SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-69:2013

01-januar-2013

Elektromedicinska oprema - 2-69. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za koncentriranje kisika (ISO/DIS 80601-2-69:2012)

Medical Electrical Equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO/DIS 80601-2-69:2012)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO/DIS 80601-2-69:2012)

Appareils électromédicaux - Partie 2-63 : exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO/DIS 80601-2-69:2012)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-69 rev**

ICS:

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

oSIST prEN ISO 80601-2-69:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Will supersede EN ISO 8359:2009

English Version

Medical Electrical Equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO/DIS 80601-2-69:2012)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN ISO 80601-2-69:2012) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 8359:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 80601-2-69:2012 has been approved by CEN as a prEN ISO 80601-2-69:2012 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-69

ISO/TC **121**/SC **3** Secretariat: **ANSI**

Voting begins on **2012-10-25** Voting terminates on **2013-03-25**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Medical Electrical Equipment —

Part 2-69: **Particular requirements for basic safety and essential performance of oxygen concentrator equipment**

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

[Revision of second edition (ISO 8359:1996)]

ICS 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO/IEC 80601-2-69 was prepared by a joint working group of 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.*

This first edition of ISO 80601-2-69 cancels and replaces the first edition of ISO 8359:1996. This edition of ISO 80601-2-69 constitutes a major technical revision of ISO 8359:1996 and includes an alignment with third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

– extending the scope to include not only the OXYGEN CONCENTRATOR but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR;

– identification of ESSENTIAL PERFORMANCE for an OXYGEN CONCENTRATOR and its ACCESSORIES;

– and the following additions:

  — tests for oxygen delivery performance;

  — new symbols;

  — new requirement for a means to prevent the propagation of fire into the OXYGEN CONCENTRATOR and its ACCESSORIES;

  — tests for cleaning and disinfection procedures; and

  — consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– 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.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

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

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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 A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Oxygen supplementation can be part of management of PATIENTS with chronic, acute–on-chronic and 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 flow rate.

The goal of long term oxygen therapy is to keep the oxygen saturation above 90 % in PATIENTS that require supplemental oxygen. The flow rate should be adjusted for rest, exertion, and sleep to meet the individual PATIENT'S needs under these various conditions. Ideally, the resting flowrate can be adjusted by monitoring pulse oximetry to $Sp0_2$ > 90 %.

Supplemental oxygen is supplied by three types of sources: OXYGEN CONCENTRATORS, compressed gas cylinders, and liquid oxygen reservoirs. This standard covers the particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of OXYGEN CONCENTRATORS. 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 82 to 95%. 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 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.

Medical Electrical Equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

IEC 60601-1:2005+Amendment 1:2012, 1.1 is replaced by:

This particular standard is applicable to 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 in the gas intended to be delivered to a single PATIENT. Such OXYGEN CONCENTRATORS are typically intended for use in the HOME HEALTHCARE ENVIRONMENT, including TRANSIT-OPERABLE use by a single PATIENT in various environments including any private and public transportation and commercial aircraft.

NOTE 1 An OXYGEN CONCENTRATOR can also be used in professional healthcare facilities.

This particular standard is applicable to a TRANSIT-OPERABLE or non-TRANSIT-OPERABLE OXYGEN CONCENTRATOR. This particular standard is applicable to an OXYGEN CONCENTRATOR integrated into or used with other ME EQUIPMENT or ME SYSTEMS.

EXAMPLE 1 An OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT or humidifier.

EXAMPLE 2 An OXYGEN CONCENTRATOR used with a flowmeter stand.

This particular standard 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.

This particular standard does not specify the requirements for OXYGEN CONCENTRATORS for use with a MEDICAL GAS PIPELINE SYSTEM which are given in ISO 10083.

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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 2 See also 4.2 of the General Standard.

This particular standard is a particular standard in the IEC 60601-1 series of standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an OXYGEN CONCENTRATOR [as defined in 201.3.203] and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the OXYGEN CONCENTRATOR and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of an OXYGEN CONCENTRATOR.

201.1.3 Collateral standards

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

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+Amendment 1:2012, Clause 2 of the general standard and 201.2 of this particular standard.

IEC 60601-1-3:2008 does not apply.

201.1.4 Particular standards

IEC 60601-1:2005+Amendment 1:2012, 1.4 is replaced by:

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 the general standard or the collateral standards.

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

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard 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 the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard 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 particular standard.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.