



SLOVENSKI STANDARD SIST EN ISO 80601-2-69:2021

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Nadomešča:

SIST EN ISO 80601-2-69:2014

Medicinska električna oprema - 2-69. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za koncentriranje kisika (ISO 80601-2-69:2020)

Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2020)

Medizinische elektrische Geräte - Teil 2-69: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO 80601-2-69:2020)

Appareils électromédicaux - Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO 80601-2-69:2020)

Ta slovenski standard je istoveten z: EN ISO 80601-2-69:2020

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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EN ISO 80601-2-69

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Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2020)

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This European Standard was approved by CEN on 15 October 2020.

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European foreword

This document (EN ISO 80601-2-69:2020) 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of an identical text or by endorsement, at the latest by May 2021, and conflicting national standards shall be withdrawn at the latest by May 2021.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.

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INTERNATIONAL
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Medical electrical equipment —
Part 2-69:
Particular requirements for the basic
safety and essential performance of
oxygen concentrator equipment

iTeh STANDARD PREVIEW
Appareils électromédicaux —
Partie 2-69: Exigences particulières pour la sécurité de base et les
performances essentielles des dispositifs concentrateurs d'oxygène

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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 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 80601-2-69:2014), which has been technically revised.

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

- changes to the low oxygen concentration *alarm condition*;
- changes to the gas outlet connector;
- changes to the test method for the filter for the delivered gas;
- reformatting to provide a unique identifier for each requirement;
- 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.

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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.

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Introduction

Oxygen supplementation can be part of management of *patients* with chronic, acute-on-chronic or acute respiratory disorders. The amount of supplemental oxygen depends on the individual *patient's* needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate.

The goal of long-term oxygen therapy is to keep the oxygen saturation above a target value in *patients* that require supplemental oxygen. The flowrate should be adjusted for rest, exertion and sleep to meet the individual *patient's* needs under these various conditions. Ideally, the resting flowrate is adjusted to maintain SpO₂ greater than the target value as indicated by pulse oximetry.

Supplemental oxygen is supplied by various sources: *medical gas pipeline systems, oxygen concentrators, compressed gas cylinders and liquid oxygen reservoirs*. *Oxygen concentrators* produce oxygen-enriched air from room air for delivery to a *patient* requiring oxygen therapy. The most common *oxygen concentrator* uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air, generating oxygen concentrations of typically 90 % to 96 %. The main component of this type of *oxygen concentrator* is the molecular sieve, which adsorbs nitrogen from air to produce a product gas, which is a mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption process.

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*.

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:

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- "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 2-69:

Particular requirements for the basic safety and essential performance of oxygen concentrator 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 specifies requirements for the *basic safety* and *essential performance* of an *oxygen concentrator* in combination with its *accessories*, hereafter referred to as *ME equipment*, intended to increase the oxygen concentration of gas intended to be delivered to a single *patient*. Such *oxygen concentrators* are typically intended for use in the *home healthcare environment* by a single *patient* in various environments including any private and public transportation as well as in commercial aircraft.

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NOTE 1 Such *oxygen concentrators* can also be used in professional healthcare facilities.

This document is applicable to a *transit-operable* and *non-transit-operable oxygen concentrator*. This document is applicable to an *oxygen concentrator* integrated into or used with other medical devices, *ME equipment* or *ME systems*.

EXAMPLE 1 An *oxygen concentrator* with integrated *oxygen conserving equipment* function or humidifier function.

EXAMPLE 2 An *oxygen concentrator* used with a flowmeter stand.

EXAMPLE 3 An *oxygen concentrator* as part of an anaesthetic system for use in areas with limited logistical supplies of electricity and anaesthetic gases^[2].

EXAMPLE 4 An *oxygen concentrator* with an integrated liquid reservoir function or gas cylinder filling system function.

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

NOTE 2 Such *accessories* can include, but are not limited to, masks, cannulae, extension tubing, humidifiers, carts, carrying cases, external power sources and *oxygen conserving equipment*.

This document does not specify requirements for *oxygen concentrators* for use with a *medical gas pipeline system*.