



SLOVENSKI STANDARD
SIST EN ISO 80601-2-87:2021

01-julij-2021

Medicinska električna oprema - 2-87. del: Posebne zahteve za osnovno varnost in bistvene lastnosti visokofrekvenčnega ventilatorja (ISO 80601-2-87:2021)

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

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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)

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Ta slovenski standard je istoveten z: EN ISO 80601-2-87:2021

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO 80601-2-87:2021)

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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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.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.

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ISO
80601-2-87

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2021-04

Medical electrical equipment —
Part 2-87:
Particular requirements for basic
safety and essential performance of
high-frequency ventilators

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Appareils électromédicaux —

Partie 2-87: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs à haute fréquence

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 and IEC 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) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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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*].

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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 [23];

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

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 [26];
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 [27] and ISO 80601-2-80 [28], the replacements for ISO 10651-6 [15];
- sleep apnoea breathing therapy *ME equipment*, which are given in ISO 80601-2-70 [25];
- *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:—¹; 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*^[39] and labelling^[40] 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^[38] as indicated in Annex FF.

201.1.3 Collateral standards

Amendment (add after existing text): [SIST EN ISO 80601-2-87:2021](https://www.iso.org/standards/catalog/standards/sist/8a63d826-b514-44c9-aeb5-7845635478ef/sist-en-iso-80601-2-87-2021)

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^[29], IEC 60601-1-9^[30], IEC 60601-1-11 and IEC 60601-1-12^[31] 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

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