ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Február 2024

STN	**Zdravotnícke elektrické prístroje Časť 2-84: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti ventilátorov v prostredí záchrannej zdravotníckej služby (ISO 80601-2-84: 2023)**	**STN EN ISO 80601-2-84** 85 2101

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (ISO 80601-2-84:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/24

Obsahuje: EN ISO 80601-2-84:2023, ISO 80601-2-84:2023

Oznámením tejto normy sa ruší
STN EN 794-3+A2 (85 2101) z decembra 2009

obsahuje farebné strany

138013

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-84

November 2023

ICS 11.040.10

Supersedes EN 794-3:1998+A2:2009

English Version

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (ISO 80601-2-84:2023)

Appareils électromédicaux - Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence (ISO 80601-2-84:2023)

Medizinische elektrische Geräte - Teil 2-84: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Notfall- und Transportbeatmungsgeräten (ISO 80601-2-84:2023)

This European Standard was approved by CEN on 1 September 2023.

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, Türkiye 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 80601-2-84:2023 E

Contents

Page

European foreword

This document (EN ISO 80601-2-84:2023) 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 May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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.

This document supersedes EN 794-3:1998+A2:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-84:2023 has been approved by CEN as EN ISO 80601-2-84:2023 without any modification.

INTERNATIONAL STANDARD

ISO 80601-2-84

Second edition
2023-11

Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

Appareils électromédicaux —

Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence

Reference number
ISO 80601-2-84:2023(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 or www.iec.ch/members_experts/refdocs).

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 https://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. In the IEC, see www.iec.ch/understanding-standards.

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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems,* 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).

This second edition cancels and replaces the first edition (ISO 80601-2-84:2020), which has been technically revised. The main changes are as follows:

— alignment with 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 IEC 60601-1-12:2014+AMD1:2020;

— added requirements for a *responsible organization* log

— added requirements for the display legibility for *operators* wearing personal protective equipment;

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— added requirements for *ventilator system recovery*;

— added requirements and definitions for *cybersecurity*; and

— harmonization with ISO 20417, where appropriate.

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

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 and www.iec.ch/national-committees.

Introduction

In referring to the structure of this document, the term

— “clause” means one of the five 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 particular 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.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

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

— "must" is used to indicate 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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

INTERNATIONAL STANDARD **ISO 80601-2-84:2023(E)**

Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of an *EMS ventilator* in combination with its *accessories*, hereafter also referred to as *ME equipment:*

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

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

— intended for use in the *EMS environment*; and

— intended for invasive or non-invasive *ventilation*.

NOTE 2 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

An *EMS ventilator* is not considered to use a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the *artificial ventilation* therapy settings.

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

NOTE 3 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 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 4 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for the following:

NOTE 5 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications, which are given in ISO 80601-2-12.

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

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13.

— *ventilators* or *accessories* intended for ventilatory support equipment (intended only to augment the *ventilation* of spontaneously breathing *patients*), which are given in ISO 80601-2-79 and ISO 80601-2-80.

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70.

— user-powered resuscitators, which are given in ISO 10651-4.

— gas-powered emergency resuscitators, which are given in ISO 10651-5.

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

— high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87.

— high-frequency oscillatory *ventilators* (HFOVs)[44], which are given in ISO 80601-2-87.

NOTE 6 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-modes*.

— respiratory high-flow therapy equipment, which are given in ISO 80601-2-90.

NOTE 7 An *EMS ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

— oxygen therapy constant flow *ME equipment*.

— cuirass or “iron-lung” *ventilators*.

201.1.2 Object

Replacement:

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an *EMS ventilator,* as defined in 201.3.228, and its *accessories*.

Accessories are included because the combination of the *EMS ventilator* and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *EMS ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles*[38] and labelling[39] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

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 DD.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[40].

