

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)

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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)

SIST EN ISO 80601-2-69:2014

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

ICS:

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

oSIST prEN ISO 80601-2-69:2013 en

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

DRAFT prEN ISO 80601-2-69 rev

October 2012

ICS 11.040.10

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)

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

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.

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

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Ref. No. prEN ISO 80601-2-69 rev:2012: E

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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.

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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

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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.

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86 **Foreword**

87 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies 88 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO 89 technical committees. Each member body interested in a subject for which a technical committee has been 90 established has the right to be represented on that committee. International organizations, governmental and 91 non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the 92 International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

94 The main task of technical committees is to prepare International Standards. Draft International Standards 95 adopted by the technical committees are circulated to the member bodies for voting. Publication as an 96 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 patentrights. 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.

102 This first edition of ISO 80601-2-69 cancels and replaces the first edition of ISO 8359:1996. This edition of 103 | ISO 80601-2-69 constitutes a major technical revision of ISO 8359:1996 and includes an alignment with third

104 edition of IEC 60601-1 and IEC 60601-1-11.

105 The most significant changes are the following modifications: S. 1120.21

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;

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

https://110.da+ds and the following additions: ist/52dcf26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014

- 111 tests for oxygen delivery performance;
- 112 new symbols;
- 113 new requirement for a means to prevent the propagation of fire into the OXYGEN CONCENTRATOR
 114 and its ACCESSORIES;
- 115 tests for cleaning and disinfection procedures; and
- 116 consideration of contamination of the breathing gas delivered to the PATIENT from the gas
 117 pathways.
- 118 In this standard, the following print types are used:
- 119 Requirements and definitions: roman type.
- 120 Test specifications: italic type.
- 121 Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 122 Normative text of tables is also in a smaller type.
- 123 TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED:
 124 SMALL CAPITALS TYPE.
- 125 In referring to the structure of this standard, the term

- 126 "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.
- 132 In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of 133 the conditions is true.
- The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, PartFor 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;
- 140 "may" is used to describe a permissible way to achieve compliance with a requirement or test.
- 141 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that 142 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.

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150 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.

156 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 $Sp0_2 > 90$ %.

160 Supplemental oxygen is supplied by three types of sources: OXYGEN CONCENTRATORS, compressed 161 gas cylinders, and liquid oxygen reservoirs. This standard covers the particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE OF OXYGEN CONCENTRATORS. OXYGEN CONCENTRATORS 162 163 produce oxygen enriched air from room air for delivery to a PATIENT requiring oxygen therapy. The 164 most common OXYGEN CONCENTRATOR uses molecular sieve beds to filter and concentrate oxygen 165 molecules from the ambient air, generating oxygen concentrations of 82 to 95%. The main 166 component of this type of OXYGEN CONCENTRATOR is the molecular sieve, which adsorbs nitrogen from 167 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. 168

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170 Medical Electrical Equipment — Part 2-69: Particular

requirements for basic safety and essential performance of oxygen concentrator equipment

173 201.1 Scope, object and related standards

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

175 **201.1.1 Scope**

176 *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.

- 183 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.
- 187 EXAMPLE 1 An OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT or humidifier.

188 EXAMPLE 2 An OXYGEN CONCENTRATOR used with a flowmeter stand.

189 This particular standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to 190 be connected to an OXYGEN CONCENTRATOR, where the characteristics of those ACCESSORIES can 191 affect the BASIC SAFETY OF ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR.

192 This particular standard does not specify the requirements for OXYGEN CONCENTRATORS for use with a 193 MEDICAL GAS PIPELINE SYSTEM which are given in ISO 10083.

194 If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to 195 ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, 196 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.

- 200 NOTE 2 See also 4.2 of the General Standard.
- 201 This particular standard is a particular standard in the IEC 60601-1 series of standards.