INTERNATIONAL STANDARD

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Transportable liquid oxygen systems for medical use — Particular requirements

Systèmes transportables d'oxygène liquide à usage médical — 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 18777 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 liquid oxygen systems which are used as a source of supply for oxygen therapy.

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 identifying the hazards that the requirement addresses.

Clauses and subclauses marked with ***** after their number have 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 (*).

Transportable liquid oxygen systems for medical use — Particular requirements

1 Scope

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

Amendments (add at end of 1.1):

1.1

This International Standard specifies requirements for the safety and essential performance of **transportable liquid oxygen systems** which are used as a supply source for oxygen therapy. These devices usually consist of a **portable unit** to be carried by or with the **patient** whilst in use and the vessel used to refill the **portable unit**. These devices are mostly used in home care applications and in health care facilities/institutions. These devices are often used without professional supervision.

Liquid oxygen vessels used as a supply source for oxygen pipeline systems are excluded from this International Standard.

The requirements of this International Standard which replace or modify the requirements of IEC 60601-1:1998 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 Internatinal 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.

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

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

EN 1251-1:2000, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1 000 litres volume — Part 1: Fundamental requirements*

EN 1251-2:2000, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1 000 litres volume — Part 2: Design, fabrication, inspection and testing*

EN 1251-3:2000, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1 000 litres volume — Part 3: Operational requirements*

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

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

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

ISO 18779, *Medical devices for conserving oxygen and oxygen mixtures — Particular requiremenrts*

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

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

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

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

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
applied part
part of the **transportable liquid oxygen system** intended to be connected to the **patient** and which in normal use

— necessarily comes into physical contact with the **patient** for the **transportable liquid oxygen system** to perform its function or

— can be brought into contact with the **patient** or

— needs to be touched by the **patient**.

[Adapted from IEC 60601-1:1988]

3.2
base unit
mobile device that is a vacuum-insulated cryogenic vessel intended to store oxygen and maintain it in the liquid state for the purpose of refilling **portable units** and that can also include an internal vaporizer and a flow control for the direct supply of gaseous oxygen to the **patient**

3.3
expected service life
period during which the performance of the **transportable liquid oxygen system** 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
liquid oxygen transfer connector
connector used to transfer liquid oxygen from the **base unit** to the **portable unit** or to refill the **base unit**

3.5
portable unit
portable device including a vacuum-insulated cryogenic vessel to maintain liquid oxygen at cryogenic temperatures, an internal vaporizer and a flow control to provide gaseous oxygen to the **patient**

3.6
transportable liquid oxygen system
system comprising one or more **portable unit**s and compatible **base units** for oxygen therapy

4 General requirements and general requirements for tests

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

Addition:

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, EN 1041 and EN 1251-1.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

d) if the size of the **portable unit** does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the **portable unit**:

- 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);
- the total weight when full.

Additions:

aa) the manufacturer shall mark the **transportable liquid oxygen system** 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 **transportable liquid oxygen system**;

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 as appropriate;

cc) labels should be clearly legible at a distance of 1 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) the total weight of the **base unit** when full;

ff) the **transportable liquid oxygen system** and its parts shall be marked regarding their proper disposal, as adequate.

6.3 Markings of controls and instruments

Additions:

The control for setting the oxygen delivered to the **patient** shall be clearly marked with regard to flow.

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:

6.8.2 d) cleaning, disinfection and sterilization.

Addition at the end of the list of items:

— any pre-use cleaning or disinfecting procedures for the **transportable liquid oxygen system** and any accessories including any specific procedure(s) necessary before the **transportable liquid oxygen system** is transferred to another **patient**;

— the methods and products for cleaning, disinfecting or sterilizing and the recommended frequencies;

— any limitations on the number of cleaning, disinfecting or sterilizing cycles.

6.8.2 aa)

Additions:

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

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

1) Intended use

— A statement of the intended uses (i.e. purpose) of the **transportable liquid oxygen system** and an explanation on how the **transportable liquid oxygen system** accomplishes that purpose;