

BS EN ISO 80601-2-72:2015



BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-72:2015. It supersedes BS EN ISO 10651-2:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee 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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English Version

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2015)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2015)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO 80601-2-72:2015)

This European Standard was approved by CEN on 7 May 2015.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-72:2015) 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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by September 2018.

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 ISO 10651-2:2009.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-72:2015 has been approved by CEN as EN ISO 80601-2-72:2015 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 Communities 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
201.11.6.4, 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11.6.4, 201.11.6.6	7.3	Only the part of the first sentence relating to design is addressed.
201.11.6.4	7.5	
201.11	7.6	
201.11.6.6, 201.11.6.7	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11135-1, ISO 11137-1 and ISO 17665-1.
201.4.6, 201.4.11, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.7.9.2.2.101, 201.7.9.2.14.101, 201.12.1.102, 201.12.1.103, 201.16, 201.101, 201.102, 201.106	9.1	
201.4.11.101, 201.9, 202, 206, 211	9.2	The 4th indent of ER 9.2 is not addressed.
201.11	9.3	
201.12.1, 201.102	10.1	The part of ER 10.1 relating to stability is not addressed.
201.7, 201.12.1, 206, 208	10.2	

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.4.3	10.3	
201.14	12.1	
201.14	12.1 a)	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9		
	12.8.1	Only the protection of the patient is covered.
201.12.4	12.8.2	Only the first sentence of ER 12.8.2 is covered.
201.7, 206	12.9	
201.7, 201.11.6.4	13.1	
201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.8, 201.9, 201.11.6.4	13.2	
201.7.9.1	13.3 a)	
201.7.2.17.101	13.3 b)	
201.7, 201.7.2.17.101 a)	13.3 c)	
201.7.2.17.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT.
201.7.2.17.101	13.3 f)	
201.7.2.101 a), 211		
	13.3 j)	
201.7.2.101 b)	13.3 k)	
201.7, 201.7.2.17.101 a)	13.3 m)	Presumption of conformity is only provided if one of the symbols 5.21 to 5.24 are utilized, as applicable.
201.7.9.1, 201.7.9.2, 201.16	13.6 a)	
201.7.9.2.5.101		
201.7, 201.7.9.2.8.101, 201.7.9.2.13.101, 201.16	13.6 d)	
201.16	13.6 f)	

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.9.2.1.101, 201.7.9.2.12, 201.16, 211	13.6 h)	
201.7	13.6 i)	
211	13.6 k)	
211	13.6 l)	
211	13.6 n)	
211	13.6 p)	

WARNING Other requirements and other EU Directives may be applicable to the products falling within the scope of this European 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
—	1.1.4	This relevant EHSR is not covered by this standard.
201.12.1, 201.12.102, 201.12.103	1.2.2	
201.7.2.101 c), 201.7.2.101 d), 201.101	1.5.4	
—	1.6.2	This relevant EHSR is not covered by this standard
201.8	1.6.3	

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Foreword

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

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

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

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

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

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

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

The most significant changes are the following modifications:

- extending the scope to include the VENTILATOR and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the VENTILATOR, and thus, not only the VENTILATOR itself;
- identification of ESSENTIAL PERFORMANCE for a VENTILATOR and its ACCESSORIES;
- modification of the obstruction of the expiratory limb (continuing AIRWAY PRESSURE) ALARM CONDITION requirement;

and the following additions:

- tests for ventilation performance;
- tests for mechanical strength (via IEC 60601-1-11);
- new symbols;

- requirements for a VENTILATOR as a component of an ME SYSTEM;
- tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);
- tests for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);
- consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

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

- *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
- *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*
- *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
- *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*
- *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use*
- *Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment*
- *Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*
- *Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*
- *Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

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

- *Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*
- *Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*
- *Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*
- *Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*
- *Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

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

Introduction

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

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

- “clause” means one of the 17 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes 7.1, 7.2, etc.), and
- “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

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

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80601,
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80601, and
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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

201.1 Scope, object, and related standards

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

201.1.1 *Scope

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

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

- intended for use in the HOME HEALTHCARE ENVIRONMENT;
- intended for use by a LAY OPERATOR;
- intended for use with PATIENTS who are dependent on mechanical ventilation for their life support.

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

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

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

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

EXAMPLES Breathing tubes, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, and DISTRIBUTED ALARM SYSTEM.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this part of ISO 80601 are not covered by specific requirements in this part of ISO 80601 except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

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

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

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

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

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

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

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

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

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

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

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

201.1.2 Object

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

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

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

201.1.3 Collateral standards

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

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

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

201.1.4 Particular standards

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

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

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

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

The numbering of clauses and subclauses of this part of ISO 80601 corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this part of ISO 80601 addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

- “Replacement” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this part of ISO 80601.
- “Addition” means that the text of this particular standard is additional to the requirements of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.
- “Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is amended as indicated by the text of this part of ISO 80601.

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

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

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

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

201.2 Normative references

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

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

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

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

Replacement:

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

IEC 60601-1-6:2010¹, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*
+Amendment 1:2013

IEC 60601-1-8:2006², *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+Amendment 1:2012

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

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

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

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

Addition:

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

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

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

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

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

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

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

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

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

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

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

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

ISO 8185:2007³, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

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

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

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

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

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

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

³ To be replaced by ISO 80601-2-74.

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

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

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

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

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

IEC 60601-1:2005⁵, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
+Amendment 1:2012

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

IEC 62366:2007⁶, *Medical devices — Application of usability engineering to medical devices*

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

201.3 Terms and definitions

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

Addition:

201.3.201

AIRWAY PRESSURE

P_{aw}

pressure at the PATIENT-CONNECTION PORT

201.3.202

BREATHING SYSTEM FILTER

BSF

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

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

201.3.203

DELIVERED VOLUME

V_{del}

volume of gas delivered through a PATIENT-CONNECTION PORT during a breath

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

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

⁴ To be published.

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

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

201.3.204

EXHAUST PORT

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

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

201.3.205

FLOW-DIRECTION-SENSITIVE COMPONENT

component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

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

201.3.206

FRESH GAS

respirable gas delivered to a VENTILATOR BREATHING SYSTEM

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

- air drawn through the emergency intake port;
- air drawn through leaks in the VENTILATOR BREATHING SYSTEM;
- gas exhaled by the PATIENT.

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

201.3.207

GAS INTAKE PORT

port through which gas is drawn for use by the PATIENT

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

201.3.208

GAS OUTPUT PORT

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

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

201.3.209

GAS RETURN PORT

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

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

201.3.210

HIGH-PRESSURE INPUT PORT

input port to which gas is supplied at a pressure exceeding 100 kPa

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

201.3.211

MANUAL VENTILATION PORT

port to which a manual inflating device can be connected

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

201.3.212

MAXIMUM LIMITED PRESSURE

$P_{\text{LIM max}}$

highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

201.3.213

MONITORING EQUIPMENT

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

201.3.214

PATIENT-CONNECTION PORT

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

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

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

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

201.3.215

PEEP

POSITIVE END-EXPIRATORY PRESSURE

positive AIRWAY PRESSURE at the end of an expiratory phase

[SOURCE: ISO 4135:2001, 3.3.11]

201.3.216

PROTECTION DEVICE

part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

201.3.217

VENTILATOR

VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT

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

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

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

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

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

201.3.218

VENTILATOR BREATHING SYSTEM

VBS

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

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

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

Additional subclause:

201.4.3.101* Additional requirements for ESSENTIAL PERFORMANCE

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

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION	a
AIRWAY PRESSURE	201.12.4.102
continuing positive-pressure	201.12.4.110
DELIVERED VOLUME	201.12.1.104
expired etCO ₂ ^b , if provided	201.12.4.104
high AIRWAY PRESSURE	201.12.4.106
hypoventilation	201.12.4.109
INTERNAL ELECTRICAL POWER SOURCE nears depletion	211.8.4.101
high leakage	201.12.4.111
low expired volume ^c , if provided	201.12.4.103
obstruction	201.12.4.107
oxygen levels ^d , if provided	201.12.4.101
^a 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by ISO 80601 series. ^b If expired volume monitoring is not provided or high leakage is not in use. ^c If etCO₂ monitoring or high leakage is not in use. ^d If a control for the setting of the inspiratory oxygen concentration is provided.	

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

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

The gas pathways shall be subject to the requirements for APPLIED PARTS according to this subclause. The VBS or its parts or ACCESSORIES that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS according to this subclause.

201.4.10.2* SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

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

Replacement of the tenth dash as follows.

- For operation from 12 V d.c. SUPPLY MAINS
 - the RATED range shall include at least 12,4 V to 15,1 V, and
 - the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V.
- for operation from 24 V d.c. SUPPLY MAINS

- the RATED range shall include at least 24,8 V to 30,3 V, and
- the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 20 V.
- for operation from other d.c. SUPPLY MAINS
 - a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Additional subclauses:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

If the VENTILATOR is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2007, then it shall operate and meet the requirements of this part of ISO 80601 throughout its RATED range of input pressure and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

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

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

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

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

201.4.11.101.2 Compatibility requirement

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

- the RATED range of input pressure shall cover the range specified in ISO 7396-1:2007, and
- under NORMAL CONDITION,
 - 1) the maximum 10 s average input flow required by the VENTILATOR for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port, and
 - 2) the transient input flow shall not exceed 200 l/min averaged for 3 sor
 - 3) the ACCOMPANYING DOCUMENTS shall disclose the following:
 - i) the maximum 10 s average input flow required by the VENTILATOR for each gas at a pressure of 280 kPa, measured at the gas input port;
 - ii) the maximum transient input flow averaged for 3 s required by the VENTILATOR for each gas at a pressure of 280 kPa, measured at the gas input port;

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

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings and by inspection of the ACCOMPANYING DOCUMENTS.

EXAMPLE The highest driving gas consumption, the highest FRESH GAS delivery, and, if provided, the highest RATED gas consumption at any gas power supply output.

201.5 General requirements for testing of ME EQUIPMENT

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

Addition:

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

201.5.101.1 VENTILATOR test conditions

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

201.5.101.2* Gas flowrate and leakage specifications

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

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

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

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

201.5.101.3* VENTILATOR testing errors

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

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking, and documents

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

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

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

Replacement:

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

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101, 201.7.2.13.101, and 201.7.2.17.101 and shall be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATOR, if applicable. If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

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

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

201.7.2.13.101 Additional requirements for physiological effects

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

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

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

- a) description of the contents;
- b) identification reference to the batch, type, or serial number or symbols 5.1.5, 5.1.6, or 5.1.7 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 1, symbol 2, or symbol 3);
- c) for packages containing natural rubber latex, the word "LATEX" or symbol 5.4.5 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 4).

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

Check compliance by inspection.

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

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

- a) any special storage and/or handling instructions;
- b) any particular warnings and/or precautions relevant to the immediate operation of the VENTILATOR.

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

- c) for any gas-specific inputs or outlets,
 - the gas name or chemical symbol in accordance with ISO 5359:2008,
 - gas-specific colour-coding in accordance with ISO 32:1977, if colour coding is used;

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

NOTE In some countries, other colour coding is used.

- d) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;
- e) a warning not to obstruct the GAS INTAKE PORT.

EXAMPLE 2 WARNING: Gas Intake – Do not obstruct.

Check compliance by inspection.

201.7.4.2 Control devices

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

Amendment (add after the second dash):

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

201.7.4.3 * Units of measurement

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

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

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

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

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

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

201.7.9.1 Additional general requirements

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

Amendment (replace the first dash with):

- Name or trade name and address of the following:
 - the MANUFACTURER; and
 - where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,
- to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Instructions for use

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

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

Separate instructions for use shall be provided for the following:

- LAY OPERATOR;

— supervising clinician or the healthcare professional OPERATOR.

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

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

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

201.7.9.2.1.102 Additional general requirements

The instructions for use shall include the following:

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

Check compliance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include the following:

- a) warning statement to the effect of “WARNING: To prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions.”
- b) warning statement to the effect of “WARNING: Do not cover the ventilator or place in a position that affects proper operation”, including applicable examples.

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

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

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

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

- d) * a warning statement to the effect of “WARNING: Do not add any attachments or accessories to the ventilator that are not listed in the instruction for use as the ventilator might not function correctly.”
- e) * if the instructions for use include a VBS configuration with a BSF exposed to the humidity from nebulisation or humidification, a warning statement to the effect of “WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage.”

- f) warning statement to the effect of “WARNING: Do not use the ventilator at an altitude above (insert maximum RATED altitude) or outside a temperature of [insert RATED temperature range]. Using the ventilator outside of this temperature range or above this altitude can affect the ventilator performance which consequently can result in patient death.”
- g) * warning statement to the effect of “WARNING: Do not connect the ventilator to the battery of a battery-powered wheelchair unless the connection is listed in the instruction for use of the ventilator or wheelchair as this can affect the ventilator performance which can consequently result in patient death.”
- h) warning statement to the effect of “WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use to prevent adverse ventilator performance which can consequently result in patient death.”
- i) warning statement to the effect of “WARNING: To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories”.
- j) if applicable, a warning statement to the effect of “WARNING: The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser.”
- k) if applicable, a warning statement to the effect of “WARNING: Unintentional leaks cause indicated volume and expired CO₂ values to differ from actual patient values.”

Check compliance by inspection of the instructions for use.

201.7.9.2.8.101 * Additional requirements for start-up PROCEDURE

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

The instructions for use for the LAY OPERATOR shall disclose a method by which the following can be functionally tested to determine if they are operating correctly:

- the assembled breathing tubes and related ACCESSORIES;
- switchover to and operation from the INTERNAL ELECTRICAL POWER SUPPLY;
- all ALARM SIGNALS, including the ALARM SIGNALS from DISTRIBUTED ALARM SYSTEMS,

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

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

The specifications of any required ACCESSORIES or test equipment needed to perform these tests shall be disclosed in the instructions for use for the LAY OPERATOR.

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

NOTE 2 Additional requirements are also found in 201.15.102.

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

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

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 * Additional requirements for operating instructions

201.7.9.2.9.101.1 * LAY OPERATOR operating instructions

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

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

EXAMPLE 1 Acceptable range of water level in a HUMIDIFIER.

EXAMPLE 2 Interval of calibration of a flow sensor.

- b) an explanation of the meaning of the IP classification marked on the ME EQUIPMENT;
c) an indication as to whether the VENTILATOR is intended for non-invasive ventilation;

EXAMPLE 3 MASK ventilation.

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

- high leakage;
- INTERNAL ELECTRICAL POWER SOURCE nears depletion;
- low AIRWAY PRESSURE;
- low inspiratory pressure;
- obstruction;
- power failure of external mains;
- power failure of external DC power

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

- low expired volume;
- oxygen levels

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

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

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101.2 * Supervising clinician operating instructions

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

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

- b) methods for controlling the cycling;
- c) parameter settings;
- d) range of parameter settings;
- e) any limitation of parameter settings;
- f) * a description of how at least the following ALARM CONDITIONS, if included, can be tested:
 - continuing positive-pressure;
 - DELIVERED VOLUME;
 - high AIRWAY PRESSURE;
 - high expiratory volume;
 - hypoventilation; and
 - low expiratory volume.

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

- g) the RATED range of the following characteristics of the assembled OPERATOR-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained:
 - inspiratory gas pathway resistance;
 - expiratory gas pathway resistance;
 - compliance.

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

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

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

- h) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER, and
 - EXAMPLES Dead space and resistance.
- i) a statement as to whether any portion of the gas supplied to a HIGH-PRESSURE INPUT PORT is supplied to the PATIENT.

Check compliance by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection, and sterilization

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

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

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

201.7.9.2.13.101 Additional requirements for maintenance

The instructions for use shall disclose the following:

- a) a description of periodic visual safety inspections that should be performed by the OPERATOR;
- b) the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging and replacement.

Check compliance by inspection of the instructions for use.

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

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

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

EXAMPLE Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.
- b) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the VENTILATOR.

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

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose the following:

- a) summary description of the filtering and/or smoothing techniques for all measured and/or computed variables that are displayed or used for control;
- b) interdependence of control functions;
- c) pneumatic diagram of the VENTILATOR, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use;
- d) summary description of the means of initiating and terminating the inspiratory phase while the ventilator is operating in each of its ventilatory modes;
- e) means by which the continuing pressure ALARM CONDITION is detected and a summary description of the detection algorithm;
- f) statement to the effect that the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories intended to be used to connect to the patient prior to use.

Check compliance by inspection of the technical description.