

Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO 80601-2-87:2021)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-87:2021 sisaldab Euroopa standardi EN ISO 80601-2-87:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-87:2021 consists of the English text of the European standard EN ISO 80601-2-87:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.04.2021.	Date of Availability of the European standard is 28.04.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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English Version

Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO 80601-2-87:2021)

Appareils électromédicaux - Partie 2-87: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs à haute fréquence (ISO 80601-2-87:2021)

Medizinische elektrische Geräte - Teil 2-87: Besondere Festlegungen an die Sicherheit und die wesentlichen Leistungsmerkmale von Hochfrequenz Beatmungsgeräten (ISO 80601-2-87:2021)

This European Standard was approved by CEN on 2 April 2021.

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## European foreword

This document (EN ISO 80601-2-87:2021) 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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.

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

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 80601-2-87:2021 has been approved by CEN as EN ISO 80601-2-87:2021 without any modification.

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## 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.

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 IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

##### 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 a *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.

\* A *high-frequency ventilator* is not considered a *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 <sup>[23]</sup>;

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 <sup>[24]</sup>;
- *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84, the replacement for ISO 10651-3 <sup>[13]</sup>;

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 <sup>[26]</sup>;
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 <sup>[27]</sup> and ISO 80601-2-80 <sup>[28]</sup>, the replacements for ISO 10651-6 <sup>[15]</sup>;
- sleep apnoea breathing therapy *ME equipment*, which are given in ISO 80601-2-70 <sup>[25]</sup>;
- *bi-level positive airway pressure (bi-level PAP) ME equipment*;
- *continuous positive airway pressure (CPAP) ME equipment*;

- respiratory high-flow *ME equipment*, which are given in ISO 80601-2-90:—<sup>1</sup>; and
- cuirass or “iron-lung” *ventilation equipment*.

This document is a particular standard in the IEC 60601 series, the IEC 80601 series and the ISO 80601 series.

### 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*<sup>[39]</sup> and labelling<sup>[40]</sup> guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745<sup>[38]</sup> as indicated in Annex FF.

### 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<sup>[29]</sup>, IEC 60601-1-9<sup>[30]</sup>, IEC 60601-1-11 and IEC 60601-1-12<sup>[31]</sup> 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+AMD1:2012+AMD2:2020 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 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

<sup>1</sup> Under preparation. Stage at the time of publication: ISO/DIS 80601-2-90:2020.

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 <sup>[29]</sup>, 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.

Clause 2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

*Replacement:*

ISO 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

*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+AMD1:2017, *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 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 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 20417:2020, *Medical devices — Information to be supplied by the manufacturer*

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

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

ISO 80601-2-84:2020, *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*

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<sup>2</sup> Under preparation. Stage at the time of publication: ISO/DIS 80601-2-74:2020

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+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007+AMD1:2020+AMD2:2020, *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+AMD1:2020+AMD2:2020, *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+AMD1:2020, *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 62366-1:2015+AMD1:2020, *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*

### 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

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

#### 201.3.201

##### accompanying information

information accompanying or *marked* on a *medical device* or *accessory* (3.1) for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.