INTERNATIONAL STANDARD

ISO 18779

First edition
2005-02-15

Medical devices for conserving oxygen and oxygen mixtures — Particular requirements

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

Reference number
ISO 18779:2005(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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).

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.

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 (*).

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 devices[1)] 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*

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.

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

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.

6.8.2aa)

Additions:

The instruction for use shall include the following as far as applicable:

NOTE The following requirements are grouped under an appropriate headline as they usually appear in the instructions for use. This has been done for convenience of the people involved in this. This does not mean that the required information in the instructions for use is to be presented in the order as listed below.

1) * Intended use

— a statement of the intended uses (i.e. if it is for continuous use or not, see 3.6) of the conserving device and an explanation on how the conserving device accomplishes that purpose;

— a description of the type(s) of the oxygen source that is to be used (e.g. transportable liquid oxygen system, gaseous oxygen supply or oxygen concentrator).

2) Precautions and hazards

— a warning statement of the hazards associated with oxygen equipment and therapy;

— precautions to minimize the risk of strangulation of the **patient**. This is accomplished by providing instructions for routing of **patient** wires and tubing in the device labelling;

— precautions to minimize hazards due to exposure to toxic materials from the conserving device occasioned by abnormal conditions (see Clause 10);

— the location of all latex-based components;

— advice on other hazards and risks associated with the conserving device;

— a warning statement to the effect that the device and its setting should be used only as prescribed.

3) Conserving device information

— a description of the types of trigger signal (e.g. flow, pressure) that the conserving device is able to recognize;

— a description of the principles of operation of the conserving device, including the principles of oxygen or oxygen mixture dosage, timing and the settings thereof;

— a statement that the setting has to be determined for each **patient** individually with the system to be used and that settings from constant respiratory gases flow application might not be applicable;

— principle of operation, e.g. bolus or constant flow of oxygen and oxygen mixtures delivered to the **patient**;

— range of setting of oxygen and oxygen mixtures delivered to the **patient**;

— **accuracy** of the delivery of respirable gases to the **patient** with regard to the settings;

— range of breathing frequency specified for use;

— range of oxygen and oxygen mixture supply pressures specified for use;

— range of supply flows specified for use;

— range of electrical supply voltage and current specified for use;

— type of battery to be used and expected operating time under the condition(s) specified by the manufacturer;

— if re-chargeable batteries are used, information about the procedure to re-charge and the time necessary to fully re-charge under the condition specified by the manufacturer;

— information on how oxygen and oxygen mixture supply to the **patient** is assured in a case of conserving device failure and the amount of flow delivered to the **patient** under such a condition;

— explanation of the function and meaning of each alarm and indicator provided with the conserving device;

— a statement that the conserving device may not be able to detect all respiratory efforts of the **patient**.

4) Operating information

— clear, simple diagrams and illustrations of the fully assembled and ready-to-operate conserving device;

— steps required to prepare the conserving device for operation;

— the procedure necessary to determine the state of the battery;

— diagrams, illustrations or photos showing proper connection of the **patient** to the conserving device and other equipment;

— proper connection of auxiliary devices;

— description of appropriate warm-up procedures and intervals;

— drawings or photos of all controls, alarms and indicators provided with the conserving device;

— explanation of the use of the controls, alarms and indicators;

— range of operation of the conserving device (e.g. flowrate, bolus setting);

— a step-by-step procedure for checking proper functioning of all controls, indicators and alarms;

— list of error messages, if applicable, their meaning and the corrective steps that can be taken by the operator;

— a trouble shooting guide for use when there are indications of a conserving device malfunction during checkout and/or operation;

— procedures to follow in the event of a conserving device alarm condition;

— warnings concerning the precautions necessary to avoid possible unsafe use of the conserving device;

— connection and proper use of remote alarm units, including recommended placement and the importance of the operator being able to access the **patient** when the alarm is activated;

— legible reproductions of all required labels and hazard warnings on the conserving device;

— description of the circumstances when it might be appropriate to contact the provider of the conserving device;

— information concerning the disposal of the conserving device and its components (e.g. battery).

5) Operator maintenance instructions

— methods and materials for cleaning and disinfecting the conserving device;

— schedule of operator-initiated maintenance including any specific procedure(s) necessary before the conserving device is transferred to another **patient**;

— battery care and maintenance procedures, including instructions for recharging or replacement;

— description of periodic visual safety inspections that should be performed by the operator.

6) Patient information

— a listing of accessories intended to be used for application to the **patient** (e.g. masks or nasal cannulas) recommended by the manufacturer and instructions on how they are fitted to the conserving device;

— checking for proper operation;

— circumstances which might require sensor adjustment (e.g. change of tubing system);

— circumstances related to the use of the conserving device that could cause a hazardous situation (e.g. bio-incompatibility, chemical or thermal injury).

7) Operating environment information

— the ranges of temperature, atmospheric pressure and humidity for operation and for storage;

— the time from switching “ON” to obtaining specified operating performance;

— description of known or recognizable conditions of the environment that can affect the safe and effective operation of the conserving device, including the following items:

  — facility information, including a description of what should be expected if electricity to the conserving device is lost;

  — effects of lint, dust, sun, artificial light, heat or humidity;

  — effects and possible sources of electromagnetic (conducted and radiated) interference;

  — effects and causes of electrostatic discharge;

  — list of other devices that pose potential electrical problems;

  — effects of fluctuation(s) in electrical supply mains or battery voltage;

  — other sources of interference;

  — steps that can be taken by the operator to identify and minimize environmental interference.

8) Service information

— the recommended methods and frequency of routine inspection, testing, calibration, repair and periodic service;

— a list of facilities that provide service, and their locations;

— **expected service life** of the conserving device;

— shelf life and expected service life of sensors;

— information concerning the disposal of the conserving device or components thereof.

6.8.3 Technical description

Additions:

aa) the technical description shall include the following:

— equipment specifications for the conserving device functions that are applicable to the operation and use of the device;

— a statement as to whether or not pacemaker pulse rejection and defibrillator protection are included;

— a description of equipment required for conserving device use and any specifications necessary for sensors, cables, tubing, batteries and any other accessories;

— step-by-step procedures to prepare the conserving device for initial and subsequent use;

— a recommendation to the effect that a risk assessment should be carried out prior to installation to assure proper connection with other equipment;

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

— step-by-step procedures recommended for determining whether the conserving device is susceptible to the levels of electromagnetic interference occurring at the use location, a recommendation to periodically repeat the testing, and recommended action to take if the conserving device fails the test;

— precautions and a schedule of maintenance and calibrations necessary.

6.101 Legibility

Safety indications shall be legible and correctly perceived by an individual with a visual acuity of 1 (corrected if necessary) from a distance of 1 m at a range of illumination of 100 lx to 1 500 lx, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the normal line of sight of the operator.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows:

10.1 Transport and storage

Replacement:

The conserving device (not including the battery) shall be capable, while packed for transport and storage, of being exposed to an environmental temperature range of − 40 °C to + 70 °C and at relative humidity up to 95 %, non-condensing.

After such an exposure, the transportable liquid oxygen system shall meet the requirements of this International Standard and shall remain operational.

10.2.1 Environment

Replacement:

— an ambient temperature range of − 10 °C to + 40 °C;

— a relative humidity range of 15 % to 95 %, non-condensing;

— for conserving devices for hospital use only, IEC 60601-1:1988 applies.

10.2.2 Power supply

When powered from mains voltages, the conserving device should operate within its specification, without changing a voltage selection switch when voltage fluctuation does not exceed ± 20 % of the nominal voltage.

Addition:

10.3 Disposal

Consideration should be given to the disposal of packaging wastes.

11 Not used

IEC 60601-1:1988, Clause 11 applies.

12 Not used

IEC 60601-1:1988, Clause 12 applies.

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies, except as follows:

21.6 Portable and mobile equipment

Addition:

The conserving device is considered to be a portable and mobile piece of equipment and shall be capable of withstanding the stresses caused by rough handling.

Compliance is checked by the tests a) and b) of IEC 60601-1:1988, and its amendments and the following additional tests:

c) mechanical shock

Test the conserving device in accordance with IEC 60068-2-32 shock test (free fall), procedure 1, with the following severity levels:

— height: 1 m;

— number of falls: 2 falls on each face.

After each of these tests, the conserving device shall perform within the manufacturer's specifications and meet the requirements of this International Standard.

d) vibration resistance.

Test the conserving device in accordance with IEC 60068-2-64 broad-band random vibration test, reproducibility medium, with the following severity levels:

— frequency range 10 Hz to 150 Hz;

— acceleration spectral density: 1 $(m/s^2)^2/Hz$ (g^2/Hz) from 10 Hz to 12 Hz, decreasing at a rate of 3 dB per octave from 12 Hz to 150 Hz;

— duration: 30 min on each orthogonal axis.

During each of these tests, visually inspect the conserving device. After each of these tests, the conserving device shall perform within the manufacturer's specifications and meet the requirements of this International Standard.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies, except as follows:

Addition:

Means shall be provided to prevent pressure in excess of the maximum inlet pressure specified by the manufacturer.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

33 Infrared radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultraviolet energy

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

36 Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies.

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 applies.

38 Marking and accompanying documents

IEC 60601-1:1988, Clause 38 applies.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 applies.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

43 * Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows:

43.2 Oxygen enriched atmospheres

Replacement:

In order to reduce the risk to **patients**, other persons or the surroundings due to fire, ignitable material, under normal and **single fault conditions**, shall not at the same time be subjected to conditions in which:

— the temperature of the material is raised to its minimum ignition temperature.

The minimum ignition temperature is determined in accordance with IEC 60079-4, using the oxidizing conditions present under normal and **single fault conditions**.

*Compliance is checked by determining the temperature the material is raised to under normal and **single fault condition**.*

If sparking can occur under normal or **single fault condition**(s), the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal condition(s) with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

IEC 60601-1:1988, Clause 44 applies, except as follows:

Amendment:

44.3 Spillage

The conserving device and its components shall be so constructed that spillage does not wet component parts which, when wetted, can cause a **safety hazard**.

Compliance is checked by the test in 44.3 of IEC 60601-1:1988.

44.6 Ingress of liquids

Amendment:

The enclosures of the conserving device and its components shall be classified as protected against vertical falling water drop in accordance with IEC 60529.

Compliance is checked by the tests of IEC 60529. Following each of these tests visually inspect the device and perform a functional test.

44.7 Cleaning, sterilization and disinfection

Amendment:

All components not specified by the manufacturer as for single **patient** use, which come into contact with the **patient,** shall be capable of being sterilized or disinfected.

*Compliance is checked by a review of the **accompanying documents** for methods of sterilization or disinfection and by inspection of the relevant validation reports.*

44.8 Compatibility with substances used with the equipment

Replacement:

The conserving device and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the conserving device or its components during **normal use**.

Only non-toxic material from the conserving device and its components shall come into contact with the **patient** or the operator during **normal use**.

Any toxic materials listed within national or regional regulations [3)] and any other known toxic materials used in the conserving device shall be packaged in a manner that prevents **patient** and operator contact.

Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during **normal use** or routine procedures.

Compliance is checked by inspection of the relevant validation reports.

The conserving device shall comply with ISO 15001.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

3) See Bibliography.

46 Human errors

IEC 60601-1:1988, Clause 46 applies, except as follows:

Addition:

In order to minimize operator errors and consider human factors in the design of the conserving device, controls that merit the operator's close attention should be arranged close to the operator's line of sight when observing the **patient**.

NOTE 1 Attention is drawn to IEC 60601-1-6 [3].

47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, except as follows:

Addition:

49.101 Backup power

All mains powered **conserving devices intended for continuous use** shall have a battery power backup. The battery power backup shall automatically be activated when the mains power is outside the specified range of the manufacturer, unless the over-current protection has been activated.

The conserving device shall be fully operational within 5 s of the battery backup power being activated.

The battery shall have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 h.

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows:

Addition:

51.101 Accuracy of oxygen or oxygen mixtures delivered to the patient

The amount of oxygen or oxygen mixtures delivered to the **patient** shall be within ± 15 % of the set value as specified by the manufacturer.

NOTE This may be accomplished by a volume tolerance or a flow tolerance given.

Compliance is checked by simulation (until activation of the alarm function where it exists).

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies, except as follows:

56.3

Addition:

56.3aa) Outlet connector

The outlet connector of the conserving device shall be in compliance with EN 13544-2.

56.7 Batteries

Addition to c):

Means shall be provided to determine the state of the battery power supply.

56.10 Actuating parts of controls

Addition to b):

Operator-adjustable-controls shall include a means to prevent unintentional changes from the intended position.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing – Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

101 Additional requirements

101.1 General requirements

A self-test shall be included in the conserving device, for confirmation by the operator, to operate or exercise all visual and auditory **alarm signals** and status indicators each time the conserving device is turned on.

101.2 Constructional requirements

101.2.1 Strangulation protection

Provision shall be made in routing, retention devices, or other means to minimize the risk of strangulation of the **patient** by wires or tubing.

101.2.2 Low battery alarm (if fitted)

Conserving devices intended for continuous use shall have auditory and visual low-battery alarms that are activated at least 15 min, before the battery has insufficient charge remaining to supply power for conserving device operation.

Audio-pausing for the auditory low-battery **alarm signal** shall be provided but the visual low-battery **alarm signal** shall remain activated until the battery is depleted.

101.2.3 Battery compartments

Battery compartments should be designed to prevent the risk of accidentally short-circuiting the battery.

If a **safety hazard** or conserving device malfunction could result from incorrect connection or replacement of a battery, the conserving device shall be designed to prevent incorrect polarity of connection.

101.2.4 Electrical power indicators

A visual indicator shall be provided to indicate that the conserving device is energized.

Such an indicator shall be located conspicuously on the conserving device and shall distinguish between battery power and line power sources when both sources are provided.

If the conserving device incorporates a means for battery charging, a visual indication that the battery is charging shall be provided.

101.3 Alarms

101.3.1 Functional requirements

The **conserving device intended for continuous use** shall be provided with an alarm function with a visual and auditory signal to indicate:

— when inadequate respiratory effort from the **patient** is detected within 15 s;

— when the supply power falls below the value specified by the manufacturer;

— when the supply of respirable gases is below the value specified by the manufacturer.

101.3.2 Alarm signal requirements

101.3.2.1 General alarm signal requirements

An **alarm signal** shall continue to be activated until it is manually reset, unless the condition causing indicator activation resolves.

101.3.2.2 Visual signals

Visual **alarm signals** and status indicators shall be legible at a distance of 1 m, when viewed by an individual with visual acuity of 1 (corrected if necessary), under conditions having a range of illumination from 100 lx to 1 500 lx.

101.3.2.3 Auditory signals

Auditory **alarm signals**, which indicate the need for immediate attention to the **patient**, should be distinct from other types of auditory indicators.

Sound level measured at a distance of 1 m should be at least 65 dB (A-weighted) for conserving devices and 70 dB (A-weighted) for conserving devices intended for use in health care facilities.

Permanently disabling of auditory **alarm signals** shall not be provided.

Except in the case of the low-battery alarm, the activation of an **audio-pause** state of any auditory **alarm signal** shall not exceed 2 min. This activation shall be accompanied by a visual indication of **audio-pause**.

Auditory **alarm signals** may automatically reset if the condition generating the alarm resolves.

101.3.3 * Remote alarms

The remote alarm unit shall not cause a **safety hazard** to the **patient** under **normal conditions** and under **single fault condition**.

The remote alarm unit shall function under **single fault conditions** (see 3.1).

The remote alarm unit shall provide visual and auditory **alarm signals** when an alarm function at the site of the **patient** has been activated and when the unit is unable to detect a signal from the conserving device.

Using a remote alarm unit shall not disable the alarm functions at the conserving device.

The remote alarm unit should provide visual and auditory **alarm signals** when the power is outside the range specified by the manufacturer.

If the conserving device is battery-operated, the remote alarm unit shall have auditory and visual low-battery alarms that are activated at least 15 min before the battery has insufficient charge remaining to supply power for normal operation of the remote alarm unit.

These low-battery alarms shall remain activated until the battery is depleted.

The low-battery alarm shall have a means for **audio-pause** of the auditory low-battery **alarm signal** but not for inactivating the visual low-battery signal.

If the remote alarm unit is line power operated, a battery backup that is automatically activated within 5 s of the line power being outside the range of supply power as specified by the manufacturer shall be provided.

Annexes

IEC 60601-1:1988, Appendices apply, except as follows:

Addition:

The following Annexes are added:

Annex AA
(informative)

Rationale

AA.0 General

This Annex provides a concise rationale for the important requirements of this International Standard and is intended for those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the current requirements will facilitate any revision of this International Standard necessitated by those developments.

The clauses in this Annex have been numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

AA.1 Scope

Over the years oxygen therapy outside the health care facilities/institutions environment has become a regular part of medical treatment. Oxygen concentrators, liquid oxygen and gaseous oxygen supply systems are used in home care applications. Cost considerations and considerations with regard to the achievement of a greater autonomy for the **patient** by using mobile systems led to the development of conserving devices. In the meantime, these systems have become state-of-the art for mobile oxygen therapy and for liquid oxygen and gaseous oxygen supply systems in home care use.

Safety and essential performance considerations with regard to oxygen compatibility, electrical and pneumatic safety, uninterrupted availability of the oxygen supply to the **patient**, alarm functions, compatibility and safety of connections from the oxygen supply source and the **patient** application accessories led to the development of this International Standard.

AA.6.8.2 Instructions for use

The need to know the basic workings of a conserving device, its principles of operation, and many of its detailed specifications should be self-evident. It is important that the operator have all of this information available, and that he/she knows well of any possible adverse effect on the function of the conserving device due to a number of different environmental conditions. It should be equally self-evident that the operator should be provided all instructions necessary to become familiar with the device for proper pre-use check, proper application, proper operation, proper interpretation of alarm, etc. all of which are essential for the **patient**.

AA.6.8.2aa) 1) Intended use

On a case-by-case basis, clinicians should take this definition into consideration when deciding on an appropriate conserving device for a **patient**.

AA.43 Fire prevention

Reports of fire caused by medical electrical equipment are unusual. However, when such fires occur in the health care environment they can have tragic consequences.

The risk of fire is fundamentally determined by the three elements which are necessary in order to start a fire:

— ignitable material (fuel);

— temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of the General Standard, the objective in the design of the equipment must be to ensure that under both normal and **single fault conditions**, and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur, provided it is self-limiting so that no **safety hazard** is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, whilst in environments containing oxidants thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs but there is at present no documented evidence as to the power level at which this might occur for different materials and environments where the potential spark power dissipation deviates from well established safe practice. Therefore, specific spark tests should be conducted simulating the most unfavourable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use, the requirements for minimizing fire risk are based on limitation of temperature and electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen which is given in the American NFPA publication 53M [1] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. Simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous, depending in particular, on the manner in which the power may be dissipated and the proximity and type of any “fuel” present.

It is therefore, now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under **single fault conditions**, in a typical electrical circuit, the possible number of failure modes is very high. In this case full assurance of safety may only be possible with the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under **single fault condition**.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under **single fault condition**.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.101.3.3 Remote alarms

Considering the home care environment without professional supervision, the **patient** depends on the proper functioning of the conserving device and its remote **alarm systems** – if used. Therefore, it was considered necessary to require proper function also under **single fault condition** for both the conserving device and the remote **alarm system**. **Patients** are monitored also by remote **alarm systems**, therefore a failure of the remote **alarm system** also has to be considered a **safety hazard** for the **patient**.

Annex BB
(informative)

Environmental aspects

The environmental impact generated by a **device for conserving oxygen and oxygen mixtures** is mainly isolated to the following occurrences:

— impact at local environment during **normal use**;

— use, cleaning and disposal of consumables during testing and **normal use**;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the life cycle of the **device for conserving oxygen and oxygen mixtures**.

See Table BB.1 for a mapping of the life cycle of a **device for conserving oxygen and oxygen mixtures** related to aspects of the environment.

Table BB.1 — Environmental aspects addressed by clauses of this standard

Environmental aspects (Inputs and outputs)		**Product life cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	1.2	1.2	1.2	1.2
2	Energy consumption	1.2	1.2	1.2 42	—
3	Emission to air	1.2	1.2	1.2 6.8.2.8 36 42 43 44 45 56.7	1.2
4	Emission to water	1.2	1.2	1.2 44	1.2
5	Waste	1.2	1.2 10.1	1.2 6.1 6.8.2 44 56.7	1.2 6.1 6.8.2

Table BB.1 (*continued*)

Environmental aspects (Inputs and outputs)		**Product life cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
6	Noise	—	—	1.2 35 101.3	—
7	Migration of hazardous substances	1.2	—	1.2 6.1 6.8.2 25 44 45 48 56.7	1.2
8	Impacts on soil	—	—	—	1.2 6.8.2
9	Risks to the environment from accidents or misuse	1.2	—	1.2 6.8.2 44 45 56 101.2 101.3	1.2

Annex CC
(informative)

Index of defined terms

Bibliography

[1] NFPA 53M – Fire Hazards in Oxygen-Enriched Atmospheres – 1990 Edition [4)]

[2] IEC 60601-1-2:2001, *Medical electrical equipment — Part 1: General requirements for safety; 2. Collateral standard: Electromagnetic compatibility — requirements and tests*

[3] IEC 60601-1-6, *Medical Electrical Equipment — Part 1-6: General Requirements for Safety — Collateral Standard: Usability*

[4] EN 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

[5] Council Directive 67/548/EEC of 27 June 1967 amended, on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (and more especially Annex I which gives the list of dangerous substances classified in accordance with the provisions of Article 3)

4) Available from the National Fire Protection Association, Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 USA.

ICS 11.040.10

Price based on 25 pages