103.1 201.12.4.103.2
Accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT, if so equipped	201.12.1.103
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
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 external reserve electrical power source	201.11.8.101.2 c)
Behaviour of the VENTILATOR while the INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source is recharging	201.11.8.101.2 d)
Conditions under which the VENTILATOR maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101 c)
Cross-reference to the additional information in the technical description, if the technical description is separable	201.7.9.2.16.101
Date of issue or the revision of the instructions for use	201.7.9.2.1.101 b)
Description of the algorithm that determines the ALARM LIMIT values of expired volume MONITORING EQUIPMENT, if so equipped	201.12.4.103.1 201.12.4.103.2
Disclosure of any restrictions on the placing of components within the VENTILATOR BREATHING SYSTEM, if applicable	201.7.9.2.14.101 a)
For ACCESSORIES supplied separately where marking the ACCESSORY is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101
For a VENTILATOR, an explanation of the meaning of the IP classification marked on the ME EQUIPMENT	201.7.9.2.9.101 d)
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	201.102.7.2
For a VENTILATOR intended for non-invasive ventilation, information on how to connect CO_2 MONITORING EQUIPMENT to the VBS shall be disclosed in the instructions for use unless such equipment is an integral part of the VBS	201.102.7.2
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 reused	201.7.9.2.1.101 a)
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
Indication as to whether the VENTILATOR is intended for non-invasive ventilation	201.7.9.2.9.101 e)
Information on how to connect the expired volume MONITORING EQUIPMENT, if not so equipped	201.12.4.103.1
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 required for the oxygen concentration in the DELIVERED VOLUME to change from a volume fraction of 21 % to 90 % of the maximum settable oxygen concentration	201.12.1.104

Table 201.C.103 — *(continued)*

Description of requirement	Subclause
List of contents of technical description, if the technical description is separable	201.7.9.2.16.101
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	201.12.1.102
Maximum error of the DELIVERED VOLUME in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.101
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	201.12.1.101
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	201.12.1.102
Maximum error of the PEEP in relation to the set value for a pressure-controlled breath in NORMAL CONDITION	201.12.1.102
Maximum error of the PEEP in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.101
MAXIMUM LIMITED PRESSURE	201.7.9.2.9.101 a)
Means by which the MAXIMUM WORKING PRESSURE is ensured	201.7.9.2.9.101 a)
Means by which the reserve power source can be tested	201.11.8.101.2 b)
Method by which all of the ALARM SIGNALS can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101
Operational time of the power sources when fully charged	201.11.8.101.2 a)
Processing or reprocessing PROCESS instructions for the VENTILATOR and its ACCESSORIES	201.11.6.6
RATED range of expiratory gas pathway resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)
RATED range of inspiratory gas pathway resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)
RATED range of VBS compliance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b)
RATED range to which the MAXIMUM WORKING PRESSURE can be set, if adjustable	201.7.9.2.9.101 a)
Recommended ventilation mode and settings for closed suctioning	201.9.101
Statement that AIRWAY PRESSURE can be subatmospheric during the expiratory phase for a VENTILATOR that can generate subatmospheric pressure in the expiratory phase, if applicable	201.7.9.2.9.101 a)
Statement to the effect that antistatic or electrically conductive hoses or tubing are not be used in the VENTILATOR BREATHING SYSTEM	201.7.9.2.14.101
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
Statement to the effect that the VENTILATOR is to be equipped with MONITORING EQUIPMENT for indicating expired volume at the PATIENT-CONNECTION PORT before being put into service, if not so equipped	201.12.4.103.1
Subatmospheric pressure limit at the PATIENT-CONNECTION PORT, for VENTILATORS that can generate subatmospheric pressure in the expiratory phase	201.7.9.2.9.101 a)

Table 201.C.103 — *(continued)*

Description of requirement	Subclause
Warning statement to the effect that adding attachments or other components or sub-assemblies to the ventilator breathing system can change the pressure gradient across the ventilator breathing system and that such changes to the ventilator breathing system can affect the ventilator performance	201.7.9.2.2.101 c)
Warning statement to the effect that nebulisation or humidification can increase the resistance of BREATHING SYSTEM FILTERS and that the OPERATOR needs to monitor the BREATHING SYSTEM FILTER frequently for increased resistance and blockage	201.7.9.2.2.101 d)
Warning statement to the effect that the VENTILATOR accuracy can be affected by the gas added by use of a nebuliser, if applicable	201.7.9.2.2.101 h)
Warning statement to the effect that the ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected, including applicable examples	201.7.9.2.2.101 a)
Warning statement to the effect that the VENTILATOR shall not be used in a hyperbaric chamber, if applicable	201.7.9.2.2.101 e)
Warning statement to the effect that the VENTILATOR shall not be used with nitric oxide, if applicable	201.7.9.2.2.101 f)
Warning statement to the effect that the VENTILATOR shall not be used with helium or mixtures with helium, if applicable	201.7.9.2.2.101 g)
Warning statement to the effect that, in case of VENTILATOR failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT death	201.7.9.2.2.101 b)
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 the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this standard and indicate which checks are performed automatically	201.7.9.3.101
Disclosure of the essential technical characteristics of each recommended BREATHING SYSTEM FILTER	201.7.9.3.1.101 d)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3
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 b)
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 of initiating and terminating the inspiratory phase in each mode of the VENTILATOR	201.7.9.3.1.101 c)

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005, Annex D applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

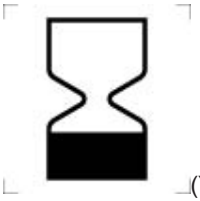
No	Symbol	Reference	Title
1	 (YYYY-MM)	Symbol 5:12 ISO 15223-1:2007 ISO 7000-2607	Use by date
2		Symbol 5:20 ISO 15223-1:2007 ISO 7000-2499	Sterile
3		Symbol 5.21 ISO 15223-1:2007 ISO 7000-2500	Sterilized using aseptic processing techniques
4		Symbol 5.22 ISO 15223:2007 ISO 7000-2501	Sterilized using using ethylene oxide
5		Symbol 5.23 ISO 15223-1:2007 ISO 7000-2502	Sterilized using irradiation
6		Symbol 5:24 ISO 15223-1:2007 ISO 7000-2503	Sterilized using steam or dry heat

Table 201.D.2.101 — (*continued*)

No	Symbol	Reference	Title
7		Symbol 5.14 ISO 15223-1:2007 ISO 7000-2492	Batch code
8		Symbol 5.15 ISO 15223-1:2007 ISO 7000-2493	Catalog number
9		Symbol 5.16 ISO 15223-1:2007 ISO 7000-2498	Serial number
10		ISO 7000-2725	Presence of, contains, natural rubber latex

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

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

Subclause 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 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 the gas pathways of the VBS and its parts or ACCESSORIES are subject to the requirements for APPLIED PARTS, these issues are addressed by the requirements already in the general standard.

Subclause 201.4.3.101 – Additional requirements for ESSENTIAL PERFORMANCE

The modern critical care VENTILATOR with an active exhalation valve 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 than those that have been set by the OPERATOR. ESSENTIAL PERFORMANCE as "ventilation within the ALARM LIMITS set by the OPERATOR" is inclusive of those breaths that the PATIENT modifies outside of the ventilatory parameters set by the OPERATOR, but still within the ALARM LIMITS which are considered safe by the OPERATOR. It is expected that the OPERATOR will set appropriate ALARM LIMITS which thereby define the ESSENTIAL PERFORMANCE for a particular PATIENT.

Subclause 201.4.11.101 – Additional requirements for pressurized gas input

A critical care VENTILATOR designed to be connected to a pressurised 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 pressurised gas supply.

Pressurised 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 pressure range of 280 kPa to 600 kPa under NORMAL CONDITION. It is expected that critical care VENTILATORS should operate to their declared specification with any supply pressure within this range.

In the case of a pressure regulator failure the gas supply pressure could rise to the pressure regulator's supply pressure – which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1000 kPa. All gas-powered ME EQUIPMENT should be designed so as not to present an unacceptable RISK if its supply pressure rises up to this value but in the case of critical care VENTILATORS it is considered that, because all the VENTILATORS in a critical care unit could be affected simultaneously, it is not acceptable that such VENTILATORS should just generate an ALARM SIGNAL and shut down under these overpressure conditions. For this reason, there is a specific requirement that VENTILATORS should continue operation with acceptable performance, 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 pressurised gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the VENTILATOR. This requirement is stated in subclause 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 whilst supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, 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 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 (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 minimise pressure drop, such transient demands can generally be accommodated from the gas stored locally within the pipe work of the MEDICAL GAS PIPELINE SYSTEM. There can be temporary pressure drops of the input pressure at the inlet of the VENTILATOR, to below 280 kPa, due to transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the MANUFACTURER. MANUFACTURERS need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their 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 in INTENDED USE are permitted, but their ACCOMPANYING DOCUMENTS are required to disclose those flows and warn of the need of 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 specific conditions specified for the test do not allow a direct comparison between the two values. The committee 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 spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101 – Additional requirements for general requirements for testing of ME EQUIPMENT

After due consideration, the committee decided that where this standard specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end value of both ranges should be applicable to both ranges. This means that a MANUFACTURER is free to use a round number end value (e.g., 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to satisfy also the test requirements of the adjacent range. This permits, for example, one VENTILATOR to have a declared range DELIVERED VOLUME of 300 ml to 1000 ml and another 100 ml to 300 ml, with each VENTILATOR only being required to be tested for the conditions specified for ▌AC1⟩ ≥ ⟨AC1▐ 300 ml or ▌AC1⟩ ≥ ⟨AC1▐ 300 ml respectively.

Subclause 201.5.101.2 – Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~ 37 °C) irrespective of the temperature of the gas delivered by 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 pressurised 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 standard for all requirements concerning gas input.

However, VENTILATORS complying with this standard are likely to be inflating the PATIENT'S lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from a VENTILATOR. With a standard temperature of 0 °C, 1 l of gas referenced to STPD (Standard Temperature Pressure Dry) can expand the lungs 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 inspired flow inside the VENTILATOR. When, however, the flow transducer is located at the Y-piece, the relative humidity can be anything up to 100 %. When a HEAT AND MOISTURE EXCHANGER is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the HEAT AND MOISTURE EXCHANGER. With a turbine-based VENTILATOR that uses ambient air, the humidity of the drawn-in air can be unknown to the VENTILATOR. All these effects together will inevitably introduce some errors in the conversion of the measured flow signal to BTPS reference conditions. However, these errors are only in the range of several percent. For DELIVERED VOLUMES greater than 50 ml, the committee came to the conclusion that the permitted inaccuracy of the measurement of ±(4 ml + 15 %) is sufficiently wide and includes the inaccuracy of the flow transducer and the inaccuracy of the conversion to BTPS conditions. However, it remains the responsibility of the MANUFACTURER to VERIFY that the accuracy requirements of 201.12.1 and 201.12.4.103 are met.

Subclause 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 also recognise the significance of the uncertainty in their own measurements when testing to this standard.

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 standard.

Subclause 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.

Subclause 201.7.4.3 – Unit of measure

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.2.2.101 – Additional requirements for warnings and safety notices

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 airflow.

When there is low humidity in the air (gaseous phase moisture) the gaseous water molecules will 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 properties of a filter medium that govern the degree to which this interaction with water takes place is its relative affinity for water. A medium which readily attracts water is termed "hydrophilic" and a medium which

repels water is termed “hydrophobic”. These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

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

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

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

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

Subclause 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 the measuring sensors and the ALARM SIGNAL generation.

Subclause 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, e.g. as can be required to provide the greater length needed during MRI procedures. 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.

Subclause 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.

Subclause 201.7.9.2.16.101 – Additional requirements for reference to the technical description

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

Subclause 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.

Subclause 201.9.101 – Additional requirements for suction procedures

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

A closed SUCTION CATHETER is provided with an adaptor that permits its connection at the PATIENT-CONNECTION PORT. When used as intended, an in-line or closed SUCTION CATHETER and related suction equipment become an ACCESSORY to the VENTILATOR and an extension of the VBS. When a VBS is equipped with a SUCTION CATHETER adaptor, the PATIENT-end of the closed SUCTION CATHETER adaptor becomes the 'new' PATIENT-CONNECTION PORT.

While use of closed SUCTION CATHETERS is regarded as expected NORMAL USE by an OPERATOR, the related subatmospheric pressures within the VBS have been known to damage some VENTILATORS. [23][35]

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

Subclause 201.11.6.5.101 – Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM

Critical care VENTILATORS are LIFE-SUPPORTING ME EQUIPMENT OR SYSTEMS. Fluids commonly found in the critical care environment include saline, blood and other body fluids.

The committee agreed that the IP22 designation provided the most appropriate requirements to ensure that the VENTILATOR, its ACCESSORIES and parts maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during NORMAL USE.

Subclause 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. [8] The requirements for hygienic reprocessing of this standard 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 regard 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); and

— the necessity to guarantee the proven standardised procedures in a consistently high and verifiable quality, based on an established quality management system.

The recommended reprocessing PROCESS should be determined by:

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

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

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S 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:

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

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

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

— the microorganism's resistance to the recommended 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 previous use,

   — the previous reprocessing PROCESSES, and

   — transportation and storage;

b) the RISKS from subsequent uses, such as the following:

   — residues from the previous use (such as secretions, other body fluids, and drugs),

   — residues from the previous reprocessing PROCESSES such as cleaning agents, disinfectants and other substances, including their reaction products,

   — changes of physical, chemical or functional properties of the device, and

   — changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the RISK of transmission of any pathogenic microorganisms.

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

— the RISKS involved in the reprocessing PROCESS;

— the cost effectiveness of the reprocessing PROCESS;

— the practicability of the reprocessing PROCESS;

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

— the efficiency of the reprocessing PROCESS;

— the reproducibility of the reprocessing PROCESS;

— quality management requirements of the reprocessing PROCESS; and

— the 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 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 regard 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.

Subclause 201.12.1 – Accuracy of controls and instruments

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 critical care VENTILATOR with regard to the parameters specified. The test procedures have been written as type tests (additional information is found in 3.135 and Clause 5 of the general standard), with the expectation that MANUFACTURERS will design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified will encompass any results obtained by a type test performed in accordance with the test procedures specified in this subclause.

Subclause 201.12.1.103 – DELIVERED VOLUME monitoring

Evidence is accumulating that both volutrauma and barotrauma can result in respiratory morbidity and affect long term respiratory outcome. Overstretching of the lung results in a decrease of the compliance in the respiratory system, an increase in the water content of the lungs and microscopic evidence of alveolar and interstitial edema, alveolar hemorrhage and neutrophil infiltration. [30] The immature lung is especially vulnerable to injury due to overstretching of the lungs. [32] Volutrauma has been characterized by airway modeling and airway hyper-responsiveness in infant rats. [31] In addition the early onset of airway hyper-responsiveness is a predictor of bronchopulmonary dysplasia in human infants, [32] a condition resulting in permanent lung injury. [33] 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 201.12.1.102). 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- 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 ventilation mode until such time as the cardiorespiratory status of the PATIENT has stabilized allowing a change to volume-control ventilation.

The committee expects to make DELIVERED VOLUME monitoring mandatory in the future with the first amendment to this standard.

Subclause 201.12.1.104 – Response of the VENTILATOR to an increase in O_2 concentration

It is important that changes in the delivered oxygen concentration can be made without major delay. This is especially relevant in cases where a rapid increase of the inspired oxygen concentration is necessary for PATIENT care. For instance, it is common practice to preload the PATIENT with more than 90 % oxygen for a brief period prior to open suctioning. Depending on the design of the VENTILATOR and depending on the settings, significant delays can occur.

The committee could not develop a maximum delay as there are too many possible clinical scenarios. However, the OPERATOR needs to know how a VENTILATOR will respond, particularly to a request for a sudden increase in oxygen concentration delivery.

As a result, a test method has been developed. The results of this test are required to be disclosed in the instructions for use so that an OPERATOR can effectively care for the PATIENT.

Subclause 201.12.4.102 – Measurement of AIRWAY PRESSURE

Additional information is also found in the rationale for subclause 201.12.1.104.

The site in the VBS at which pressure is sensed varies from VENTILATOR to VENTILATOR. Generally, the MANUFACTURER chooses one of two strategies:

— measuring the AIRWAY PRESSURE by direct sampling at the PATIENT-CONNECTION PORT**:** or

— indirectly estimating the pressure at the PATIENT-CONNECTION PORT by measuring the pressures at two locations in the VENTILATOR, on the inspiratory side of the VBS (at the “to PATIENT” port) and on the expiratory side of the VBS (at the “from PATIENT” port), and, after mathematical manipulation, averaging the two values.

Even if the first strategy is chosen, the actual pressure transducer will be located inside of the VENTILATOR enclosure with narrow-diameter “plastic” tubing linking the pressure-sampling port at the PATIENT-CONNECTION PORT to the sampling nipple on the pressure transducer. And for safety reasons a separate transducer will likely measure the pressure on the inspiratory side at the “to PATIENT” port. The displayed AIRWAY PRESSURE, however, is always expected to estimate accurately the true value that would be measured at the PATIENT-CONNECTION PORT. Pressure measurement via the first strategy accurately reflects the true AIRWAY PRESSURE within the error of the pressure transducer.

If the MANUFACTURER selects the second strategy for the prediction of the true AIRWAY PRESSURE, at least two methodologies can be used to arrive at estimates of this AIRWAY PRESSURE.

Assuming that during inspiration the gas in the expiratory limb is essentially stagnant, one can conclude that the pressure measured on the expiratory side of the VBS reflects the true AIRWAY PRESSURE. And conversely during exhalation, if one assumes stagnant conditions in the inspiratory limb, the pressure measured on the inspiratory side of the VBS can be taken as the AIRWAY PRESSURE. However, if “bias” or “base” flows during inspiration and exhalation result in significant pressure losses across these individual limbs, these pressure losses need to be estimated. The AIRWAY PRESSURE on the inspiratory side, $P_Y^I(t)$, can be approximated by Equation (1):

$$P_Y^I(t) = P_I(t) - \dot{V}_I(t) \times R_I \quad (1)$$

where

$P_I(t)$ = measured pressure on the inspiratory side of the VBS,

$\dot{V}_I(t)$ = flow in the inspiratory limb, and

R_I = resistance of the inspiratory limb

The AIRWAY PRESSURE on the expiratory side, $P_Y^E(t)$, can be approximated by Equation (2):

$$P_Y^E(t) = P_E(t) + \dot{V}_E(t) \times R_E \quad (2)$$

where

$P_E(t)$ = measured pressure on the expiratory side of the VBS,

$\dot{V}_E(t)$ = flow in the expiratory limb, and

R_E = resistance of the expiratory limb

Taking the average of the inspiratory and expiratory pressures is shown in Equation (3), which arrives at the best estimate the AIRWAY PRESSURE, $\bar{P}_Y(t)$.

$$\bar{P}_Y(t) \cong \frac{P_Y^I(t) + P_Y^E(t)}{2} \quad (3)$$

The application of this last method requires a method to estimate R_I and R_E. With appropriate algorithms and regular cross checking of the two pressure transducers, the reliability and accuracy of $\bar{P}_Y(t)$ is assured.

Subclause 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 their ventilation. Therefore, it is recommended that a VENTILATOR be designed to initially use a lower priority ALARM CONDITION, which escalates to a higher priority if the ALARM LIMIT violation persists. The initial ALARM CONDITION priority and the priorities and timing of the escalation should be determined by the severity of the potential HARM to the PATIENT in combination with the length of time that the OPERATOR has to prevent the HARM from occurring.

Subclause 201.12.4.104– MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

The value chosen for the MAXIMUM LIMITED PRESSURE[19][24] 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 to supply both high PEEP and high insufflation pressures for specific PATIENTS who have not responded favourably to optimal ventilation-management strategies aimed at lung protection and lung recruitment. In such cases the OPERATOR can, as a last resort, elect to ventilate using high PEEP and high insufflation pressure. After consideration of these two conflicting needs, the committee agreed to retain the 125 hPa value used in previous ventilator standards for the MAXIMUM LIMITED PRESSURE.

Subclause 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 represents a significant corruption of the VENTILATOR'S ability to provide essential respiratory support to the PATIENT, which requires prompt action by the OPERATOR.

Examples of causes for 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 standard. Practice shows that clinically used ALARM LIMITS are not always sensitive enough to provide early and specific detection of this potentially HAZARDOUS SITUATION.

Subclause 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 buildup 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 (expiratory work of breathing, missing triggers), but can develop into total obstruction. It is therefore desirable to detect and alert the OPERATOR to an increased

resistance of the expiratory limb as early as possible to give the OPERATOR sufficient time for remedy without interrupting ventilation.

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

Subclause 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 of 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; a specific sequence of key or switch operations.

Subclause 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 must 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.

Subclause 201.13.102 – Failure of one gas supply to a VENTILATOR

This subclause addresses the HAZARDOUS SITUATION created when an entire unit (e.g. the whole critical care unit or all of the operating theatres) experiences simultaneous failure of multiple VENTILATORS caused by the loss of a single pressurized gas source where at least one gas source is provided by a pressurized MEDICAL GAS PIPELINE SYSTEM.

EXAMPLE 1 A VENTILATOR is connected to both air and oxygen MEDICAL GAS PIPELINE SYSTEM and one of the MEDICAL GAS PIPELINE SYSTEMS fails. The VENTILATOR then uses the other MEDICAL GAS PIPELINE SYSTEM to supply gas.

EXAMPLE 2 A blower-based VENTILATOR connected to an oxygen MEDICAL GAS PIPELINE SYSTEM and that MEDICAL GAS PIPELINE SYSTEM fails. The VENTILATOR then uses the room air provided by its blower.

Subclause 201.13.103 – Independence of ventilation control function and related RISK CONTROL measures

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

Subclause 201.15.3.5.101.1 – Shock and vibration

ME EQUIPMENT, including VENTILATORS, in NORMAL USE, used within a professional healthcare facility, or HOME HEALTHCARE ENVIRONMENT will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used in a professional healthcare facility and the HOME HEALTHCARE ENVIRONMENT needs to be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M1. IEC 60721-3-7 indicates that this class applies within, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

In reviewing the random vibration tests of IEC 60068-2-64:2008, the committee determined that the environment included careful handling in vehicles (including airborne vehicles). Since a critical care VENTILATOR is not intended for such environments, the maximum frequency of the acceleration amplitude was limited to 500 Hz which is more reflective of non-vehicle environments.

The intention of these tests is to assess mechanical stresses on the VENTILATOR in NORMAL USE and not to assess the suitability of the design for the EXPECTED SERVICE LIFE or fatigue.

Subclause 201.15.3.5.101.2 – Shock and vibration for a MOBILE VENTILATOR

MOBILE VENTILATORS (those intended to operate while the PATIENT is being transported within a healthcare facility) are expected to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE while they are being moved. Some DEGRADATION is permitted, but the PATIENT is expected to continue to be adequately and safely ventilated. Rationale for 202.6.2.1.10 contains additional information regarding appropriate acceptance criteria for ESSENTIAL PERFORMANCE.

Subclause 201.101.1 – Protection against reverse gas leakage

These conditions are necessary to maintain PATIENT safety by protecting the MEDICAL GAS PIPELINE SYSTEM from contamination via reverse flow.

The basic requirements of this subclause were introduced into standards more than a decade ago because of the HARM due to reverse gas leakage that was known to have occurred in connection with medical devices that use multiple gas sources.

With devices fitted with multiple gas input ports for the same gas, the HAZARDOUS SITUATION results from the undetected loss of backup gas supplies due to back leakage into the primary supply. With gas input ports for different gasses, the HAZARD is contamination of one gas source by gas from another source. The contamination HAZARD is particularly likely to occur while the medical device is left in a condition where it is connected to the gas supplies but is not drawing flow from the gas supply system.

VENTILATORS are frequently equipped with multiple gas input ports either to achieve a greater flow or to use a local backup supply, e.g., a gas cylinder, in parallel with a pipeline supply. With such systems the backup supply could be depleted prematurely during use or, when connected but not in use, could deplete without detection and not be available when required in an emergency.

With a VENTILATOR equipped with more than one different gas input port, even very small leakages from one of the gas systems to the other can cause considerable build up of contamination in a MEDICAL GAS PIPELINE SYSTEM over extended periods during which little flow is withdrawn.

More than 10 years of experience has demonstrated that these requirements are effective RISK CONTROL measures.

Subclause 201.101.3.1 – 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.

Subclause 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 International Standard.

Subclause 201.102.4 – Water management

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 will contain a finite quantity of moisture. Water management in the VBS requires attention, whether or not the VBS contains an active HUMIDIFIER, with or without heated wires in the inspiratory or the expiratory limbs of the VBS, or a passive or an active HME at the PATIENT-CONNECTION PORT.

Proper management of the PATIENT'S airway secretions and mucociliary transport system requires that the VENTILATOR compensate for the humidity deficit caused by intubation, which bypasses the upper airways where the normal humidification PROCESS would begin. Excess moisture delivered to the PATIENT-CONNECTION PORT can flood the cilia located in the bronchial airways, diminishing their ability to move mucus toward the trachea. On the other hand insufficient humidification of the inspired breathing gas dries the bronchial airways, which leads to thickening of the mucous secretions and likely increased airway resistance or worse. A balanced approach to humidification is needed to maintain healthy cilia. Liquefied mucus can be readily aspirated using a SUCTION CATHETER.

Optimal humidification of the PATIENT'S airways results from an understanding of the physics of the techniques chosen to add water vapour to the inspiratory gas stream. Depending on the system selected for delivering humidified breathing gas to the PATIENT (for example, active vapour HUMIDIFIER with or without heated wires, conventional HME or active HME), condensate can accumulate in the inspiratory limb of the VBS. If condensation occurs, the VBS will need to provide a method by which the liquid can be removed.

In all but the most unusual circumstances, gas leaving the alveoli is saturated at 37 °C. Rainout persists as the moist gas cools and moves toward the PATIENT-CONNECTION PORT, and is conducted back to the VENTILATOR. If an HME is fitted at the PATIENT-CONNECTION PORT, approximately 50 % to 70 % of the water vapour will be trapped in the HME. Whatever the configuration of the expiratory limb of the VBS, the water vapour content of the exhaled gas will be significant, nearing saturation. Without heated wires, the returning gas cools, causing significant condensation. As in the inspiratory limb, this liquid needs to be removed. The presence of heated wires in the expiratory limb lessens or eliminates condensation before the expired gas enters the GAS RETURN PORT of the VENTILATOR, but from this point to the EXHAUST PORT the gas tends to cool further, so more moisture will condense. The VBS needs to include some means to manage this additional condensed water.

Subclause 201.102.7.2 – Non-invasive ventilation

The inaccuracies are due to the nature of the non-intentional leaks (such as those that occur when a PATIENT'S mouth opens when on a nasal mask or when the mask seal begins leaking when the pressure inside reaches a certain pressure.

Subclause 201.103 – Spontaneous breathing during loss of power supply

Electrical or pneumatic power outside the values required for normal operation can affect all VENTILATORS in a given unit. This is not limited to a loss of power but also includes excessive power. Although this is an infrequent event, it constitutes a particularly difficult situation because many or all VENTILATORS can become simultaneously compromised. It is therefore imperative that such a PATIENT can breathe spontaneously under these conditions until alternative ventilation is provided.

A previous version of this standard (IEC 60601-2-12:2001) required disclosure of the resistance under failure conditions. Previous standards for critical care VENTILATORS have required that the pressure drop be less than 6 hPa (6 cmH_2O) at 60 l/min for adults. PATIENTS in a critical care unit usually don't generate such high inspiratory flows. Considering this and that ACCESSORIES can be placed in the VBS, the committee came to the conclusion that this value is unnecessarily design restrictive. In addition, spontaneous breathing is only needed to bridge the time until alternative ventilation is provided. The committee came to the conclusion that a mere disclosure is not sufficient. The chosen values are regarded as more realistic and sufficient for this infrequent event and were tailored to the intended range of DELIVERED VOLUMES.

Subclause 201.104 – Training

The modern critical care VENTILATOR is a complex LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM whose use requires specific training for each MANUFACTURER'S make and model. Different MANUFACTURERS often refer to similar modes of ventilation by different names, and, although in principle similar to another MANUFACTURER'S VENTILATOR, their mode is unique in sometimes minor and sometimes complex ways. It is essential, therefore, that however experienced the OPERATOR, every person involved with its operation and setup is fully trained in the VENTILATOR'S operational characteristics, in particular its controls, capabilities and limitations, prior to any use.

Subclause 201.105 – Indication of duration of operation

VENTILATORS require maintenance for continued safe use. A practicable means to ensure that this information is available to the OPERATOR or the RESPONSIBLE ORGANIZATION is to require that the VENTILATOR keep track of how long it has been in operation.

Subclause 201.106.2 – Connection to electronic health record

Electronic documentation of PATIENT care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual PATIENT through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. In some countries, there is a governmental directive to provide electronic health records by 2015. [18] Electronic data transmission to the electronic health record is essential to meet this requirement.

The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09.

Subclause 201.106.3 – Connection to DISTRIBUTED ALARM SYSTEM

PATIENTS who are VENTILATOR-dependent are usually located in clinical environments that are staffed with OPERATORS in sufficiently close proximity to hear ALARM SIGNALS coming from the PATIENT'S room. However, many PATIENTS are in lower acuity rooms without OPERATORS in close proximity to the PATIENT'S room. PATIENTS also can be in enclosed (positive or negative pressure) isolation rooms. In these settings, it can be difficult or impossible for OPERATORS to hear ALARM SIGNALS. As a result, an appropriate response can be delayed with catastrophic results. A DISTRIBUTED ALARM SYSTEM facilitates delivery of ALARM SIGNALS to remotely located OPERATORS, thereby permitting a timely response and intervention to support PATIENT care.

The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09.

Subclause 201.108 – Timed ventilatory pause

Pausing mechanical ventilation is necessary for certain clinical PROCEDURES.

EXAMPLES Chest x-ray at an OPERATOR-chosen level of inflation, chest x-ray at end expiration, measuring central venous pressure or cardiac output, measuring respirophasic blood pressure variation, suctioning the airway, turning the PATIENT.

Currently, in order to avoid nuisance ALARM SIGNALS and to avoid cycling the VENTILATOR while the VBS is disconnected from the PATIENT, OPERATORS usually turn off the VENTILATOR and thereby incur the RISK of undetected prolonged apnoea by subsequently forgetting to turn the VENTILATOR back on.

Alternatively, the x-ray technicians manually attempt to synchronize chest x-ray exposure to ventilatory phase through hand-eye coordination, with varying effectiveness. Automated synchronization of x-ray exposure and ventilation would provide clinical benefits. [28]

In addition, there are situations where, to permit the minimum disruption of ventilation, the initiation of the ventilatory pause needs to come from external equipment. This is particularly important for those PROCEDURES,

e.g., high doses of radiation, where the OPERATOR needs to evacuate the immediate area or when manual synchronization would be less effective. [28]

As part of the RISK MANAGEMENT PROCESS, special attention should be paid to ensuring that the PATIENT'S lungs remains adequately ventilated when either externally generated or repetitive ventilatory pauses occur.

The expiratory pause should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09.

Subclause 202.6.2.1.10 – Compliance criteria

It is not the intent of the committee to require that the immunity tests be performed multiple times (e.g. with volume-controlled breath type and pressure-controlled breath type at several DELIVERED VOLUMES), but that the MANUFACTURER should determine which breath type and DELIVERED VOLUME represents the worst case for a given IMMUNITY test and use those conditions.

The committee considered whether a pressure error acceptance criterion was necessary. For a given set of test conditions and parameters, the compliance and resistance is fixed. As a result, an error in pressure is reflected as an error in DELIVERED VOLUME. Therefore the committee considers the DELIVERED VOLUME acceptance criteria sufficient.

Subclause 208.6.3.3.2.101 – Additional requirements for characteristics of ALARM CONDITION logging

Optimal management of a PATIENT requires the ability to review the history of important ALARM CONDITIONS. This is a more reasonable means of RISK CONTROL in the critical care environment for a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM than LATCHING ALARM SIGNALS. Additional information is also found in IEC 60601-1-8:2006, Annex A, for 6.12 – ALARM CONDITION logging.

Subclause 208.6.8.4.101 – Additional requirements for termination of ALARM SIGNAL inactivation

Permitting very long pauses of ALARM SIGNALS can be hazardous for the PATIENT since the OPERATOR will not be notified of the existence of an ALARM CONDITION. However, PATIENT management often requires delicate procedures that can be disrupted by auditory ALARM SIGNALS. Therefore, extending AUDIO PAUSED by OPERATOR action is useful to prevent the VENTILATOR from disturbing the OPERATOR or others in the vicinity (e.g. surgeon or cardiologist) in the PATIENT'S room.

VENTILATORS should be equipped with an AUDIO PAUSED capability that permits the OPERATOR to pause the ALARM SIGNALS prior to the creation of an ALARM CONDITION. Such a capability permits the OPERATOR to minimize nuisance auditory ALARM SIGNALS in situations that are known to be associated with creation of nuisance ALARM CONDITIONS. A 'planned' disconnect is a common situation where this capability is needed. Examples include open suctioning, BREATHING SYSTEM FILTER change, or insertion of a medication treatment. A closed suctioning mode should also include such a capability.

Annex BB
(informative)

Reference to the Essential Principles

This document has been prepared to support the essential principles of safety and performance of a VENTILATOR, its ACCESSORIES or parts as medical devices according to ISO/TR 16142:2006. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table BB.1 maps the clauses and subclauses of this document with the essential principles of ISO/TR 16142:2006.

Table BB.1 — Correspondence between this document and the essential principles

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
1, 2, 3	All	
1	201.13, 201.106, 201.107, 201.108, 206	And via IEC 60601-1-6
2	201.13, 201.103, 201.105, 201.106	
3	201.12.1, 201.12.4, 201.102, 201.105, 201.108	
4	201.12.1, 201.12.4, 201.13, 201.15, 201.102, 201.105	
5	201.7	
6	201.103	
7.1	201.9, 201.11	
7.2	201.11	
7.3	201.11	
7.4	–	Not applicable
7.5	201.11, 201.13	
7.6	201.11, 201.13	
8.1	201.11	
8.1.1	–	Not applicable
8.1.2	–	Not applicable
8.2	–	Not applicable
8.3	–	Not applicable
8.4	–	Not applicable
8.5	201.11	
8.6, 8.7	201.7	
9.1	201.8, 201.9, 201.11, 201.14, 201.15, 201.16, 201.101, 201.102, 201.106, 201.108	
9.2	201.8, 201.9, 201.12, 201.15, 201.101, 201.106, 201.108, 202, 206	

Table BB.1 — (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
9.3	201.8, 201.11, 201.13, 201.15	
10.1	201.12	
10.2	201.12	
10.3	201.7	
11.1.1	201.10, 201.12, 201.17, 202	
11.2.1	–	Not applicable
11.2.2	–	Not applicable
11.3	201.10, 201.12	
11.4	201.7	
11.5.1	–	Not applicable
11.5.2	–	Not applicable
11.5.3	–	Not applicable
12.1	201.14	
12.2	201.11.8	
12.3	201.12, 201.11.8	
12.4	201.12.4, 201.12, 208	
12.5	201.17, 202	
12.6	201.8, 201.15, 201.16	
12.7.1	201.9, 201.15, 201.16	
12.7.2	201.9, 201.16	
12.7.3	201.9, 201.16	
12.7.4	201.7, 201.8, 201.15, 201.16, 201.101	
12.7.5	201.11, 201.15, 201.16	
12.8.1	201.12, 201.101	
12.8.2	201.7, 201.12	
12.8.3	201.7, 201.12, 201.104, 201.107, 206	
13.1	201.7, 201.16	
14.1	201.11	

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[2] ISO 10651-2, *Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 2: Home care ventilators for ventilator-dependent patients*

[3] ISO 10651-3, *Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators*

[4] ISO 10651-4, *Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators*

[5] ISO 10651-6, *Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices*

[6] ISO 14159, *Safety of machinery — Hygiene requirements for the design of machinery*

[7] ISO 14971, *Medical devices — Application of risk management to medical devices*

[8] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[9] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable devices*

[10] IEC 60601-1-3:2008, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*

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[12] IEC 60721-3-7, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

[13] IEC/TR 60721-4-7:2003, *Classification of environmental conditions — Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 — Portable and non-stationary use*

[14] IEC/TR 60878:2003, *Graphical symbols for electrical equipment in medical practice*

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

[16] ASTM F2761-09, *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*

[17] Council directive 93/42/EEC of 14 June 1993 concerning medical devices, The Council of the European Communities, including Amendments: 398L0079 (OJ L 331 07.12.1998 p. 1) and 300L0070 (OJ L 313 13.12.2000 p. 22)

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