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Medical electrical equipment —

Part 2-69: Particular requirements for the 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

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Contents

Page

Foreword v
Introduction vii
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 7
201. 8 Protection against electrical *hazards* from *ME equipment* 14
201. 9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 14
201. 10 Protection against unwanted and excessive radiation *hazards* 16
201. 11 Protection against excessive temperatures and other *hazards* 16
201. 12 Accuracy of controls and instruments and protection against hazardous outputs 20
201. 13 *Hazardous situations* and fault conditions for *ME equipment* 25
201. 14 *Programmable electrical medical systems (PEMS)* 25
201. 15 Construction of *ME equipment* 25
201. 16 *ME systems* 26
201. 17 Electromagnetic compatibility of *ME equipment* and *ME systems* 26
201.101 Outlet connector 26
201.102 Requirements for parts and *accessories* 27
201.103 Functional connection 28
201.104 * Indication of duration of operation 28
201.105 Integrated conserving equipment function 29
202 Electromagnetic disturbances – Requirements and tests 29
202.4.3.1 * Configurations 29
206 Usability 30
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 31
211.4.2.2 Environmental operating conditions 31
Annex C (informative) Guide to marking and labelling requirements for *ME equipment* and *ME systems* 32
Annex D (informative) Symbols on marking 37

Annex AA (informative) Particular guidance and rationale **39**

Annex BB (informative) Reference to the IMDRF *essential principles* and labelling guidances **46**

Annex CC (informative) Reference to the *essential principles* **51**

Annex DD (informative) Reference to the general safety and performance requirements **55**

Annex EE (informative) Terminology — alphabetized index of defined terms **59**

Bibliography **62**

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.

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.

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 SpO_2 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:

— “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.

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.

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*.

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

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

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

The object of this document is to establish particular *basic safety* and *essential performance* requirements for an *oxygen concentrator* (as defined in 201.3.202) and its *accessories*.

NOTE 1 *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*.

NOTE 2 This document has been prepared to address the relevant *essential principles*[8] and labelling[9] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex BB.

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[7] as indicated in Annex DD.

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012+AMD2: 2020, 1.3 applies with the following addition:

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3:2008+AMD1:2013 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the

collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.4 in this document addresses the content of Clause 4 of the IEC 60601-1-11collateral 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 document.

— "Addition" means that the text of this document 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 document.

Clauses, subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 211 for IEC 60601-1-11, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+AMD1:2012+AMD2: 2020, Clause 2 applies, except as follows:

Replacement:

ISO 15223-1:—[1], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

[1] Under preparation. Stage at the time of publication: ISO/DIS 15223-1:2020.

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

ISO 80601-2-67:2020, *Medical Electrical Equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2: 2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 *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*

IEC 60601-1-11:2015+AMD1:2020, *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*

IEC 62366-1:2015+AMD1:2020, *Medical devices – Application of usability engineering to medical devices*

EN 13544-2:2002+AMD1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3744:2010, ISO 7396-1:2016, ISO 9000:2015, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 80601-2-67:2020, ISO 80601-2-74:2017, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015, IEC 62366-1:2015+AMD1:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE An index of defined terms is found in Annex EE.

Addition:

201.3.201
flow-direction-sensitive component
component or *accessory* through which gas flow is in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:—[1], definition 3.1.7, modified — Added 'or *accessory*' and replaced 'must' with 'is']

201.3.202
oxygen concentrator
ME equipment, which by selective removal of constituents of ambient air, increases the concentration of oxygen in the output gas

201.4 General requirements

IEC 60601-1:2005+AMD1:2012, Clause 4 applies, except as follows:

201.4.3 *Essential performance*

IEC 60601-1:2005+AMD1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for *essential performance*

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
The oxygen concentration in the delivered gas, in both *normal condition* and *single fault condition,* within the performance levels as indicated in the instructions for use or generation of an *alarm condition*	201.12.1.101[a] 201.12.1.102 201.12.1.103
power supply failure *technical alarm condition*	201.11.8.101.1
internal electrical power source nears depletion *technical alarm condition*	201.11.8.101.2
low oxygen concentration *technical alarm condition*	201.12.4.102
malfunction *technical alarm condition*	201.13.2.101
start-up period *technical alarm condition*	201.12.4.4.101.2

[a] Subclause 202.8.1.101 indicates methods of evaluating delivered oxygen concentration as acceptance criteria following specific tests required by this document.

201.4.6 * *ME equipment* or *ME system* parts that contact the *patient*

Amendment (add at end of 4.6 prior to the conformance check):

a) An *oxygen concentrator* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause (i.e., 4.6 of the general standard).

201.5 General requirements for testing of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies, except as follows:

Addition:

201.5.101 * Additional requirements for general requirements for testing of *ME equipment*

a) For the purposes of this document, tolerances declared in the *accompanying documents* shall include the uncertainty of the measurement used to determine the specification.

b) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the technical description.

Check conformance by inspection of the accompanying documents and the technical description.

201.6 Classification of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 *ME equipment* identification, marking and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2 applies, except as follows:

Amendment (at the end of the second sentence of the second paragraph of the conformance check):

Replace '*1 m*' with '*1 m* and for *body-worn ME equipment* 0,4 m'.

Additional subclauses:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

   1) fulfil the requirements of 201.7.2.101; and

   2) be marked with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of an *oxygen concentrator*, if applicable.

b) If marking the *accessory* is not practicable, this information may be placed in the instructions for use.

NOTE Additional requirements are found in 201.102.

Check conformance by inspection and inspection of the risk management file for any limitations or adverse effects of the accessory.

201.7.2.13.101 Additional requirements for physiological effects

a) Any natural rubber latex-containing components in the *gas pathways* or *accessories* shall be marked as containing latex.

b) Such marking shall be *clearly legible*.

c) Symbol ISO 7000-2725 or symbol 5.4.5 from ISO 15223-1:—, (Table 201.D.1.101, symbol 4) may be used.

d) The instructions for use shall also disclose any natural rubber latex-containing components.

Check conformance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

a) The indication of single use shall be consistent for a *model or type reference*.

b) The packaging for a *model or type reference* that is for single use shall be marked accordingly.

c) Packages shall have *clearly legible* markings of:

   1) a description of the contents;