Irish Standard
I.S. EN 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)

I.S. EN ISO 80601-2-87:2021

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:	*Published:*
EN ISO 80601-2-87:2021	2021-04-28

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2021-05-27	11.040.10
	NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 80601-2-87:2021 is the adopted Irish version of the European Document EN 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)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-87

April 2021

ICS 11.040.10

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.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 80601-2-87:2021 E

Contents

Page

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.

This page is intentionally left blank

INTERNATIONAL STANDARD

ISO 80601-2-87

First edition
2021-04

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

Reference number
ISO 80601-2-87:2021(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

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.

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*].