SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-72:2022

01-junij-2022

Medicinska električna oprema - 2-72. del: Posebne zahteve za osnovno varnost in bistvene lastnosti respiratorjev za oskrbo od aparata odvisnih pacientov na domu (ISO/DIS 80601-2-72:2022)

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO/DIS 80601-2-72:2022)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO/DIS 80601-2-72:2022)

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/DIS 80601-2-72:2022)

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

ICS:

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

oSIST prEN ISO 80601-2-72:2022 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

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ISO/TC **121**/SC **3**

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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

ICS: 11.040.10

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

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CS will add the contents table at the FDIS stage.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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 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).

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 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 compared to the previous edition are as follows:

The most significant changes are the following modifications:

- 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 60601-1-11:2015+AMD1:2020;
- reformatted according to most recent Central Secretariat editing rules;
- 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 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

This part of ISO 80601 specifies requirements for *lung ventilators* that are intended for use in the *home healthcare environment* for *patients* who are dependent for *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 part of ISO 80601,

— “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 part of ISO 80601 are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular part of ISO 80601 are by number only.

In this part of ISO 80601, 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 part of ISO 80601 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 utilize a *physiologic closed-loop control system* unless it uses a physiological *patient* variable to adjust the *ventilation* therapy settings.

This part of ISO 80601 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 part of ISO 80601 are not covered by specific requirements in this part of ISO 80601 except in IEC 60601-1:2005+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.

This part of ISO 80601 does not specify the requirements for:

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

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

— *ventilators* or *accessories* intended for emergency and transport which are given in ISO 80601-2-84;

— *ventilators* or *accessories* intended for homecare 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;

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

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

NOTE 6 An ISO 80601-2-72 *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

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

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

— oxygen therapy constant flow *ME equipment*; and

— cuirass and "iron-lung" *ventilators.*

201.1.2 Object

Replacement:

The object of this part of ISO 80601 is to establish particular *basic safety* and *essential performance* requirements for a *ventilator,* as defined in 201.3.217, and its *accessories*.

Accessories are included because the combination of the *ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles*[31] and labelling[32] 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[33] as indicated in Annex EE.

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

NOTE The general standard is 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 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-12 do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards can 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 part of ISO 80601 as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this part of ISO 80601 corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this part of ISO 80601 addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

— "Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard is replaced completely by the text of this part of ISO 80601.

— "Addition" means that the text of this particular standard is additional to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard.

— "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this part of ISO 80601.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to IEC 60601-1:2005+AMD1:2012+AMD2:2020, any applicable collateral standards, and this part of ISO 80601 taken together.

Where there is no corresponding clause or subclause in this part of ISO 80601, the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this part of ISO 80601.

201.2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:

Replacement:

ISO 15223-1:2021, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2008+AMD1:2017, *Low-pressure hose assemblies for use with medical gases*

ISO 5367:—[1], *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the* medical *device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62304:2006+AMD1:2015, *Medical device software - Software life cycle processes*

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[1] Under preparation. Stage at the time of publication: ISO/FDIS 5367:2022.

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 3 applies, except as follows:

Addition:

201.3.201
accompanying information
information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202
acknowledged
state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: *Acknowledged* only affects *alarm signal*s that are active at the time of the *operator* action*.*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37]

201.3.203
airway device
device intended to provide a *gas pathway* to and from the *patient's* airway

[SOURCE: ISO 4135:2021, 3.8.1.2]

201.3.204
airway pressure
P_{aw}
pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

[SOURCE: ISO 4135:2021, 3.1.4.41.1]

201.3.205
alarm condition delay
time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.206
alarm limit
threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.207
alarm off
state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.4]

201.3.208
alarm paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.209
alarm setting
alarm system configuration, including but not limited to:
– *alarm limits*;
– the characteristics of any *alarm signal* inactivation states; and
– the values of variables or parameters that determine the function of the *alarm system*

Note 1 to entry: Some algorithmically-determined *alarm settings* can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.8]

201.3.210
alarm signal generation delay
time from the onset of an *alarm condition* to the generation of its *alarm signal(s)*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]

201.3.211
artificial ventilation
intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

EXAMPLE Means used to provide *artificial ventilation* are manual resuscitation; mouth-to-mouth resuscitation; automatic *ventilation*; mechanical *ventilation*.

Note 1 to entry: Common classifications of areas of application of *artificial ventilation* are: emergency; transport; home-care; anaesthesia; critical care; rehabilitation.

Note 2 to entry: Classifications used to denote means used for *artificial ventilation* include: positive-pressure; negative-pressure; gas-powered; *operator*-powered; electrically-powered.

Note 3 to entry: Negative-pressure *ventilation* elevates the relative pressure in the airway by intermittently lowering the pressure in the *lungs*.

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.212
attack
attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset

[SOURCE: IEC 81001-5-1:2021, 3.5]

201.3.213
audio off
state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.12]

201.3.214
audio paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

201.3.215
BAP
quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

201.3.216
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.