
**Medical devices for conserving oxygen
and oxygen mixtures — Particular
requirements**

*Économiseurs médicaux d'oxygène et de mélanges oxygénés —
Exigences particulières*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 18779 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

This International Standard specifies requirements for oxygen and oxygen mixture saving devices (called here conserving devices) that are used to supply respiratory gases during therapy.

These devices are for domiciliary use only.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a requirement and to identify the hazards that the requirement addresses.

Clauses and subclauses marked with an asterisk (*) after their number have a corresponding rationale contained in Annex AA.

This International Standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical electrical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

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To facilitate the use of this International Standard, the following drafting conventions have been applied.

This International Standard uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

- “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this International Standard.
- “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.
- “Amendment” means that an existing element of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- notes and examples: smaller roman type;

- description of type of document change and test methods: *italic type*;
- terms defined in the General Standard IEC 60601-1:1988, Clause 2, or in this Particular Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

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Medical devices for conserving oxygen and oxygen mixtures — Particular requirements

1 * Scope

IEC 60601-1:1988, Clause 1, applies except as follows:

Amendment (add at end of 1.1):

1.1

This International Standard specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices¹⁾ are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the **patient's** demand when used in home care applications. These devices are generally used without continual professional supervision.

These devices are also used in health care facilities/institutions.

This International Standard covers two types of conserving devices (see 3.5 and 3.6): **conserving devices intended for continuous use** and those not intended for continuous use.

This International Standard covers active devices only, e.g. pneumatically or electrically controlled devices, and does not cover devices such as reservoir cannulas.

This International Standard also includes conserving devices which are part of a system, e.g. pressure regulators, oxygen concentrators or liquid oxygen vessels.

The requirements of this International Standard which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

1.4

Addition:

NOTE Planning and design of products complying with this International Standard can have environmental impact during the product life cycle. Environmental aspects are addressed in Annex BB. Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

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

1) Referred to as “conserving devices” throughout the document.

EN 980:2003, *Graphical symbols for use in the labelling of medical devices*

EN 1041:1998, *Information supplied by the manufacturer with medical devices*

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

EN 13544-2:2003, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 60601-1:1988 + A1:1991 + A2:1995 and corrigendum 1995 mod), *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60529:2001, *Degree of protection provided by enclosures (IP code)*

IEC 60068-2-32:1975, *Environmental testing — Part 2: Tests — Test Ed: Free fall. (A 1:1982 + A 2:1990)*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration broad-band random (digital control) and guidance*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Methods of test for ignition temperature*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:1988, ISO 4135 and the following apply.

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3.1 accuracy
quality that characterizes the ability of the conserving device to give indications approximating to the true value of the quantity measured

3.2 applied part
part of the conserving device intended to be connected to the **patient** and which in **normal use**:

- necessarily comes into physical contact with the **patient** for the conserving device to perform its function or
- can be brought into contact with the **patient** or
- needs to be touched by the **patient**

3.3 expected service life
period during which the performance of the conserving device or any of its components is expected to meet the requirements of this International Standard when used and maintained according to the **accompanying documents**

3.4 shelf life
period during which the conserving devices or any of its components are stored in its original container under conditions in accordance with the **accompanying documents**

3.5**device for conserving oxygen and oxygen mixtures**²⁾

portable device intended to increase the efficiency of the delivery of oxygen or oxygen mixtures to **patients**

3.6**conserving devices intended for continuous use**

conserving device that includes means to ensure that the health of the **patient** will not be compromised by a **single fault condition** or by the failure of oxygen or oxygen mixture supply

4 General requirements and general requirements for tests

IEC 60601-1:1988, Clauses 3 and 4 apply, except as follows:

Additions:

3.1 No safety hazard in normal use and in single fault condition

Add at the end of the subclause.

A **conserving device intended for continuous use** which fails to perform its function during **normal use** and under **single fault conditions** without appropriate alarm is considered to present a **safety hazard**.

4.101 Other test methods

Test methods other than those specified in this International Standard, but of equal or greater **accuracy** may be used to verify compliance with requirements.

5 Classification

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IEC 60601-1:1988, Clause 5 applies, except as follows:

Replacement:

5.2 Applied part classification

The equipment and its **applied parts** shall be classified as type BF or type CF.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6 applies, except as follows

Addition:

Information and marking shall comply with EN 980 and EN 1041.

2) Referred to as “conserving devices” throughout the document.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

- d) if the size of the conserving device does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the conserving device:
- the name of the manufacturer;
 - a serial or lot or batch identifying number;
 - symbol ISO 7000-0434 (or see Table D1, Symbol 14 in of IEC 60601-1:1988).

Additions:

- aa) the manufacturer shall mark the conserving device with a caution to refer the **user** or operator to the **accompanying documents** or symbol ISO 7000-0434 for the expected adverse effects on the performance of the conserving device;
- bb) packages for single use components shall be durably marked with the following words: “single use” or “single **patient** use” or the symbol ISO 7000-1051;
- cc) labels should be clearly legible at a distance of 0,5 m in a range of illumination from 100 lx to 1 500 lx by an individual with a visual acuity of 1 (corrected if necessary);
- dd) labels should be resistant to removal or blurring from disinfectants and other **normal use** of the device;
- ee) on conserving devices for use in health care facilities/institutions only a warning to the effect that: “The device is not for use in home care environment” shall be permanently labelled;
- ff) the conserving device and its parts shall be marked regarding their proper disposal, as adequate.

6.3 Markings of controls and instruments

Additions:

All controls which increase or decrease a function shall be marked with a legible indication to inform the operator which action(s) is (are) required to increase or decrease the controlled function.

Controls should be identified with their associated markings.

6.8 Accompanying documents

Additions:

6.8.2 * Instructions for use

Additions:

6.8.2d) Cleaning, disinfection and sterilization

Addition at the end of the list of items:

- any pre-use cleaning or disinfecting procedures for the conserving device and any accessories including any specific procedure(s) necessary before the conserving device is transferred to another **patient**;
- methods and products for cleaning, disinfecting or sterilizing and the recommended frequencies;
- any limitations on the number of cleaning, disinfecting or sterilizing cycles.