



SLOVENSKI STANDARD

SIST EN ISO 80601-2-67:2021

01-januar-2021

Nadomešča:

SIST EN ISO 18779:2005

Medicinska električna oprema - 2-67. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za shranjevanje kisika (ISO 80601-2-67:2020)

Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO 80601-2-67:2020)

Medizinische elektrische Geräte - Teil 2-67: Besondere Festlegungen für die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiergeräten ISO 80601-2-67:2020

Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène ISO 80601-2-67:2020

Ta slovenski standard je istoveten z: EN ISO 80601-2-67:2020

ICS:

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

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EUROPEAN STANDARD
NORME EUROPÉENNE
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Supersedes EN ISO 18779:2005

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Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO 80601-2-67:2020)

Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène (ISO 80601-2-67:2020)

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This European Standard was approved by CEN on 8 October 2020.

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European foreword

This document (EN ISO 80601-2-67:2020) 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of an identical text or by endorsement, at the latest by May 2021, and conflicting national standards shall be withdrawn at the latest by May 2021.

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 18779:2005.

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, Turkey and the United Kingdom.

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INTERNATIONAL STANDARD

ISO
80601-2-67

Second edition
2020-10

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

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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).

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 <http://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.

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, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical 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 80601-2-67:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

- clarified the accessibility of inlet and outlet *connectors*;
- formatted to provide a unique identifier for each requirement; and
- harmonization with the 'A2 project' of the general standard.

A list of all parts in the ISO 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.

ISO 80601-2-67:2020(E)

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;
- *test specifications and 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” 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 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.

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.

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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

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, 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^[2], an oxygen concentrator^[7] or liquid oxygen equipment^[4].

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, 7.2.13 and 8.4.1.