SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-12:2021

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Medicinska električna oprema - 2-12. del: Posebne zahteve za osnovno varnost in bistvene lastnosti ventilatorjev za intenzivno nego (ISO/DIS 80601-2-12:2021)

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/DIS 80601-2-12:2021)

Medizinische elektrische Geräte - Teil 2-12: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Beatmungsgeräten für die Intensivpflege (ISO/DIS 80601-2-12:2021)

Appareils électromédicaux - Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs (ISO/DIS 80601-2-12:2021)

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

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Medical electrical equipment —

Part 2-12:
Particular requirements for basic safety and essential performance of critical care ventilators

Appareils électromédicaux —

Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs

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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 third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been technically revised. The main changes compared to the previous edition are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020.

— reformatted according to most recent Central Secretariat editing rules;

— 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;

— clarified high *airway pressure alarm condition* requirements;

— added requirements for *ventilator system recovery*; and

— harmonization with ISO 20417, where appropriate.

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

132 Any feedback or questions on this document should be directed to the user's national standards body. A
133 complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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 201.12 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.

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.

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 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

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 A.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 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. *Ventilators* for this environment are considered life-sustaining.

NOTE 2 For the purposes of this document, such a *ventilator* can provide transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 3 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

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

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

A critical care *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 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*.

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 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 document is not applicable to *ME equipment* or *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on *artificial ventilation*.

NOTE 6 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

This document is not applicable to *ME equipment* that is intended solely to augment the *ventilation* of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[19];

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84[24];

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment,* which are given in ISO 80601-2-72[21];

— *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79[22] and ISO 80601-2-80[23];

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[20];

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

— high-frequency *ventilators*, which are given in ISO 80601-2-87[25];

NOTE 7 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

— respiratory high-flow therapy equipment, which are given in ISO 80601-2-90[26];

— oxygen therapy constant flow *ME equipment*; and

— cuirass or “iron-lung” *ventilation* equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator* 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*[39] and labelling[40] 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 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 and IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3[27], IEC 60601-1-9[28], IEC 60601-1-11[30] and IEC 60601-1-12[31] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may 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 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document 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 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 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 document.

"Addition" means that the text of this document 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 document.

Subclauses, figures or tables 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, 208 for IEC 60601-1-8, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, 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 particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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:—[1], *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 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

[1] Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

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:—[2], *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:—[3], *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

[2] Under preparation. Stage at the time of publication: ISO/FDIS 17664-1:2020.

[3] Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-74:2021.