Elektrilised meditsiiniseadmed. Osa 2-69: Erinõuded hapnikukontsentraatorite esmasele ohutusele ja olulistele toimimisnäitajatele

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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-69:2014 sisaldab Euroopa standardi EN ISO 80601-2-69:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-69:2014 consists of the English text of the European standard EN ISO 80601-2-69:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.07.2014.	Date of Availability of the European standard is 16.07.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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.

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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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by July 2017.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 80609-2-69:2014 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.

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)	
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	

Contents

Page

Foreword 5
Introduction 7
201.1 Scope, object and related standards 1
201.2 Normative references 3
201.3 Terms and definitions 4
201.4 General requirements 5
201.5 General requirements for testing of ME EQUIPMENT 6
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 6
201.7 ME EQUIPMENT identification, marking and documents 6
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 12
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 12
201.10 Protection against unwanted and excessive radiation HAZARDS 13
201.11 Protection against excessive temperatures and other HAZARDS 13
201.12 Accuracy of controls and instruments and protection against hazardous outputs 16
201.13 HAZARDOUS SITUATIONS and fault conditions 20
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 20
201.15 Construction of ME EQUIPMENT 20
201.16 ME SYSTEMS 20
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 21
201.101 Outlet connector 21
201.102 Requirements for parts and ACCESSORIES 21
201.102.1 * General 21
201.102.2 Labelling 21
201.102.3 * Fire RISK reduction in ACCESSORIES 22
201.103 SIGNAL INPUT/OUTPUT PART 22
201.103.1 General 22
201.103.2 * Connection to a DISTRIBUTED ALARM SYSTEM 22
201.103.3 * Connection for remote control 23
201.104 * Indication of duration of operation 23
201.105 Integrated CONSERVING EQUIPMENT 23
202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests 23
202.6.2.1.10 Compliance criteria 23
206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability 23
208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 24

211 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 24
211.4.2.2 Environmental operating conditions 24
ANNEX C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 25
Annex D (informative) Symbols on marking 29
Annex AA (informative) Particular guidance and rationale 30
Annex BB (informative) Reference to the Essential Principles 37

Figures

Figure 201.101 – Standard resistance 13

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.

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 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, including TRANSIT-OPERABLE use by a single PATIENT in various environments including any private and public transportation as well as in commercial aircraft.

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

This particular standard is applicable to a TRANSIT-OPERABLE and non-TRANSIT-OPERABLE OXYGEN CONCENTRATOR. This particular standard 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 [10] or humidifier [4].

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. [3]

EXAMPLE 4 An OXYGEN CONCENTRATOR with an integrated liquid reservoir or gas cylinder filling system.

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.