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Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO/DIS 80601-2-87:2020)

Medizinische elektrische Geräte - Teil 2-87: Besondere Festlegungen an die Sicherheit und die wesentlichen Leistungsmerkmale von Hochfrequenzbeatmungsgeräten (ISO/DIS 80601-2-87:2020)

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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. 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. 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.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC62, *Electrical equipment in medical practice*, Subcommittee 62D: *Electric equipment*.

This is the first edition of ISO 80601-2-87.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

Introduction

In this document, the following print types are used:

– Requirements and definitions: roman type

– *Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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

In referring to the structure of this document, the term

– “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

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

– “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;

– “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

– “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

– "can" is used to describe a possibility or capability; and

– "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

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.

Medical Electrical Equipment — Part 2-87: Particular requirements for basic safety and essential performance of high-frequency critical care ventilators

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of a *high-frequency ventilator* (*HFV*) in combination with its *accessories*, hereafter referred to as *ME equipment:*

— intended for use in an environment that provides specialized care for *patients* whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a *professional healthcare facility;*

NOTE 1 For the purposes of this document, such an environment is referred to as a critical care environment. *High-frequency ventilators* for this environment are considered life-sustaining.

NOTE 2 For the purposes of this document, such a *high-frequency ventilator* can provide transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 3 A *high-frequency ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *ventilator* intended for the *emergency medical services environment*.

— intended to be operated by a *healthcare professional operator*;

— intended for those *patients* who need differing levels of support from *artificial ventilation* including *ventilator-dependent patients;* and

— capable of providing more than 150 *inflations*/min.

There are three principal designations of *HFV*:

— high frequency percussive *ventilation* (HFPV, with a typical *HFV frequency* of (60 to 1 000) *HFV inflations*/min);

— high frequency jet *ventilation* (HFJV, with a typical *HFV frequency* of (100 to 1 500) *HFV inflations*/min); and

— high frequency oscillatory *ventilation* (HFOV, with a typical *HFV frequency* of (180 to 1200) *HFV inflations*/min and typically having an active *expiratory phase*).

Additionally, *HFV* designations can be combined together or with *ventilation* at *rates* less than 150 *inflations*/min.

[1] The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

* A *high-frequency ventilator* is not considered to utilize *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the *ventilation* therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *HFV breathing system*, or to a *high-frequency ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *high-frequency ventilator*.

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 document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005.

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

This document is not applicable to *ME equipment* that is intended solely to augment the *ventilation* of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

— non-*high-frequency ventilators* or *accessories* which provide conventional *ventilation* for use in critical care environments, which are given in ISO 80601-2-12;.

NOTE 5 An *HFV* can incorporate conventional critical care *ventilator operational modes*, in which case ISO 80601-2-12 is applicable to those modes.

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13 [3] [2];

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84, the future replacement for ISO 10651-3 [4];

NOTE 6 An *HFV* can incorporate *EMS ventilator* capability.

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment,* which are given in ISO 80601-2-72 [5];

— *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 [6] and ISO 80601-2-80 [7], the replacements for ISO 10651-6 [8];

— sleep apnoea breathing therapy *ME equipment*, which are given in ISO 80601-2-70 [9];

— *continuous positive airway pressure* (*CPAP*) *ME equipment*;

— oxygen therapy constant flow *ME equipment*; and

[2] Figures in square brackets refer to the Bibliography.

— cuirass or “iron-lung” *ventilation* equipment.

This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of documents.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *high-frequency ventilator,* as defined in 201.3.201, and its *accessories*.

NOTE 1 *Accessories* are included because the combination of the *high-frequency ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *high-frequency ventilator*.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 [10] as indicated in Annex DD.

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3 [11], IEC 60601-1-9 [12], IEC 60601-1-11 and IEC 60601-1-12 [13] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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.

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

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document 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 document.

"Addition" means that the text of this document 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 document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. 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 [11], etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, 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 particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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.

Clause 2 of the general standard applies, except as follows:

Replacement:

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

ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014 +AMD6:2014+AMD7:2016+AMD8:2017, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *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 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

Addition:

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

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

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2014, *Anaesthetic and respiratory equipment -- Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems -- Fundamentals and vocabulary*

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 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories*

ISO 17664:2017, *Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications-- Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment -- Vocabulary and semantics*

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 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements*

ISO 80601-2-12:— [3] (Ed 2), *Medical electrical equipment — Part 2-12: Particular requirements for the basic safety and essential performance of critical care ventilators*

ISO 80601-2-55:2018 (Ed 2), *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment*

ISO 80601-2-84:— [4], *Medical electrical equipment — Part 2- 84: Particular requirements for basic safety and essential performance of emergency and transport ventilators*

IEC 60068-2-27:2008, *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*

IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007, *Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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*

IEC 60601-1-12:2014, *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services 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*

[3] Under preparation. Stage at the time of publication: ISO FDIS 80601-2-12:2019.

[4] Under preparation. Stage at the time of publication: ISO FDIS 80601-2-84:2019.

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

EN 15986:2011, *Symbols for medical devices containing phthalates*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2011, ISO 7396-1:2016, ISO 8836:2014, ISO 9000:2015, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-10:2007, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 60601-2-2:2009, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-12:—, ISO 80601-2-74:2017, ISO 80601-2-84:— and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

– IEC Electropedia: available at http://www.electropedia.org/

– ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found Annex EE.

201.3.201
high-frequency ventilator
HFV
ME equipment intended to provide *ventilation* of the *lungs* of the *patient* when connected to the airway of the *patient* using a *rate* greater than 150 *inflations*/min

Note 1 to entry: Inflation rates are specified as per minute solely when differentiating from conventional-rate *ventilation*. All normative requirements regarding HFV are written using inflation rates per second.

201.3.202
HFV breathing system
pathways through which gas flows to or from the *HFV* and to or from the *patient*

201.3.203
HFV inflation
periodic *ventilator* action intended to increase the volume of gas in the *lungs*

201.3.204
HFV volume
volume of gas delivered through the *patient-connection port* or at the distal outlet of the jet system during an *HFV inflation*

Note 1 to entry: The effective volume delivered to the *lung* can be significantly smaller than the *HFV volume*. The leakage of uncuffed tracheal tubes and even small changes in resistance or compliance of the respiratory system (e.g. by secretion in the airways, through the use of a different *HFV breathing system* or tracheal tube) can change the volume delivered to the *lung*.

Note 2 to entry: The achievable *HFV volume* depends characteristically on the *HFV frequency*. In general, lower *HFV frequencies* permit higher *HFV volumes*.