
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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Appareils électromédicaux

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

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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](http://Foreword-Supplementary%20information).

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;

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- 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.

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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.

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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 60601-11:2015, 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.

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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:

(standards.iteh.ai)

201.3.201

AIRWAY PRESSURE

P_{aw}

pressure at the PATIENT-CONNECTION PORT

[ISO 80601-2-72:2015](https://standards.iteh.ai/catalog/standards/sist/c56d3740-1728-4ccc-a6ea-d5ae3c56d9de/iso-80601-2-72-2015)

<https://standards.iteh.ai/catalog/standards/sist/c56d3740-1728-4ccc-a6ea-d5ae3c56d9de/iso-80601-2-72-2015>

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.