SLOVENSKI STANDARD
SIST EN ISO 80601-2-69:2014

01-oktober-2014

Nadomešča:
SIST EN ISO 8359:2009
SIST EN ISO 8359:2009/A1:2012

Medicinska električna oprema - 2-69. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za koncentriranje kisika (ISO 80601-2-69:2014)

Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2014)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO 80601-2-69:2014)

Appareils électromédicaux - Partie 2-63 : exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO 80601-2-69:2014)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-69:2014**

ICS:

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

SIST EN ISO 80601-2-69:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-69

July 2014

ICS 11.040.10

Supersedes 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 80601-2-69:2014)

Appareils électromédicaux - Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO 80601-2-69:2014)

Medizinische elektrische Geräte - Teil 2-69: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO 80601-2-69:2014)

This European Standard was approved by CEN on 28 May 2014.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 80601-2-69:2014 E

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Foreword

This document (EN ISO 80601-2-69:2014) 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 January 2015, and conflicting national standards shall be withdrawn at the latest by July 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-69:2014 has been approved by CEN as EN ISO 80601-2-69:2014 without any modification.

Annex ZA
(informative)

Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.11.6.4, 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the PATIENT are addressed.
201.11.6.4, 201.11.6.6	7.3	Only the part of the first sentence of ER 7.3 relating to design is addressed.
201.11.6.4	7.5	
201.11	7.6	
201.11.6.6, 201.11.6.7	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11135-1, ISO 11137-1 and ISO 17665-1.
201.4.6, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.14.101, 201.12.1.101, 201.12.1.102, 201.12.1.103, 201.16, 201.101, 201.102	9.1	
201.9, 202, 206, 211	9.2	The 4th indent of ER 9.2 is not addressed.
201.11	9.3	
201.12.1, 201.102	10.1	The part of ER 10.1 relating to stability is not addressed.

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7, 201.12.1, 206, 208	10.2	
201.7.4.3	10.3	
201.14	12.1	
201.14	12.1 a)	
202	12.5	
201.8	12.6	
201.9, 211	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.101, 201.15, 201.103	12.7.4	
201.11	12.7.5	
201.12.1	12.8.1	Only the protection of the PATIENT is covered.
201.12.4	12.8.2	Only the first sentence of ER 12.8.2 is covered.
201.7, 206	12.9	
201.7, 201.11.6.4	13.1	
201.7.2.1, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.8, 201.9, 201.11.6.4	13.2	
201.7.9.1	13.3 a)	
201.7.2.17.101	13.3 b)	
201.7, 201.7.2.17.101 a)	13.3 c)	
201.7.2.17.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT.
201.7.2.17.101	13.3 f)	
201.7.2.101 a), 211	13.3 i)	
201.7.2.101 b), 201.7.2.101 d), 211	13.3 j)	
201.7.2.101 b)	13.3 k)	
201.7, 201.7.2.17.101 a)	13.3 m)	Presumption of conformity is only provided if one of the symbols 5.21 to 5.24 from ISO 15223-1:2012 are utilized, as applicable.
201.7.9.1, 201.7.9.2, 201.16	13.6 a)	
201.7.9.2.5.101	13.6 b)	
201.7.9.2.14.101, 201.16, 201.102	13.6 c)	
201.7, 201.7.9.2.8.101, 201.7.9.2.13.101, 201.16	13.6 d)	

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.16	13.6 f)	
201.7.9.2.1.101, 201.7.9.2.12, 201.16, 211	13.6 h)	
201.7	13.6 i)	
211	13.6 k)	
211	13.6 k)	
211	13.6 l)	
211	13.6 n)	
201.12.1.103, 211	13.6 p)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
—	1.1.4	This relevant EHSR is not covered by this European Standard.
201.12.1, 201.12.101	1.2.2	
201.7.2.101 c), 201.7.2.101 d), 201.101	1.5.4	
—	1.6.2	This relevant EHSR is not covered by this European Standard.
201.8	1.6.3	

INTERNATIONAL STANDARD

ISO 80601-2-69

First edition
2014-07-15

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

Reference number
ISO 80601-2-69:2014(E)

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Published in Switzerland

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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 the 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 flowrate.

The goal of long term oxygen therapy is to keep the oxygen saturation above 90 % 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 SpO_2 > 90 % 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. 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 typically 82 % 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.