BRITISH STANDARD

BS EN ISO 18777:2009

Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)

ICS 11.040.99

BSI British Standards

National foreword

This British Standard is the UK implementation of EN ISO 18777:2009. It is identical to ISO 18777:2005. It supersedes BS EN ISO 18777:2005 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2009.

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Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)

Systèmes transportables d'oxygène liquide à usage médical - Exigences particulières (ISO 18777:2005)

Flüssigsauerstoffsysteme für medizinische Anwendungen - Besondere Anforderungen (ISO 18777:2005)

This European Standard was approved by CEN on 24 February 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 18777:2009: E

Foreword

The text of ISO 18777:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 18777:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18777:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directives.

For relationship with EC Directives, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 18777:2005 has been approved by CEN as a EN ISO 18777:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA. confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA. - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	All	
5	All	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
6	13, 13.2	
6.1	13.1, 13.3, 13.4, 13.5	
6.1, 6.8	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
6.3	10.2, 10.3, 12.8, 12.9	
6.8	13.1, 13.3, 13.4, 13.6	
6.8.2 aa) 2)	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.

6.101	12.9	
7	12.6	
8	12.6	
9	12.6	
10.1	5	
10.2	5	
13	12.6	
14	12.6	
15	12.6	
16	12.6, 12.7	
17	12.6	
18	12.6	
19	12.6	
20	12.6	
21	12.7	
22	12.7	
23	12.7	
24	12.7	
25	12.7	
26	12.7.2, 12.7.3	
27	12.8	
28	12.7	
29	11	
36	9.2, 12.5	
38	13	
39	9.2, 9.3, 12.6, 12.7	
40	9.2, 9.3, 12.6, 12.7	
41	9.2, 9.3, 12.6, 12.7	
42	12.7	
43	9.3, 12.7	
44.3	7.6, 12.6	
44.6	7.6, 12.6	
44.7	8.1	
44.8	7.1, 7.3, 7.5, 9.3	

45	12.7	
46	9, 10, 12.9	
47	12.5	
48	7.1, 7.5	
49	9.2, 12.8	
50	10	
51	10, 12.8	
52	12.1, 12.6, 12.7, 12.8	
53	5	
54	9	
55	9	
56	9	
56.3	9.1	
56.7	12.2	
57	12.6, 12.7	
58	12.6, 12.7	
101.2.1	9.2, 12.8	
101.2.3	12.8	
101.2.4	12.8	
101.2.6	12.8	
101.2.7	12.2	
101.2.8	9.3, 12.6, 12.8	
101.3	12.3, 12.8	

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

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 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 (*).

INTERNATIONAL STANDARD **ISO 18777:2005(E)**

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;

— a description of the principles of operation of the **transportable liquid oxygen system**, including the settings of the **transportable liquid oxygen system**.

2) Precautions and hazards

— A warning with regard to safe handling of oxygen;

— a warning with regard to the effect that the **base unit** or the portable system shall not be positioned within 3 m of any open flame and that the **base unit** and **portable unit** shall not be placed closer than 20 cm from any source of ignition (appropriate examples of sources of ignition should be provided);

— a warning statement to the effect that the room or any other place where the **transportable liquid oxygen system** is refilled or used should be provided with the air exchange necessary to prevent accumulation of oxygen;

— a warning statement to the effect that the **transportable liquid oxygen system** should not be covered;

— a warning statement to the effect that the **transportable liquid oxygen system** should not be used if the liquid oxygen connector of the **portable unit** is not compatible with the **base unit**;

— a statement as to what to do in case of a leak at the **liquid oxygen transfer connector**;

— precautions to minimize hazards due to exposure to toxic materials from the **transportable liquid oxygen system** occasioned by abnormal conditions;

— a warning statement to the effect that transportation or use in public transportation systems might be restricted with a recommendation to consult with the transportation company prior to use the public transportation system.

NOTE This statement might need to be more stringent for air or sea transportation.

— The location of all latex-based components;

— advice of other hazards and risks associated with the **transportable liquid oxygen system**;

— a warning statement to the effect that, the **transportable liquid oxygen system** should be used only as prescribed by the physician;

— an advisory statement to the effect that if continuity of oxygen supply is required, monitoring to ensure an adequate supply of oxygen to the **patient** should be used and/or a secondary oxygen supply should be available all the time during therapy.

3) Information on the transportable liquid oxygen system

— The range of oxygen flow settings delivered to the **patient**;

— the accuracy of the oxygen flow setting;

— the 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(s) specified by the manufacturer;

— information on how oxygen supply to the **patient** is ensured in case of **transportable liquid oxygen system** failure and the flow delivered to the **patient** under that condition;

— an explanation of the function and meaning of each alarm and indicator provided with the **transportable liquid oxygen system**.

4) Operating information

— Clear, simple diagrams and illustrations of the fully assembled and ready-to-operate **transportable liquid oxygen system**;

— the steps required to prepare the **transportable liquid oxygen system** for operation;

— a detailed description including illustrations and diagrams if necessary, of the filling procedure of the **portable unit**;

— an instruction to close the flow control valve when the **transportable liquid oxygen system** is empty;

— a warning statement to the effect that the **base unit** and the **portable unit** should be purged and the **liquid oxygen transfer connector** clean;

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

— diagrams, illustrations or photographs showing associated proper connection of the **patient** to the **transportable liquid oxygen system** and other associated equipment;

— drawings or photographs of all controls, alarms and indicators provided with the **transportable liquid oxygen system**;

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

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

— a graph or a table indicating the duration of oxygen delivery at set flows under the conditions specified by the manufacturer;

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

— a troubleshooting guide for use when there are indications of a **transportable liquid oxygen system** malfunction during checkout and/or operation;

— procedures to follow in the event of a **transportable liquid oxygen system alarm condition**;

— warnings concerning the precautions necessary to avoid possible misoperation or unsafe use of the **transportable liquid oxygen system**;

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

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

— a description of the state of the **transportable liquid oxygen system** when it may be appropriate to contact the health care professional;

— information on how to secure the **portable unit** and the **base unit** during transportation to ensure integrity of the device and to ensure that no spillage of liquid oxygen occurs;

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

5) Operator maintenance instructions

— The methods and materials for cleaning and disinfecting the **transportable liquid oxygen system**;

— a schedule of operator-initiated maintenance including any specific procedure necessary before the **transportable liquid oxygen system** is transferred to another **patient**;

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

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

6) Patient information

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

— the circumstances related to the use of the **transportable liquid oxygen system** 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 storage;

— a description of known or recognizable conditions of the environment that may affect the safe and effective use or operation of the **transportable liquid oxygen system**, including the following items:

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

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

  — the effects and causes of electrostatic discharge;

  — a list of other devices that pose potential electrical problems;

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

  — other sources of interference;

  — the 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 (for the base unit see EN 1251-3);

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

— the **expected service life** of the **transportable liquid oxygen system**;

— the shelf life and **expected service life** of sensors;

— information concerning the disposal of the **transportable liquid oxygen system** or components thereof.

6.8.3 Technical description

Additions:

aa) the technical description shall include the following:

- a description of equipment required for the use of the **transportable liquid oxygen system** and any specifications necessary for cables, tubing, batteries and any other accessories;
- step-by-step procedures to prepare the **transportable liquid oxygen system** for initial and subsequent use;
- a description of how to secure the **transportable liquid oxygen system** for transport including information about the maximum forces the securing system is able to accommodate;
- step-by-step procedures recommended for determining whether the **transportable liquid oxygen system** is susceptible to the levels of electromagnetic interference occurring at the use location, a recommendation to repeat the testing periodically, and the recommended action to be taken if the **transportable liquid oxygen system** fails the test;
- a warning statement to the effect that the base and **portable unit** should be purged with oxygen prior to first being filled with liquid oxygen;
- 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 **transportable liquid oxygen system** (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 for the portable device;

  + 10 °C to + 40 °C for the **base unit**;

— a relative humidity range of:

  15 % to 95 %, non-condensing for the **portable unit**;

  30 % to 75 % non-condensing for the **base unit**.

10.2.2 Power supply

When powered from line voltages, the device should operate within its specification, without changing a voltage selection switch when voltage fluctuation is not exceeding ± 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:

Replacement:

c) carrying handles or grips affixed to the equipment shall withstand loading as described in the following test.

The handle and its means of attachment are subject to a force equal to two times the maximum weight of the equipment in the conditions given in EN 1251-2:2000, Subclause 4.4.4.2.

21.6 Portable and mobile equipment

Addition:

Subclause 4.4 of EN 1251-2:2000 applies.

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, except as follows:

Addition:

The **base unit** shall not overbalance during **normal use including** movement of the **base unit** when tilted through an angle of 15°.

Compliance is checked by application of the test specified in Subclauses 24.3 b), 24.3 c) and 24.3 d) of IEC 60601-1:1988, and its amendments, with an angle of 15°.

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 1,5 × internal working 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, except as follows:

42.3

Replacement:

The temperature of any accessible surfaces of the **transportable liquid oxygen system** with which the **patient** or an operator might come into contact shall not be less than − 10 °C at the lowest temperature specified by the manufacturer for use for the **base unit**, and not less than − 10 °C for the **portable unit** in an ambient temperature of − 5 °C.

Compliance with the requirements of 42.1 and 42.3 is checked by operation of equipment and temperature measurement as described in Clause 42.3 of the General Standard taking into account the temperatures required in the above replacement.

This requirement does not apply to the **liquid oxygen transfer connector**.

NOTE Contact of the **liquid oxygen transfer connector** with the **user** can be prevented by a protective cap.

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 condition, shall not at the same time be subjected to conditions in which:

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

— an oxidant is present.

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

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 **transportable liquid oxygen system** shall be so constructed that water spillage does not wet component parts that, when wetted, may cause a **safety hazard**.

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

44.6 Ingress of liquids

Amendment:

The **liquid oxygen transfer connector** shall be classified at least as protected against vertical falling water drop in accordance with IEC 60529. The classification in accordance with IEC 60529 should be given.

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 ambient air, 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 **transportable liquid oxygen system** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the **transportable liquid oxygen system** or its components during normal use.

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

Any toxic material listed within national or regional regulation [5] and any other known toxic materials used in the 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 **transportable liquid oxygen system** shall comply with ISO 15001.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45, EN 1251-1 and EN 1251-2 apply.

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 **transportable liquid oxygen system**, controls that need 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:

A failure of the mains supply shall not interrupt the supply of oxygen as specified by the manufacturer.

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 over time of oxygen delivered to the patient

The accuracy of the flow of oxygen over time delivered to the **patient** shall be within ± 10 % of the set value or ± 0,5 l/min whichever is greater, under the conditions specified by the manufacturer.

Compliance is checked by recording the flow for a period of 30 min.

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:

Addition:

56.3.aa) Outlet connector

The outlet connector of the **transportable liquid oxygen system** shall be in compliance with EN 13544-2.

56.7 Batteries

Addition to c):

If batteries are fitted, means shall be provided to determine the state of the battery power supply.

56.10 Actuating parts of controls

Addition to b):

Controls of **transportable liquid oxygen system**s intended for home use shall be protected from inadvertent changes or adjustment.

Operator-adjustable-controls used for calibration 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

If an alarm is fitted means shall be provided in the **transportable liquid oxygen system**, to enable the operator to test all visual and auditory alarm signals and status indicators prior to use.

101.2 Constructional requirements

101.2.1 Cryogenic vessel

All cryogenic vessels of the **transportable liquid oxygen system** shall be in compliance with EN 1251-1 and EN 1251-2.

101.2.2 Maximum mass

The **portable unit** when filled to the maximum including any integral device for conserving oxygen shall have a mass of less than 4 kg.

NOTE Any carrying system or bag is not considered to be a part of the **portable unit**.

101.2.3 Spillage of liquid oxygen

The **transportable liquid oxygen system** shall be so constructed that spillage of liquid oxygen does not create a **safety hazard** under normal conditions.

101.2.4 Gas temperature at the outlet

The **transportable liquid oxygen system** shall be so constructed that the gas temperature, at maximum flow and after 2 h of use, at the outlet of the system is not less than 0 °C with 60 % ± 15 % RH.

101.2.5 Conserving device

Any device for conserving oxygen and oxygen mixtures integrated or equipped with the **transportable liquid oxygen system** shall be in compliance with ISO 18779.

101.2.6 Content level indicator of the base unit and of the portable unit

The **base unit** and the portable shall be equipped with a means indicating the content level.

101.2.7 Low battery status indicator

A **transportable liquid oxygen system** intended for use in the home care environment shall have a low battery state indicator that activates before the battery has insufficient charge remaining to supply power for **transportable liquid oxygen system** operation.

101.2.8 Battery compartments

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

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

101.2.9 Condensing water collector

The **portable unit** shall be equipped with means for collecting condensed water.

101.3 Alarms

If an alarm is fitted, the following apply:

101.3.1 Alarm signal requirements

101.3.1.1 General alarm signal requirements

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

101.3.1.2 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.

101.3.1.3 Auditory signals

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

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 15 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.

101.3.2 * 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 should function under **single fault condition** (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 **transportable liquid oxygen system**.

Using a remote alarm unit shall not disable the alarm functions at the **transportable liquid oxygen system**.

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

If the **transportable liquid oxygen system** is battery operated, the remote alarm unit shall have auditory and visual low battery alarms that activate 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 automatically activates within 5 s for 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.1 Scope

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 present 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.

Over the years oxygen therapy outside the healthcare facility/institution environment has become a regular part of medical treatment. Considerations with regard to the achievement of a greater autonomy for the **patient**, by using mobile systems, have led to the development of transportable liquid oxygen vessels. In the meantime, these systems have become state of the art for mobile oxygen therapy and 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**, compatibility and safety of connections from the oxygen supply source and the **patient** application accessories have led to the development of this International Standard.

AA.6.8.2 Instructions for use

The need to know the basic workings of a **transportable liquid oxygen system**, 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 any possible adverse effect on the function of the **transportable liquid oxygen system** due to a number of different environmental conditions. It should be equally self-evident that the operator must be provided with all instructions necessary to become very 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.43 Fire prevention

Reports of fire caused by medical electrical equipment are unusual. However, when such fires occur in the healthcare 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** shall be to ensure that under both normal and single fault conditions, and under the oxidizsing 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 the 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 which 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 deviate from the well established safe practice, therefore, specific spark tests should be conducted simulating the most unfavourable environment which 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 to minimize fire risk are based on limitation of temperature, 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 (3) 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 conditions.

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 conditions.

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.101.3.2 Remote alarms

Considering the home care environment without professional supervision, the **patient** depends on the proper functioning of the **transportable liquid oxygen system** and its remote alarm systems, if used. Therefore, it was considered necessary to require proper function also under **single fault conditions** for both the **transportable liquid oxygen system** and the remote alarm system. **Patients** are also monitored 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 **transportable liquid oxygen system** is mainly restricted to the following occurrences:

— impact at local environment during normal use;

— spillage of liquid oxygen and the very low temperatures caused by this;

— 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 **transportable liquid oxygen system**.

See Table BB.1 for a mapping of the life cycle of a **transportable liquid oxygen system** related to aspects of the environment BB.

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	1.2 —
3	Emission to air	1.2	1.2	1.2 6.8.2 aa) 8) 42 43 44 45 56.7	1.2
4	Emission to water	1.2	1.2	1.2 44	1.2

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
5	Waste	1.2	1.2	1.2 6.1 6.8.2 44 56.7	1.2 6.1 6.8.2
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[1)]

[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)

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

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