SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-67:2024

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Medicinska električna oprema - 2-67. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za shranjevanje kisika (ISO/DIS 80601-2-67:2024)

Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO/DIS 80601-2-67:2024)

Medizinische elektrische Geräte - Teil 2-67: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiergeräten (ISO/DIS 80601 2 67:2024)

Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène (ISO/DIS 80601-2-67:2024)

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

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DRAFT International Standard

ISO/DIS 80601-2-67

Medical electrical equipment —

Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment

Appareils électromédicaux —

Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène

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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).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

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 D, *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 third edition cancels and replaces the second edition (ISO 80601-2-67:2020), which has been technically revised.

The main changes are as follows:

— updated references, where appropriate;

— harmonization with ISO 20417, where appropriate;

— updated uncertainty of measurement requirements;

— added *marking* requirements for *gas intake port*, external gas sources and MR compatibility;

— requirements for *processing* of the *enclosure*;

— added *cybersecurity* recommendations; and

— updated *connector* requirements.

A list of all parts in the ISO 80601 and 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

Long-term oxygen therapy has been demonstrated in randomized, controlled clinical trials to prolong survival in *patients* with chronic respiratory disease and documented hypoxemia. Typical sources of therapeutic long-term oxygen therapy include gaseous oxygen from cylinders or from liquid oxygen and oxygen from an oxygen concentrator.

Most clinicians prescribe low flow oxygen therapy as continuous flow oxygen (CFO) delivery in l/min. CFO systems deliver the flow of oxygen without regard for the *patient's* breathing rate or pattern. Outside of the institutional care setting, the provision of CFO therapy is often a significant expense and can limit the mobility of a *patient* to the immediate vicinity of a stationary or fixed oxygen delivery system. To support mobility, *patients* use CFO from portable liquid or compressed oxygen systems with a limited storage capacity that can limit a *patient's* time and activities while away from a stationary oxygen supply.

Conserving equipment that delivers supplemental oxygen as a bolus conserves usage while allowing satisfactory *patient* arterial oxygen saturation (SaO_2) to be maintained during daily activities. *Conserving equipment* delivers supplemental oxygen unlike CFO in that the therapy gas flow is delivered only during the inspiratory phase of the breathing cycle, when it is most likely to reach the alveoli. During both the expiratory and pause phase of the breathing cycle, the flow of supplemental oxygen is stopped, minimizing waste. Because flow over time produces a volume, the bolus delivered by the *conserving equipment* is typically represented as a volume of gas. Therapy using *conserving equipment* versus CFO results in lower operating costs and longer ambulatory times for *patients* using the same CFO storage capacity.

Operation of *conserving equipment* from various *manufacturers* might differ in the dose delivery mechanism resulting in variations in oxygen therapy to the *patient*. The use of CFO numerical *markings* for dose settings on *conserving equipment* might not directly correlate with CFO settings and might lead to misinterpretation of gas delivery rates and volumes for a particular *patient*. This might result in incorrect *patient* setup and therapy delivery over all breathing rates and patterns versus CFO. Because of the differences in delivery, settings, and *markings* versus CFO therapy, *conserving equipment* use has requirements for *patient* titration to determine the proper setting(s) needed to provide adequate SaO_2 levels for the *patient* breathing patterns.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *terms defined in Clause 3 of the general standard, in this particular document or as noted: italic type*; and

— 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 three numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 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 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.

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— "should” indicates a requirement or a test is 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 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment

201.1 Scope, object and related standards

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

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

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.1 is replaced by:

This document is applicable to the *basic safety* and *essential performance* of oxygen *conserving equipment*, hereafter referred to as *ME equipment,* in combination with its *accessories* intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle, when used in the *home healthcare environment*. Oxygen *conserving equipment* is typically used by a *lay operator*.

NOTE 1 *Conserving equipment* can also be used in professional health care facilities.

This document is also applicable to *conserving equipment* that is incorporated with other equipment.

EXAMPLE *Conserving equipment* combined with a pressure regulator[4], an oxygen concentrator[12] or liquid oxygen equipment[7].

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

This document is intended to clarify the difference in operation of various *conserving equipment* models, as well as between the operation of *conserving equipment* and continuous flow oxygen equipment, by requiring standardized performance testing and labelling.

This document is only applicable to active devices (e.g. pneumatically or electrically powered) and is not applicable to non-active devices (e.g. reservoir cannulas).

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

201.1.2 Object

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.2 is replaced by:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *conserving equipment* [as defined in 201.3.207] and its *accessories*.

NOTE 1 *Accessories* are included because *accessories* can have a significant impact on the *basic safety* or *essential performance* of *conserving equipment*.

NOTE 2 This document has been prepared to address the relevant *essential principles*[17] and labelling principles[18] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex BB.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[16].

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

IEC 60601-1-2+AMD1:2020 and IEC 60601-1-6+AMD1:2013+AMD2:2020 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3 and IEC 60601-1-9 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1+AMD1:2012+AMD2:2020 is referred to in this 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 that 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 “20x”, where x is the final digit(s) 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, 206.4 in this document addresses the content of Clause 4 of the IEC 60601-1-6 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 the general standard or 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 the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which 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, figures or tables which 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, 206 for IEC 60601-1-6, 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 the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this 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:

Addition:

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

ISO 5359:2014+AMD1:2017, *Low-pressure hose assemblies for use with medical gases*

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

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2019, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)*

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 18562-1:2024, *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 80369-1:—[1], *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

EN 13544-2:2002+AMD1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

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/

NOTE An alphabetized index of defined terms is found in Annex CC.

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.]

[1] Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024.