INTERNATIONAL STANDARD

ISO 80601-2-67

Second edition
2020-10

Medical electrical equipment —

Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment

Appareils électromédicaux —

Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène

FOR BIS USE ONLY

Reference number
ISO 80601-2-67:2020(E)

© ISO 2020

FOR BIS USE ONLY

COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

 © ISO 2020 – All rights reserved

Contents

Page

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 and IEC 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) or the IEC list of patent declarations received (see http://patents.iec.ch).

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 80601-2-67:2014), which has been technically revised.

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

— clarified the accessibility of inlet and outlet *connectors*;

— formatted to provide a unique identifier for each requirement; and

— 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.

FOR THIS USE ONLY

© ISO 2020 – All rights reserved

Introduction

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.

Most clinicians prescribe low flow oxygen therapy as continuous flow oxygen (CFO) delivery in l/min. CFO systems deliver the flow of oxygen without regard for the *patient's* breathing rate or pattern. Outside of the institutional care setting, the provision of CFO therapy is often a significant expense and can limit the mobility of a *patient* to the immediate vicinity of a stationary or fixed oxygen delivery system. To support mobility, *patients* use CFO from portable liquid or compressed oxygen systems with a limited storage capacity that can limit a *patient's* time and activities while away from a stationary oxygen supply.

Conserving equipment that delivers supplemental oxygen as a bolus conserves usage while allowing satisfactory *patient* arterial oxygen saturation (SaO_2) to be maintained during daily activities. *Conserving equipment* delivers supplemental oxygen unlike CFO in that the therapy gas flow is delivered only during the inspiratory phase of the breathing cycle, when it is most likely to reach the alveoli. During both the expiratory and pause phase of the breathing cycle, the flow of supplemental oxygen is stopped, minimizing waste. Because flow over time produces a volume, the bolus delivered by the *conserving equipment* is typically represented as a volume of gas. Therapy using *conserving equipment* versus CFO results in lower operating costs and longer ambulatory times for *patients* using the same CFO storage capacity.

Operation of *conserving equipment* from various *manufacturers* might differ in the dose delivery mechanism resulting in variations in oxygen therapy to the *patient*. The use of CFO numerical markings for dose settings on *conserving equipment* might not directly correlate with CFO settings and might lead to misinterpretation of gas delivery rates and volumes for a particular *patient*. This might result in incorrect *patient* setup and therapy delivery over all breathing rates and patterns versus CFO. Because of the differences in delivery, settings, and markings versus CFO therapy, *conserving equipment* use has requirements for *patient* titration to determine the proper setting(s) needed to provide adequate SaO_2 levels for the *patient* breathing patterns.

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.

FOR BID USE ONLY

 © ISO 2020 – All rights reserved

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.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

Medical electrical equipment —

Part 2-67:
Particular requirements for basic safety and essential performance of oxygen conserving equipment

FOR BIS USE ONLY

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 is applicable to the *basic safety* and *essential performance* of oxygen *conserving equipment*, hereafter referred to as *ME equipment,* in combination with its *accessories* intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle, when used in the *home healthcare environment*. Oxygen *conserving equipment* is typically used by a *lay operator*.

NOTE 1 *Conserving equipment* can also be used in professional health care facilities.

This document is also applicable to *conserving equipment* that is incorporated with other equipment.

EXAMPLE *Conserving equipment* combined with a pressure regulator[2], an oxygen concentrator[7] or liquid oxygen equipment[4].

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

This document is intended to clarify the difference in operation of various *conserving equipment* models, as well as between the operation of *conserving equipment* and continuous flow oxygen equipment, by requiring standardized performance testing and labelling.

This document is only applicable to active devices (e.g. pneumatically or electrically powered) and is not applicable to non-active devices (e.g. reservoir cannulas).

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 IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

© ISO 2020 – All rights reserved

NOTE 2 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

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 *conserving equipment* [as defined in 201.3.201] and its *accessories*.

NOTE 1 *Accessories* are included because *accessories* can have a significant impact on the *basic safety* or *essential performance* of *conserving equipment*.

NOTE 2 This document has been prepared to address the relevant *essential principles*[11] and labelling[12] 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[10] 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+AMD1:2020 and IEC 60601-1-6+AMD1:2013+AMD2:2020 apply as modified in Clauses 202 and 206 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:— 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, 206.4 in this document addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

"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.

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, 206 for IEC 60601-1-6, 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*

Addition:

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 5359:2014+Amd.1:2017, *Low-pressure hose assemblies for use with medical gases*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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*

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

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2019, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)*

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 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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 62366-1:2015, *Medical devices — Part 1: 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 7396-1:2016, ISO 9000:2015, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 80369-1:2018, ISO 80601-2-74:2017, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015, IEC 62366-1:2015 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 alphabetized index of defined terms is found in Annex EE.

Addition:

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

201.3.201
conserving equipment
ME equipment intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle

Note 1 to entry: *Conserving equipment* can be electrically or pneumatically powered.

201.3.202
conserving equipment with monitoring function
conserving equipment suitable for use with *patients* where monitoring of oxygen delivery via the *conserving equipment* is indicated

201.3.203
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:—[2][1], 3.1.4.13, modified—changed 'must be' to 'is'.]

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.

FOR BIS USE ONLY

[2] Under preparation. Stage at the time of publication: ISO/DIS 4135:2020.

© ISO 2020 – All rights reserved

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
For *conserving equipment with monitoring function*, the delivered oxygen dose, in both *normal condition* and *single fault condition*, within the accuracy as indicated in the instructions for use	201.12.1.101[a]
or generation of an *alarm condition*	
absence of the inspiratory trigger *alarm condition*	201.12.4.101
gas supply failure *alarm condition*	201.12.4.102
For other than *conserving equipment with monitoring function*, the delivered oxygen dose, in *normal condition*, within the accuracy indicated in the instructions for use	201.12.1.101[a]
or an indication of abnormal operation	
[a] Subclause 202.8.1.101 indicates methods of evaluating delivered oxygen 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):

aa) *Conserving equipment* 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).

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) *Conserving equipment* with an *operator*-detachable oxygen inlet *connector* as specified in 201.101.1:

   1) shall operate and meet the requirements of this document throughout its *rated* range of input pressure; and

   2) shall not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.

b) *Conserving equipment* with an *operator*-detachable oxygen inlet *connector* that conforms with ISO 80369-1:2018, 5.8 shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

NOTE 1 Internal pressure regulators can be required to accommodate the *single fault condition* of maximum input pressure as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *patient*. Under this condition, the flowrate from the *conserving equipment* is likely to be outside of its specification.

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings, by functional testing in single fault condition and inspection of the risk management file.

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

201.4.11.101.2 Compatibility requirement

If *conserving equipment* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016, then:

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016; and

b) under *normal condition*,

1) the maximum 10 s average input flow required by the *conserving equipment* shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port; and

2) the transient input flow shall not exceed 200 l/min averaged for 3 s;

or:

3) the *accompanying documents* shall disclose:

i) the maximum 10 s average input flow required by the *conserving equipment* at a pressure of 280 kPa, measured at the gas input port;

ii) the maximum transient input flow averaged for 3 s required by the *conserving equipment* at a pressure of 280 kPa, measured at the gas input port; and

iii) a warning to the effect that "Warning: This *conserving equipment* is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the *risk* that the *conserving equipment* interferes with the operation of adjacent equipment."

Check conformance by functional testing in normal use and under normal condition with the most adverse operating settings and by inspection of the accompanying documents.

EXAMPLE Highest driving gas consumption, highest gas delivery and, if provided, the highest rated gas consumption at any gas power supply output.

Addition:

201.4.101 * *ME equipment* incorporated in other equipment

Conserving equipment that is incorporated with other equipment shall conform with:

a) this document; and

b) the applicable requirements from the standard for the other equipment.

Check conformance by review of the relevant test report for the applicable requirements from the standard for the other equipment.

201.5 General requirements for testing of *ME equipment*

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

Addition:

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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

201.5.101.1 *Conserving equipment* test conditions

a) For testing, *conserving equipment* shall be connected to a gas supply as specified for *normal use*, except that industrial grade oxygen may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using a substitute gas, care should be taken to ensure that:

   1) the test gas has the minimum oxygen concentration;

   2) the maximum water content; and

   3) the maximum oil content specified for *normal use*.

201.5.101.2 * Gas flowrate specifications

In this document, requirements for the flowrate and volume for the gas supplied to the *conserving equipment* and for gas delivered to the *patient* are expressed as if tested under *STPD* (*standard temperature and pressure, dry*) conditions.

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

Correct all test measurements to STPD, as appropriate.

201.5.101.3 * *Conserving equipment* testing errors

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 of each disclosed tolerance in the technical description.

Check conformance by inspection of the instructions for use 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’

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

201.7.2.2 Identification

IEC 60601-1:2005+AMD1:2012, 7.2.2 applies, except as follows:

Amendment (replace the fourth bullet of the first paragraph):

— the date of manufacture or use-by date.

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 the *conserving equipment*, if applicable.

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

NOTE The *manufacturer* of the *accessory* can be the *conserving equipment manufacturer* or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to verify conformance with this requirement. Additional requirements are found in 201.102.

Check conformance by inspection of the accessory 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) 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.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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).

b) For a specific *model or type reference*, the indication of single use shall be consistent for the *model or type reference*.

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

d) For *accessories* intended to be sterilised prior to use:

1) the protective packaging shall be suitable, taking account of the method of sterilisation 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 the following:

1) any particular storage, handling and operating instructions;

2) any particular warnings and precautions relevant to the immediate operation of the *conserving equipment*.

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

1) for gas-specific inputs,

i) the gas name or chemical symbol for oxygen in accordance with ISO 5359:2014+Amd.1:2017;

ii) gas-specific colour coding for oxygen in accordance with ISO 32:1977, if colour coding is used;

EXAMPLE For flow controls, flexible hoses, gas cylinders.

NOTE In some countries, other colour coding is used.

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

d) Notwithstanding requirements 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.

e) The marking of the oxygen delivery control:

1) shall only be numeric when labelled in units of volume; and

2) shall be such that the minimum and the maximum settings are self-evident to the *operator*.

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

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 flow specifications for the gas supplied to the *conserving equipment* 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.

201.7.9.1 Additional general requirements

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;

aa) For *conserving equipment with monitoring function*, the instructions for use shall disclose that the *conserving equipment* is suitable for use with *patients* where monitoring of oxygen delivery via the *conserving equipment* is indicated.

201.7.9.2 Instructions for use

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

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose:

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

b) if the *conserving equipment*, its parts or *accessories* are indicated for single use, and information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *conserving equipment*, its parts or *accessories* would be reused;

c) a description of the principles of operation of the *conserving equipment*, including the principles of oxygen dosage, timing, triggering and the settings thereof;

d) if a manual control of the sensitivity is provided, instructions as to how to adjust the control for optimal breath detection;

e) a pneumatic diagram of the *conserving equipment*, including a diagram for *operator*-detachable parts either supplied or recommended in the instructions for use;

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

f) a statement to the effect that the responsible organization:

1) should ensure the compatibility of the oxygen conserving equipment and all of the parts and accessories used to connect to the patient before use;

2) should ensure that the oxygen delivery settings were determined and recorded for the patient individually together with the configuration of the equipment to be used, including accessories; and

3) should periodically reassess the setting(s) of the therapy for effectiveness.

Check conformance by inspection of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include the following.

a) A warning statement to the effect that "WARNING: There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames."

b) A warning statement to the effect that "WARNING: Smoking during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire."

c) 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 only after one or more settings have been individually determined or prescribed for you at your specific activity levels;

2) be used with the specific combination of parts and accessories that are in line with the specification of the oxygen conserver manufacturer and that were used while your settings were determined."

d) A warning statement to the effect that "WARNING: The settings of this [insert model and brand] might not correspond with continuous flow oxygen."

e) A warning statement to the effect that "WARNING: The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of this [insert model and brand]."

f) A warning statement to the effect that "WARNING: Use only water-based lotions or salves that are oxygen-compatible during setup or use during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns."

g) A warning statement to the effect that "WARNING: Do not lubricate replaceable fittings, connections, tubing, or other accessories of the oxygen conserver to avoid the risk of fire and burns."

h) 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."

i) A warning statement to the effect that "WARNING: Wind or strong draughts can adversely affect accurate delivery of oxygen therapy."

EXAMPLE 1 Using this equipment beside an open window or in front of a fan can affect the accuracy of delivery of oxygen.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

EXAMPLE 2 Using this equipment in the back seat of an open convertible car can affect the accuracy of delivery of oxygen.

j) 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] is expected to adversely affect the quality of the therapy."

k) 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 on bed coverings or chair cushions, if the oxygen conserver is turned on, but not in use; the oxygen will make the materials more flammable. Turn the oxygen conserver off when not in use."

l) A warning statement to the effect that "WARNING: If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately to avoid harm."

m) A warning statement to the effect that "WARNING: Geriatric, paediatric or any other patient unable to communicate discomfort can require additional monitoring to avoid harm."

n) 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 conserver or any oxygen-carrying accessories. If you smoke, you must always turn the oxygen conserver off, remove the cannula and leave the room where either the cannula or the oxygen conserver is located. If unable to leave the room, you must wait 10 minutes after the flow of oxygen has been stopped."

o) A statement to the effect that the accessories set-up used to deliver oxygen to the patient shall include a means to reduce the propagation of fire for the safety of the patient.

NOTE This can be achieved by incorporating a means to stop the flow of gas from the *conserving equipment* in the presence of fire.

Check conformance by inspection of the instructions for use.

201.7.9.2.5.101 Additional requirements for *ME equipment* description

The instructions for use shall include:

a) a statement to the effect that the oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories;

b) a statement to the effect that the proper placement and positioning of the *patient* interface is critical to the consistent operation of this equipment;

EXAMPLE 1 The proper placement and positioning of the nasal cannula in the nose is critical to the consistent operation of this equipment.

c) the *rated* range of delivered oxygen setting;

d) the *rated* range of *set rate*;

e) information on the effects of failure of the *conserving equipment,* including any flow delivered to the *patient*;

f) a statement to the effect that some respiratory efforts of the *patient* might not trigger the *conserving equipment;*

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

g) the necessary application *accessories* and their specifications;

EXAMPLE 2 Only for use with a nasal cannula suitable for use with a flowrate between 5 l/min to 10 l/min and less than 1,5 m in length.

h) an indication as to whether the *conserving equipment* is intended for use with a tracheotomised *patient.*

Check conformance by inspection of the instructions for use.

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 *conserving equipment* is ready for use.

a) The instructions for use shall disclose how the *operator* can check for proper operation of the *conserving equipment.*

b) For *conserving equipment with monitoring function,* the instructions for use shall in addition disclose how all of the *alarm signals* can be functionally tested to determine if they are operating correctly.

c) Portions of this test may be automatically performed by the *conserving equipment* or may require *operator* action.

EXAMPLE Combination of the power-on self-test routines and *operator* actions that functionally checks the *alarm signals*.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use of an *oxygen-conserving equipment* shall include:

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

b) if applicable, the instructions for use shall include the *procedure* necessary to determine the state 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 *conserving equipment* that can become contaminated with body fluids or expired gases during both:

1) *normal condition*; and

2) *single fault condition*.

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

Additional subclauses:

201.7.9.2.13.101Additional requirements for maintenance

The instructions for use shall disclose:

a) a description of periodic visual safety inspections that should be performed by the *operator*;

b) 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.

201.7.9.2.14.101Additional requirements for *accessories*, supplementary equipment, used material

The instructions for use shall disclose:

a) the intended source of oxygen.

EXAMPLE Transportable liquid oxygen equipment, gaseous oxygen supply or oxygen concentrator.

b) If applicable, the instructions for use shall disclose:

1) any restrictions on the positioning of components within the *conserving equipment*;

EXAMPLE Where such components are *flow-direction-sensitive components*.

2) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *conserving equipment*.

EXAMPLE Use of a paediatric cannula on an adult *patient*.

Check conformance by inspection of the instructions for use and by inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1 General

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.3.1 applies, except as follows:

Amendment: (add as an additional list element)

aa) for *conserving equipment with monitoring function,* a description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during start-up and 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.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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:

Additional subclause:

201.11.2.101 * Additional requirements for fire prevention

a) The *operator*-accessible *conserving equipment* 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 mounted on the *conserving equipment enclosure*.

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.

Check conformance by inspection and the following test.

d) For conserving equipment capable of delivering oxygen in a continuous mode, set the conserving equipment 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 to towards the conserving equipment.

h) Confirm that the fire is not propagating back through the outlet connector into the conserving equipment 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 *conserving equipment* 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, 11.3 b) 3).

Check conformance by application of the tests of IEC 60601-1:2005, 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 *conserving equipment* 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:

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

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

2) *cleaning* and *sterilization*.

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

bb) *Conserving equipment 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 *conserving equipment* and its *accessories* shall:

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

2) shall 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 conserving equipment 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 instructions 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+AMD1:2012, 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 *conserving equipment*, 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 *gas pathways*.

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

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

dd) The *gas pathways* of a *conserving equipment*, 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*.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

gg) The instructions for use of a *conserving equipment*, 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.

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 of a *conserving equipment* shall be *clearly legible* under the conditions specified in 201.7.1.2 of this document.

Check conformance by application of the tests of 201.7.1.2.

Additional subclauses:

201.12.1.101 * *Verification* of oxygen delivery

a) With the *conserving equipment* operating in *normal condition*, the delivered oxygen volume per breath as determined under the test conditions specified in Table 201.102 shall be disclosed in a tabular representation in the instructions for use.

EXAMPLE ± (1 ml/breath +10 % of the set initial value/breath).

b) Additionally, the deviation of delivered oxygen volume per breath shall be disclosed in the instructions for use.

c) This deviation shall not exceed ±15 %.

d) The instructions for use shall disclose the maximum deviation of the delivered oxygen at 20 breaths/min over the *rated* range of environmental operating conditions.

e) The *verification* of oxygen delivery of the *conserving equipment* shall either be:

1) determined for each *conserving equipment* configuration indicated in the instructions for use; or

2) determined for the worst-case configurations indicated in the instructions for use.

f) If a worst-case configuration is used, the rationale for its selection shall be documented in the *risk management file*.

g) Pneumatic inspiratory trigger sensitivity under the test conditions specified in this document shall be disclosed in the technical description.

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

h) If provided, non-pneumatic inspiratory trigger sensitivity and test methods shall be disclosed in the technical description.

i) Additional sensitivity specifications and test methods may be disclosed in the technical description.

Check conformance by inspection of the technical description and of the risk management file for the rationale, if applicable, and with the following tests:

j) Delivered oxygen setting

1) Set up the conserving equipment as shown in Figure 201.101 with the variable restrictor open.

2) Utilize the test parameters of the first row of Table 201.102. Wait for steady-state conditions to be achieved.

NOTE Some conserving equipment, particularly at higher set rates and when connected to an oxygen concentrator, can take more than 15 min to achieve steady-state conditions.

3) Determine the delivered oxygen through integration of the flow signal provided by the flow sensor from the start of the inspiration until the end of the delivered oxygen capture time as indicated in Table 201.102.

4) Repeat 3) for 30 breaths and average the 30 measurements.

5) Determine the deviation of the delivered oxygen from that indicated in the instructions for use.

6) Repeat 2) to 5) for each row of Table 201.102.

7) Repeat 2) to 6) for each volume delivery setting of the conserving equipment.

k) Inspiratory trigger sensitivity

The sensitivity of the conserving equipment triggering is evaluated by creating a ramping subatmospheric pressure on the cannula of -0,5 cmH_2O per second.

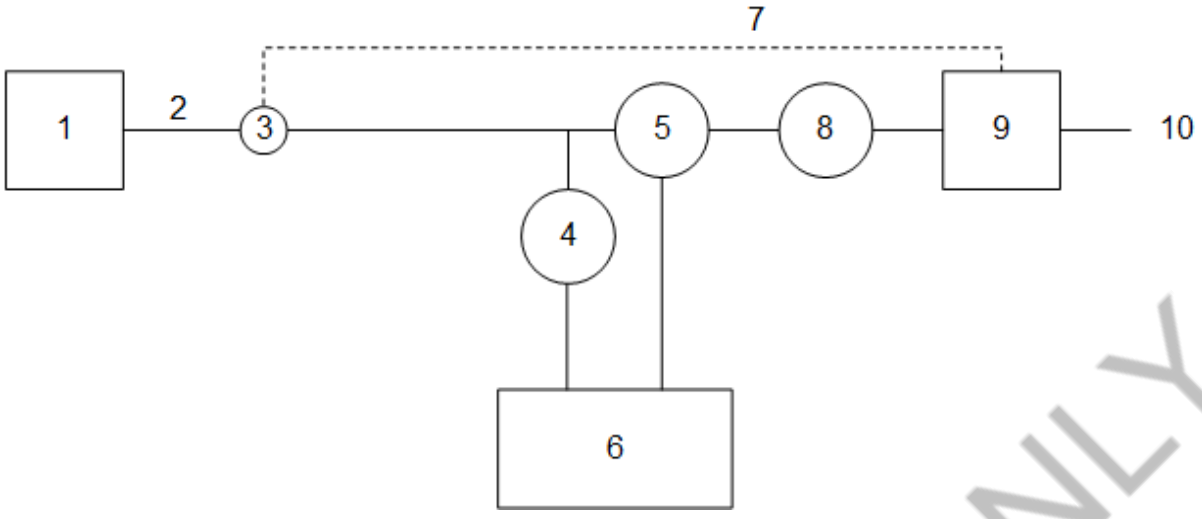
1) Measure the minimum pressure achieved immediately before the onset of gas flow.

2) Confirm that the trigger pressure is less than the value indicated in the technical description.

3) Repeat 1) and 2) for 10 breaths and average the 10 measurements.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved



Key

1 *conserving equipment* under test
2 *accessory* connection tubing, if specified separately
3 *accessory* cannula
4 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
5 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms
6 data acquisition system, with a minimum sample rate of 200 samples/s
7 optional dual lumen connection for cannula trigger lumen
8 variable restrictor
9 trigger source as specified by the *manufacturer*
10 exhaust port

If testing a dual lumen cannula, connect the pressure sensor (4) to the sensing lumen (7).

Figure 201.101 — *Verification* of oxygen delivery, typical test setup

Table 201.102 — *Verification* of oxygen delivery test parameters

Set rate min^{-1}	***Inspiratory time*** s	**Delivered oxygen capture time**[a] s
15	1,33	0,80
20	1,00	0,60
25	0,80	0,48
30	0,67	0,40
35	0,57	0,34
40	0,50	0,30

[a] The delivered oxygen capture time begins at the start of inspiration and ends at the indicated time.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Absence of the inspiratory trigger *alarm condition*

a) *Conserving equipment with monitoring function* shall be equipped with an *alarm system* that detects an *alarm condition* to indicate the absence of the inspiratory trigger for not more than 60 s.

b) The absence of the inspiratory trigger *alarm condition* shall be at least *low priority* with an auditory *alarm signal*.

Check conformance by functional testing.

201.12.4.102 Gas supply failure *alarm condition*

a) *Conserving equipment with monitoring function* shall be equipped with an *alarm system* that detects an *alarm condition* to indicate when the supply of respirable gas is below the value necessary for normal operation.

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

Check conformance by functional testing.

201.12.4.103 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 conserving equipment as indicated in Figure 201.101 with the variable restrictor open.

c) Set the conserving equipment to the maximum demand flowrate setting of normal use and simulate a triggering set rate of 20 breath/min.

d) Close the variable restrictor to stop flow.

e) Wait 1 min.

f) Repeat c) to e) after creating each relevant single fault condition.

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

201.13 *Hazardous situations* and fault conditions

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 13 applies.

201.14 *Programmable electrical medical systems* (*PEMS*)

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

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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

Conserving equipment 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 *conserving equipment* shall be considered to form an *ME system* with the *conserving equipment*.

Check conformance by application of the relevant tests of IEC 60601-1:2005+AMD1:2012.

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 Gas connections

201.101.1 Oxygen inlet *connector*

An oxygen inlet *connector* of the *conserving equipment* not intended for connection to a *medical gas pipeline system*, for which the connection is *operator*-detachable without the use of a *tool* shall conform with:

a) ISO 80369-1:2018; or

NOTE It is expected that the R2 *connector* of ISO 80369-2[6] will meet this criterion.

b) female 9/16-18 UNF-2A-RH fitting.

Check conformance by inspection and application of the tests of ISO 80369-1:2018.

201.101.2 Connection to the *medical gas pipeline system*

If an *operator*-detachable hose assembly is provided for connection between the *conserving equipment* and the *medical gas pipeline system*, it shall conform with ISO 5359:2014+Amd.1:2017.

Check conformance by application of the tests of ISO 5359:2014+Amd.1:2017.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

201.101.3 Outlet *connector*

a) An outlet *connector* of the *conserving equipment* shall conform with:

   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 fitting.

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

c) The outlet *connector* shall be marked with:

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

   2) the *rated* range of gas flowrate.

d) 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 *conserving equipment* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *conserving equipment* or by another entity ("third-party manufacturer" or healthcare provider).

Check conformance by the tests of this document.

201.102.2 Labelling

a) The *accompanying document* 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;

   for which the *accessory is* specified for use.

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

   1) oxygen conserving equipment, 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 conserving equipment and all of the parts or accessories used to connect to the patient before use; and

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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

5) a warning statement to the effect that "WARNING: There is a risk of fire associated with oxygen therapy. Do not use near sparks or open flames.";

6) a warning statement to the effect that "WARNING: Smoking during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire."

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 *conserving equipment* or the *conserving equipment* itself shall be equipped with 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.

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.

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

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 conserving equipment, as appropriate.

NOTE The oxygen source can be the conserving equipment.

f) Set the oxygen source to deliver a continuous flowrate of 10 l/min ± 1 l/min or at the maximum flow setting of the conserving equipment through the accessory.

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 propagated towards the oxygen source and that the fire extinguishes.

i) Repeat d) to h) at 0,5 l/min ± 0,1 l/min or for a conserving equipment source, repeat at both the minimum and maximum flowrate settings.

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

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

201.103 Oxygen pressure regulators

Oxygen pressure regulators integral with the *conserving equipment* shall conform with ISO 10524-1:2018 or ISO 10524-3:2019, as appropriate.

Check conformance by inspection and application of the tests of ISO 10524-1:2018 or ISO 10524-3:2019.

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 *conserving equipment* delivering oxygen through a cannula using the conditions and parameters of Table 201.102.

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 *conserving equipment* 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;

EXAMPLE Switchover to continuous flow.

5) initiation of an unintended operation; and

6) deviation of the delivered oxygen dose, greater than 15 %, averaged over a one-minute interval.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

206 Usability

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

a) For *conserving equipment*, the following shall be considered *primary operating functions*:
   1) setting the delivered oxygen control;
   2) configuring the *conserving equipment,* including connection of the detachable parts to the *conserving equipment*;
   3) starting the *conserving equipment* from power off; and
   4) turning off the *conserving equipment.*

b) The following functions, if available, also shall be considered *primary operating functions*:
   1) switchover to continuous flow;
   2) setting the *operator*-adjustable controls:
      i) setting *alarm limits*;
      ii) inactivating *alarm signals*.

c) The following action associated with oxygen delivery also shall be considered a *primary operating function* even though it is not performed on the *conserving equipment*:
   1) positioning the cannula on the *patient.*

Annexes of the IEC 60601-1:2005+AMD1:2012+AMD2:2020 apply, except as follows:

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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 *conserving equipment*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of *conserving equipment*, its parts or *accessories*

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Any particular warnings and/or precautions relevant to the immediate operation of the equipment	201.7.2.101 b)
Containing natural rubber latex, if applicable	201.7.2.13.101
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101
For each *conserving equipment*, part and *accessory*, an arrow indicating the direction of the flow for *flow-direction-sensitive components*, if applicable	201.7.2.101 d)
For each *conserving equipment*, part and *accessory*, contains phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, if applicable	201.11.7 dd) 1)
For gas delivery control, non-numeric marking with self-evident minimum and maximum	201.7.2.101
For packaging, a description of the contents	201.7.2.17.101 a)
For packaging, an identification reference to the batch, type or serial number	201.7.2.17.101 b)
For packaging, contains phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, if applicable	201.11.7 dd) 2)
For packaging, contains natural rubber latex, if applicable	201.7.2.17.101 c)
Gas name or chemical symbol for any gas-specific inputs, if applicable	201.7.2.101 c)
Gas-specific colour coding for any gas-specific inputs, if applicable	201.7.2.101 c)

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

201.C.2 *Accompanying documents*, general

Amendment:

Additional requirements for general information to be included in the *accompanying documents* of *conserving equipment* 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	201.5.101.3
For *accessories,* range of oxygen flows for which they are *rated*	201.102.2
For each *conserving equipment*, part and *accessory*, a statement to the effect that incompatible parts or accessories can result in degraded performance	201.102.2 b)
For each *conserving equipment*, part and *accessory*, a statement to the effect that oxygen conserving equipment, its parts and accessories are specified for use at specific flows	201.102.2 a)
For each *conserving equipment*, part and *accessory*, a statement to the effect that the responsible organization is accountable for ensuring the compatibility of the oxygen conserving equipment and all of the parts or accessories used to connect to the patient before use	201.102.2 c)
For each *conserving equipment*, part and *accessory*, a warning statement regarding use of lotions and salves	201.102.2 d)
For each *conserving equipment*, part and *accessory*, a warning statement regarding the risk of fire	201.102.2 e)
For each *conserving equipment*, part and *accessory*, a warning statement regarding the risk of smoking	201.102.2 f)
Maximum time-weighted average input flow, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow, if applicable	201.4.11.101.2 3) ii)
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
Units of measurement for volumes, flows and leakages	201.7.4.3
Warning that the conserving equipment is a high flow device, if applicable	201.4.11.101.2 3) iii)

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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

Amendment:

Additional requirements for information to be included in the instructions for use of *conserving equipment* 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 *conserving equipment*, if applicable	201.7.9.2.14.101 c)
Any natural rubber latex containing components, if applicable	201.7.2.13.101
Delivered oxygen volume per breath for each setting in *normal condition,* tabular representation	201.12.1.101
Deviation of the delivered oxygen volume per breath	201.12.1.101
Explanation of the meaning of the IP classification marked on the equipment	201.7.9.2.9.101
For *accessories* supplied separately where marking the *accessory* is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101 b)
For *conserving equipment*, its parts or *accessories* intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *conserving equipment*, its parts or *accessories* would be reused	201.7.9.2.1.101 a)
For *conserving equipment*, pneumatic diagram, including a diagram for *operator*-detachable parts	201.7.9.2.1.101 d)
For *conserving equipment with monitoring function*, 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
For each *conserving equipment*, its parts and *accessories* that contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, 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 *conserving equipment* that can become contaminated with body fluids or expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12
Information on the effects of failure, including effect on flow	201.7.9.2.5.101 e)
Inspiratory trigger sensitivity, pneumatic	201.12.1.101
Instructions for *processing* the *conserving equipment* and its *accessories*	201.11.6.6 cc)
Intended source of oxygen	201.7.9.2.14.101 a)
Internal electrical power source care and maintenance, if applicable	201.7.9.2.13.101 b)
Manual control of the sensitivity for optimal breath detection instructions, if provided	201.7.9.2.1.101 c)

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Description of requirement	Subclause
Maximum deviation of the delivered oxygen volume per breath at 20 breaths/min over the *rated* range of environmental operating conditions	201.12.1.101
Method by which the *operator* can check for proper operation of the equipment	201.7.9.2.8.101
Necessary application *accessories* and their specifications	201.7.9.2.5.101 g)
Periodic visual safety inspections	201.7.9.2.13.101 a)
Principles of operation of the *conserving equipment*, including the principles of oxygen dosage, timing, triggering and the settings	201.7.9.2.1.101 b)
Procedure to determine the state of the *internal electrical power source*, if applicable	201.7.9.2.9.101
Rated range of breathing frequency	201.7.9.2.5.101 d)
Rated range of oxygen delivery setting	201.7.9.2.5.101 c)
Restrictions on the placing of components within the *conserving equipment*, if applicable	201.7.9.2.14.101 b)
Statement to the effect that some respiratory efforts of the *patient* might not trigger the *conserving equipment*	201.7.9.2.5.101 f)
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 responsible organization should ensure that the oxygen delivery settings were determined and recorded for the patient individually together with the configuration of the equipment to be used, including accessories	201.7.9.2.1.101 e)
Statement to the effect that the responsible organization should periodically reassess the setting(s) of the therapy for effectiveness	201.7.9.2.1.101 e)
Tracheotomised *patient*, an indication as to whether the *conserving equipment* is intended for use with	201.7.9.2.5.101 h)
Warning statement regarding strong draughts	201.7.9.2.2.101 i)
Warning statement regarding the correspondence between models of oxygen conservers	201.7.9.2.2.101 e)
Warning statement regarding the correspondence to continuous oxygen flow	201.7.9.2.2.101 d)
Warning statement regarding the effect of changing the spare parts	201.7.9.2.2.101 h)
Warning statement regarding the need for extra monitoring	201.7.9.2.2.101 m)
Warning statement regarding the risk of lubricating	201.7.9.2.2.101 g)
Warning statement regarding the risk of fire	201.7.9.2.2.101 a)
Warning statement regarding the risk of smoking	201.7.9.2.2.101 b)
Warning statement regarding the risk of smoking in the same room	201.7.9.2.2.101 n)

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Description of requirement	Subclause
Warning statement regarding use as prescribed, settings, activity levels and *accessories*	201.7.9.2.2.101 c)
Warning statement regarding use of lotions and salves	201.7.9.2.2.101 f)
Warning statement regarding use outside the *rated* altitude or temperature	201.7.9.2.2.101 j)
Warning statement regarding when to turn off the oxygen conserver	201.7.9.2.2.101 k)

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

Amendment:

Additional requirements for information to be included in the technical description of a *conserving equipment* or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
For *conserving equipment with monitoring function*, description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document and indicating which checks are performed automatically	201.7.9.3.101
Inspiratory trigger sensitivity, non-pneumatic, if provided	201.12.1.101
Inspiratory trigger sensitivity test method, non-pneumatic, if provided	201.12.1.101

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

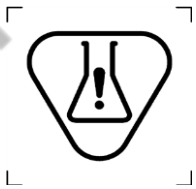
Annex D
(informative)

Symbols on marking

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 60878:2015[9]	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 60878:2015[9]	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 60878:2015[9]	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 60878:2015[9]	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 60878:2015[9]	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.

Additional Annexes:

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a 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 201.1.1 — Scope

The aim of oxygen therapy is to obtain the desired SaO_2 in a *patient*. *Conserving equipment* is intended to obtain the desired SaO_2 while optimizing the usage from the oxygen supply. A previous standard for *conserving equipment* did not include standardized performance testing and labelling which made comparing the performance of *conserving equipment* difficult[5]. This document is intended to reduce this ambiguity between *conserving equipment* models by requiring both standardized performance testing and disclosure.

There are several variables that make this difficult. Breathing frequency affects the actual dose delivered with continuous flow oxygen because a faster breathing rate generally reduces *inspiratory time*, which in turn reduces the volume of the dose of oxygen. Some *conserving equipment* mimics this phenomenon in varying degrees. Other *conserving equipment* delivers the same volume dose regardless of rate. Although a standardization of dose can be accomplished at one breathing frequency, the relative dose can differ at other frequencies.

Oxygen *conserving equipment* frequently is incorporated into or with other devices. When a *manufacturer* produces such a combination device, they need to be aware that there can be standards for the other device, as well. In this circumstance, the combined product is expected to be evaluated according to both standards.

EXAMPLE Evaluating a combined pressure regulator-*conserving equipment* to both this document and ISO 10524-1.

Subclause 201.4.3.101 — Additional requirements for *essential performance*

The committee considered that the accuracy of set oxygen delivery (i.e. the delivered oxygen per breath*)* is a key component of the *essential performance* of a *conserving equipment*.

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

Since the *conserving equipment* 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 *conserving equipment* and its *accessories* need to be investigated regarding *biocompatibility* and compatibility with substances

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

that might pass into the *patient* via the *gas pathways*. Also of concern are electrical *hazards* should any electrical components 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 201.4.11.101 — Additional requirements for pressurized gas input

Conserving equipment designed to be connected to a pressurised gas supply is required to continue to operate reliably throughout the *rated* range of supply pressures; and these pressures can only be maintained if the *conserving equipment* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. *Conserving equipment* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurised gas supply.

Pressurised medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant standards, supply gas-specific terminal outlets at a pressure that is within an internationally agreed pressure range of 280 kPa to 600 kPa under *normal condition*. *Conserving equipment* should operate to its declared specification with any supply pressure within this range.

In the case of a pressure regulator failure the gas supply pressure could rise to the pressure regulator's supply pressure, which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific *medical gas pipeline systems* are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered *ME equipment* should be designed so as to not present an unacceptable *risk* if its supply pressure rises up to this value.

Conserving equipment with maximum *rated* input pressures exceeding 600 kPa is required to fulfil these conditions at up to twice its maximum *rated* input pressure.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems* supplying compressed medical gases through gas-specific terminal outlets are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the low-pressure hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a diversity factor (a factor agreed between the supplier and *responsible organization* to be appropriate for each section of the installation). Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flow of 60 l/min to the required proportion of terminal outlets. However, if the simultaneous flow demand from many adjacent *conserving equipment* exceeds 60 l/min there is an increased possibility that the *conserving equipment* input pressure could fall below 280 kPa, mainly because of the decrease in pressure upstream of the terminal unit due to increased demand from other terminal units.

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a *patient* demand system can result in a *conserving equipment* requiring transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimise pressure drop, such transient demands can generally be accommodated from the gas stored locally within the piping of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the inlet of the *conserving equipment*, to below 280 kPa, due to transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to

FOR BSI USE ONLY

 © ISO 2020 – All rights reserved

evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their *conserving equipment* when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulators conforming to ISO 10524-1.

Conserving equipment that can draw greater average or transient flows during *normal use* are permitted, but the *accompanying documents* are required to disclose those flows and warn of the need of a different diversity factor.

The average flow of 60 l/min is greater than the test flow used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The committee responsible for pipeline standards, ISO TC 121/SC 6, in consultation with ISO TC 121/SC 1 & ISO TC 121/SC 3, agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of standards for *medical gas pipeline systems* (ISO 7396-1:2007[3]) and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other medical gas supply system standards permit the fitting of gas-specific terminal outlets to spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101.2 — Gas flowrate specifications

The delivery of oxygen is commonly expressed in volumetric measures, not corrected to *STPD*. Further, most oxygen delivery equipment does not adjust with environmental conditions to maintain constant mass delivery, although there is usually an effect of barometric pressure and temperature on the delivery. This effect varies depending on the design of the equipment.

EXAMPLE Liquid or compressed gas systems commonly meter flow from a reservoir at 1,3 bar gauge pressure through a critical orifice. Changing barometric pressure will cause variance in the quantity of oxygen delivered proportional to the absolute inlet pressure, the result being neither constant volume nor constant mass. In contrast, *oxygen concentrators* often meter flow through a needle valve based on *patient's* reading of a variable area flowmeter (rotameter). The ball in this equipment responds to gas velocity. Therefore, the output approximates a constant volume with changing conditions.

It is desired to have a standardized measure for delivered oxygen volume. What is intended is that the expressed volume be that volume which would be expected if the equipment were operated under standard conditions. If actual test conditions differ from standard conditions, then a correction should be applied based on the known operational characteristics of that equipment (i.e. its sensitivity to temperature and pressure). This is different from simply correcting the measured volume to standard conditions.

[3] Withdrawn.

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

Subclause 201.5.101.3 — *Conserving equipment* testing errors

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

Similarly, it is important for a third-party tester 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 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 ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

Subclause 201.7 — *ME equipment* identification, marking and documents

It is an established understanding that for *ME equipment* used in healthcare facilities, the instructions for use are intended for the professional clinical *operator* of the *ME equipment* as well as the *responsible organization*. It is expected that these individuals are trained medical professionals.

It is only recently, with the introduction of IEC 60601-1-11, that due consideration has been given to who is the *operator* and the *responsible organization* where *ME equipment* is intended for use in the *home healthcare environment*. In that International Standard, the concept of *lay operator* is introduced. The *lay operator* is the non-professional healthcare person who is operating the *ME equipment* within the *home healthcare environment*. This person can be the carer for the *patient* within the home or can be the *patient*. Where the *ME equipment* is prescribed by a medical professional, it is their responsibility to ensure that a suitable *lay operator* has been appropriately trained and has a copy of the instructions for use. Where *ME equipment* is acquired by the *patient* or by a non-medical entity, it is assumed that the *patient* is the *lay operator*.

In the light of these considerations, the requirements for the instructions for use specified in this document have been written from the perspective that they need to be suitable not only for a professional clinical *operator* but also for a *lay operator*, whether that individual is a nominated carer or the *patient*.

Subclause 201.7.1.2 — Legibility of markings

In order to change the settings of *conserving equipment*, the *operator* needs to be within an arm's length of the control. *Conserving equipment* is typically *body-worn* or *hand-held* equipment that is at a normal reading distance when operated.

Subclause 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.3.1.101 — Additional general requirements

The *manufacturer* is expected to express the description of the *conserving equipment* in general terms so the reader can understand the important behaviour of the *conserving equipment,* e.g. mean values and their time specifications, number of breaths and delays.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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 *conserving equipment*; and

— by providing a means to stop the flow of gas towards the *patient* in the case that the *applied part* becomes ignited.

Although these *risk control* methods are not expected to prevent the *patient* from being seriously burned by this dangerous behaviour, they are intended to reduce the *risk* of the more serious propagation of fire from causing *harm* to others.

Subclause 201.11.3.101 — 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[8] 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 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 *conserving equipment*, their *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 *conserving equipment*, *accessory* or part.

Therefore, *conserving equipment*, their *accessories* and parts require an appropriate level of *disinfection*, depending on their use, but rarely need to be sterile.

Recommendations for hygienic *processing* of *conserving equipment*, their *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* of this document are intended to:

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

— help all parties involved in the *processing* of *conserving equipment*, their *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.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

It should be noted that *conserving equipment*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *conserving equipment* 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 *conserving equipment*, their reusable *accessories* and parts that have been used are required to undergo a *processing procedure*, 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 a *conserving equipment*, 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 standardised *procedures* in a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing* should be determined by:

— the potential degree and type of contamination of the *conserving equipment*, *accessories* or parts; and

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *conserving equipment*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing 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 detail so 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 *conserving equipment*, *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*.

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

The *risks* posed by a reprocessed *conserving equipment*, *accessories* or parts are determined by the following factors:

a) undesired effects, which can result from the following:

- 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 *conserving equipment*, *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 *conserving equipment*, *accessories* or parts.

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

The *responsible organization* should verify that manual *cleaning* and *disinfection* of the *conserving equipment*, *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

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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. This ensures that cleaned and disinfected *conserving equipment*, *accessories* or its parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganism. This is important when *equipment*, *accessories* or its parts, collectively or individually comes in contact with the next *patient*, *operator* or other person.

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

Following any *processing procedure*, a safety and functional testing of the *conserving equipment* (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 *conserving equipment*.

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

Subclause 201.12.1.101 — *Verification* of oxygen delivery

The general standard requires *manufacturers* to declare accuracies and to address the associated *risks* in the *risk management process*. One of the associated *risks* is lack of consistency between *manufacturers* in their declarations of dose and accuracy, both in terms of the reference settings used and the conditions of testing. Consistency in these situations can only be achieved by means of internationally agreed-upon standards and these requirements have been formulated in order to fulfil this objective.

The test settings and conditions, and for certain parameters minimum requirements, specified in this subclause have been selected by the committee as those necessary to demonstrate adequate *essential performance* of *conserving equipment*. The test *procedures* have been written as *type tests* (additional information is found in 3.135 and Clause 5 of the general standard), with the expectation that *manufacturers* will design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified will encompass any results obtained by a *type test* performed in accordance with the test *procedures* specified in this subclause.

Current labelling varies widely from one *conserving equipment* model to another. Some *conserving equipment* deliver a fixed dose volume regardless of respiratory rate, some a fixed minute volume (variable dose volume over respiratory rate), and some are a combination thereof. *Conserving equipment* models can have as much as 100 % different volume delivery under similar breathing conditions.

This test is based on the assumption that gas delivered in the early portion of inhalation reaches the alveoli and gas delivered later in inhalation will only fill anatomical dead space. To determine the "useful" oxygen delivery, the committee determined that 60 % of inhalation time would be considered to be the time that oxygen delivery reaches the alveoli. The numbers in the table for the oxygen dose capture window reflect that percentage, assuming an *I:E ratio* of 1:2.

Oxygen delivery throughout all of inhalation is not all useful. The last portion of inhaled volume goes to filling dead space, not into the functional units of the lungs[14]. This phenomenon is exacerbated in obstructive disease because tidal volume is limited (so the dead space volume is a greater portion of the

FOR BIS USE ONLY

 © ISO 2020 – All rights reserved

inhaled volume). Also, the inspiratory flow tends to be higher early in inhalation and so a greater portion of the late *inspiratory time* is spent filling dead space.

Although the exact portion of functional *inspiratory time* (during which oxygen delivery will reach the lungs) is variable, it is clear that it is less than 100 %. Reference [15] and [16] suggest 50 % while Reference [13] shows correlation in a bench study to 0,6 seconds or 60 % of a 1 s inhalation time.

The exact amount of useful oxygen derived from a longer pulse will vary from *patient* to *patient*. What is important is to recognize that not all of the *inspiratory time* is useful. Longer times will favour *conserving equipment* with longer, lower flowrate delivery. Shorter times favour *conserving equipment* with very fast, high flowrate delivery. The 60 % portion chosen for this document is a compromise.

All of this variability supports the decision of the committee to not permit the marking of the oxygen delivery control to be only numeric in 201.7.2.101. An only numeric marking could imply a correlation to a specific numerical dose or flowrate to some prescribers.

Subclause 201.102.1 — General

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

Subclause 201.102.3 — Fire propagation *risk* reduction in *accessories*

Refer to the rationale for subclause 201.11.2.101.

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 breathing frequencies and delivered oxygen doses), but that the *manufacturer* should determine which breathing *set rate* and oxygen dose represents the worst case for a given *immunity* test and use those conditions.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

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 *conserving equipment*, 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[11] and labelling principles IMDRF/GRRP WG/N52:2019[12]. 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**[11]	**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, 201.12.4	
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*.
5.3.1 f)	201.11.7, 201.12.1.101	Covered for *biocompatibility* and accuracy.
5.3.2	201.11.6.6, 201.11.7	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Essential principle of IMDRF/GRRP WG/N47: 2018[11]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.3.3	201.11.7	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	
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, 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1	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, 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1	
5.5.7	201.12.1.101	
5.5.6	201.12.101	
5.6.1	201.9, 201.11	
5.6.4	201.101	
5.6.5	201.11	
5.7.1	201.13	
5.7.5	202	
5.7.6	202	
5.7.7	201.8, 201.13	
5.8.1	201.14	
5.8.2	201.14	
5.9.1 a)	201.12.1.101	
5.9.1 c)	201.7.1.2	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Essential principle of IMDRF/GRRP WG/N47: 2018[11]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.10	201.7, 201.7.2.4.101, 201.7.2.101, 201.7.9.2, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.14.101, 201.7.9.3.1, 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	Only the requirements related to design are addressed, excluding nanomaterials.
6.4.1	201.12.1.101	
6.4.2	201.12.4.101, 201.12.4.102, 201.12.4.103, 201.13	

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[12]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.1.1	201.7, 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	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Labelling principles of IMDRF/GRRP WG/N52: 2019[12]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.2.17	201.7.2.17.101	
5.3.1	201.7, 206	
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	
5.3.21	201.7.2.101	
5.3.26	201.7.9.2.1.101, 201.7.9.2.12	
5.3.27	201.7.9.2.14.101, 201.16.1.101	
9.1	201.7, 201.7.9.2, 206	
9.2	201.7, 201.7.9.2, 206	
9.3	201.7, 201.7.9.2, 206	
9.4	201.7, 201.7.9.2, 206	
9.6	201.7, 201.7.9.2, 206	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Annex CC
(informative)

Reference to the *essential principles*

This document has been prepared to support the *essential principles of safety and performance* of *conserving equipment*, its *accessories* or parts as medical devices according to ISO 16142-1:2016. 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 ISO 16142-1:2016. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the *essential principles* of ISO 16142-1:2016.

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

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

***Essential principle* of ISO 16142-1:2016, Annex B**	**Corresponding clause(s)/sub-clause(s) of this document**	**Qualifying remarks/Notes**
1	All	The part relating to manufacturing is not addressed
a)	206	
b)	206	
2	201.4, 201.4.3.101	The part relating to manufacturing is not addressed
a)	All	
b)	201.4, 201.4.3.101	The part relating to manufacturing is not addressed
c)	201.4.3.101, 201.7, 201.12.4	
d)	201.7	
3	All	The part relating to manufacturing is not addressed
4	All	
5	201.4, 201.15	
6	201.4	
8.1	—	
a)	201.7.2.13.101, 201.11.7	
b)	201.11.7	
8.2	201.11.6.6, 201.11.7	
8.3	201.11.6.6, 201.11.7	
8.4	201.11.7	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
9.1	201.11.6.6	
a)	201.11.6.6	
b)	201.11.6.6, 201.11.6.7	
c)	201.11.7	
9.6	201.7.2.17.101	
12.1	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1	
12.2	—	
a)	201.9	
b)	201.12.1, 201.12.4, 206	
c)	202	
g)	202	
12.4	201.11, 201.11.2.101, 201.11.3.101	
13.1	201.12.1	
13.2	201.12.1	
13.3	201.7, 201.12.1, 206	
15.1	201.14	
15.2	201.14	
16.1	201.13	
16.5	202	
16.6	202	
16.7	201.8, 201.13	
17.1	201.9, 201.11	
17.4	201.101, 201.103	
17.5	201.101	
17.6	201.11	
18.1	201.12.1.101	
18.2	201.12.4.101,201.12.4.102, 201.12.4.103, 201.13	
19.1	201.7.1.2, 201.12.1, 206	
19.2	201.7.1.2, 201.12.1, 206	
20.1	201.12.1, 206	
20.2	201.12.1, 206	
20.3	201.7.9.2.8.101	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
21.1	201.7, 201.7.2.4.101, 201.7.2.101, 201.7.9.2, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.14.101, 201.7.9.3.1, 201.102.2	
21.2	201.7.2.17.101 a) 1)	
21.3	201.7.2.101	
21.4	201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.11.7 ee)	
21.5	—	
a)	201.7.9.1	
b)	201.7.2.17.101 a) 1)	
d)	201.7.2.17.101 a) 2)	
i)	201.7.2.101 b) 1)	
j)	201.7.2.17.101 b) 1)	
k)	201.7.2.101 b) 2)	
21.7	—	
a)	201.7.9.1	
b)	201.7.2.17.101 a) 1)	
d)	201.7.2.17.101 b)	
i)	201.7.2 b) 2)	
k)	201.7.9.2.8.101, 201.7.9.2.14.101, 201.16	
l)	201.7.9.2.8.101	
p)	201.7.9.2.12 aa), 201.7.9.2.13.101	
21.9	—	
a)	201.7.9.2.1.101 f) 3)	
b)	202	
f)	201.12.1.101	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Annex DD
(informative)

Reference to the general safety and performance requirements

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745[10]. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific general safety and performance requirements of regulation (EU) 2017/745[10]. Other means are possible. Table DD.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745.

NOTE When a general safety and performance requirement does not appear in Table DD.1, it means that it is not addressed by this document.

Table DD.1 — Correspondence between this document and the general safety and performance requirements

General safety and performance requirements (GSPR) of regulation (EU) 2017/745, Annex I[10]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
5 a)	201.12.1, 206	
5 b)	206	
6	All	
7	201.4, 201.15	
8	201.4	
10.1 a)	201.7.2.13.101, 201.11.7	Only the requirements related to toxicity are covered.
10.1 b)	201.11.7	This requirement is covered with respect to the *gas pathways.*
10.1 d)	201.11.6.6, 201.11.7	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
10.1 g)	201.11.6.6 bb)	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
10.1 h)	201.11.7, 201.12.1.101, 201.12.4.103	Covered for *biocompatibility*, *verification* of oxygen delivery and outlet pressure
10.2	201.11.6.6, 201.11.7	Only the part relating to design is addressed
10.3	201.11.6.6, 201.11.7	Only the part relating to design is addressed.
10.4.1	201.11.7	Only the part relating to design is addressed.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

General safety and performance requirements (GSPR) of regulation (EU) 2017/745, Annex I[10]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
10.4.1 a)	201.11.7 cc), 201.11.7 dd)	Covered when the list of substances of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 is applied.
10.4.1.b)	201.11.7 cc), 201.11.7 dd)	
10.4.2	201.11.7 ff)	
10.4.5	201.11.7 dd), 201.11.7 ee), 201.11.7 ff), 201.11.7 gg)	
10.6	201.11.7	Only the part relating to design is addressed.
11.1	201.11.6	Only the part relating to design is addressed.
11.1 b)	201.11.6.6	Only the part relating to design is addressed.
11.1 c)	201.11.6.6, 201.11.6.7	
11.1 d)	201.11.7	
11.2	201.11.6.6	
11.7	201.7.2.17.101	
14.1	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1	
14.2 a)	201.9, 201.12.1, 201.12.4, 206	Only the part relating to design is addressed.
14.2 b)	202	Only the part relating to design is addressed.
14.2 f)	202	Only the part relating to design is addressed.
14.3	201.11, 201.11.2.101, 201.11.3.101	Only the part relating to design is addressed.
14.5	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.14.101, 201.16.1.101, 201.101, 201.102.1	Covered with respect to use with the listed *accessories*, integrated *conserving equipment*, connecting *accessories* and *operator*-detachable components and positioning of the *patient*-interface.
14.6	201.12.1, 201.12.1.101, 206	
15.1	201.12.1.101	The part relating to stability is not addressed.
17.1	201.14	
17.2	201.14	
18.1	201.13	
18.5	202	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

General safety and performance requirements (GSPR) of regulation (EU) 2017/745, Annex I[10]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
18.6	202	
18.7	201.8, 201.13	
20.1	201.9, 201.11	
20.4	201.101, 201.103	
20.5	201.101	Only the part relating to design is addressed.
20.6	201.11	
21.1	201.12.1, 201.12.1.101	Only the protection of the *patient* is covered.
21.2	201.12.4., 201.12.4.101, 201.12.4.103, 201.13	Only the first sentence is covered.
21.3	201.7.1.2, 201.12.1, 206	
22.1	201.12.1, 206	Only the requirements related to design are addressed.
22.2	201.12.1, 206	Only the requirements related to design are addressed.
22.3	201.7.9.2.8.101	
23.1	201.7, 201.11.7	The part relating to the website is not addressed.
23.1 a)	201.7.9.2.1.101, 206	
23.1 b)	201.7.2.101	
23.1 g)	201.7.9.2.1.101, 201.7.9.2.2.101	
23.1 h)	201.7.2.13.101, 201.7.2.17.101, 201.7.2.101 c) 1), 201.7.2.101 c) 2), 201.11.7 ee)	
23.2 b)	201.7.2.17.101 a) 1)	The part relating to intended purpose is not addressed.
23.2 c)	201.7.9.1	
23.2 d)	201.7.9.1	
23.2 f)	201.11.7 dd), 201.11.7 ee), 201.11.7 gg)	
23.2 g)	201.7.2.17.101 a) 2)	
23.2 i)	201.7.2.17.101	
23.2 k)	201.7.2.101 b) 1)	
23.2 m)	201.7.2.17.101 b) 2), 201.7.2.101	
23.4 a)	201.7.2.17.101, 201.7.2.101, 201.7.9.1	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

General safety and performance requirements (GSPR) of regulation (EU) 2017/745, Annex I[10]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
23.4 e)	201.7.9.2.5.101 c), 201.7.9.2.5.101 d)	
23.4 f)	201.7.9.2.5.101 a), 201.7.9.2.5.101 b), 201.7.9.2.14.101	
23.4 g)	201.7.9.2.5.101 a), 201.7.9.2.5.101 b)	
23.4 h)	201.12.1.101 a), 201.12.1.101 b)	
23.4 k)	201.7.9.2.8.101, 201.7.9.2.13.101	
23.4 n)	201.7.9.2.12	
23.4 q)	201.7.9.2.8.101, 201.7.9.2.14.101, 201.16	
23.4 s)	201.7.9.2.1.101, 201.7.9.2.2.101, 201.11.7, 202	

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Annex EE
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP)[4] and the IEC Electropedia[5] provide access to many of these terms and definitions.

Term	*Source*
accessory	IEC 60601-1:2005, 3.3
accompanying document	IEC 60601-1:2005, 3.4
alarm condition	IEC 60601-1:2005+AMD1:2012, 3.141
alarm limit	IEC 60601-1-8:2006, 3.3
alarm signal	IEC 60601-1:2005+AMD1:2012, 3.142
alarm system	IEC 60601-1:2005+AMD1:2012, 3.143
applied part	IEC 60601-1:2005, 3.8
basic safety	IEC 60601-1:2005, 3.10
biocompatibility	ISO 18562-1:2017, 3.2
body-worn	IEC 60601-1:2005+AMD1:2012, 3.144
cleaning	ISO 17664:2017, 3.1
clearly legible	IEC 60601-1:2005+AMD1:2012, 3.15
connector	ISO 80369-1:2018, 3.4
conserving equipment	201.3.201
conserving equipment with monitoring function	201.3.202
continuous operation	IEC 60601-1:2005, 3.18
disinfection	ISO 17664:2017, 3.3
enclosure	IEC 60601-1:2005, 3.26
essential performance	IEC 60601-1:2005+AMD1:2012, 3.27
essential principles	ISO 16142-1:2016, 3.3
essential principles of safety and performance	ISO 16142-1:2016, 3.3
flow-direction-sensitive component	201.3.203
gas pathway	ISO 18562-1:2017, 3.5
hand-held	IEC 60601-1:2005+AMD1:2012, 3.37
harm	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.38
hazard	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.39

[4] Available at: https://www.iso.org/obp/ui/#home

[5] Available at http://www.electropedia.org/.

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Term	*Source*
hazardous situation	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.40
home healthcare environment	IEC 60601-1-11:2015+AMD1:2020, 3.1
I:E ratio	ISO 19223:2019, 3.4.19
immunity	IEC 60601-1-2:2014, 3.8
inspiratory time (t_I)	ISO 19223:2019, 3.4.8
internal electrical power source	IEC 60601-1:2005, 3.45
lay <adj>	IEC 60601-1-11:2015, 3.2
low priority	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.151
manufacturer	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.55
maximum limited pressure	ISO 19223:2019, 3.13.3
ME equipment (medical electrical equipment)	IEC 60601-1:2005, 3.63
ME system (medical electrical system)	IEC 60601-1:2005, 3.64
mechanical hazard	IEC 60601-1:2005, 3.66
medical gas pipeline system	ISO 7396-1:2016, 3.36
model or type reference	IEC 60601-1:2005, 3.66
normal condition	IEC 60601-1:2005, 3.70
normal use	IEC 60601-1:2005, 3.71
operator	IEC 60601-1:2005, 3.73
patient	IEC 60601-1:2005+AMD1:2012, 3.76
primary operating function	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.146
procedure	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.88
process	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.89
processing	ISO 17664:2017, 3.8
PEMS (programmable electrical medical systems)	IEC 60601-1:2005, 3.90
rated <value>	IEC 60601-1:2005, 3.97
residual risk	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.100
responsible organization	IEC 60601-1:2005, 3.101
risk	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.102
risk control	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.105
risk management	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.107
risk management file	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.108
set rate	ISO 19223:2019, 3.5.1.1
single fault condition	IEC 60601-1:2005+AMD1:2012, 3.116
standard temperature and pressure, dry	ISO 80601-2-74:2017, 201.3.220
sterilization	ISO 17664:2017, 3.17
STPD	ISO 80601-2-74:2017, 201.3.220

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Term	*Source*
tool	IEC 60601-1:2005, 3.127
type test	IEC 60601-1:2005, 3.135
usability	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.136
use specification	IEC 62366-1:2015, 3.23
validated	ISO 9000:2015, 3.8.13
verification (verified)	IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.138

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

Bibliography

[1] ISO 4135:—[6], *Anaesthetic and respiratory equipment — Vocabulary and semantics*

[2] ISO 10524 (series), *Pressure regulators for use with medical gases*

[3] ISO 14159, *Safety of machinery Hygiene requirements for the design of machinery*

[4] ISO 18777:2005, *Transportable liquid oxygen systems for medical use — Particular requirements*

[5] ISO 18779:2005, *Medical devices for conserving oxygen and oxygen mixtures — Particular requirements*

[6] ISO 80369-2:—[6], *Small bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

[7] ISO 80601-2-69:2020, *Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

[8] IEC 60695-11-10:2013, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods*

[9] IEC/TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

[10] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. *OJ L 117, Official Journal of the European Union,* pp. 1-175

[11] IMDRF/GRRP WG/N47:2018[7], *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*

[12] IMDRF/GRRP WG/N52:2019[8], *Labeling Principles for Medical Devices and IVD Medical Devices*

[13] BLISS PL, MCCOY RW, ADAMS AB. Characteristics of demand oxygen delivery systems: maximum output and setting recommendations. *Respir Care* 2004, **49**, pp.160–165

[14] KERN R, CUGELL D. Long-term home oxygen treatment for chronic obstructive lung disease. *IM* 1984, **5**, pp.94-10

[15] TIEP BL, CHRISTOPHER KL, SPOFFORD BT, JR GOODMAN, WORLEY PD, MACY SL. Pulsed Nasal and Transtracheal Oxygen Delivery. *Chest* 1990, **97**, pp.364-368

[6] Under preparation. Stage at the time of publication: ISO/CD 80369-2:2020.

[7] Available at http://www.imdrf.org/documents/documents.asp.

[8] Available at http://www.imdrf.org/documents/documents.asp.

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

[16] TIEP BL, LEWIS, MI. O2 Conserving and Conserving Devices in Chronic Lung Disease. *Chest* 1987, **92**, pp.263-272

FOR BIS USE ONLY

© ISO 2020 – All rights reserved

FOR BIS USE ONLY

ICS 11.040.10

Price based on 57 pages

© ISO 2020 – All rights reserved