
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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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.

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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.

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** $P_{\text{LIM max}}$

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".

201.7.9.1 Additional general

IEC 60601-1:2005+Amendment 1:2012, 7.9.1 applies, except as follows:

Amendment (replace the first dash with):

- Name or trade name and address of
 - the MANUFACTURER; and
 - where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,
- to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Instructions for use

IEC 60601-1:2005+Amendment 1:2012, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall include the following:

- a) a statement of the time required from switching on the OXYGEN CONCENTRATOR until it can be relied upon to deliver the set flowrate and concentration of oxygen;
- b) a statement that the air intake as well as the exhaust of the OXYGEN CONCENTRATOR should be located in a well-ventilated area;
- c) a statement advising the OPERATOR of actions to take when the OXYGEN CONCENTRATOR indicates an abnormal condition;
- d) a statement that the OXYGEN CONCENTRATOR should be located so as to avoid pollutants or fumes;
- e) if the OXYGEN CONCENTRATOR, its parts or ACCESSORIES are intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the OXYGEN CONCENTRATOR, its parts or ACCESSORIES would be reused;
- f) a statement to the effect that the oxygen delivery settings of the oxygen concentrator should periodically reassessed for the effectiveness of the therapy.

NOTE In some countries, the supervising clinician has the responsibility to periodically reassess the oxygen delivery settings.

If applicable, the instructions for use shall disclose the following:

- g) at least one type of humidifier which is suitable for use with the OXYGEN CONCENTRATOR and its preferred location.

Check compliance by inspection.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include:

- a) a warning statement to the effect that “WARNING: There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.”
- b) a warning statement to the effect that “WARNING: To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition [insert model and brand] must

— be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.

— be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.”

- c) a warning statement to the effect that “WARNING: Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns”.
- d) a warning statement to the effect that “WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.”
- e) a warning statement to the effect that “WARNING: Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.”
- f) a warning statement to the effect that “WARNING: Use of this device at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range] or a relative humidity above [insert maximum RATED relative humidity] is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of the therapy.”
- g) a warning statement to the effect that “WARNING: Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the oxygen concentrator is turned on, but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.”
- h) a warning statement to the effect that “WARNING: If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.”
- i) a warning statement to the effect that “WARNING: Geriatric, paediatric or any other patient unable to communicate discomfort can require additional monitoring and or a distributed alarm system to convey the information about the discomfort and or the medical urgency to the responsible care giver to avoid harm.”
- j) a warning statement to the effect that “WARNING: Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located.

If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or mask or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off before smoking.”

- k) a warning statement to the effect that “WARNING: Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen carrying accessories.”

Check compliance by inspection of the instructions for use.

201.7.9.2.5.101 Additional requirements for ME EQUIPMENT description

The instructions for use shall include

- a) a statement to the effect that the oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories.
- b) a statement to the effect that the proper placement and positioning of the PATIENT interface is critical to the effectiveness of the therapy.

EXAMPLE The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.

- c) a diagram for the connection of OPERATOR-detachable parts either supplied or recommended.
- d) the RATED range of both the oxygen delivery flowrate and the concentration of oxygen as a function of flowrate:

- at STPD (standard temperature and pressure dry) conditions; and

NOTE For the purposes of this standard, STPD is 101,3 kPa at an operating temperature of 20 °C, dry.

- over the RATED ranges of ambient temperature, humidity and atmospheric pressure.

201.7.9.2.8.101 * Additional requirements for start-up PROCEDURE

NOTE For the purposes of this standard, a start-up PROCEDURE is a pre-use functional test that is used to determine whether the OXYGEN CONCENTRATOR is ready for use.

The instructions for use shall include:

- a) details how the OPERATOR can check for proper operation of the OXYGEN CONCENTRATOR including a qualitative test for system gas leakage and gas flowrate at the application ACCESSORY.

EXAMPLE 1 Connect the nasal cannula to the gas outlet connector of the oxygen concentrator or, if used, to the bubble humidifier outlet connector per the manufacturer's instructions. With the oxygen concentrator turned on adjust the flowmeter to the desired flowrate. Gas should be flowing freely to the nasal cannula. You should be able to hear or feel the flow of gas to the prongs of the nasal cannula. Wave your hand in front of the prongs. If you do not feel the gas flowing, check the cannula connections for leaks.

EXAMPLE 2 Place the end of the nasal cannula under the surface of a half -full cup of water and look for the bubbles.

- b) how to functionally check the ALARM SIGNALS. Portions of this test may be automatically performed by the OXYGEN CONCENTRATOR or may require OPERATOR action.

EXAMPLE Combination of the power-on self-test routines and OPERATOR action that functionally check the ALARM SIGNALS.

- c) a diagram for the set-up of OPERATOR-detachable parts either supplied or recommended by the MANUFACTURER.

Check compliance by inspection.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use of an OXYGEN CONCENTRATOR shall include an explanation of the meaning of the IP classification marked on the ENCLOSURE.

If applicable, the instructions for use shall include the PROCEDURE necessary to determine the remaining capacity or operation time of the INTERNAL ELECTRICAL POWER SOURCE.

Check compliance by inspection.

201.7.9.2.12 Cleaning, disinfection, and sterilization

IEC 60601-1:2005+Amendment 1:2012, 7.9.2.12 applies, except as follows:

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

The instructions for use shall identify the portions of the gas pathways through the OXYGEN CONCENTRATOR that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

201.7.9.2.13.101 Additional requirements for maintenance

The instructions for use shall include

- a) the intervals at which cleaning PROCEDURES need to be performed and the items required for such cleaning.
- b) a statement to the effect that no lubricants other than those recommended by the manufacturer are to be used.
- c) if applicable, the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging or replacement.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

If applicable, the instructions for use shall disclose

- a) any restrictions on the OPERATOR-accessible components on the OXYGEN CONCENTRATOR and within the set-up of the application ACCESSORIES.

EXAMPLE 1 Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

- b) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the OXYGEN CONCENTRATOR.

EXAMPLE 2 Use of a paediatric cannula on an adult PATIENT.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

201.7.9.2.16.101 * Additional requirements for reference to the technical description

Where the technical description is supplied as a separate document from the instructions for use, then the instructions for use shall, wherever appropriate, provide a cross-reference to the additional information available in the technical description.

Check compliance by inspection.

201.7.9.3.101 Additional requirements for the technical description

The technical description shall include

- a) a description of the principles of operation of the OXYGEN CONCENTRATOR.
- b) a pneumatic diagram of the OXYGEN CONCENTRATOR, including a diagram for the connection of OPERATOR-detachable parts either supplied or recommended in the instructions for use.
- c) a description of a method for SERVICE PERSONNEL to check the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this standard, if not performed automatically during start-up. The technical description shall disclose which checks are performed automatically.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+Amendment 1:2012, Clause 8 applies, except as follows:

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+Amendment 1:2012, Clause 9 applies, except as follows:

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

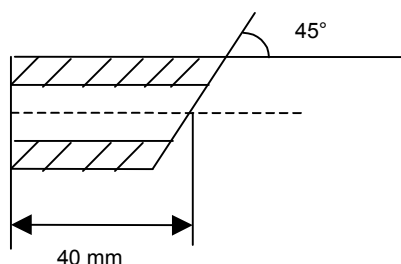
The A-weighted SOUND PRESSURE LEVEL emitted by the OXYGEN CONCENTRATOR when tested in accordance with the method in this subclause shall be disclosed in the instructions for use:

- for an OXYGEN CONCENTRATOR with a continuous flow mode, at a flowrate setting of 3 l/min or the maximum flowrate setting if this is less than 3 l/min as well as for the maximum flowrate setting if this setting is greater or equal than 4 l/min; and
- for an OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT, the maximum demand flow rate setting of NORMAL USE.

The SOUND POWER LEVEL and the tested flowrate also shall be disclosed in the instructions for use.

Check compliance with the following test:

- a) For an OXYGEN CONCENTRATOR with a continuous flow mode, place the OXYGEN CONCENTRATOR on the sound-reflecting plane and attach 10 m $\pm$ 1 m of oxygen tubing.
- b) Attach the standard resistance (as indicated in Figure 201.101) to the PATIENT-end of the oxygen tubing. Set the OXYGEN CONCENTRATOR to a flowrate of approximately 3 l/min or the maximum flowrate setting if this is less than 3 l/min.
- c) Acoustically isolate the oxygen tubing and the gas leaving the standard resistance by a suitable means out of the testing area so that the noise caused by the oxygen tubing and the gas flow does not interfere with the sound measurement of the OXYGEN CONCENTRATOR.
- d) Using a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2002, measure the SOUND PRESSURE LEVELS at 10 positions in a hemisphere with a radius from the geometric centre of the OXYGEN CONCENTRATOR as specified in 7.2.3 and 8.1.1 of ISO 3744:2010.
- e) Calculate the A-weighted SOUND PRESSURE LEVEL averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.
- f) Verify that the A-weighted background level of extraneous noise, including any INFORMATION SIGNALS, is at least 6 dB below that measured during the test.
- g) Calculate the SOUND POWER LEVEL according to 8.2.5 of ISO 3744:2010.
- h) Verify that the tested flowrate is disclosed in the instructions for use and verify that the measured SOUND PRESSURE LEVEL and the SOUND POWER LEVEL do not exceed those disclosed in the instructions for use.
- i) Repeat c) to h) at the maximum flowrate setting if this setting is greater than or equal to 4 l/min.
- j) For an OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT, repeat a) through h) in a conserving mode using the test setup of Figure 201.101 of ISO 80601-2-67:2014, connecting the standard resistance to the exhaust port. Simulate a breathing frequency of 20 breaths/min at the maximum demand flowrate of NORMAL USE.



NOTE The internal diameter is 2 mm.

Figure 201.101 – Standard resistance

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+Amendment 1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+Amendment 1:2012, Clause 11 applies, except as follows:

201.11.1 Maximum temperature during NORMAL USE

Amendment (add note after 3rd dash):

NOTE For the purposes of this standard, the gas discharged from the exhaust port shall be treated as part of the ENCLOSURE.

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Amendment (add between the existing paragraphs):

At the maximum flowrate, the temperature of the delivered gas of an OXYGEN CONCENTRATOR shall not be warmer than 6°C above the ambient temperature.

Additional subclause:

201.11.2.101 * Additional requirements for fire prevention

The OPERATOR-accessible OXYGEN CONCENTRATOR outlet connector and any administration ACCESSORY outlet connector shall include a means to prevent the propagation of fire back through the outlet connector. This means shall not be detachable by the OPERATOR without the use of a TOOL. This means also may stop the flow of gas.

EXAMPLES An integral humidifier or a humidifier used with the OXYGEN CONCENTRATOR is such an ACCESSORY.

Check compliance by inspection and the following test.

- a) For an OXYGEN CONCENTRATOR capable of delivering oxygen in a continuous mode, set the OXYGEN CONCENTRATOR to the maximum continuous flowrate of NORMAL USE, with ACCESSORY connection tubing of approximately 2 m length connected to the outlet connector. For an OXYGEN CONCENTRATOR not capable of delivering oxygen in a continuous mode, go to step e).
- b) Wait for steady-state conditions to be achieved.
- c) Ignite the ACCESSORY connection tubing or cannula at the end opposite to the outlet connector.
- d) Observe the fire propagating along the connecting tubing towards the OXYGEN CONCENTRATOR.
- e) Verify that the fire is not propagating back through the outlet connector into the OXYGEN CONCENTRATOR or ACCESSORY and that the fire extinguishes at this point.
- f) For an OXYGEN CONCENTRATOR equipped with integrated oxygen CONSERVING EQUIPMENT, set the OXYGEN CONCENTRATOR to the maximum demand flowrate setting of NORMAL USE, with ACCESSORY connection tubing of approximately 2 m length connected to the outlet connector. A separate OXYGEN CONCENTRATOR may be used for this step.
- g) Connect a breath simulator at the end opposite to the outlet connector. Simulate breathing at a frequency of 20 breath/min.
- h) Perform steps b) to e).

201.11.6.4 Leakage

Amendment (add after existing text):

The MANUFACTURER of the OXYGEN CONCENTRATOR, its parts and ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

An OXYGEN CONCENTRATOR, its parts or ACCESSORIES that contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked that it contains phthalates on the device itself or on the packaging. The symbols of EN 15986:2011 may be used. If the intended use of an OXYGEN CONCENTRATOR, its parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The instructions for use shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by inspection of the RISK MANAGEMENT FILE.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

Gas pathways through the OXYGEN CONCENTRATOR and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in 11.6.7 of IEC 60601-1:2005+Amendment 1:2012). Dismantling may be used.

Amendment (add additional requirement and replace the compliance test):

OXYGEN CONCENTRATOR ENCLOSURES shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the RISK of cross infection of the next PATIENT.

Instructions for processing and reprocessing the OXYGEN CONCENTRATOR and its ACCESSORIES shall comply with ISO 17664:2004 and ISO 14937:2009 and shall be disclosed in the instructions for use.

NOTE ISO 14159 provides guidance for the design of ENCLOSURES.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this standard could be affected by the cleaning or the disinfecting of the OXYGEN CONCENTRATOR or its parts or ACCESSORIES, clean and disinfect them 10 times in accordance with the methods indicated in the instruction for use, including any cooling or drying period. After these PROCEDURES, ensure that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Verify that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are also found in IEC 60601-1:2005+Amendment 1:2012, 11.6.6.

Additional subclauses:

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

201.11.8.101.1 TECHNICAL ALARM CONDITION for power supply failure

An OXYGEN CONCENTRATOR shall be equipped with an ALARM SYSTEM that includes a power supply failure TECHNICAL ALARM CONDITION to indicate when the power supply falls below the value necessary to maintain normal operation. The power supply failure TECHNICAL ALARM CONDITION shall be at least LOW PRIORITY with an auditory ALARM SIGNAL.

If the normal operation of the OXYGEN CONCENTRATOR is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the power supply failure TECHNICAL ALARM CONDITION shall not be activated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance with the following test:

- a) *Cause the power supply/SUPPLY MAINS to drop below the RATED value until either the supply failure ALARM CONDITION occurs or normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*
- b) *Verify that the specified TECHNICAL ALARM CONDITION occurs at or prior to loss of normal operation, unless normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE.*
- c) *If normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE, verify that the switchover is indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.*

201.11.8.101.2 INTERNAL ELECTRICAL POWER SOURCE

If the OXYGEN CONCENTRATOR has an INTERNAL ELECTRICAL POWER SOURCE, the OXYGEN CONCENTRATOR shall be equipped with a means of determining the remaining capacity or operation time provided by this power source. This indication may be qualitative.

NOTE 1 See IEC 60601-1, 3.45, for an explanation of INTERNAL ELECTRICAL POWER SOURCES.

An OXYGEN CONCENTRATOR with an INTERNAL ELECTRICAL POWER SOURCE shall be equipped with an ALARM SYSTEM that includes a LOW PRIORITY TECHNICAL ALARM CONDITION to indicate when the INTERNAL ELECTRICAL POWER SOURCE nears depletion, prior to the loss of all power. As the INTERNAL ELECTRICAL POWER SOURCE depletes, with sufficient time or capacity to permit the OPERATOR to take appropriate action, the depleted INTERNAL ELECTRICAL POWER SOURCE TECHNICAL ALARM CONDITION shall be escalated to include an auditory ALARM SIGNAL. The instructions for use shall disclose this time or capacity.

Any switchover to or from the INTERNAL ELECTRICAL POWER SOURCE as well as the charging of the INTERNAL ELECTRICAL POWER SOURCE shall not change normal operation of a TRANSIT-OPERABLE OXYGEN CONCENTRATOR unless accompanied by an INFORMATION SIGNAL or LOW PRIORITY TECHNICAL ALARM CONDITION to indicate that a change in operating mode has occurred.

NOTE 2 For the purposes of this standard, changing normal operation includes:
 —changes in programmable parameters or settings;
 —reset to default settings; and
 —initiation of an unintended operation.

The instructions for use for an OXYGEN CONCENTRATOR with an INTERNAL ELECTRICAL POWER SOURCE shall disclose the operational time of the power source when fully charged at the end of the EXPECTED SERVICE LIFE of the INTERNAL ELECTRICAL POWER SOURCE.

Check compliance by functional testing and inspection of the instructions for use.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+Amendment 1:2012, Clause 12 applies, except as follows.

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls and indicators of an OXYGEN CONCENTRATOR shall be marked with their function and be CLEARLY LEGIBLE under the conditions specified in the general standard, 7.1.2.

Check compliance by application of the tests of IEC 60601-1:2005+Amendment 1:2012, 7.1.2.

Additional subclauses:

201.12.1.101 Accuracy of continuous flowrate

In the continuous flow mode, an OXYGEN CONCENTRATOR shall be equipped with a flowrate indicator that indicates the total flowrate of delivered gas. The indicator shall be marked in l/min and shall be accurate to $\pm 10\%$ of the indicated flowrate or ± 200 ml/min, whichever is greater, at a backpressure of 0 kPa and 7 kPa.

Check compliance with the following test.

- a) *Set up the OXYGEN CONCENTRATOR as indicated in Figure 201.102 and, if applicable, set into the continuous flow mode.*
- b) *With the variable restrictor completely open, set the flowrate on the OXYGEN CONCENTRATOR so that the flowrate indicator is approximately 20 % of the maximum RATED flowrate or for an OXYGEN CONCENTRATOR that uses a fixed orifice to regulate flow, choose the orifice closest to 20 % of the maximum RATED flowrate.*
- c) *Operate the OXYGEN CONCENTRATOR for 15 min or until the low oxygen concentration or start-up period TECHNICAL ALARM CONDITION is no longer true, whichever is greater, and measure the flowrate of the delivered gas.*
- d) *Verify that delivered flowrate is within $\pm 10\%$ of the indicated flowrate or ± 200 ml/min, whichever is greater.*

- e) Set the variable restrictor so that the pressure monitor indicates $7 \text{ kPa} \pm 1 \text{ kPa}$.
- f) Verify that delivered flowrate is within $\pm 10 \%$ of the indicated flowrate or $\pm 200 \text{ ml/min}$, whichever is greater.
- g) Repeat c) to f) with the flowrate on the OXYGEN CONCENTRATOR set to approximately 100 % of the maximum RATED flowrate and set to approximately 50 % of the maximum RATED flowrate or for an OXYGEN CONCENTRATOR that uses a fixed orifice to regulate flow, test each orifice separately.

201.12.1.102 Accuracy of triggered flowrate

An OXYGEN CONCENTRATOR with integrated CONSERVING EQUIPMENT shall comply with 201.12.1.101 of ISO 80601-2-67:2014.

Check compliance by application of the tests of 201.12.1.101 of ISO 80601-2-67:2014.

201.12.1.103 * Accuracy of concentration

The minimum concentration of oxygen in the delivered gas when the OXYGEN CONCENTRATOR is operated at the maximum RATED flowrate shall not be less than the minimum volume fraction specified in the instructions for use.

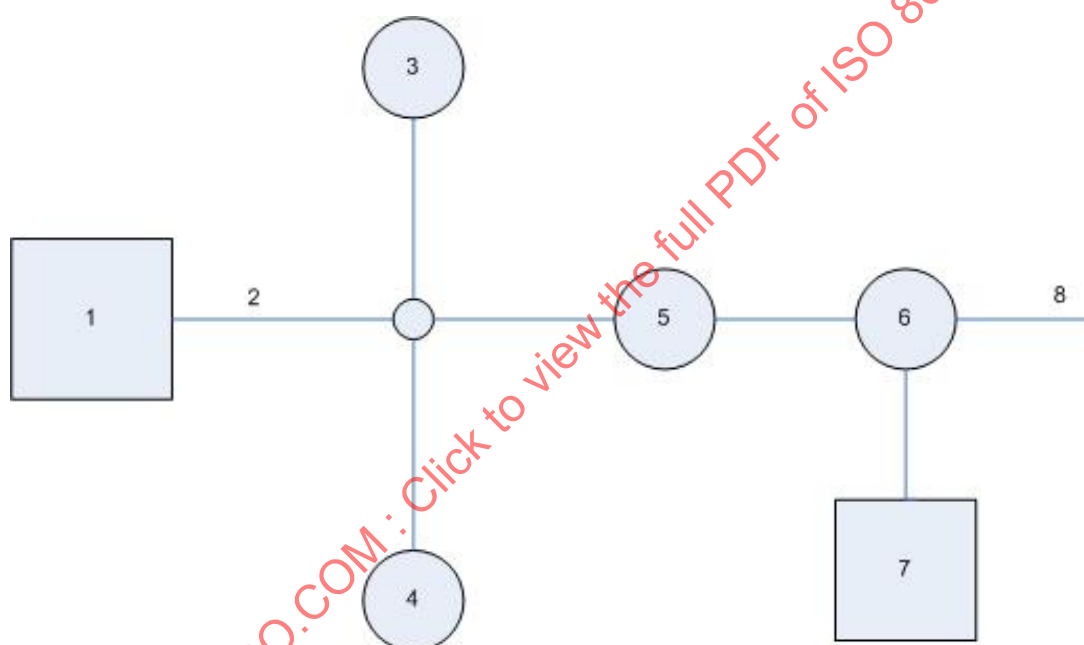
The instructions for use shall disclose the oxygen concentration as a function of flowrate over the RATED range in tabular form including the minimum, the maximum and each integer settings in between or the equivalent discrete flowrate settings.

NOTE Subclause 5.4 a) of the general standard requires that ME EQUIPMENT be tested under the least favourable working conditions as specified in the instructions for use.

Check compliance with the following test.

- a) For an OXYGEN CONCENTRATOR with a continuous flow mode, set up the OXYGEN CONCENTRATOR as indicated in Figure 201.102. Disable or bypass the humidifier, if present.
- b) With the variable restrictor completely open, set the flowrate on the OXYGEN CONCENTRATOR to approximately the maximum RATED flowrate.
- c) Operate the OXYGEN CONCENTRATOR until it stabilizes.
- d) Measure the oxygen concentration.
- e) Connect a standard resistance of Figure 201.101 to the outlet (8).
- f) Repeat c) and d) with the input voltage set to 85 % of the minimum RATED mains voltage and 110 % of the maximum RATED mains voltage.
- g) At a NOMINAL mains voltage, repeat c) and d) at the minimum and maximum RATED operating temperatures.
- h) Repeat c) and d) at the minimum and maximum RATED operating atmospheric pressures.
- i) At a NOMINAL operating atmospheric pressure, repeat c) and wait 6 h at the minimum RATED relative humidity. Repeat d).
- j) Repeat c) and wait 6 h at maximum RATED relative humidity and maximum RATED temperature. Repeat d).
- k) Verify that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.

- l) At NOMINAL conditions, set the flowrate to approximately 1 l/min or the lowest discrete flowrate setting.
- m) Repeat c) and d).
- n) Repeat l) setting the flowrate at approximately each integer l/min in the RATED flowrate range or at each discrete flowrate setting.
- o) Verify that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.
- p) For an OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT, repeat b) through o) in the conserving mode using the test setup of Figure 201.101 of ISO 80601-2-67:2014, connecting the standard resistance to the exhaust port.
- q) Verify that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.



Key

- 1 OXYGEN CONCENTRATOR under test
- 2 ACCESSORY connection tubing, approximately 2 m in length of inner diameter 6 mm $\pm$ 1 mm
- 3 thermometer
- 4 pressure monitor
- 5 variable flow restrictor
- 6 flowmeter
- 7 oxygen monitor
- 8 outlet

Figure 201.102 — Oxygen delivery performance, typical test setup

201.12.1.104 Outlet pressure

The MAXIMUM LIMITED PRESSURE in NORMAL CONDITION and SINGLE FAULT CONDITION shall be disclosed in the instructions for use.

Check compliance with the following test.

- a) Set up the OXYGEN CONCENTRATOR as indicated in Figure 201.102.
- b) For an OXYGEN CONCENTRATOR with a continuous flow mode, with the variable restrictor completely open, set the flowrate on the OXYGEN CONCENTRATOR to approximately the maximum RATED flowrate.
- c) Operate the OXYGEN CONCENTRATOR until it stabilizes as indicated in the instructions for use.
- d) Close the variable restrictor to stop flow.
- e) Wait 1 min.
- f) Repeat c) to e) after creating each relevant SINGLE FAULT CONDITION.
- g) Verify that the outlet pressure does not exceed the value indicated in the instructions for use for the entire period of the test.
- h) For an OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT, with the variable restrictor completely open, set the OXYGEN CONCENTRATOR to the maximum demand flow rate setting of NORMAL USE and simulate a triggering frequency of 20 breath/min.
- i) Repeat b) to g).

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.4.101 Additional requirements for incorrect output**201.12.4.4.101.1 Flowrate control**

An OXYGEN CONCENTRATOR shall be equipped with a means to adjust the flowrate of the delivered gas.

Check compliance by inspection.

201.12.4.4.101.2 Indication of start-up period

An OXYGEN CONCENTRATOR shall be equipped with an ALARM SYSTEM that includes a LOW PRIORITY TECHNICAL ALARM CONDITION to indicate when the oxygen concentration in the delivered gas has not reached the minimum RATED concentration during the start-up period. This ALARM CONDITION need not be activated if the start-up period is less 120 s.

Check compliance by functional testing.

201.12.4.102 Low oxygen concentration ALARM CONDITION

An OXYGEN CONCENTRATOR shall be equipped with an ALARM SYSTEM that detects a low oxygen concentration TECHNICAL ALARM CONDITION to indicate when the oxygen concentration in the delivered gas is less than expected. The low oxygen concentration TECHNICAL ALARM CONDITION shall activate before the concentration drops below 82 % volume fraction. The low oxygen concentration TECHNICAL ALARM

CONDITION shall be at least LOW PRIORITY with an auditory ALARM SIGNAL. The low oxygen concentration TECHNICAL ALARM CONDITION shall not stop the flow of output gas. The low oxygen concentration TECHNICAL ALARM CONDITION need not be activated during the start-up period.

Check compliance by inspection.

201.12.4.103 Delivered gas filter

The OXYGEN CONCENTRATOR shall be equipped with a means to filter particles greater than 1,0 µm to ISO Class 5 levels, as specified in ISO/DIS 14644-1:2010, Table 1, from entering the delivered gas. The filter shall be placed downstream of the oxygen concentrating means of the OXYGEN CONCENTRATOR.

Check compliance by inspection and the following test.

- a) *Sample the gas delivered from the OXYGEN CONCENTRATOR using the method of ISO/DIS 14644-1:2010, Annex A, for a single sampling site.*
- b) *Verify that the gas meets ISO Class 5 levels.*

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005+Amendment 1:2012, Clause 13 applies, except as follows:

Additional subclauses:

201.13.2.101 Additional specific SINGLE FAULT CONDITIONS

An OXYGEN CONCENTRATOR shall be equipped with an ALARM SYSTEM that detects TECHNICAL ALARM CONDITION(S) to indicate the malfunction of the OXYGEN CONCENTRATOR. The following individual faults, where applicable, shall be included:

- overheating;
- compressor failure;
- obstruction of gas pathways;
- oxygen generation means failure; and
- pressure failure.

Check compliance by inspection and functional testing.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+Amendment 1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+Amendment 1:2012, Clause 15 applies.

201.16 ME SYSTEMS

IEC 60601-1:2005+Amendment 1:2012, Clause 16 applies, except as follows:

Additional subclause:

201.16.1.101 Additional general requirements for ME SYSTEMS

ACCESSORIES connected to the OXYGEN CONCENTRATOR shall be considered to form an ME SYSTEM with the OXYGEN CONCENTRATOR.

Check compliance by application of the relevant tests of IEC 60601-1:2005+Amendment 1:2012.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+Amendment 1:2012, Clause 17 applies, except as follows:

Additional subclause:

201.17.101 Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

NOTE An OXYGEN CONCENTRATOR and its ACCESSORIES are not considered LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEMS.

New clauses:

201.101 Outlet connector

An outlet connector of the OXYGEN CONCENTRATOR that is OPERATOR-detachable without the use of a TOOL shall comply with ISO 80369-1:2010.

NOTE It is expected that the RESP-6000 (R2) connector of ISO 80369-2 will meet this criterion.

Check compliance by inspection and application of the tests of ISO 80369-1:2010.

201.102 Requirements for parts and ACCESSORIES**201.102.1 * General**

An OXYGEN CONCENTRATOR, its parts and ACCESSORIES shall comply with the requirements of this particular standard, whether they are produced by the MANUFACTURER of the OXYGEN CONCENTRATOR or by another entity ("third-party manufacturer" or healthcare provider).

Check compliance by the tests of this standard.

201.102.2 Labelling

The range of oxygen flows and maximum pressure for which the ACCESSORIES are specified for use shall be disclosed in the ACCOMPANYING DOCUMENTS.

EXAMPLE The maximum oxygen flow for which the nasal cannula is specified.

Statements shall be included in the ACCOMPANYING DOCUMENT of each OXYGEN CONCENTRATOR part and ACCESSORY to the effect that:

- a) an oxygen concentrator, its parts and accessories are specified for use at specific flows;
- b) incompatible parts or accessories can result in degraded performance;

- c) the responsible organization is accountable for ensuring the compatibility of the oxygen concentrator and all of the parts or accessories used to connect to the patient before use; and
- d) a warning statement to the effect that "WARNING: Use only water-based lotions or salves that are oxygen-compatible prior to and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns."

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 * Fire RISK reduction in ACCESSORIES

The APPLIED PART that delivers gas to the PATIENT from an OXYGEN CONCENTRATOR shall be equipped with or connected to a means to stop the flow of gas towards the PATIENT in the case that the APPLIED PART becomes ignited. The means of protection should be located as close to the PATIENT as practicable.

EXAMPLE The means to stop the flow of gas towards the PATIENT located at the junction between the nasal cannula and the oxygen supply tubing.

NOTE 1 This means is intended to prevent the propagation of fire towards the ME EQUIPMENT from the APPLIED PART.

NOTE 2 Additional fire prevention requirements are found in 201.11.2.101.

Check compliance by inspection and the following test.

- a) *Connect the APPLIED PART under test, including the means to stop the flow of gas towards the PATIENT in the case that the APPLIED PART becomes ignited, to oxygen tubing of approximately 2 m length which is connected to the outlet of a valve which can stop the flow of gas.*
Connect the inlet of the valve with oxygen tubing of approximately 2 m length to the outlet connector of an oxygen source with a pressure of 600 kPa to 700 kPa.
- b) *Set the oxygen source to deliver a continuous flowrate of 10 l/min $\pm$ 1 l/min through the APPLIED PART.*
- c) *Ignite the APPLIED PART under test at the patient end.*
- d) *Observe the fire propagating along the APPLIED PART towards the oxygen source and verify that the flow of oxygen is stopped when the fire reaches the means to stop the flow, and that the fire is not propagating through the means towards the oxygen source and that the fire extinguishes at this point.*

201.103 Signal input/output part

201.103.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained:

- a) if connections to the SIGNAL INPUT/OUTPUT PARTS of an OXYGEN CONCENTRATOR are disrupted;
- b) when any wire in the SIGNAL INPUT/OUTPUT PART is opened or shorted to any other wire in the SIGNAL INPUT/OUTPUT PART; or
- c) if the equipment connected to the SIGNAL INPUT/OUTPUT PART fails.

Check compliance by functional testing.

201.103.2 * Connection to a distributed alarm system

An OXYGEN CONCENTRATOR should be equipped with a SIGNAL INPUT/OUTPUT PART that permits connection to a DISTRIBUTED ALARM SYSTEM.

201.103.3 * Connection for remote control

An OXYGEN CONCENTRATOR may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for external control of the OXYGEN CONCENTRATOR.

201.104 * Indication of duration of operation

An OXYGEN CONCENTRATOR shall have means to indicate, either automatically or by OPERATOR action, the cumulative time of operation of the OXYGEN CONCENTRATOR. The OXYGEN CONCENTRATOR should also have means to indicate the time since the last or until the next preventive maintenance. These means may be restricted to SERVICE PERSONNEL.

Check compliance by inspection.

201.105 Integrated conserving equipment

An OXYGEN CONCENTRATOR with integrated CONSERVING EQUIPMENT shall comply with ISO 80601-2-67:2014.

Check compliance by application of the tests of ISO 80601-2-67:2014.

202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2.1.10 * Compliance criteria

IEC 60601-1-2:2007, 6.2.1.10 is replaced by:

Under the test conditions specified in 6.2 of IEC 60601-1-2:2007, an OXYGEN CONCENTRATOR shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE while using the setup of Figure 201.102 with the flowrate set to approximately 50 % of the maximum RATED flowrate. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:

- component failures;
- changes in programmable parameters or settings;
- reset to default settings;
- change of operating mode;
- initiation of an unintended operation;
- change of the oxygen concentration greater than 10 % volume fraction averaged over a one-minute interval; and
- change of the flowrate greater than 10 % averaged over a one-minute interval.

206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 60601-1-6:2010+Amendment 1:2013 applies except as follows:

For an OXYGEN CONCENTRATOR, the following shall be considered PRIMARY OPERATING FUNCTIONS:

- a) configuring the OXYGEN CONCENTRATOR, including connection of the detachable parts to the OXYGEN CONCENTRATOR;
- b) setting the flowrate control;
- c) starting the OXYGEN CONCENTRATOR from power off; and
- d) turning off the OXYGEN CONCENTRATOR.

The following functions, if available, shall also be considered PRIMARY OPERATING FUNCTIONS:

- e) performing the start-up PROCEDURE;
- f) setting up the humidifier specified or recommended for use with the OXYGEN CONCENTRATOR;
- g) determining the remaining capacity or operation time provided by the INTERNAL ELECTRICAL POWER SOURCE;
- h) setting up connections to the DISTRIBUTED ALARM SYSTEM as well as disconnecting the DISTRIBUTED ALARM SYSTEM;
- i) cleaning or replacing the air intake filter, and
- j) setting the OPERATOR-adjustable controls;
 - setting ALARM LIMITS,
 - inactivating ALARM SIGNALS, and
 - reactivating ALARM SIGNALS.

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

IEC 60601-1-8:2006+Amendment 1:2012 applies.

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

IEC 60601-1-11:2010 applies except as follows:

211.4.2.2 Environmental operating conditions

Amendment (add the note prior to element a) of the compliance test):

NOTE During the test normal operation of the OXYGEN CONCENTRATOR will deplete the ambient oxygen inside the environmental chamber if the gas output leaves the environmental chamber. An external air source is required to compensate and monitoring of the oxygen concentration inside the chamber is recommended.

Annexes of the general standard apply, except as follows.

Annex C (informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of OXYGEN CONCENTRATOR, its parts and ACCESSORIES are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a OXYGEN CONCENTRATOR, its parts or ACCESSORIES

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Any particular warnings and/or precautions relevant to the immediate operation of the equipment	201.7.2.101 b)
Containing natural rubber latex, if applicable	201.7.2.13.101
Containing phthalates, if applicable	201.11.6.4
For ACCESSORIES supplied separately, an indication of any limitations or adverse effects on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR, if applicable	201.7.2.4.101
For ACCESSORIES supplied separately, the requirements of 201.7.2.101	201.7.2.4.101
For an OXYGEN CONCENTRATOR with a continuous flow mode, a flowrate indicator marked in l/min	201.12.1.101
For each OXYGEN CONCENTRATOR, part and ACCESSORY, an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS, if applicable	201.7.2.101 c)
For packaging, a description of the contents	201.7.2.17.101 a)
For packaging, an identification reference to the batch, type or serial number	201.7.2.17.101 b)
For packaging, containing natural rubber latex, if applicable	201.7.2.17.101 c)
For packaging, containing phthalates, if applicable	201.11.6.4
Function of controls and indicators	201.12.1
Warning against removal of the cover by unauthorized persons	201.7.2.101 d)
Warning to the effect that "No Open Flame"	201.7.5 b)
Warning to the effect that "No Smoking"	201.7.5 a)

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of an OXYGEN CONCENTRATOR or its parts are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general

Description of requirement	Subclause
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Declared tolerances including the measurement uncertainty of the measurement used to determine the specification	201.5.101.2
For each OXYGEN CONCENTRATOR, part and ACCESSORY, a statement to the effect that an oxygen concentrator, its parts and accessories are specified for use at specific flows	201.102.2 a)
For each OXYGEN CONCENTRATOR, part and ACCESSORY, a statement to the effect that incompatible parts or accessories can result in degraded performance	201.102.2 b)
For each OXYGEN CONCENTRATOR, part and ACCESSORY, a statement to the effect that the responsible organization is accountable for ensuring the compatibility of the oxygen concentrator and all of the parts or accessories used to connect to the patient before use	201.102.2 c)
For each OXYGEN CONCENTRATOR, part and ACCESSORY, warning statement regarding use of lotions and salves	201.102.2 d)
Name or trade name and address of the MANUFACTURER, and where the MANUFACTURER does not have an address within the locale, an authorized representative	201.7.9.1
Range of oxygen flows for which ACCESSORIES are RATED	201.102.2
Units of measure for volumes, flows and leakages	201.7.4.3

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for information to be included in the instructions for use of an OXYGEN CONCENTRATOR or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use (1 of 3)

Description of requirement	Subclause
Any adverse effect of any recommended ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE or of the OXYGEN CONCENTRATOR, if applicable	201.7.9.2.14.101 b)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101
At least one type of humidifier which is suitable for use with the OXYGEN CONCENTRATOR	201.7.9.2.1.101 g)
Delivered oxygen concentration as a function of flowrate in tabular form	201.12.1.103
Diagram for the connection of OPERATOR-detachable parts either supplied or recommended in the instructions for use	201.7.9.2.5.101 c)
Explanation of the meaning of the IP classification marked on the equipment	201.7.9.2.9.101
For ACCESSORIES supplied separately where marking the ACCESSORY is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101
For an OXYGEN CONCENTRATOR, its parts and ACCESSORIES intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the OXYGEN CONCENTRATOR, its parts or ACCESSORIES would be reused	201.7.9.2.1.101 f)
For an OXYGEN CONCENTRATOR, its parts or ACCESSORIES that contain phthalates, information on RESIDUAL RISKS for treatment of children or that of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.6.4
For an OXYGEN CONCENTRATOR with an INTERNAL ELECTRICAL POWER SOURCE, the remaining time or capacity of the power source when the depleted ALARM CONDITION is escalated	201.11.8.101.2

Table 201.C.103 — (2 of 3)

Description of requirement	Subclause
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For an OXYGEN CONCENTRATOR with an INTERNAL ELECTRICAL POWER SOURCE, the end of EXPECTED SERVICE LIFE operational time of the power source when fully charged	201.11.8.101.2
Identification of portions of the gas pathways through the OXYGEN CONCENTRATOR that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION	201.7.9.2.12
INTERNAL ELECTRICAL POWER SOURCE care and maintenance, if applicable	201.7.9.2.13.101 d)
Intervals at which cleaning PROCEDURES need to be performed and the items required for such cleaning	201.7.9.2.13.101 b)
Instructions for processing and reprocessing the OXYGEN CONCENTRATOR and its ACCESSORIES	201.11.6.6
MAXIMUM LIMITED PRESSURE	201.12.1.104
Method by which all of the ALARM SIGNALS can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 b)
Method by which the OPERATOR can check for proper operation of the equipment	201.7.9.2.8.101 a)
Minimum volume fraction of delivered oxygen at the maximum RATED flowrate	201.12.1.103
Periodic visual safety inspections	201.7.9.2.13.101 a)
Preferred location of any humidifier	201.7.9.2.1.101 a)
PROCEDURE to determine the state of the INTERNAL ELECTRICAL POWER SOURCE, if applicable	201.7.9.2.9.101
RATED range of oxygen delivery flowrate and concentration of oxygen as a function of flowrate	201.7.9.2.5.101 d)
Restrictions on the positioning of components within the OXYGEN CONCENTRATOR, if applicable	201.7.9.2.14.101 a)
SOUND POWER LEVEL	201.9.6.2.1.101
SOUND PRESSURE LEVEL and tested flowrate	201.9.6.2.1.101
Statement advising the OPERATOR of actions to take when the OXYGEN CONCENTRATOR indicates an abnormal condition	201.7.9.2.1.101 d)
Statement of the time required from switching on the OXYGEN CONCENTRATOR until it can be relied upon to deliver the set flowrate and concentration of oxygen	201.7.9.2.1.101 b)
Statement that the air intake as well as the exhaust of the OXYGEN CONCENTRATOR should be located in a well-ventilated area	201.7.9.2.1.101 c)
Statement that the OXYGEN CONCENTRATOR should be located so as to avoid pollutants or fumes	201.7.9.2.1.101 e)
Statement to the effect that no lubricants are other than those recommended by the manufacturer should be used	201.7.9.2.13.101 c)
Statement to the effect that the oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories	201.7.9.2.5.101 a)
Statement to the effect that the proper placement and positioning of the patient interface is critical to the consistent operation of this equipment	201.7.9.2.5.101 b)
Warning statement regarding the need for extra monitoring	201.7.9.2.2.101 j)
Warning statement regarding the risk of lubricating	201.7.9.2.2.101 e)

Table 201.C.103 — (3 of 3)

Description of requirement	Subclause
Warning statement regarding the risk of smoking	201.7.9.2.2.101 b)
Warning statement regarding the risk of smoking in the same room	201.7.9.2.2.101 k)
Warning statement regarding the effect of changing the spare parts	201.7.9.2.2.101 f)
Warning statement regarding the risk of fire	201.7.9.2.2.101 a)

Warning statement regarding use as prescribed, both settings and ACCESSORIES	201.7.9.2.2.101 c)
Warning statement regarding use outside the RATED altitude, temperature or relative humidity	201.7.9.2.2.101 g)
Warning statement regarding use of lotions and salves	201.7.9.2.2.101 d)
Warning statement regarding when to turn off the OXYGEN CONCENTRATOR	201.7.9.2.2.101 h)
Warning statement regarding when to seek medical assistance	201.7.9.2.2.101 i)
Cross reference to the additional information available in the technical description, if the technical description is separable	201.7.9.2.16.101

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of an OXYGEN CONCENTRATOR or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of a method for SERVICE PERSONNEL to check the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this standard, if not performed automatically during start-up	201.7.9.3.101 c)
Description of the principle of operation of the OXYGEN CONCENTRATOR	201.7.9.3.101 a)
Disclose which ALARM SYSTEM functional checks are performed automatically	201.7.9.3.101 c)
Pneumatic diagram of the OXYGEN CONCENTRATOR including a diagram of OPERATOR-detachable parts either supplied or recommended in the instructions for use	201.7.9.3.101 b)
RESPONSIBLE ORGANIZATION should ensure the compatibility of the OXYGEN CONCENTRATOR and all of the parts used to connect to the PATIENT before use	201.7.9.3.101 d)
RESPONSIBLE ORGANIZATION should ensure that the oxygen delivery settings were determined for the PATIENT individually with the configuration of the equipment to be used, including ACCESSORIES	201.7.9.3.101 d)
RESPONSIBLE ORGANIZATION should periodically reassess the setting(s) of the therapy for effectiveness	201.7.9.3.101 d)

Annex D (informative)

Symbols on marking

Annex D of the general standard applies, except as follows:

Addition:

Table 201.D.1.101 — Additional symbols on marking

No.	Symbol	Reference	Title
1		ISO-7000-2492 Symbol 5.1.5 ISO 15223-1:2012	Batch code
2		ISO-7000-2498 Symbol 5.1.7 ISO 15223-1:2012	Serial number
3		ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:2012	Presence of, contains, natural rubber latex
EN 15986:2011 provides additional information for phthalate symbols.			

Table 201.D.2.101 — Additional safety signs

No.	Safety sign	Reference	Title
1		ISO 7010:2011 Safety sign P002	No smoking
2		ISO 7010:2011 Safety sign P003	No open flame: Fire, open ignition source and smoking prohibited

Additional Annexes:

Annex AA (informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the clauses in this document. The numbering is, therefore, not consecutive.

Subclause 201.4.3.101 – Additional requirements for ESSENTIAL PERFORMANCE

The supplemental oxygen provided by an OXYGEN CONCENTRATOR to PATIENTS that require it is ESSENTIAL PERFORMANCE. PATIENTS are prescribed oxygen doses as needed. Excessive oxygen can be harmful. An OXYGEN CONCENTRATOR is expected to provide an oxygen dose within the performance levels indicated in its instructions for use or generate a TECHNICAL ALARM CONDITION that indicates otherwise since an OXYGEN CONCENTRATOR is not normally single failure functional. PATIENTS are expected to have an alternative or backup means to receive supplemental oxygen in case of OXYGEN CONCENTRATOR failure or loss of SUPPLY MAINS for OXYGEN CONCENTRATOR operation.

Subclause 201.4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Since the OXYGEN CONCENTRATOR and its ACCESSORIES are likely to be draped over or around the PATIENT, they are likely to come into direct contact with the PATIENT during NORMAL USE. Additionally, the gas pathways conduct fluids into or out of the PATIENT. As such, the gas pathways of the OXYGEN CONCENTRATOR and its ACCESSORIES need to be investigated regarding biocompatibility and compatibility with substances that might pass into the PATIENT via the gas pathways. Also of concern are electrical HAZARDS should any circuitry be incorporated into the ACCESSORIES. By ensuring that the gas pathways are subject to the requirements for APPLIED PARTS, these issues are addressed by the requirements already in the general standard.

Subclause 201.5.101.1 – ME EQUIPMENT testing errors

When testing an OXYGEN CONCENTRATOR performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows. Because of the relative significance of these uncertainties, it is important that MANUFACTURERS allow for measurement uncertainty when declaring parameter accuracy.

Similarly, it is important for third-party testers to recognise the significance of the uncertainty in their own measurements when testing to this standard. In practice, this means that, for example, if a

MANUFACTURER determines that a parameter has a tolerance of $\pm 7\%$ but that the measurement uncertainty is $\pm 3\%$ then a parameter tolerance of $\pm 10\%$ is declared. If a third-party tester subsequently obtains an error of the measured value for that parameter of $\pm 15\%$, with a measurement uncertainty of $\pm 5\%$, then the third-party tester has to accept the MANUFACTURER'S claim.

The test equipment used to verify ESSENTIAL PERFORMANCE of an OXYGEN CONCENTRATOR should be at least 10 times the accuracy of the MANUFACTURER'S stated tolerance.

Subclause 201.7.1.2 – Legibility of markings

In order to change the settings of a BODY-WORN OXYGEN CONCENTRATOR, the OPERATOR will need to be within an arm's length of the means of setting at a normal reading distance when operated.

Subclause 201.7.4.3 – Units of measurement

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas $0\text{ }^{\circ}\text{C}$ is used as standard temperature in physics, either $20\text{ }^{\circ}\text{C}$ or $21,2\text{ }^{\circ}\text{C}$ ($70\text{ }^{\circ}\text{F}$) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature ($\sim 37\text{ }^{\circ}\text{C}$) irrespective of the temperature of the gas delivered by an OXYGEN CONCENTRATOR. The volume of a given amount of gas increases by about 13,5 % from $0\text{ }^{\circ}\text{C}$ to $37\text{ }^{\circ}\text{C}$ or by 5,8 % from $20\text{ }^{\circ}\text{C}$ to $37\text{ }^{\circ}\text{C}$.

Gas delivery systems supplying pressurised gas to medical equipment, including an OXYGEN CONCENTRATOR, follow engineering conventions and specify gas quantities and flowrates at STPD (Standard Temperature and Pressure, Dry) conditions. This practice is followed in this standard for all requirements concerning gas input.

However, an OXYGEN CONCENTRATOR complying with this standard is likely to be providing gas to the PATIENT relative to a local atmospheric pressure between 70 kPa and 110 kPa and is likely to use a variable or calibrated orifice to set the flowrate. Because such orifices function by reference to the ambient pressure, ATPD is the appropriate set of reference conditions to use.

Subclause 201.7.9.2.8.101 – Additional requirements for start-up PROCEDURE

In some designs, adequate checking of the ALARM SYSTEM can be performed with a combination of OPERATOR-action and the power-on self-test routines that VERIFIES the integrity of the software and the integrity of the processor controlling the OXYGEN CONCENTRATOR, as well the measuring sensors and the ALARM SIGNAL generation.

Subclause 201.7.9.2.16.101 – Additional requirements for reference to the technical description

Instructions for use are often kept as simple as possible so that the OPERATOR can easily find and follow important information. Therefore more technical information, such as required by this subclause, is better placed in the technical description. However, without adequate cross-referencing, an OPERATOR facing a problem might not be aware that additional information is readily available in a separate document.

Subclause 201.11.2.101 – Additional requirements for fire prevention

Many PATIENTS who are on supplemental oxygen were and still are smokers. It is reasonably foreseeable that PATIENTS who are on supplemental oxygen will continue to smoke. In fact it is known that they do continue to smoke despite the warnings in the instructions for use.

As a result it is necessary to reduce the RISK associated with this dangerous behaviour:

- by preventing the propagation of fire back through the outlet connector into the OXYGEN CONCENTRATOR; and
- by providing a means to stop the flow of gas towards the PATIENT in the case that the APPLIED PART becomes ignited.

Although these RISK CONTROL methods are not expected to prevent the PATIENT from being seriously burned by this dangerous behaviour, they are intended to reduce the RISK of the more serious propagation of fire from causing HARM to others.

Subclause 201.11.6.6 – Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

The essential principles of ISO 16142 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the PATIENT on whom they are being used or the employees or third parties interacting with them.

This means that an OXYGEN CONCENTRATOR, its ACCESSORIES and parts cannot be used if there is a potential RISK of the PATIENT, OPERATOR or other person being infected as a result of contact with the OXYGEN CONCENTRATOR, ACCESSORY or part.

Therefore an OXYGEN CONCENTRATOR, its ACCESSORIES and parts require an appropriate level of disinfection, depending on their use, but rarely need to be sterile.

Recommendations for hygienic reprocessing of an OXYGEN CONCENTRATOR, its ACCESSORIES and parts are based on the general hygiene requirements for the reprocessing of medical devices and the need to take into consideration the special requirements and needs of PATIENT care in the clinical environment. [9] The requirements for hygienic reprocessing in this standard are intended to:

- make the RESPONSIBLE ORGANIZATION for reprocessing the OXYGEN CONCENTRATOR aware of how to implement these tasks in a responsible manner through appropriate delegation; and
- help all parties involved in the reprocessing of an OXYGEN CONCENTRATOR, its ACCESSORIES and parts to comply with the MANUFACTURER'S instructions.

The cleaning and disinfection PROCEDURES of the MANUFACTURER are also intended to provide practical support to all those involved in PATIENT care in the clinical environment with regard to implementing the hygiene measures required for the PATIENT'S safety.

It should be noted that an OXYGEN CONCENTRATOR, as all other medical devices that have been contaminated with human pathogenic microorganisms, is a potential source of infection for humans. Any OXYGEN CONCENTRATOR that has already been used on another PATIENT is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and reprocessing PROCEDURES are essential to protect the next person handling the device or the next PATIENT on whom the device is used. Hence an OXYGEN CONCENTRATOR, its re-usable ACCESSORIES and parts that have been used are required to undergo a reprocessing PROCESS, following the MANUFACTURER'S instructions, prior to reuse by another PATIENT.

The following basic considerations need to be addressed by the MANUFACTURER when specifying the reprocessing instructions of an OXYGEN CONCENTRATOR, its ACCESSORIES or parts:

- protecting the PATIENT, the OPERATOR and the RESPONSIBLE ORGANIZATION (including personnel involved in performing the reprocessing PROCESS);
- the limits of the PROCEDURES used for reprocessing (such as the number of reprocessing cycles); and
- the necessity to guarantee the proven standardised PROCEDURES in a consistently high and verifiable quality, based on an established quality management system.

The recommended reprocessing PROCESS should be determined by:

- the potential degree and type of contamination of the OXYGEN CONCENTRATOR, ACCESSORIES or parts; and
- the RISK of infecting another PATIENT resulting from their reuse and the type of application of the OXYGEN CONCENTRATOR.

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S rebreathing under SINGLE FAULT CONDITION should be considered.

On the basis of the above, a VERIFIED and VALIDATED documented reprocessing PROCEDURE needs to be specified in such details that the outcome is reproducible. An acceptable RESIDUAL RISK from the HAZARD of infection for the next PATIENT can be assumed if:

- the documented reprocessing PROCEDURE'S effectiveness has been VERIFIED through appropriate scientific methods by the MANUFACTURER; and
- the reliability of the documented reprocessing PROCEDURES has been VERIFIED in practice through appropriate quality assurance measures by the RESPONSIBLE ORGANIZATION carrying out the reprocessing PROCEDURES.

When selecting and evaluating the reprocessing PROCEDURES, the MANUFACTURER should consider:

- the amount and type of pathogenic microorganisms expected to contaminate the OXYGEN CONCENTRATOR, ACCESSORIES or parts;
- the RISK for the pathogenic microorganisms to be transmitted to the PATIENT, OPERATOR or other persons; and
- the microorganism's resistance to the recommended reprocessing PROCEDURES.

The RISKS posed by a reprocessed OXYGEN CONCENTRATOR, ACCESSORIES or parts are determined by the following factors:

a) undesired effects, which can result from:

- the previous use,
- the previous reprocessing PROCESSES, and
- transportation and storage;

b) the RISKS from subsequent uses, such as the following:

- residues from the previous use (such as secretions, other body fluids, and drugs),
- residues from the previous reprocessing PROCESSES such as cleaning agents, disinfectants and other substances, including their reaction products,
- changes of physical, chemical or functional properties of the device, and
- changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the RISK of transmission of any pathogenic microorganisms.

When considering the suitability of the reprocessing PROCESS and the feasibility of the reprocessing PROCESS for the OXYGEN CONCENTRATOR, ACCESSORIES or parts, the MANUFACTURER should consider the following points:

- the RISKS involved in the reprocessing PROCESS;
- the cost effectiveness of the reprocessing PROCESS;
- the practicability of the reprocessing PROCESS;
- the availability of the cleaning equipment and the cleaning agents specified in the reprocessing PROCESS;