SLOVENSKI STANDARD
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Prenosni sistemi tekočega kisika za medicinsko uporabo - 1. del: Splošne in posebne zahteve za osnovne enote (ISO/DIS 18777-1:2024)

Transportable liquid oxygen systems for medical use - Part 1: Common requirements and particular requirements for base units (ISO/DIS 18777-1:2024)

Flüssigsauerstoffsysteme für medizinische Anwendungen - Teil 1: Allgemeine Anforderungen und besondere Anforderungen für Basiseinheiten (ISO/DIS 18777-1:2024)

Systèmes transportables d'oxygène liquide à usage médical - Exigences particulières - Partie 1: unités de base (ISO/DIS 18777-1:2024)

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Transportable liquid oxygen systems for medical use —

Part 1: Common requirements and particular requirements for base units

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121 *Anaesthetic and respiratory equipment* Subcommittee SC 6, *Medical gas supply systems* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition together with ISO 18777-2 cancels and replaces ISO 18777:2005 which has been technically revised.

The main changes are as follows:

- the standard has been split into two parts:
  - Part 1 Common requirements and particular requirements for *base units*; and
  - Part 2 Particular requirements for *Portable units*.
- part 1 includes requirements that are common to both *base units* and *portable units*. Part 2 cross references these common requirements as appropriate;
- the format of the document has been changed from the IEC to the ISO format; and
- requirements for the *transfilling device* have been included.

A list of all parts in the ISO 18777 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Transportable liquid oxygen systems comprise a *base unit* and a *portable unit* for use primarily in home-care applications and without professional supervision. This document specifies requirements that are common to both *base units* and *portable units* and requirements that are specific to *base units.* *Base units* can be used solely to store the liquid oxygen for refilling the *portable unit* or can, if fitted with a flow outlet and *flow control*, also be used to provide a controlled flow of oxygen for inhalation by the patient.

Base units comprise:

- a double-walled vacuum-insulated cryogenic container for storing liquid oxygen (LOX) at approximately –180 °C;
- a content level indicator;
- a heat exchanger to convert liquid oxygen to gaseous oxygen and warming it to ambient temperature;
- a *transfilling device*; and can also include a separate filling connector.

Annex A contains rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a particular requirement to address the identified hazards.

Transportable liquid oxygen systems for medical use — Part 1: common requirements and particular requirements for base units

1 Scope

This document specifies common requirements for transportable liquid oxygen systems and specific requirements for *base units. Base units* are used as a store for liquid oxygen for refilling *portable units*. They can also, if fitted with a flow outlet and *flow control*, be used as a source for the supply of oxygen direct to the patient.

Stationary liquid oxygen systems used for oxygen pipeline supply systems are excluded from this document.

NOTE 1: Throughout this document the term “units” is used where the requirement applies to both *base units* and *portable units.*

NOTE 2: ISO 18777 Part 2 specifies those requirements specific to *portable units*.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 17256:202X[1], *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 21029-1:2018+A1:2019, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1 000 litres volume — Part 1: Design, fabrication, inspection and tests*

ISO 21029-2, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1 000 litres volume — Part 2: Operational requirements*

ISO 23208, *Cryogenic vessels — Cleanliness for cryogenic service*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

ISO 80601-2-67, Medical electrical equipment — Part 2-67: *Particular requirements for basic safety and essential performance of oxygen conserving equipment*

EN 837-1:1998, Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements, and testing

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp
— IEC Electropedia: available at https://www.electropedia.org/

NOTE: the terms defined in clause 3 are delineated throughout this document by *italic font*.

3.1
base unit

transportable vacuum insulated cryogenic vessel for storing liquid oxygen, used for refilling the *portable unit* and can also be used as the supply source for administering oxygen to the patient

3.2

conserving device

device that reduces the amount of oxygen consumed by delivering gas intermittently and synchronized with the patient's inspiratory cycle

Note 1 to entry: Conserving devices can be electrically or pneumatically powered.

[SOURCE: ISO 80601-2-67:202 (201.3.201) modified by replacing equipment/ME equipment with device and conserving with amount of oxygen consumed]

3.3
flow control

means for setting and indicating the flow

3.4
maximum allowable working pressure
MAWP
Ps

maximum effective gauge pressure permissible at the top of the vessel in its normal operating position including the highest effective pressure during filling and discharge

[SOURCE ISO -21029-1:3.17 modified: note 1 to entry deleted)

3.5
portable unit

refillable, vacuum insulated cryogenic vessel for administering a controlled flow of gaseous oxygen to the patient whilst mobile

3.6

transfilling device

device for transferring liquid oxygen from a *base unit* to a *portable unit*

NOTE to entry: *transfilling devices* can also be used as the means to fill *base units* from large liquid oxygen sources.

4 General requirements

4.1 Risk management

4.1.1 Manufacturers shall assess the risks, in accordance with ISO 14971, when the units are transported, stored, installed and operated under normal and single fault conditions and maintained according to the manufacturer's instructions.

Check conformance by inspection of the risk management file.

4.1.2 Any risks identified shall be reduced to an acceptable level.

NOTE 1: A situation in which a fault is not detected is considered a normal condition.

NOTE 2: Annex E lists known hazards that should be taken into account during a risk assessment.

Check conformance by inspection of the risk management file.

4.2 Usability

Manufacturers shall apply a usability engineering process, (e.g. IEC 60601-1-6 and IEC 62366), to assess and mitigate any risks caused by usability problems associated with correct use (i.e. normal use) and use errors.

Check conformance by inspection of the usability engineering file.

4.3 Materials

NOTE: There is rationale for this clause in A.4.3.

4.3.1 Materials, which come in contact with liquid or gaseous oxygen under normal or single fault conditions, shall:

a) be resistant to corrosion;
b) be compatible with oxygen;
c) conform with ISO 15001 and ISO 23208; and
d) if liable to shed particles, shall not be used for highly strained components and parts liable to wear, (e.g. springs)

NOTE 1: Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2: Oxygen compatibility is usually defined as the ability of a material to coexist with oxygen and a moderate ignition source.

NOTE 3: Many materials which do not burn in air will do so in an oxygen-enriched environment, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies to ignite in an oxygen atmosphere. Many such materials can be ignited by friction at a valve seat or by adiabatic compression when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 4: Design considerations and criteria for the selection of metallic and non-metallic materials that are compatible with oxygen are given in Annexes C and D of ISO 15001.

Check conformance by inspection of the technical documentation.

4.3.2 Components with breathing gas pathways shall be evaluated for biocompatibility according to ISO 18562-1. Any identified risks shall be reduced to an acceptable level.

4.3.3 Units and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the unit or its components during normal use.

Check conformance by inspection of the technical documentation.