ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Január 2016

STN	**Zdravotnícke elektrické prístroje. Časť 2-72: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti ventilátorov pre pacientov v domácej zdravotnej starostlivosti závislých od ventilátora (ISO 80601-2-72: 2015).**	**STN EN ISO 80601-2-72** 85 2103

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)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/15

Obsahuje: EN ISO 80601-2-72:2015, ISO 80601-2-72:2015

Oznámením tejto normy sa ruší
STN EN ISO 10651-2 (85 2103) zo septembra 2009

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NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-72

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Supersedes EN ISO 10651-2:2009

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.

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, 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 United Kingdom.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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	12.7.3	
201.8, 201.15, 201.101.1, 201.101.2	12.7.4	
201.11	12.7.5	
201.12.1	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 i)	
201.7.2.101 b), 201.7.2.101 d), 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	13.6 b)	
201.7.9.2.14.101, 201.16, 201.102	13.6 c)	
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	

STN EN ISO 80601-2-72: 2016

INTERNATIONAL STANDARD ISO 80601-2-72

First edition
2015-09-01

Medical electrical equipment

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

Appareils électromédicaux

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

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Foreword

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

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

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

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

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

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

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

The most significant changes are the following modifications:

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

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

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

and the following additions:

— tests for ventilation performance;

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

— new symbols;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

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

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

201.1 Scope, object, and related standards

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

201.1.1 *Scope

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

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

— intended for use in the HOME HEALTHCARE ENVIRONMENT;

— intended for use by a LAY OPERATOR;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

201.1.2 Object

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

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

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

201.1.3 Collateral standards

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

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

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

201.1.4 Particular standards

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

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

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

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

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

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

Replacement:

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

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

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

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

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

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

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

Addition:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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ed 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.