INTERNATIONAL STANDARD

ISO 80601-2-69

Second edition
2020-11

Medical electrical equipment —

Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-69:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

— changes to the low oxygen concentration *alarm condition*;

— changes to the gas outlet connector;

— changes to the test method for the filter for the delivered gas;

— reformatting to provide a unique identifier for each requirement;

— harmonization with the 'A2 project' of the general standard.

A list of all parts in the ISO and IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Oxygen supplementation can be part of management of *patients* with chronic, acute-on-chronic or acute respiratory disorders. The amount of supplemental oxygen depends on the individual *patient's* needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate.

The goal of long-term oxygen therapy is to keep the oxygen saturation above a target value in *patients* that require supplemental oxygen. The flowrate should be adjusted for rest, exertion and sleep to meet the individual *patient's* needs under these various conditions. Ideally, the resting flowrate is adjusted to maintain SpO_2 greater than the target value as indicated by pulse oximetry.

Supplemental oxygen is supplied by various sources: *medical gas pipeline systems*, *oxygen concentrators*, compressed gas cylinders and liquid oxygen reservoirs. *Oxygen concentrators* produce oxygen-enriched air from room air for delivery to a *patient* requiring oxygen therapy. The most common *oxygen concentrator* uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air, generating oxygen concentrations of typically 90 % to 96 %. The main component of this type of *oxygen concentrator* is the molecular sieve, which adsorbs nitrogen from air to produce a product gas, which is a mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption process.

Long-term oxygen therapy has been demonstrated in randomized, controlled clinical trials to prolong survival in *patients* with chronic respiratory disease and documented hypoxemia. Typical sources of therapeutic long-term oxygen therapy include gaseous oxygen from cylinders or from liquid oxygen and oxygen from an *oxygen concentrator*.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications and terms defined in Clause 3 of the general standard, in this particular document or as noted: italic type*; and

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term.

— "clause" means one of the three numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.); and

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may” is used to describe a permission (e.g., permissible way to achieve conformance with a requirement or test;

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Medical electrical equipment

Part 2-69:
Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

201.1 * Scope, object and related standards

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

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

IEC 60601-1:2005+AMD1:2012, 1.1 is replaced by:

This document specifies requirements for the *basic safety* and *essential performance* of an *oxygen concentrator* in combination with its *accessories*, hereafter referred to as *ME equipment,* intended to increase the oxygen concentration of gas intended to be delivered to a single *patient*. Such *oxygen concentrators* are typically intended for use in the *home healthcare environment* by a single *patient* in various environments including any private and public transportation as well as in commercial aircraft.

NOTE 1 Such *oxygen concentrators* can also be used in professional healthcare facilities.

This document is applicable to a *transit-operable* and non-*transit-operable oxygen concentrator.* This document is applicable to an *oxygen concentrator* integrated into or used with other medical devices, *ME equipment* or *ME systems*.

EXAMPLE 1 An *oxygen concentrator* with integrated oxygen *conserving equipment* function or humidifier function.

EXAMPLE 2 An *oxygen concentrator* used with a flowmeter stand.

EXAMPLE 3 An *oxygen concentrator* as part of an anaesthetic system for use in areas with limited logistical supplies of electricity and anaesthetic gases[2].

EXAMPLE 4 An *oxygen concentrator* with an integrated liquid reservoir function or gas cylinder filling system function.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *oxygen concentrator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *oxygen concentrator*.

NOTE 2 Such *accessories* can include, but are not limited to, masks, cannulae, extension tubing, humidifiers, carts, carrying cases, external power sources and oxygen *conserving equipment.*

This document does not specify requirements for *oxygen concentrators* for use with a *medical gas pipeline system*.

If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

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

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

NOTE 1 *Accessories* are included because the combination of the *oxygen concentrator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *oxygen concentrator*.

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

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

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

201.1.3 Collateral standards

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.4 in this document addresses the content of Clause 4 of the IEC 60601-1-11collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words.

— "Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

— "Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

— "Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

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

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

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

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

201.2 Normative references

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

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

Replacement:

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

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

Addition:

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

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

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

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

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

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

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

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

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

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

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

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

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

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

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

201.3 Terms and definitions

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

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

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

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

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

Addition:

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

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

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

201.4 General requirements

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

201.4.3 *Essential performance*

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

Additional subclause:

201.4.3.101 * Additional requirements for *essential performance*

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

Table 201.101 — Distributed *essential performance* requirements

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

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

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

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

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

201.5 General requirements for testing of *ME equipment*

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

Addition:

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

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

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

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

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

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

201.7 *ME equipment* identification, marking and documents

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

201.7.1.2 * Legibility of markings

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

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

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

Additional subclauses:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

   1) fulfil the requirements of 201.7.2.101; and

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

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

NOTE Additional requirements are found in 201.102.

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

201.7.2.13.101 Additional requirements for physiological effects

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

b) Such marking shall be *clearly legible*.

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

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

Check conformance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

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

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

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

   1) a description of the contents;

2) an identification reference to the batch, type or serial number:

   i) symbol ISO 7000-2492 or symbol 5.1.5, from ISO 15223-1:— (Table 201.D.1.101, symbol 1,) may be used for batch;

   ii) symbol ISO 7000-2493 or symbol 5.1.6 from ISO 15223-1:— (Table 201.D.1.101, symbol 2) may be used for type;

   iii) symbol ISO 7000-2498 or symbol 5.1.7 from ISO 15223-1:— (Table 201.D.1.101, symbol 3) may be used for serial number;

3) if containing natural rubber latex,

   i) the word "LATEX", or

   ii) the symbol ISO 7000-2725 or symbol 5.4.5 from ISO 15223-1:— (Table 201.D.1.101, symbol 4).

d) Protective packaging shall maintain the integrity and cleanliness of the contents.

e) For *accessories* intended to be sterilized prior to use:

1) the protective packaging shall be suitable taking account of the method of sterilization indicated by the *manufacturer*; and

2) the protective packaging shall minimise the *risk* of microbial contamination.

Check conformance by inspection.

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

a) The marking of *ME equipment*, parts and *accessories* shall be *clearly legible.*

b) The marking of *ME equipment*, parts and *accessories* shall include:

1) any particular storage, handling and operating instructions;

2) any particular warnings and precautions relevant to the immediate operation of the *oxygen concentrator*.

c) If applicable, *operator*-accessible *ME equipment*, parts and *accessories* shall have *clearly legible* markings of the following:

1) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*; and

2) a warning against removal of the *access cover* by unauthorized persons.

d) Notwithstanding requirement b) and c), if the size of *ME equipment*, parts or *accessory*, or the nature of its *enclosure*, does not allow affixation of these markings, the remaining markings shall be included in the instructions for use.

Check conformance by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 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 *STPD* (*standard temperature and pressure, dry*).

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

201.7.5 *Safety signs*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.5 applies, except as follows:

Amendment (add before the conformance test):

The following *safety signs* shall be *clearly legible* from the intended position of the *operator*:

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

bb) *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+AMD1:2012, 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;

Addition:

201.7.9.1.101 Additional general requirements

The *accompanying documents* shall instruct the *responsible organization* to assess the needs of the *patient* for backup supplies of supplementary oxygen in case of *oxygen concentrator* or power failure:

a) at installation based on

  1) the condition of the *patient*,

  2) the environment in which the *patient* lives, and

  3) the ability to resupply the *patient* with backup supplies of supplementary oxygen; and

b) periodically as these attributes change.

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101Additional general requirements

The instructions for use shall include the following:

a) a summary of the *use specification* (see IEC 62366-1:2015);

b) 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;

c) a statement that the air intake as well as the exhaust of the *oxygen concentrator* should be located in a well-ventilated area;

d) a statement advising the *operator* of actions to take when the *oxygen concentrator* indicates an abnormal condition;

e) a statement that the *oxygen concentrator* should be located so as to avoid pollutants or fumes;

f) 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* were reused;

g) a statement to the effect that the oxygen delivery settings of the *oxygen concentrator* should be 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.

h) a statement to the effect that the *accessories* and *oxygen concentrator* setup used to deliver oxygen to the *patient* should include a means, as specified in the instructions for use, to reduce the extent of the propagation of fire if ignition occurs;

EXAMPLE Such means include, but are not limited to, a heat or smoke detector that stops the flow of gas in the tubing or stops the *oxygen concentrator*.

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

i) at least one type of humidifier that is suitable for use with the *oxygen concentrator* and its preferred location.

Check conformance by inspection.

201.7.9.2.2.101Additional 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:

   1) be used with settings that have been individually determined or prescribed for you at your activity levels with your accessories;

   2) be used with the specific combination of parts and accessories that are in line with the specification of the concentrator or accessory manufacturer.";

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-based 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 more 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 or open flames within the same room as the oxygen concentrator or any oxygen-carrying accessories. If you 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.";

k) a warning statement to the effect that "WARNING: Open flames during oxygen therapy are dangerous and are 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 conformance by inspection of the instructions for use.

201.7.9.2.5.101Additional 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:

1) at *STPD* conditions; and

2) over the *rated* ranges of ambient temperature, humidity and atmospheric pressure.

201.7.9.2.8.101* Additional requirements for start-up *procedure*

For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used to determine whether or not 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 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 3 Combination of the power-on self-test routines and *operator* action that functionally checks the *alarm signals*.

Check conformance by inspection.

201.7.9.2.9.101Additional requirements for operating instructions

The instructions for use of an *oxygen concentrator* shall include, if applicable, the *procedure* necessary to determine the remaining capacity or operation time of the *internal electrical power source*.

Check conformance by inspection of the instructions for use.

201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization*

IEC 60601-1:2005+AMD1:2012, 7.9.2.12 applies, except as follows:

Amendment: (add after normal use)

and *single fault condition*

Amendment: (add after bulleted list)

aa) 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.

Check conformance by inspection of the instructions for use.

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:

   1) on the oxygen concentrator; and

   2) within the setup 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 conformance by inspection and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.2.15 Environmental protection

IEC 60601-1:2005+AMD1:2012, 7.9.2.15 applies, except as follows:

Amendment (add after the existing paragraph):

aa) Particular attention shall be given to the disposal of the molecular sieves.

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 document, if not performed automatically during start-up.

   1) The technical description shall disclose which checks are performed automatically.

Check conformance by inspection of the technical description.

201.8 Protection against electrical *hazards* from *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies, except as follows:

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) 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:

   1) for an *oxygen concentrator* with a continuous flow mode,

      i) at a flowrate setting of 3 l/min, or

      ii) the maximum flowrate setting if this is less than 3 l/min,

      iii) as well as for the maximum flowrate setting if this setting is greater than or equal to 4 l/min; and

   2) for an *oxygen concentrator* with integrated oxygen *conserving equipment* function, at the maximum demand flow rate setting of *normal use*.

b) The instructions for use shall disclose:

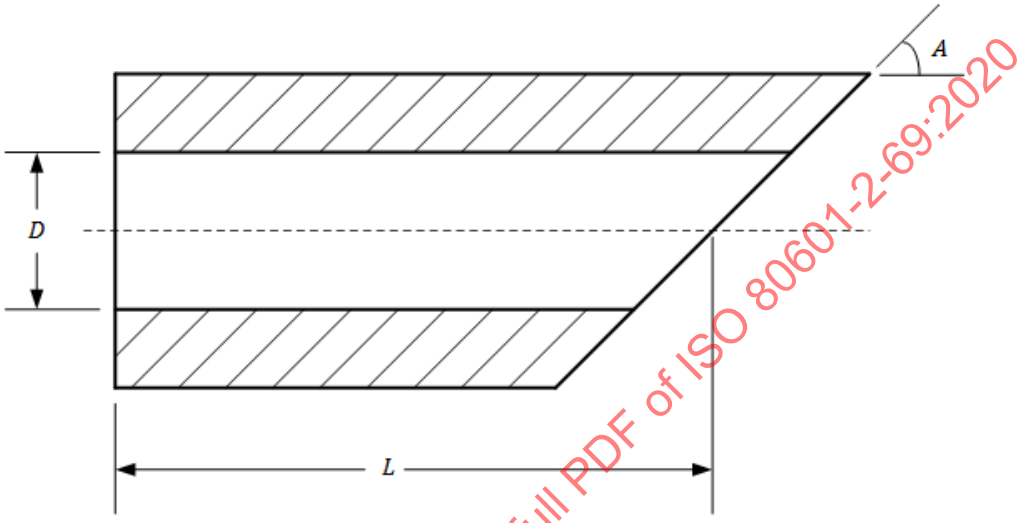
   1) the *sound power level*; and

   2) the tested flowrates.

Check conformance with the following test:

c) For an oxygen concentrator with a continuous flow mode, place the oxygen concentrator on a sound-reflecting plane and attach 10 m ± 1 m of oxygen tubing.

d) 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.



Key

D is the internal diameter: (4 ± 0,1) mm

L is the length: (40 ± 1) mm

A is the angle (45 ± 1) °

Break all edges with 0,15 mm to 0,20 mm radius or 45° chamfer. Drawing is not to scale.

Figure 201.101 – Standard resistance

e) 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.

f) Using a microphone of the sound level meter conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, 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.

g) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

h) Confirm that the A-weighted background level of extraneous noise, including any information signals, is at least 6 dB below that measured during the test.

i) Calculate the sound power level according to 8.2.5 of ISO 3744:2010.

j) Confirm that the test flowrate is disclosed in the instructions for use and confirm that the sound pressure level and the sound power level do not exceed those disclosed in the instructions for use.

k) Repeat e) to j) at the maximum flowrate setting if this setting is greater than or equal to 4 l/min.

l) For an oxygen concentrator with integrated oxygen conserving equipment function, repeat e) through j) in a conserving mode, connecting the standard resistance to the exhaust port. Simulate a breathing frequency of 20 breaths/min at the maximum demand flowrate of normal use.

m) Confirm that the measured sound pressure level and the sound power level do not exceed those disclosed in the instructions for use.

201.10 Protection against unwanted and excessive radiation *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies.

201.11 Protection against excessive temperatures and other *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows:

201.11.1 Maximum temperature during *normal use*

Amendment (add after 3rd dash):

aa) For the purposes of this document, 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):

In *normal use* and *single fault condition*, 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

a) 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.

EXAMPLE An integral humidifier or a humidifier used with the *oxygen concentrator* is such an *accessory*.

b) This means shall not be detachable by the *operator* without the use of a *tool.*

c) This means also may stop the flow of gas (see 201.102.3).

Check conformance by inspection and the following test.

d) 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. Drape the tubing over the enclosure.

e) Wait for the steady-state condition to be achieved.

f) Ignite the accessory connection tubing or cannula at the end opposite to the outlet connector.

g) *Observe the fire propagating along the connecting tubing towards the oxygen concentrator.*

h) *Confirm 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. Confirm that the enclosure does not burn for more than 30 s (see 201.11.3.101).*

Additional subclause:

201.11.3.101 * Additional requirements for fire *enclosures* of *ME equipment*

The *enclosure* of an *oxygen concentrator* capable of delivering oxygen in a continuous mode shall conform with the requirements for *fixed ME equipment* or *stationary ME equipment* in IEC 60601-1:2005+AMD2:2020, 11.3 b) 3).

Check conformance by inspection or application of the tests of IEC 60601-1:2005+AMD2:2020, 11.3 b) 3).

201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (replace the conformance check with the following):

aa) *Gas pathways* through the *oxygen concentrator* and its *accessories* not intended for single use that can become contaminated with body fluids or expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

1) for *cleaning* and *disinfection*; or

2) *cleaning* and *sterilization*.

NOTE Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012.

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

bb) *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*.

cc) Instructions for *processing* the *oxygen concentrator* and its *accessories* shall

1) conform to ISO 17664:2017 and ISO 14937:2009, as appropriate, and

2) be disclosed in the instructions for use.

NOTE ISO 14159[3] provides guidance for the design of *enclosures*.

Check conformity by inspection of the risk management file. When conformity with this document could be affected by the cleaning or the disinfecting of the oxygen concentrator or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life in accordance with the methods indicated in the instruction for use, including any cooling or drying period. Confirm that basic safety and essential performance are maintained after these procedures. Confirm 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 conformance test):

NOTE Additional requirements are found also in IEC 60601-1:2005+Amendment 1:2012, 11.6.6 and IEC 60601–1-11:2015, Clause 8.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the conformance statement).

aa) The *manufacturer* of any *oxygen concentrator*, its parts and *accessories* shall address in the *risk management process* the *risks* associated with the *biocompatibility* and potential contamination of the gas stream arising from the *gas pathways*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

NOTE The testing for particle emissions over the *expected service life* is required by ISO 18562-2:2017[4].

cc) Special attention shall be given to substances that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction.

dd) An *oxygen concentrator*, its parts and *accessories* that contain phthalates or other substances, in a concentration that is above 0,1 % weight by weight, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, shall be marked as containing such substances:

1) on the device itself; or

2) on the packaging.

ee) The symbol of ISO 7000-3723 or symbol 5.4.10 of ISO 15223-1:— (Table 201.D.2.101, symbol 6) may be used for such hazardous substances.

ff) A specific justification for the use of these substances shall be included in the *risk management file*.

gg) The instructions for use of an *oxygen concentrator*, its parts or *accessories* that contain endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction or that could result in sensitisation or an allergic reaction by the *patient* or *operator* shall contain information:

1)on *residual risks*; and

2)if applicable, on appropriate precautionary measures.

Check conformance by confirming conformity to ISO 18562-1:2017, inspection of the instructions for use and inspection of the risk management file for identification of the presence of substances that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction and justification for their use.

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

a) 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.

b) The power supply failure *technical alarm condition* shall be at least *low priority* with an auditory *alarm signal*.

c) 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.

d) Any such switchover to an *internal electrical power source* shall be indicated by an *information signal* or a *low priority technical alarm condition.*

Check conformance with the following test.

e) 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.

f) Confirm 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.

g) If normal operation is maintained by a switchover to an internal electrical power source, confirm 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*

a) 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.

b) This indication may be qualitative.

NOTE See IEC 60601-1, 3.45, for an explanation of *internal electrical power sources.*

c) 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.

d) 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*.

e) The instructions for use shall disclose this time or capacity.

f) 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 For the purposes of this document, changing normal operation includes:
- changes in programmable parameters or settings;
- reset to default settings; and
- initiation of an unintended operation.

g) 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 conformance 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+AMD1:2012+AMD2:2020, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The controls and indicators of an *oxygen concentrator* shall be:

1) marked with their function; and

2) *clearly legible* under the conditions specified in 201.7.1.2.

bb) An *oxygen concentrator* that can operate in both a continuous flowrate mode and a triggered flow (i.e. with integrated *conserving equipment* function) mode shall indicate the mode of operation.

cc) The *oxygen concentrator* may provide means to reduce the visibility of its controls and indicators either automatically or by an *operator* action.

dd) If provided, the *oxygen concentrator* shall automatically resume normal visibility:

1) during an *alarm condition*; and

2) by a single *operator* action.

Check conformance by application of the tests of 201.7.1.2.

Additional subclauses:

201.12.1.101 Accuracy of continuous flowrate

a) In the continuous flow mode, an *oxygen concentrator* shall be equipped with a flowrate indicator that indicates the total flowrate of delivered gas.

b) The indicator shall be:

1) marked in l/min; and

2) accurate to:

i) ±10 % of the indicated flowrate, or

ii) ±200 ml/min, whichever is greater;

3) at a backpressure of:

iii) 0 kPa, and

iv) 7 kPa.

Check conformance with the following test.

c) Set up the oxygen concentrator as indicated in Figure 201.102 and, if applicable, set into the continuous flow mode.

d) 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.

e) 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.

f) Confirm that delivered flowrate is within ±10 % of the indicated flowrate or ±200 ml/min, whichever is greater.

g) Set the variable restrictor so that the pressure monitor indicates 7 kPa ±1 kPa.

h) Confirm that delivered flowrate is within ±10 % of the indicated flowrate or ±200 ml/min, whichever is greater.

i) Repeat e) to h) 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. For an oxygen concentrator that uses a fixed orifice to regulate flow, repeat e) to h) by testing each orifice separately.

201.12.1.102 Accuracy of triggered flow

For an *oxygen concentrator* with integrated *conserving equipment* function, the requirements for triggered flow are found in 201.12.1.101 of ISO 80601-2-67:2020.

201.12.1.103 * Accuracy of concentration

a) 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.

b) The instructions for use shall disclose the oxygen concentration as a function of flowrate over the *rated* range in tabular form including:

1) the minimum;

2) the maximum; and

3) 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 conformance with the following test.

c) 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.

d) With the variable restrictor completely open, set the flowrate on the oxygen concentrator to approximately the maximum rated flowrate.

e) Connect a standard resistance of Figure 201.102 to the outlet (8).

f) Operate the oxygen concentrator until it stabilizes.

g) Measure the oxygen concentration.

h) Repeat f) and g) for each of the following conditions:

1) at the input voltage set to 85 % of the minimum rated mains voltage;

2) at the input voltage set to 110 % of the maximum rated mains voltage;

3) at a nominal mains voltage;

4) at the minimum rated operating temperatures;

5) at the maximum rated operating temperatures;

6) at the minimum rated operating atmospheric pressures;

7) at the maximum rated operating atmospheric pressures;

8) after preconditioning for 6 h at a nominal operating atmospheric pressure and at the minimum rated relative humidity; and

9) after preconditioning for 6 h at the maximum rated relative humidity and at the maximum rated temperature.

i) Confirm that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.

j) At nominal conditions, set the flowrate to approximately 1 l/min or the lowest discrete flowrate setting.

k) Repeat f) and g).

l) Repeat j), setting the flowrate at approximately each integer l/min in the rated flowrate range or at each discrete flowrate setting.

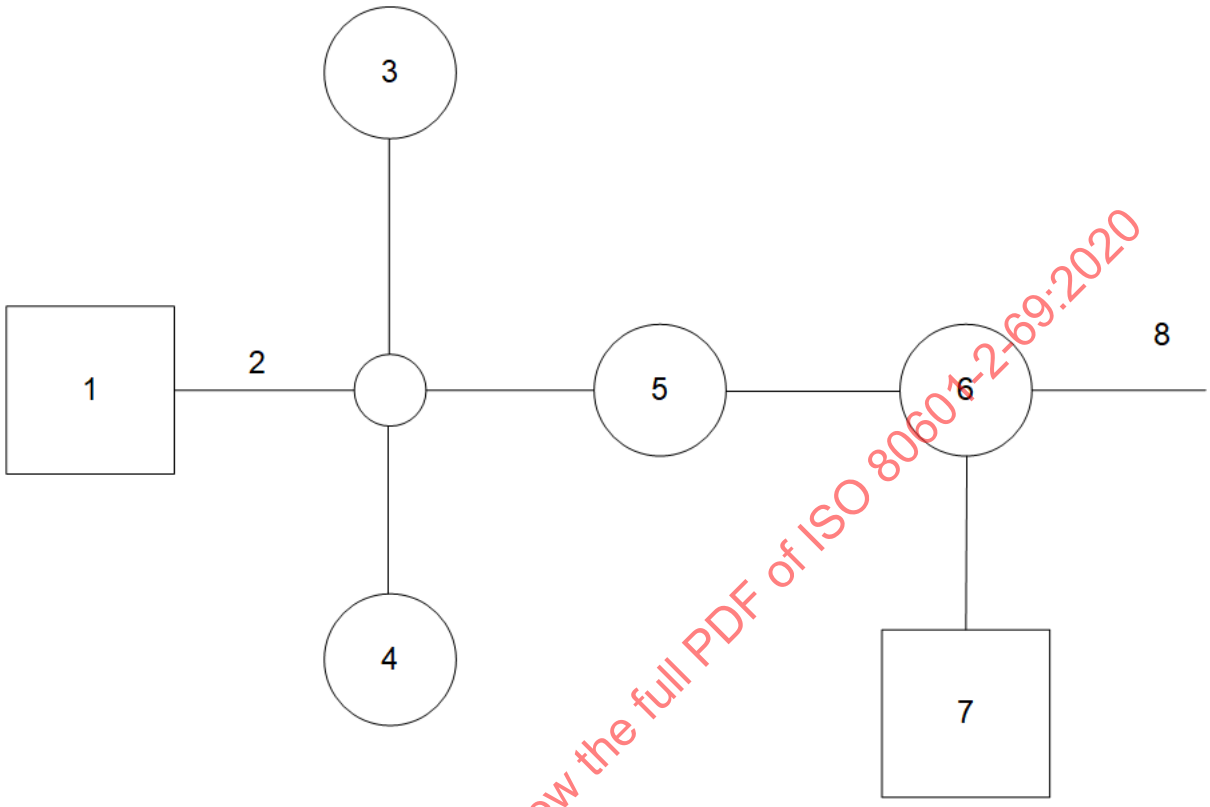
m) Confirm that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.

n) For an oxygen concentrator with integrated oxygen conserving equipment function, repeat b) through o) in the conserving mode at a breathing frequency of 15 min^{-1} using the test setup of ISO 80601-2-67:2020, Figure 201.101, connecting the standard resistance to the exhaust port and the oxygen sensor between the variable restrictor and the trigger source.

NOTE Items 4, 5, and 6 of the test setup of Figure 201.101 of ISO 80601-2-67:2020 are not required for this test.

o) Confirm that each measured oxygen concentration in the delivered gas was not less than the minimum value indicated in the instructions for use.

p) Repeat n) and o) at breathing frequencies of 20 min^{-1}, 25 min^{-1}, 30 min^{-1}, 35 min^{-1} and 40 min^{-1}.



Key

1 *oxygen concentrator* under test
2 *accessory* connection tubing, approximately 2 m in length of inner diameter 6 mm ± 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

a) The *maximum limited pressure* in *normal condition* and *single fault condition* shall be disclosed in the instructions for use.

Check conformance with the following test.

b) Set up the oxygen concentrator as indicated in Figure 201.102.

c) 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.

d) Operate the oxygen concentrator until it stabilizes as indicated in the instructions for use.

e) Close the variable restrictor to stop flow.

f) Wait 1 min.

g) Repeat d) to f) after creating each relevant single fault condition.

h) Confirm that the outlet pressure does not exceed the value indicated in the instructions for use for the entire period of the test.

i) For an oxygen concentrator with integrated oxygen conserving equipment function, 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.

j) Repeat d) to h).

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 conformance by inspection.

201.12.4.4.101.2 Indication of start-up period

a) 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.

b) This *alarm condition* need not be activated if the start-up period is less than 120 s.

Check conformance by functional testing.

201.12.4.102 * Low oxygen concentration *alarm condition*

a) 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.

b) The low oxygen concentration *technical alarm condition* shall activate within 30 min of the concentration dropping below 82 % volume fraction.

c) The low oxygen concentration *technical alarm condition* shall be at least *low priority* with an auditory *alarm signal*.

d) The low oxygen concentration *technical alarm condition* shall not stop the flow of output gas.

e) The low oxygen concentration *technical alarm condition* need not be activated during the start-up period.

f) The low oxygen concentration *alarm condition* need not be labelled low oxygen concentration.

Check conformance by functional testing.

201.12.4.103 Filter for the delivered gas

a) The *oxygen concentrator* shall be equipped with a means to filter particles from entering the delivered gas.

b) The filter shall be placed downstream of the oxygen concentrating means of the *oxygen concentrator*.

NOTE Additional requirements are found in 201.11.7 bb).

Check conformance by inspection.

201.13 *Hazardous situations* and fault conditions for *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 13 applies, except as follows:

Additional subclauses:

201.13.2.101 Additional specific *single fault conditions*

a) An *oxygen concentrator* shall be equipped with an *alarm system* that detects *technical alarm condition(s)* to indicate a malfunction of the *oxygen concentrator*.

b) The following individual faults, where applicable, shall be included:

1) overheating;

2) compressor failure;

3) obstruction of *gas pathways*;

4) oxygen generation means failure; and

5) pressure failure.

Check conformance by inspection and functional testing.

201.14 *Programmable electrical medical systems (PEMS)*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 applies.

201.15 Construction of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 15 applies, except as follows:

Additional subclause:

201.15.101 Mode of operation

An *oxygen concentrator* shall be suitable for *continuous operation*.

Check conformance by inspection.

201.16 *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 conformance 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+AMD1:2012+AMD2:2020, Clause 17 applies.

Additional subclauses:

201.101 *Outlet connector*

a) The outlet connector of the *oxygen concentrator* shall be:

   1) the nipple of EN 13544-2:2002+AMD1:2009, Figure 1, with a maximum internal bore diameter of 2,95 mm; or

   2) a male 9/16-18 UNF-2A-RH thread.

      i) The nipple of EN 13544-2+AMD1:2009 may be connected to this male 9/16-18 UNF-2A-RH thread without the use of a *tool*.

b) The outlet connector shall be marked with:

   1) the *rated* range of gas pressure; and

   2) the *rated* range of gas flowrate.

c) The outlet connector may be marked with:

   1) a text string; or

   2) symbol ISO 7000-0795 (see Table 201.D.1.101, symbol 5).

Check conformance by inspection.

201.102 *Requirements for parts and accessories*

201.102.*1* ** General*

The parts and *accessories* of an *oxygen concentrator* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *oxygen concentrator* or by another entity ("third-party manufacturer").

Check conformance by the tests of this document.

201.102.*2* *Labelling*

a) The *accompanying documents* of an *accessory* shall disclose:

1) the *rated* range of oxygen flows; and

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

2) the *rated* maximum pressure.

b) Statements shall be included in the *accompanying document* of each *oxygen concentrator* part and *accessory* to the effect that:

1) an oxygen concentrator, its parts and accessories are specified for use at specific flows;

2) incompatible parts or accessories can result in degraded performance;

3) 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

4) "WARNING: Use only water-based lotions or salves that are oxygen-compatible prior to and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns."

Check conformance by inspection of the accompanying document.

201.102.*3* ** Fire propagation risk reduction means*

a) The *applied part* that delivers gas to the *patient* from an *oxygen concentrator* or the *oxygen concentrator* itself shall be equipped with or connected to a means to stop the flow of gas towards the *patient* if the *applied part* becomes ignited.

b) The means of protection or detection should be located as close to the *patient* as practicable to stop the flow of oxygen as quickly as possible.

c) The means may be accomplished by having the *oxygen concentrator* stop the flow of gas when the *applied part* becomes ignited.

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 conformance by inspection and the following test.

d) Connect the applied part under test, including the means to stop the flow of gas towards the patient, to oxygen tubing of approximately 2 m in length that is connected to the outlet of a valve, which can stop the flow of gas.

e) 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 or the oxygen concentrator, as appropriate.

f) Set the oxygen source to deliver a continuous flowrate of 10 l/min ± 1 l/min, or for an oxygen concentrator source the maximum flowrate setting, through the applied part.

g) Ignite the applied part under test at the patient end.

h) Observe the fire propagating along the applied part towards the oxygen source and confirm that the flow of oxygen is stopped, and that the fire is not propagating towards the oxygen source and that the fire extinguishes.

i) Repeat d) to g) at 0,5 l/ min ± 0,1 l/min or for an oxygen concentrator source, the minimum flowrate settings.

j) Repeat d) to i) for each applied part listed in the instructions for use.

201.103 *Functional connection*

201.103.*1* *General*

Basic safety and *essential performance* shall be maintained

a) if connections to the *functional connection* of an *oxygen concentrator* are disrupted;

b) when any wire in the *functional connection* is opened or shorted to any other wire in the *functional connection;*

c) if the equipment connected to the *functional connection* fails.

Check conformance by functional testing.

201.103.*2* * Connection to a *distributed alarm system*

An *oxygen concentrator* should be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

201.103.*3* ** Connection for remote control*

An *oxygen concentrator* may be equipped with a *functional connection* for connection for external control of the *oxygen concentrator*.

201.104 ** Indication of duration of operation*

a) An *oxygen concentrator* shall have means to indicate the cumulative time of operation of the *oxygen concentrator,* either:

1) automatically; or

2) by *operator* action.

b) The *oxygen concentrator* should also have means to indicate:

1) the time since the last; or

2) until the next preventive maintenance.

c) These means may be restricted to *service personnel*.

Check conformance by inspection.

201.105 *Integrated conserving equipment function*

An *oxygen concentrator* with integrated *conserving equipment* function shall conform to ISO 80601-2-67:2020

Check conformance by application of the tests of ISO 80601-2-67:2020.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 applies except as follows:

202.4.3.1 * Configurations

Amendment (replace the second dash of 4.3.1 with):

— the *oxygen concentrator* delivering oxygen while using the setup of Figure 201.102 with the flowrate set to approximately 50 % of the maximum *rated* flowrate.

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Additional subclause:

202.8.1.101 Additional general requirements

a) The *oxygen concentrator* shall be tested according to the requirements for the *home healthcare environment*.

b) The following degradations, if associated with *basic safety* and *essential performance*, shall not be allowed:

1) component failures;

2) changes in programmable parameters or settings;

3) reset to default settings;

4) change of operating mode;

5) initiation of an unintended operation;

6) change of the oxygen concentration greater than 10 % volume fraction averaged over a one-minute interval; and

7) change of the flowrate greater than 10 % averaged over a one-minute interval.

206 Usability

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows:

a) For an *oxygen concentrator*, the following shall be considered *primary operating functions*:

1) configuring the *oxygen concentrator,* including connection of the detachable parts to the *oxygen concentrator*;

2) setting the flowrate control;

3) starting the *oxygen concentrator* from power off; and

4) turning off the *oxygen concentrator.*

b) The following functions, if available, shall also be considered *primary operating functions*:

1) performing the start-up *procedure*;

2) setting up the humidifier specified or recommended for use with the *oxygen concentrator*;

3) determining the remaining capacity or operation time provided by the *internal electrical power source*;

4) setting up connections to the *distributed alarm system* as well as disconnecting the *distributed alarm system*;

5) *cleaning* or replacing the air intake filter, and

6) setting the *operator*-adjustable controls;

i) setting *alarm limits*,

ii) inactivating *alarm signals*, and

iii) reactivating *alarm signals*.

Check conformance by inspection of the usability engineering file.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015+AMD1:2020 applies except as follows:

211.4.2.2 Environmental operating conditions

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

NOTE 101 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 can be needed to compensate for this loss and monitoring of the oxygen concentration inside the chamber can be needed.

Annexes of the IEC 60601-1:2005+AMD1:2012+AMD2:2020 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

Amendment:

Additional requirements for marking on the outside of the *oxygen concentrator*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of an *oxygen concentrator*, its parts or *accessories*

Description of marking	Subclause
Any particular storage, handling and operating instructions	201.7.2.101 b) 1)
Any particular warnings and precautions relevant to the immediate operation of the equipment	201.7.2.101 b) 2)
Containing natural rubber latex, if applicable	201.7.2.13.101 a)
Containing endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction substances, if applicable	201.11.7 dd) 1)
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 a) 2)
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101 a) 1)
For an *oxygen concentrator* with a continuous flow mode, a flowrate indicator marked in l/min	201.12.1.101 b) 1)
For an *oxygen concentrator* with both a continuous flow mode and a triggered flow mode, the mode of operation	201.12.1 bb)
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) 1)
For packaging, a description of the contents	201.7.2.17.101 c) 1)
For packaging, an identification reference to the batch, type or serial number	201.7.2.17.101 c) 2)
For packaging, containing natural rubber latex, if applicable	201.7.2.17.101 c) 3)
For packaging, containing endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction substances, if applicable	201.11.7 dd) 2)
For packaging, single use, if applicable	201.7.2.17.101 b)
Function of controls and indicators	201.12.1 1)

Description of marking	Subclause
Outlet connector rated range of gas pressure	201.101 c) 1)
Outlet connector rated range of gas flowrate	201.101 c) 2)
Warning against removal of the cover by unauthorized persons	201.7.2.101 c) 2)
Warning to the effect of "No Open Flame"	201.7.5 bb)
Warning to the effect of "No Smoking"	201.7.5 aa)

201.C.2 *Accompanying documents*, general

Amendment:

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
Declared tolerances including the measurement uncertainty of the measurement used to determine the specification	201.5.101 a)
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 b) 1)
For each *oxygen concentrator*, part and *accessory*, a statement to the effect that incompatible parts or accessories can result in degraded performance	201.102 b) 2)
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 b) 3)
For each *oxygen concentrator*, part and *accessory*, warning statement regarding use of lotions and salves	201.102 b) 4)
Instruct the *responsible organization* to assess the ability to resupply the *patient* at installation	201.7.9.1.101 a) 3)
Instruct the *responsible organization* to assess the condition of the *patient* at installation	201.7.9.1.101 a) 1)
Instruct the *responsible organization* to assess the environment in which the *patient* lives at installation	201.7.9.1.101 a) 2)
Instruct the *responsible organization* to periodically reassess the attributes of 201.7.9.1.101 a)	201.7.9.1.101 b)
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 and maximum pressure for which an *accessory* is *rated*	201.102.2 a)
Units of measure for volumes, flows and leakages expressed in *STPD*	201.7.4.3

201.C.3 *Accompanying documents*, instructions for use

Amendment:

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

Description of requirement	Subclause
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* 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 d)
At least one type of humidifier which is suitable for use with the *oxygen concentrator* and its preferred location	201.7.9.2.1.101 i)
Delivered oxygen concentration as a function of flowrate in tabular form	201.12.1.103 b)
Details for checking proper operation including gas leakage test and flowrate	201.7.9.2.8.101 a9
Diagram for the connection of *operator*-detachable parts either supplied or recommended in the instructions for use	201.7.9.2.5.101 c)
Disposal of molecular sieve	201.7.9.2.15 aa)
For *accessories* supplied separately where marking the *accessory* is not practicable, the requirements of 201.7.2.101 and 201.7.2.4.101	201.7.2.4.101 b)
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 e)
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 g)
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* were reused	201.7.9.2.1.101 f)
For an *oxygen concentrator*, its parts or *accessories* that contain endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction substances, information on *residual risks* for treatment of children or that of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.7 gg)
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 aa)
Instructions for *processing* the *oxygen concentrator* and its *accessories*	201.11.6.6 cc)
Internal electrical power source care and maintenance, if applicable	201.7.9.2.13.101 c)
Intervals at which *cleaning procedures* need to be performed and the items required for such *cleaning*	201.7.9.2.13.101 a)
Maximum limited pressure	201.12.1.104 a)
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)
Minimum volume fraction of delivered oxygen at the maximum *rated* flowrate	201.12.1.103 a)

Description of requirement	Subclause
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 at *STPD*	201.7.9.2.5.101 d) 1)
Rated range of oxygen delivery flowrate and concentration of oxygen as a function of flowrate over the *rated* ranges of temperature, humidity and atmospheric pressure	201.7.9.2.5.101 d) 2)
Restrictions on the positioning of components within the *oxygen concentrator*, if applicable	201.7.9.2.14.101 a) 1)
Restrictions on the positioning the application accessories, if applicable	201.7.9.2.14.101 a) 2)
Sound power level	201.9.6.2.1.101 a)
Sound pressure level and tested flowrate	201.9.6.2.1.101 b)
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 other than those recommended by the manufacturer should to be used	201.7.9.2.13.101 b)
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)
Statement to the effect that the settings should be periodically reassessed for therapy effectiveness	201.7.9.2.1.101 g)
Statement to the effect that the setup should include a means to reduce the extent of fire if ignition occurs	201.7.9.2.1.101 h)
Summary of the *use specification*	201.7.9.2.1.101 a)
Warning statement regarding the effect of changing the spare parts	201.7.9.2.2.101 e)
Warning statement regarding the risk of fire	201.7.9.2.2.101 a)
Warning statement regarding the risk of lubricating	201.7.9.2.2.101 d)
Warning statement regarding the risk of smoking	201.7.9.2.2.101 j)
Warning statement regarding the risk of open flames in the same room	201.7.9.2.2.101 k)
Warning statement regarding use as prescribed, both settings and *accessories*	201.7.9.2.2.101 b)
Warning statement regarding use of lotions and salves	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 f)

Description of requirement	Subclause
Warning statement regarding patients unable to communicate need additional monitoring	201.7.9.2.2.101 i)
Warning statement regarding when to seek medical assistance	201.7.9.2.2.101 h)
Warning statement regarding when to turn off the *oxygen concentrator*	201.7.9.2.2.101 g)

201.C.4 *Accompanying documents*, technical description

Amendment:

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 document, 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)
Disclosure of which *alarm system* functional checks are performed automatically	201.7.9.3.101 c) 1)
Measurement uncertainty for each disclosed tolerance	201.5.101 b)
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)

Annex D
(informative)

Symbols on marking

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

Addition:

Table 201.D.1.101 — Additional symbols on marking

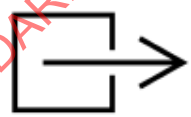
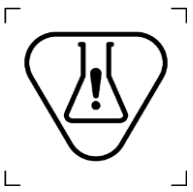
No.	Symbol	Reference	Title
1		ISO-7000-2492 Symbol 5.1.5 ISO 15223-1:— IEC/TR 60878:2015[6]	Batch code To identify the *manufacturer's* batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
2		ISO 7000-2493 Symbol 5.1.6 ISO 15223-1:— IEC/TR 60878:2015[6]	Catalogue number To identify the *manufacturer's* catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
3		ISO 7000-2498 Symbol 5.1.7 ISO 15223-1:— IEC/TR 60878:2015[6]	Serial number To identify the *manufacturer's* serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
4		ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:— IEC/TR 60878:2015[6]	Contains or presence of [natural rubber latex] On medical devices: to indicate that the equipment contains the identified product or substance. Replace "XXX" with the symbol or other identification of the substance that is contained or present, where LATEX is used for natural rubber latex.
5		ISO 7000-0795 IEC/TR 60878:2015[6]	Output; exit To identify an exit, for example of a hydraulic pump. For electrical (signal) output, use symbol IEC 60417-5035.
6		ISO 7000-3723 Symbol 5.4.10 ISO 15223-1:—	Contains hazardous substances Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.

Table 201.D.2.101 — Additional safety signs

No.	Safety sign	Reference	Title
1		ISO 7010-P002 IEC/TR 60878:2015[6]	No smoking To prohibit smoking.
2		ISO 7010-P003 IEC/TR 60878:2015[6]	No open flame: Fire, open ignition source and smoking prohibited To prohibit smoking and all forms of open flame.

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

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

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* take into account the 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 document. In practice, this means that, for example, if a *manufacturer* determines that a parameter has a tolerance of ±7 % but that the measurement uncertainty is ±3 % then a parameter tolerance of ±10 % is declared. If a third-party tester

subsequently obtains an error of the measured value for that parameter of ± 5 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

The accuracy of the test equipment used to verify *essential performance* of an *oxygen concentrator* should be significantly better than the accuracy of the *manufacturer's* stated tolerance of the *oxygen concentrator*.

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 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~37 °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 °C to 37 °C or by 5,8 % from 20 °C to 37 °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* conditions. This practice is followed in this document for all requirements concerning gas input.

However, an *oxygen concentrator* conforming with this document 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, *STPD* 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 201.7.9.3.101 — 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 often 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* if 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 201.11.3.101 — Additional requirements for fire *enclosures* of *ME equipment*

In the event of ignition from an external source, for instance the nasal canula, the committees decided to impose the FV-1 flammability rating for the *enclosure* to ensure that any fire extinguishes quickly. The flammability requirement for the fire *enclosures* in the general standard is metal or FV-1 or better. The FV-1 vertical flame test requirement for a single specimen in IEC 60695-11-10:2013[5] is for the flame to extinguish within 30 s. The test method is in IEC 60695-11-10:2013, Clause 9.

Subclause 201.11.6.6 — *Cleaning* and *disinfection* of *ME equipment* or *ME system*

The *essential principles* of ISO 16142-1:2016 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 *processing* of an *oxygen concentrator*, its *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and the need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* in this document are intended to:

— make the *responsible organization* for *processing* the *oxygen concentrator* aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the *processing* of an *oxygen concentrator*, its *accessories* and parts to conform 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 *processing 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 reusable *accessories* and parts that have been used are required to undergo *processing*, 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 *processing* instructions of an *oxygen concentrator*, its *accessories* or parts:

— protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles); and

— the necessity to guarantee the proven standardized *procedures* in a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedures* 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 *processing 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 *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*; and

— the reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing 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 *processing 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 *processing*, 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 *processing* 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 *processing* and the feasibility of the *processing* for the *oxygen concentrator*, *accessories* or parts, the *manufacturer* should consider the following points:

— the *risks* involved in the *processing*;

— the cost effectiveness of the *processing* ;

— the practicability of the *processing* ;

— the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing*;

— the efficiency of the *processing*;

— the reproducibility of the *processing*;

— quality management requirements of the *processing*; and

— the environmental impact of the *processing* and the disposal of the *oxygen concentrator*, *accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *oxygen concentrator*, *accessories* or parts, depending on the type of use.

The *responsible organization* should verify that manual *cleaning* and *disinfection* of the *oxygen concentrator*, *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that cleaned and disinfected *oxygen concentrator*, *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next *patient*, *operator* or person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, safety and functional testing of the *oxygen concentrator* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *oxygen concentrator*.

The extent and type of the tests depend on the *oxygen concentrator*, *accessory* or part and these need to be defined in the *accompanying document*.

Subclause 201.12.1.103 — Accuracy of concentration

Testing at the *rated relative humidity* and temperature is particularly important for *oxygen concentrators* since the concentration of oxygen produced can be significantly reduced by high *relative humidity*. Water vapour is adsorbed by the molecular sieve and has to be removed at each operating cycle. High levels of environmental humidity and temperature are likely to be encountered where *oxygen concentrators* are used in *home healthcare environments* that are not air conditioned.

IEC 60601-1-11 requires the disclosure of the *rated relative humidity* range and marking of the equipment where the *rated relative humidity* range is less than 15 % to 93 %. The *rated relative humidity* range is a critical operating parameter for the appropriate selection of an *oxygen concentrator*.

Subclause 201.12.4.102 — Low oxygen concentration *alarm condition*

Oxygen concentrators are not life-supporting devices. Studies have shown that the typical use of *oxygen concentrators* (non-*transit operable*) in the home is 15 h/d to 18 h/d, depending upon the locale[12]. Furthermore, studies have shown that *patients* maintain acceptable oxygen saturation (SpO_2) levels when breathing reduced levels or 21 % oxygen in room air nocturnally.

Oxygen concentrators are configured either with or without an Oxygen Percentage Indicator (OPI). *Oxygen concentrators* with an OPI have a means for monitoring oxygen concentration and generate a *technical alarm condition* when a low oxygen concentration is detected. Due to the monitoring interval and the response time of the OPI, there can be a delay of up to 30 min before the *alarm condition* is generated.

Oxygen concentrators without an OPI do not have the means to monitor the oxygen concentration. However, degradation or loss of oxygen concentration is primarily caused by blockage of the air-intake system, contaminated underperforming sieve materials or control valve malfunction. Any of these events result in one or more of the following fault conditions: overheating; compressor failure; or pressure failure. Any of these fault conditions generates a *technical alarm condition*. These fault conditions are included in 201.13.2.101. The additional specific *single fault conditions* requirements of 201.13.2.101 require the generation of a *technical alarm condition* in the event of a malfunction.

Oxygen concentrators without an OPI generate a *technical alarm condition* within the same time frame as those equipped with an OPI. In either case (OPI or non-OPI), a *technical alarm condition* is generated to indicate degradation or loss of oxygen therapy.

An *alarm condition delay* not exceeding 30 min is acceptable since it provides the *patient* a period of 8 h to begin use of an alternate source of oxygen previously provided for immediate use and a single shift time of 8 h for repair or replacement of the malfunctioning *oxygen concentrator*[10][11].

Subclause 201.102.1 — General

It is the responsibility of the *manufacturer* of *oxygen concentrator accessories* to verify that their product conforms with the requirements of this document.

Subclause 201.102.3 — Fire propagation *risk* reduction means

600 kPa was chosen as the driving pressure for the oxygen source in the test because 600 kPa is the maximum *normal condition* pressure permitted for driving respiratory application *accessories* when these *accessories* are used with *medical gas pipeline systems*.

Refer to the rationale for subclause 201.11.2.101.

Subclause 201.103.2 — Connection to a *distributed alarm system*

Patients who are on supplemental oxygen are usually located in the *home healthcare environment* where an *operator* (caregiver) might not be sufficiently close to hear *alarm signals* coming from the *patient's* room. As a result, an appropriate response can be delayed. A *distributed alarm system* facilitates delivery of *alarm signals* to remotely located *operators*, thereby permitting a timely response and intervention to support *patient* care.

EXAMPLE A *distributed alarm system* in a parent's bedroom.

Subclause 201.103.3 — Connection for remote control

Most *oxygen concentrators* have a control setting for the flowrate as well as the mode of operation.

EXAMPLE 1 In continuous flow mode, setting the flowrate.

EXAMPLE 2 If the *oxygen concentrator* is equipped with integrated oxygen *conserving equipment* function, setting continuous flow mode versus a demand mode.

EXAMPLE 3 In demand mode, setting the trigger sensitivity or volume of the bolus/breathe of integrated oxygen *conserving equipment* function.

It is not uncommon for these parameters to be monitored from some distance because the clinical condition of the *patient* requires periodic adjustments of the *oxygen concentrator* settings based on the *patient's* vital signs. In these situations, it can be advantageous to be able to change the *concentrator* settings remote from the *oxygen concentrator*.

EXAMPLE 4 Controlling the settings from a central location in a nursing home where the *oxygen concentrator* is in the *patient's* room.

Furthermore, it is foreseeable that an increasing number of *patients* will be monitored at home by a medical care / vigilance centre located at a distance from the *patient's* home and that those *patients' oxygen concentrators* will be expected to be capable of having their settings remotely controlled.

Subclause 201.104 — Indication of duration of operation

An *oxygen concentrator* requires maintenance for continued safe use. A practicable means to ensure that this information is available to the *operator* or the *responsible organization* is to require that the *oxygen concentrator* keep track of how long it has been in operation.

Subclause 202.4.3.1 — Configurations

It is not the intent of the committee to require that the *immunity* tests be performed multiple times (e.g. at several flowrates), but that the *manufacturer* should determine which flowrate represents the worst case for a given *immunity* test and use those conditions.

Annex BB
(informative)

Reference to the IMDRF *essential principles* and labelling guidances

This document has been prepared to support the *essential principles* and labelling requirements of an *oxygen concentrator*, its *accessories* or parts as a medical device according to the International Medical Device Regulators Forum (IMDRF). This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of IMDRF/GRRP WG/N47:2018[8] and labelling principles IMDRF/GRRP WG/N52:2019[9]. Other means are possible. Table BB.1 maps the clauses and subclauses of this document with the essential principles of IMDRF/GRRP WG/N47:2018. Table BB.2 maps the clauses and subclauses of this document with the labelling principles of IMDRF/GRRP WG/N52:2019.

NOTE 1 When an *essential principle* does not appear in Table BB.1, it means that it is not addressed by this document.

Table BB.1 — Correspondence between this document and the *essential principles*

***Essential principle* of IMDRF/GRRP WG/N47:2018[8]**	**Corresponding clause(s)/ sub-clause(s) of this document**	**Qualifying remarks/Notes**
5.1.1	All	The part relating to manufacturing is not addressed
5.1.3	201.4, 201.4.3.101	The part relating to manufacturing is not addressed
5.1.3 a)	201.4, 201.4.3.101	
5.1.3 b)	201.4.3.101, 201.7, 201.11.8.101.1, 201.12.4	
5.1.4	201.7	
5.1.5 a)	201.12.1, 206	
5.1.5 b)	206	
5.1.6	All	
5.17	201.4, 201.15	
5.19	201.4	
5.3.1 a)	201.7.2.13.101, 201.11.7	Only the requirements related to toxicity are covered.
5.3.1 b)	201.11.6.6, 201.11.7	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
5.3.1 e)	201.11.6.6 bb)	Covered for *normal use* including *cleaning* and *disinfection*.

Essential principle of IMDRF/GRRP WG/N47:2018[8]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.3.1 f)	201.11.7, 201.12.1.101, 201.12.1.102, 201.12.1.103, 201.12.1.104	Covered for *biocompatibility* and accuracy.
5.3.2	201.11.6.6, 201.11.7	
5.3.3	201.11.7, 201.12.4.103	Only the requirements related to design are addressed
5.3.5	201.11.6.6	
5.3.5 a)	201.11.6.6	
5.3.5 b)	201.11.6.6, 201.11.6.7, 201.12.4.103	
5.3.5 c)	201.11.7	
5.4.1	201.11.6.6	
5.5.1	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.5.101 b), 201.7.9.2.5.101 b), 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1, 201.105	Covered with respect to use with the listed *accessories*, latex-containing components, integrated *conserving equipment*, connecting *accessories* and *operator*-detachable components and positioning of the *patient*-interface
5.5.2 a)	201.9	
5.5.2 b)	201.12.1, 201.12.4, 206	
5.5.2 c)	202	Covered with respect to magnetic fields, external electrical and electromagnetic effects and electrostatic discharge.
5.5.2 h)	202	Covered with respect to electromagnetic disturbances.
5.5.3	201.11, 201.11.2.101, 201.11.3.101	
5.5.5	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.5.101 b), 201.7.9.2.5.101 c), 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1, 201.105	
5.5.7	201.12.1.101, 206	
5.5.8	201.7.9.2.15	
5.6.1	201.9, 201.11, 211	
5.6.3	201.9.6.2.1.101	
5.6.4	201.101, 201.7.9.2.5.101 b), 201.7.9.2.5.101 c)	
5.6.5	201.11	
5.7.1	201.13	
5.7.2	201.11.8.101.1	

Essential principle of IMDRF/GRRP WG/N47:2018[8]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.7.3	201.11.8.101.1	
5.7.5	202	
5.7.6	202	
5.7.7	201.8, 201.13, 201.13.2.101	
5.8.1	201.14	
5.8.2	201.14	
5.9.1 a)	201.12.1.101, 201.12.1.102, 201.12.1.103, 201.12.1.104	
5.9.1 c)	201.7.1.2, 201.12.1, 206	
5.10	201.7, 201.7.2.4.101, 201.7.2.101, 201.7.9.1, 201.7.9.1.101, 201.7.9.2, 201.7.9.2.1.101, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.8.101, 201.7.9.2.9.101, 201.7.9.2.14.101, 201.7.9.3.101, 201.102.2	
5.12.1	201.12.1, 206	
5.12.2	201.12.1, 206	
5.12.3	201.7.9.2.8.101	
6.1.1	201.11.7	This requirement is covered with respect to the *gas pathways*.
6.1.2	201.11.6.6, 201.11.7	
6.1.3	201.11.7, 201.12.4.103	Only the requirements related to design are addressed, excluding nanomaterials.
6.4.1	201.12.1.101, 201.12.1.102, 201.12.1.103, 201.12.1.104	
6.4.2	201.12, 201.12.4.4.101, 201.12.4.4.101.1, 201.12.4.4.101.2, 201.12.4.102, 201.13, 201.13.2.101	

NOTE 2 When a labelling principle does not appear in Table BB.2, it means that it is not addressed by this document.

Table BB.2 — Correspondence between this document and the labelling principles

Labelling principles of IMDRF/GRRP WG/N52:2019[9]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.1.1	201.7, 201.7.9.2, 206	
5.1.4	201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	
5.1.5	201.7, 201.7.9.2.1.101, 201.7.9.2.2.101	
5.2.1	201.7.2.101	
5.2.2	201.7.2.17.101, 201.7.2.101	
5.2.3	201.7.2.17.101	
5.2.5	201.7.2.17.101	
5.2.9	201.7, 201.7.9.1	
5.2.10	201.7.9.1	
5.2.11	201.7.9.1	
5.2.12	201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	
5.2.13	201.7.2.17.101	
5.2.14	201.7.2.17.101	
5.2.17	201.7.5 aa), bb)	
5.2.18	201.7.2.17.101	
5.3.1	201.7, 206	
5.3.5	201.7, 201.7.9.2	
5.3.8	201.7	
5.3.9	201.7, 201.7.9.1, 201.7.2.101, 201.7.2.17.101	
5.3.10	201.7	
5.3.11	201.7	
5.3.12	201.5.101.3, 201.7.4.3, 201.12.1.101	
5.3.13	201.7, 201.7.9.1, 201.7.2.101, 201.7.2.17.101	
5.3.14	201.7.9.2.13.101, 201.7.9.2.14.101, 201.102.2	
5.3.17	201.7	
5.3.18	201.7.9.2.8.101	
5.3.20	201.7.9.2.13.101	
5.3.21	201.7.2.101	
5.3.22	201.7.9.2.15	
5.3.26	201.7.9.2.1.101, 201.7.9.2.12	