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

*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

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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](http://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](http://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](http://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](http://www.iso.org/members.html).

## 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*].