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Meditsiinilised elektriseadmed. Osa 2-12: Erinõuded kriitilise meditsiiniabi andmisel kasutatavate ventilaatorite esmase ohutuse ja peamiste toimivusnõuete osas (ISO 80601-2-12:2011)

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 80601-2-12:2011 sisaldab Euroopa standardi EN ISO 80601-2-12:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-12:2011 consists of the English text of the European standard EN ISO 80601-2-12:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.04.2011.	Date of Availability of the European standard text 15.04.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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ICS 11.040.10

Võtmesõnad: elektriline meditsiiniaparaat, kaitse elektrilöökide vastu, kaitse mehaaniliste ohtude vastu, kiirguskaitse, klassifikatsioonid, kunstliku hingamise aparaat, määratlused, ohutusnõuded, tulekaitse, õnnetuste vältimine,

Inglisekeelsed võtmesõnad: accident prevention, artificial breathing apparatus, classifications, definitions, electro medical apparatus, fire protection, protection against electric shocks, protection against mechanical hazards, radiation protection, safety requirements,

Standardite reprodutseerimis- ja levitamisõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-12

April 2011

ICS 11.040.10

Supersedes EN 794-1:1997+A2:2009

English Version

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

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

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

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

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

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

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 80601-2-12:2011: E

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Foreword

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

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

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

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

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

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

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

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

Endorsement notice

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

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Annex ZA
(informative)

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

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

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

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

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

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Table ZA.1 — (*continued*)

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

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

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

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

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

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Introduction

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

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

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

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

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

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

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this International Standard not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier than 5 years from the date of publication for equipment already in production.

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Medical electrical equipment —

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

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201.1 Scope, object and related standards

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

201.1.1 Scope

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

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

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

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

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

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

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

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

NOTE 3 A critical care VENTILATOR, when operating in such a mode, is not considered LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

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

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

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

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

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

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

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

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

201.1.2 Object

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

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

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

201.1.3 Collateral standards

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

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

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

201.1.4 Particular standards

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

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

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

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

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

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

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

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

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

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

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

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

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

The term “this standard” is used to make reference to IEC 60601-1:2005, any applicable collateral standards and this particular standard taken together.

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

201.2 Normative references

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

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

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

Replacement:

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

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

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

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

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Addition:

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

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

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

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

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

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

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

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

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

ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ISO 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

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

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

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

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

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

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5) To be published.

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

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