SLOVENSKI STANDARD

oSIST prEN ISO 80601-2-67:2019

01-oktober-2019

Medicinska električna oprema - 2-67. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za shranjevanje kisika (ISO/DIS 80601-2-67:2019)

Medical Electrical Equipment - Part 2-67:Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO/DIS 80601-2-67:2019)

Medizinische elektrische Geräte- - Teil 2-67: Besondere Festlegungen für die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiergeräten (ISO/DIS 80601-2-67:2019)

Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles dee économiseurs d'oxygène (ISO/DIS 80601-2-67:2019)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-67**

ICS:

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

oSIST prEN ISO 80601-2-67:2019 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 80601-2-67

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

Secretariat: **ANSI**

Voting begins on:
2019-07-25

Voting terminates on:
2019-10-17

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 dee économiseurs d'oxygène

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.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 80601-2-67:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

CONTENTS

CONTENTS 3
FOREWORD 5
INTRODUCTION 7
201.1 Scope, object and related standards 9
201.2 Normative references 11
201.3 Terms and definitions 13
201.4 General requirements 14
201.5 General requirements for testing of *ME equipment* 16
201.6 Classification of *ME equipment* and *ME systems* 16
201.7 *ME equipment* identification, marking and documents 16
201.8 Protection against electrical *hazards* from *ME equipment* 23
201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 23
201.10 Protection against unwanted and excessive radiation *hazards* 23
201.11 Protection against excessive temperatures and other *hazards* 23
201.12 Accuracy of controls and instruments and protection against hazardous outputs 25
201.13 *Hazardous situations* and fault conditions 29
201.14 *Programmable electrical medical systems* (*PEMS*) 29
201.15 Construction of *ME equipment* 29
201.16 *ME systems* 29
201.17 Electromagnetic compatibility of *ME equipment* and *ME systems* 29
201.101 Gas connections 30
201.102 Requirements for parts and *accessories* 30
201.103 Oxygen pressure regulators 32
202 Electromagnetic disturbances – Requirements and tests 32
206 Usability 33
Annex C (informative) Guide to marking and labelling requirements for *ME equipment* and *ME systems* 34
Annex D (informative) Symbols on marking 38
Annex AA (informative) Particular guidance and rationale 39
Annex BB (informative) Reference to the *essential principles* 48
Annex CC (informative) Reference to the general safety and performance requirements 51
Annex DD (informative) Terminology — Alphabetized index of defined terms 55

Figure 201.101 — *Verification* of oxygen delivery, typical test setup 27

Table 201.101 — Distributed *essential performance* requirements 14
Table 201.102 — *Verification* of oxygen delivery test parameters 28
Table 201.C.101 — Marking on the outside of *conserving equipment*, its parts or *accessories* 34
Table 201.C.102 — *Accompanying documents*, general 35
Table 201.C.103 — Instructions for use 35
Table 201.C.104 — Technical description 37
Table 201.D.1.101 — Additional symbols on marking 38
Table BB.1 — Correspondence between this document and the essential principles 48
Table CC.1 — Correspondence between this document and the general safety and performance requirements 51

INTERNATIONAL ORGANIZATION for STANDARDISATION

_____

MEDICAL ELECTRICAL EQUIPMENT –

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

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. 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. 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.

ISO 80601-2-67 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition of ISO 80601-2-67 cancels and replaces the first edition of ISO 80601-2-67[1] [1](2014). This edition of ISO 80601-2-67 constitutes a minor technical revision of the first edition of ISO 80601-2-67[1] and includes an alignment with the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, including its Amendment 1, the second edition of IEC 60601-1-8, including its Amendment 1, and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

– clarified the accessibility of inlet and outlet connectors; and

– formatted to provide a unique identifier for each requirement.

[1] Figures in square brackets refer to the Bibliography.

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 (SaO2) 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 breath cycle, when it is most likely to reach the alveoli. During both the expiratory and pause phase of the breath 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 requires *patient* titration to determine the proper setting(s) needed to provide adequate SaO_2 levels for the *patient* breathing patterns.

This document is intended to reduce ambiguity between operation of various *conserving equipment* models and CFO by requiring standardized performance testing and labelling.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications and terms defined in Clause 3 of the general standard[2], 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

[2] The general standard is IEC 60601-1:2005 +AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

– "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.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

– "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

– "may" is used to describe a permission (e.g., permissible way to achieve conformance with a requirement or test);

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

– "must" is used 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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of standards.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 * Scope, object and related standards

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

201.1.1 Scope

IEC 60601-1:2005+AMD1:2012, 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.

NOTE 2 *Conserving equipment* can be used with an oxygen concentrator.

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

NOTE 3 *Conserving equipment* conforming with this document can be incorporated with other devices that have their own standards, in which case the combination needs to conform with both standards.

EXAMPLES *Conserving equipment* combined with a pressure regulator (ISO 10524 series), an oxygen concentrator[2] or liquid oxygen equipment[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, 7.2.13 and 8.4.1.

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

This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of standards.

201.1.2 Object

IEC 60601-1:2005, 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 201.3.201] 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 of safety and performance* of ISO 16142-1:2016 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 as indicated in Annex CC.

201.1.3 Collateral standards

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

IEC 60601-1-2 and IEC 60601-1-6 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3[4] does 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[3] and collateral standards as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* and *essential performance* requirements.

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

For brevity, IEC 60601-1 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.

---

3 The general standard is IEC 60601-1:2005 +AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

"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 3.147, 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, 203 for IEC 6060-1-3, 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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

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

Replacement:

ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014 +AMD6:2014+AMD7:2016, *Graphical symbols -- Safety colours and safety signs -- Registered safety signs*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*
+Amendment 1:2013[4]

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

Addition:

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

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

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

ISO 9000:2015, *Quality management systems -- Fundamentals and vocabulary*

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2005, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*
+Amendment 1:2013

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 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 16142-1:2016, *Medical devices -- Recognized essential principles of safety and performance of medical devices -- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664:2017, *Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of 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 19223-1:2019, *Lung ventilators and related equipment -- Vocabulary and semantics*

[4] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-74:2017, *Medical electrical equipment -- Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

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

IEC 60601-1-2:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

IEC 62366-1:2015, *Medical devices -- Part 1: Application of usability engineering to medical devices*

EN 13544-2:2002, *Respiratory therapy equipment - Part 2: Tubing and connectors*
+Amendment1:2009

EN 15986:2011, *Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2016, ISO 9000:2015, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 80601-2-74:2017, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-11:2015, IEC 62366-1:2015 and the following apply.

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

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

– ISO Online browsing platform: available at http://www.iso.org/obp

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

Addition:

201.3.201
conserving equipment
ME equipment intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle

Note to entry: *Conserving equipment* can be electrically or pneumatically powered.