
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.

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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+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 SaO₂

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:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101 and shall be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the CONSERVING EQUIPMENT, if applicable. If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.13.101 Additional requirements for physiological effects

Any natural rubber latex-containing components in the gas pathways or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.4.5 from ISO 15223-1:2012, (Table 201.D.1.101, symbol 3) may be used. The instructions for use shall also disclose any natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages shall be CLEARLY LEGIBLE and shall be marked as follows:

- a) with a description of the contents;
- b) with an identification reference to the batch, type or serial number or one of symbol 5.1.5 or symbol 5.1.7 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 1 or symbol 2);
- c) with, for packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 3).

For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE.

Check compliance by inspection.

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

The marking of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

- a) any particular storage and/or handling instructions;
- b) any particular warnings and/or precautions relevant to the immediate operation of the CONSERVING EQUIPMENT.

If applicable, the marking of OPERATOR-accessible ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

- c) for gas-specific inputs,
 - the gas name or chemical symbol for oxygen in accordance with ISO 5359:2008;
 - gas-specific colour coding for oxygen in accordance with ISO 32:1977, if colour coding is used;

EXAMPLES For flow controls, flexible hoses, gas cylinders.

NOTE In some countries, other colour coding is used.

- d) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL.

The marking of the oxygen delivery control shall not only be numeric and the marking shall be such that the minimum and the maximum settings are self-evident to the OPERATOR.

Check compliance by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+A1:2012, 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 standard, STPD is 101,3 kPa at an operating temperature of 20 °C, dry.

201.7.9.1 Additional general requirements

IEC 60601-1:2005+A1:2012, 7.9.1 applies, except as follows:

Amendment (replace the first dash with):

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

201.7.9.2 Instructions for use

IEC 60601-1:2005+A1:2012, 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) 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;
- b) a description of the principles of operation of the CONSERVING EQUIPMENT, including the principles of oxygen dosage, timing, triggering and the settings thereof;
- c) if a manual control of the sensitivity is provided, instructions as to how to adjust the control for optimal breath detection;
- d) a pneumatic diagram of the CONSERVING EQUIPMENT, including a diagram for OPERATOR-detachable parts either supplied or recommended in the instructions for use;

- e) a statement to the effect that the responsible organization
 - should ensure the compatibility of the oxygen conserving equipment and all of the parts and accessories used to connect to the patient before use,
 - 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
 - should periodically reassess the setting(s) of the therapy for effectiveness.

Check compliance by inspection.

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
 - be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
 - be used with the specific combination of parts and accessories that are in line with the specification of the 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 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.

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 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 of 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.”

Check compliance by inspection of the instructions for use.

201.7.9.2.5.101 Additional requirements for ME EQUIPMENT description

The instructions for use shall include the following.

- 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 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 breathing frequency.
- 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.
- g) The necessary application ACCESSORIES and their specifications.
EXAMPLE Only for use with a nasal cannula suitable for use between 5 l/min to 10 l/min and less than 1,5 m length.
- h) An indication as to whether the CONSERVING EQUIPMENT is intended for use with a tracheotomised PATIENT.

Check compliance by inspection of the instructions for use.

201.7.9.2.8.101 Additional requirements for start-up PROCEDURE

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

The instructions for use shall disclose how the OPERATOR can check for proper operation of the CONSERVING EQUIPMENT.

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. 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 check the ALARM SIGNALS.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use of CONSERVING EQUIPMENT shall include an explanation of the meaning of the IP classification marked on the ME EQUIPMENT.

If applicable, the instructions for use shall include the procedure necessary to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

Check compliance by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

IEC 60601-1:2005+A1:2012, 7.9.2.12 applies, except as follows:

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

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

Additional subclauses:

201.7.9.2.13.101 Additional 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.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use shall disclose:

- a) the intended source of oxygen.

EXAMPLE 1 Transportable liquid oxygen equipment, gaseous oxygen supply or oxygen concentrator.

If applicable, the instructions for use shall disclose

- b) any restrictions on the positioning of components within the CONSERVING EQUIPMENT;

EXAMPLE 2 Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

- c) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the CONSERVING EQUIPMENT.

EXAMPLE 3 Use of a paediatric cannula on an adult PATIENT.

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

201.7.9.3.1 General

IEC 60601-1:2005+A1:2012, 7.9.3.1 applies, except as follows:

Amendment: (add as a ninth list element)

- 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 standard, if not performed automatically during start-up and which checks are performed automatically.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+A1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+A1:2012, Clause 11 applies, except as follows:

Additional subclause:

201.11.2.101 * Additional requirements for fire prevention

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. This means shall not be detachable by the OPERATOR without the use of a TOOL.

EXAMPLES An integral humidifier or a humidifier mounted on the CONSERVING EQUIPMENT ENCLOSURE.

Check compliance by inspection and the following test.

- a) For CONSERVING EQUIPMENT capable of delivering oxygen in a continuous mode, set the CONSERVING EQUIPMENT to the maximum continuous flow rate of NORMAL USE, with ACCESSORY connection tubing of approximately 2 m length connected to the outlet connector. For CONSERVING EQUIPMENT not capable of delivering oxygen in a continuous mode, go to step e).
- b) Wait for steady-state conditions to be achieved.
- c) Ignite the ACCESSORY connection tubing or cannula at the end opposite to the outlet connector.
- d) Observe the fire propagating along the connecting tubing to towards the CONSERVING EQUIPMENT and verify that the fire is not propagating back through the outlet connector into the CONSERVING EQUIPMENT or ACCESSORY.

NOTE 1 A fire that does not propagate along the tubing (i.e. it extinguishes) is considered a passing test.

- e) Set the CONSERVING EQUIPMENT to the maximum demand flow rate setting of NORMAL USE and triggered at a frequency of 20 breath/min. Perform steps b) to d).

NOTE 2 The triggering can be accomplished by using a test nose that provides the triggering signal.

201.11.6.4 Leakage

Amendment (add after existing text):

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

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

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

Gas pathways through the CONSERVING EQUIPMENT and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow dismantling for cleaning and disinfection or cleaning and sterilization (additional requirements are found in 11.6.7 of IEC 60601-1:2005+A1:2012). Dismantling may be used.

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

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.

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

NOTE ISO 14159 provides guidance for the design of ENCLOSURES.

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

201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are found in also IEC 60601-1:2005+A1:2012, 11.6.6.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+A1:2012, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls of a CONSERVING EQUIPMENT shall be CLEARLY LEGIBLE under the conditions specified in the general standard, 7.1.2.

Check compliance by application of the tests of IEC 60601-1:2005+A1:2012, 7.1.2.

Additional subclauses:

201.12.1.101 * VERIFICATION of oxygen delivery

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. Additionally, the deviation of delivered oxygen volume per breath shall be disclosed in the instructions for use. This deviation shall not exceed $\pm 15\%$.

EXAMPLE $\pm (1 \text{ ml/breath} + 10\% \text{ of the set initial value/breath}).$

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.

The VERIFICATION of oxygen delivery of the CONSERVING EQUIPMENT shall either be:

- determined for each CONSERVING EQUIPMENT configuration indicated in the instructions for use; or
- determined for the worst case configurations indicated in the instructions for use.

If a worst case configuration is used, the rationale for its selection shall be documented in the RISK MANAGEMENT FILE.

Pneumatic inspiratory trigger sensitivity under the test conditions specified in this standard shall be disclosed in the technical description. If provided, non-pneumatic inspiratory trigger sensitivity and test methods shall be disclosed in the technical description. Additional sensitivity specifications and test methods may be disclosed in the technical description.

Check compliance by inspection of the technical description and of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the following tests:

a) Delivered oxygen setting

- 1) *Set up the CONSERVING EQUIPMENT as shown in Figure 201.101.*
- 2) *Utilize the test parameters and settings of the first row of Table 201.102. Wait for steady-state conditions to be achieved.*

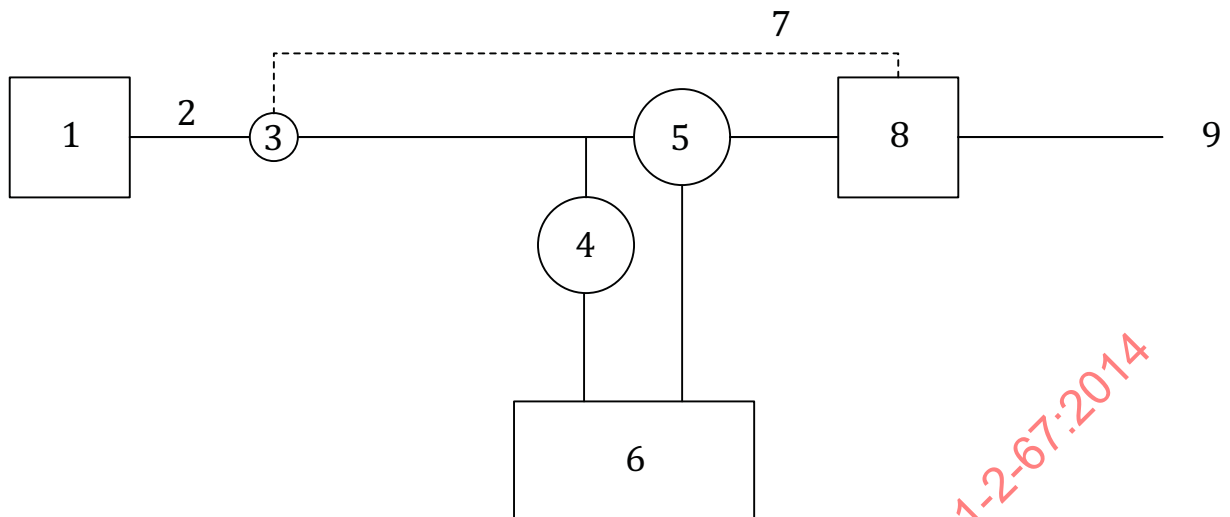
NOTE Some CONSERVING EQUIPMENT, particularly at higher breath rates and when connected to an oxygen concentrator, can take more than 15 min to achieve steady-state conditions.

- 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 delivery setting.*

b) Inspiratory trigger sensitivity

The sensitivity of the CONSERVING EQUIPMENT triggering is evaluated by creating a ramping negative pressure on the cannula of -0,5 cmH₂O per second.

- 8) *Measure the minimum pressure achieved immediately before the onset of gas flow.*
- 9) *Verify that the trigger pressure is less than the value indicated in the technical description.*
- 10) *Repeat 8) and 9) for 10 breaths and average the 10 measurements.*



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 minimum sample rate of 200 samples/s
- 7 optional dual lumen connection for cannula trigger lumen
- 8 trigger source as specified by the MANUFACTURER
- 9 exhaust port

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

Figure 201.101 — VERIFICATION of oxygen delivery, typical test setup

Table 201.102 — VERIFICATION of oxygen delivery test parameters

Breathing frequency min ⁻¹	INSPIRATORY TIME s	Delivered oxygen capture time 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
The delivered oxygen capture time begins at the start of inspiration and ends at the indicated time.		

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Absence of a detected PATIENT breath ALARM CONDITION

CONSERVING EQUIPMENT WITH MONITORING FUNCTION shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate the absence of a PATIENT breath for more than 15 s. The absence of a PATIENT breath ALARM CONDITION shall be at least LOW PRIORITY with an auditory ALARM SIGNAL.

Check compliance by functional testing.

201.12.4.102 Gas supply failure ALARM CONDITION

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. The gas supply failure ALARM CONDITION shall be at least LOW PRIORITY with an auditory ALARM SIGNAL.

Check compliance by functional testing.

201.12.101 * Protection against accidental adjustments

Means of protection against accidental adjustment of controls shall be provided, including accidental turning off of the CONSERVING EQUIPMENT. The USABILITY of these means of protection shall be evaluated in the USABILITY ENGINEERING PROCESS.

NOTE The requirements for the USABILITY ENGINEERING PROCESS are found in IEC 60601-1:2005+A1:2012, 12.2 and IEC 60601-1-6:2010+A1:2013.

Check compliance by functional testing and inspection of USABILITY ENGINEERING FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005+A1:2012, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+A1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 15 applies, except as follows:

Additional subclauses:

201.15.101 Mode of operation

CONSERVING EQUIPMENT shall be suitable for CONTINUOUS OPERATION.

Check compliance by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005+A1:2012, 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 compliance by application of the relevant tests of IEC 60601-1:2005+A1:2012.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 17 applies.

New clauses:

201.101 Gas connections

201.101.1 Oxygen inlet connector

An oxygen inlet connector of the CONSERVING EQUIPMENT that is OPERATOR-accessible without the use of a TOOL shall comply with ISO 80369-1:2010.

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

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

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 comply with ISO 5359:2008.

Check compliance by application of the tests of ISO 5359:2008.

201.101.3 Outlet connector

An outlet connector of the CONSERVING EQUIPMENT that is OPERATOR-accessible without the use of a TOOL shall comply with ISO 80369-1:2010.

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

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

201.102 Requirements for parts and ACCESSORIES

201.102.1 * General

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

Check compliance by the tests of this standard.

201.102.2 Labelling

The range of oxygen flows for which ACCESSORIES are RATED for shall be disclosed in the ACCOMPANYING DOCUMENT.

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

Statements shall be included in the ACCOMPANYING DOCUMENT of each CONSERVING EQUIPMENT, part and ACCESSORY to the effect that:

- a) Oxygen conserving equipment, its parts and accessories are specified for use at specific flows.
- b) Incompatible parts or accessories can result in degraded performance.
- c) The responsible organization is accountable for ensuring the compatibility of the oxygen conserving equipment and all of the parts or accessories used to connect to the patient before use.
- d) 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 or oil based lotions or salves to avoid the risk of fire and burns."
- e) 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."
- f) 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 compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 * Fire RISK reduction in ACCESSORIES

The APPLIED PART that delivers gas to the PATIENT from CONSERVING EQUIPMENT shall be equipped with a means to stop the flow of gas towards the PATIENT in the case that the APPLIED PART becomes ignited. The means of protection should be located as close to the PATIENT as practicable. The means may be accomplished by having the CONSERVING EQUIPMENT stop the flow of gas when the APPLIED PART becomes ignited.

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

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

NOTE 2 Additional fire prevention requirements are found in 201.11.2.101.

Check compliance by inspection and the following test.

- a) Connect the ACCESSORY under test to the outlet connector of an oxygen source.

NOTE 3 The oxygen source can be the CONSERVING EQUIPMENT.

- b) Set the oxygen source to deliver a continuous flow rate of $10 \text{ l/min} \pm 1 \text{ l/min}$ or at the maximum flow setting of the CONSERVING EQUIPMENT through the ACCESSORY.
- c) Ignite the ACCESSORY under test at the end opposite to the outlet connector of the oxygen source.
- d) Observe the fire propagating along the ACCESSORY towards the oxygen source and verify that the flow of oxygen is stopped when the fire reaches the means to stop the flow, and that the fire is not propagated through the means towards the oxygen source.

NOTE 4 A fire that does not propagate along the tubing (i.e. it extinguishes) is considered a passing test.

201.103 Oxygen pressure regulators

Oxygen pressure regulators integral with the CONSERVING EQUIPMENT shall comply with ISO 10524-1:2006 or ISO 10524-3:2005+A1:2013, as appropriate.

Check compliance by inspection and application of the tests of ISO 10524-1:2006 or ISO 10524-3:2005+A1:2013.

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

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

202.6.2.1.10 * Compliance criteria

Subclause 6.2.1.10 of IEC 60601-1-2:2007 is replaced by:

Under the test conditions specified in 6.2 of IEC 60601-1-2:2007, CONSERVING EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE while delivering oxygen through a cannula using the conditions and parameters of Table 201.102. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:

- component failures;
- changes in programmable parameters or settings;
- reset to default settings;
- change of operating mode;
EXAMPLE Switch-over to continuous flow.
- initiation of an unintended operation; and
- deviation of the delivered oxygen dose, greater than 15 %, averaged over a one minute interval.

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

IEC 60601-1-6:2010+A1:2013 applies except as follows:

For CONSERVING EQUIPMENT, the following shall be considered PRIMARY OPERATING FUNCTIONS:

- a) setting the delivered oxygen control;
- b) configuring the CONSERVING EQUIPMENT, including connection of the detachable parts to the CONSERVING EQUIPMENT;
- c) starting the CONSERVING EQUIPMENT from power off; and
- d) turning off the CONSERVING EQUIPMENT.

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

- e) switchover to continuous flow;
- f) setting the OPERATOR-adjustable controls;
 - setting ALARM LIMITS;
 - inactivating ALARM SIGNALS.

The following actions associated with oxygen delivery also shall be considered PRIMARY OPERATING FUNCTIONS even though they are not performed on the CONSERVING EQUIPMENT:

- g) positioning the cannula on the PATIENT.

208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+A1:2012 applies.

211 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2010 applies.

Annexes of the general standard apply, except as follows.

Annex A (informative)

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

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

Additional requirements for marking on the outside of 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, if applicable	201.11.6.4
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, if applicable	201.11.6.4
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)

201.C.2 ACCOMPANYING DOCUMENTS, general

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
CONSERVING EQUIPMENT is a high flow device warning, if applicable	201.4.11.101.2 3) iii)
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, warning statement regarding use of lotions and salves	201.102.2 d)
For CONSERVING EQUIPMENT, part and ACCESSORY, warning statement regarding the risk of fire	201.102.2 e)
For CONSERVING EQUIPMENT, part and ACCESSORY, 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 measure for volumes, flows and leakages	201.7.4.3

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for information to be included in the instructions for use of 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
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, information on RESIDUAL RISKS for treatment of children or that of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.6.4
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 or reprocessing the CONSERVING EQUIPMENT and its ACCESSORIES	201.11.6.6
Intended source of oxygen	201.7.9.2.14.101 a)

Table 201.C.103 — (continued)

Description of requirement	Subclause
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)
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)

Table 201.C.103 — (continued)

Description of requirement	Subclause
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, 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)
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

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 standard 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

Annex B (informative)

Symbols on marking

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

Addition:

Table 201.D.1.101 — Additional symbols on marking

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

Additional Annexes:

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

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

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. The previous standard for CONSERVING EQUIPMENT did not include standardized performance testing and labelling which made comparing the performance of CONSERVING EQUIPMENT difficult. This standard 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 per breath 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 standard 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 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 1000 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 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 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 standard conditions (STPD). Further, most oxygen delivery equipment do 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.

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

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 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 standard 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 a 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 201.7.9.2.16.101 — Additional requirements for reference to the technical description

Instructions for use are often kept as simple as possible so that the OPERATOR can easily find and follow important information. Therefore more technical information, such as required by this subclause, is better placed in the technical description. However, without adequate cross-

referencing, an OPERATOR facing a problem might not be aware that additional information is readily available in a separate document.

Subclause 201.7.9.3.1.101 — 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.

Subclause 201.11.2.101 — Additional requirements for fire prevention

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

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

- by preventing the propagation of fire back through the outlet connector into the 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 201.11.6.6 — Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

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

This means that 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 reprocessing of CONSERVING EQUIPMENT, their ACCESSORIES and parts are based on the general hygiene requirements for the reprocessing of medical devices and need to take into consideration the special requirements and needs of PATIENT care in the clinical environment.^[5] The requirements for hygienic reprocessing of this standard are intended to:

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

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

It should be noted that CONSERVING EQUIPMENT, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for