SLOVENSKI STANDARD
SIST EN ISO 80601-2-72:2023

01-oktober-2023

Nadomešča:
SIST EN ISO 80601-2-72:2015

Medicinska električna oprema - 2-72. del: Posebne zahteve za osnovno varnost in bistvene lastnosti respiratorjev za oskrbo od aparata odvisnih pacientov na domu (ISO 80601-2-72:2023)

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2023)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO 80601-2-72:2023)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2023)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-72:2023**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 80601-2-72:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-72

July 2023

ICS 11.040.10

Supersedes EN ISO 80601-2-72:2015

English Version

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2023)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2023)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO 80601-2-72:2023)

This European Standard was approved by CEN on 24 April 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 80601-2-72:2023 E

Contents

Page

European foreword

This document (EN ISO 80601-2-72:2023) 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 January 2024, and conflicting national standards shall be withdrawn at the latest by January 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 ISO 80601-2-72:2015.

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 80601-2-72:2023 has been approved by CEN as EN ISO 80601-2-72:2023 without any modification.

INTERNATIONAL STANDARD

ISO 80601-2-72

Second edition
2023-06

Medical electrical equipment —

Part 2-72: **Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients**

Appareils électromédicaux —

Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants

Reference number
ISO 80601-2-72:2023(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 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, *Electric 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).

This second edition cancels and replaces the first edition (ISO 80601-2-72:2015), which has been technically revised.

The main changes are as follows:

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— clarified high *airway pressure alarm condition* requirements;

— added requirements for *ventilator system recovery*;

— added requirements for response to an increase in set oxygen (O_2) concentration; 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

This document specifies requirements for *lung ventilators* that are intended for use in the *home healthcare environment* for *patients* who are dependent on *ventilation* for their life support. These *ventilators* are frequently used in locations where the *supply mains* driving the *ventilator* is not reliable. These *ventilators* are often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. *Lung ventilators* conforming with this standard can be used elsewhere (i.e. in healthcare facilities).

In referring to the structure of this document,

— “clause” means one of the 5 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes 201.7, 201.8, etc.); and

— “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” 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 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.

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

Medical electrical equipment —

Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

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 a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment:*

— intended for use in the *home healthcare environment;*

NOTE 2 In the *home healthcare environment*, the *supply mains* driving the *ventilator* is often not reliable.

NOTE 3 Such *ventilators* can also be used in non-critical care applications of *professional healthcare facilities.*

— intended for use by a *lay operator;* and

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

A *ventilator* is not considered to use 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 a *ventilator breathing system* or to a *ventilator* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

EXAMPLE Breathing tubes, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, and *distributed alarm system.*

NOTE 4 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 for the requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

