BS EN ISO 80601-2-67:2020

BSI Standards Publication

Medical electrical equipment

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

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Full document details: BS EN ISO 80601-2-67:2020

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-67:2020. It is identical to ISO 80601-2-67:2020. It supersedes BS EN ISO 18779:2005, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs d'oxygène (ISO 80601-2-67:2020)

Medizinische elektrische Geräte - Teil 2-67: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiergeräten (ISO 80601-2-67:2020)

This European Standard was approved by CEN on 8 October 2020.

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European foreword

This document (EN ISO 80601-2-67:2020) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2021, and conflicting national standards shall be withdrawn at the latest by May 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18779:2005.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-67:2020 has been approved by CEN as EN ISO 80601-2-67:2020 without any modification.

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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).

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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.

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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.

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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.

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Medical electrical equipment —

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

201.1 * Scope, object and related standards

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

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

201.1.1 Scope

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

This document 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.

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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.

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"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.

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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:

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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.

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

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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.

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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:

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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’

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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.

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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*.

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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;

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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.

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