INTERNATIONAL STANDARD

ISO 80601-2-67

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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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

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

ISO/IEC 80601-2-67 was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-67 cancels and replaces the first edition of ISO 18779:2005. This edition of ISO 80601-2-67 constitutes a major technical revision of ISO 18779:2005 and includes an alignment with the third edition of IEC 60601-1, including its Amendment 1, and IEC 60601-1-11.

The most significant changes are the following modifications:

– extending the scope to include not only the CONSERVING EQUIPMENT but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CONSERVING EQUIPMENT;
– identification of ESSENTIAL PERFORMANCE for a CONSERVING EQUIPMENT and its ACCESSORIES;

and the following additions:

– tests for oxygen delivery performance;
– new symbols;
– tests for cleaning and disinfection procedures; and
– consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.1, 201.2);
– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

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

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

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

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 breath cycle, when it is most likely to reach the alveoli. During both the expiratory and pause phase of the breath 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 to 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 requires PATIENT titration to determine the proper setting(s) needed to provide adequate SaO_2 levels for the PATIENT breathing patterns.

This standard is intended to reduce ambiguity between operation of various CONSERVING EQUIPMENT models and CFO by requiring standardized performance testing and labelling.

Medical electrical equipment —

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201.1 Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies, except as follows:

201.1.1 * Scope

IEC 60601-1:2005+A1:2012, 1.1 is replaced by:

This particular standard 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.

NOTE 2 CONSERVING EQUIPMENT can be used with an oxygen concentrator.

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

NOTE 3 CONSERVING EQUIPMENT complying with this particular standard can be incorporated with other devices that have their own standards, in which case the combination needs to comply with both standards.

EXAMPLES CONSERVING EQUIPMENT combined with a pressure regulator [2], an oxygen concentrator [1] or liquid oxygen equipment [6].

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 function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 4 See also 4.2 of the general standard.

This particular standard is a particular standard in the IEC 60601 series of standards.

201.1.2 Object

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

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for CONSERVING EQUIPMENT [as defined in 201.3.201] and its ACCESSORIES.

NOTE ACCESSORIES are included because ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of CONSERVING EQUIPMENT.

201.1.3 Collateral standards

IEC 60601-1:2005+A1:2012, 1.3 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and 201.2 of this particular standard.

IEC 60601-1-3:2008 does not apply.

201.1.4 Particular standards

IEC 60601-1:2005+A1:2012, 1.4 is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1:2005+A1:2012 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx represents the final digits of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3.

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

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

201.2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography beginning on page 39.

IEC 60601-1:2005+A1:2012, Clause 2 applies, except as follows:

Replacement:

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

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

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

IEC 60601-1-11:2010, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

Addition:

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

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* +Amendment 1:2010 +Amendment 2:2010

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 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2005, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves* + Amendment 1:2013

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

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

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

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

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2007, IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2010+A1:2013, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-11:2010, IEC 62366:2007+A1:2014, ISO 4135:2001 and the following apply.

NOTE An index of defined terms is found beginning on page 41.

Addition:

201.3.201

CONSERVING EQUIPMENT

ME EQUIPMENT intended to improve the utilization of the oxygen source while providing oxygen therapy intended to maintain the required PATIENT SaO_2

Note to entry: CONSERVING EQUIPMENT can be electrically or pneumatically powered.

201.3.202

CONSERVING EQUIPMENT WITH MONITORING FUNCTION

CONSERVING EQUIPMENT intended 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 has to be in one direction only for proper functioning or PATIENT safety

[SOURCE: ISO 4135:2001, definition 3.1.7, modified—added ACCESSORY and changed must to has to]

201.4 General requirements

IEC 60601-1:2005+A1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+A1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
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	
triggering signal absence 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 202.6.2.1.10 indicates methods of evaluating delivered oxygen as acceptance criteria following specific tests required by this standard.	

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

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

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

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

CONSERVING EQUIPMENT with an OPERATOR-accessible oxygen inlet connector as specified in 201.101.1, shall operate and meet the requirements of this particular standard throughout its RATED

range of input pressure and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

CONSERVING EQUIPMENT with an OPERATOR-accessible oxygen inlet connector that complies with 5.8 of ISO 80369-1:2010 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 compliance 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.

201.4.11.101.2 Compatibility requirement

If CONSERVING EQUIPMENT is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2007 then:

– the RATED range of input pressure shall cover the range specified in ISO 7396-1:2007; and

– 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 compliance 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.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT

201.5.101.1 CONSERVING EQUIPMENT test conditions

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. When using a substitute gas, care should be taken to ensure that the test gas has the minimum oxygen concentration, maximum water content and the maximum oil content specified for NORMAL USE.

201.5.101.2 * Gas flowrate specifications

In this standard, 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 1 For the purposes of this standard, 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

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 * ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+A1:2012, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+A1:2012, 7.1.2 applies, except as follows:

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

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

Additional subclauses: