INTERNATIONAL STANDARD

ISO 80601-2-69

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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

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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.

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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.

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 International 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 International 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+Amendment 1:2013 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.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 2xx, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

Where there is no corresponding clause or subclause in this particular standard, the section, 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 particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography beginning on page 37.

IEC 60601-1:2005+Amendment 1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
+Amendment 1:2013

IEC 60601-1-8:2006, *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*
+Amendment 1:2012

IEC 60601-1-11:2010, *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*

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*

ISO 7000:2012, *Graphical symbols for use on equipment -- Registered symbols*

ISO 7010:2011, *Graphical symbols -- Safety colours and safety signs -- Registered safety signs*
+Amendment 1:2012
+Amendment 2:2012

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO/DIS 14644-1:2010, *Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration*

ISO 17664:2004, *Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-67:2014, *Medical Electrical Equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
+Amendment 1:2014

EN 15986:2011, *Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3744:2010, ISO 4135:2001, ISO 7396-1:2007, IEC 60601-1:2005+Amendment 1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2010+Amendment 1:2013, IEC 60601-1-8:2006+Amendment 1:2012, IEC 60601-1-11:2010, IEC 62366:2007+Amendment 1:2014 and the following apply.

NOTE An index of defined terms is found beginning on page 38.

Addition:

201.3.201
FLOW-DIRECTION-SENSITIVE COMPONENT

component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

[ISO 4135:2001, definition 3.1.7, modified]

201.3.202
MAXIMUM LIMITED PRESSURE
***P*LIM max**
highest pressure at the outlet of the OXYGEN CONCENTRATOR during NORMAL USE or under SINGLE FAULT CONDITION

201.3.203
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+Amendment 1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+Amendment 1:2012, 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
Delivery of oxygen, 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 202.6.2.1.10 indicates methods of evaluating delivered oxygen concentration as acceptance criteria following specific tests required by this standard.	

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

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

The gas pathways of an OXYGEN CONCENTRATOR or its parts or ACCESSORIES shall be subject to the requirements for APPLIED PARTS according to this subclause. 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.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+Amendment 1:2012, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT

201.5.101.1 * ME EQUIPMENT testing errors

For the purposes of this standard, tolerances declared in the ACCOMPANYING DOCUMENTS shall include the uncertainty of the measurement used to determine the specification.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+Amendment 1:2012, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+Amendment 1:2012, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+Amendment 1:2012, 7.1.2 applies, except as follows:

Replacement (at the end of the second sentence of the second paragraph of the compliance check):

Replace '*1 m*' with '*1 m and for BODY-WORN ME EQUIPMENT 0,5 m*'

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101 and shall 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. If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

Check compliance 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

Any natural rubber latex-containing components in the gas pathways or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.45 from ISO 15223-1:2012, (Table 201.D.1.101, symbol 3) may be used. The instructions for use shall also disclose any natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

The indication of single use shall be consistent for a MODEL OR TYPE REFERENCE. The packaging for a MODEL OR TYPE REFERENCE that is for single use shall be marked accordingly.

Packages shall be CLEARLY LEGIBLE and shall be marked as follows.

a) with a description of the contents.

b) with an identification reference to the batch, type or serial number or symbol 5.1.5 or symbol 5.1.7 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 1 or symbol 2).

c) with, for packages containing natural rubber latex, the word "LATEX", or symbol 5.35 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 3).

Check compliance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

The marking of ME EQUIPMENT**,** parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following

a) any particular storage and/or handling instructions.

b) any particular warnings and/or precautions relevant to the immediate operation of the OXYGEN CONCENTRATOR.

If applicable, the marking of OPERATOR-accessible ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

c) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL.

d) a warning against removal of the ACCESS COVER by unauthorized persons.

Check compliance by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+Amendment 1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

Gas volume and flowrate specifications for gas delivered to the PATIENT shall be expressed at ATPD (ambient temperature and pressure, dry).

NOTE For the purposes of this standard, ATPD is local atmospheric pressure and temperature, dry.

201.7.5 Safety signs

IEC 60601-1:2005+Amendment 1:2012, 7.5 applies, except as follows:

Amendment (add before the compliance test):

The following safety signs shall be CLEARLY LEGIBLE from the intended position of the OPERATOR and shall include the following markings:

a) safety sign ISO 7010-P002 (Table 201.D.2.101, safety sign 1) or a warning to the effect of “No Smoking”.

b) safety sign ISO 7010-P003 (Table 201.D.2.101, safety sign 2) or a warning to the effect of “No Open Flame”.