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Transportable liquid oxygen systems for medical use —

Part 1: Common requirements and particular requirements for base units

Systèmes transportables d'oxygène liquide à usage médical —

Partie 1: Exigences communes et exigences particulières s'appliquant aux unités de base

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Foreword

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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 document 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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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:

— part 1 includes requirements that are common to both *base units* and *portable units*.

— 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 particular 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 requirements for transportable liquid oxygen systems that are common to both *base units* and *portable units* and requirements that are particular to *base units.*

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 - 2 specifies those requirements particular 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 17256:2024, *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, *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*

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 80601-2-67:2020 (201.3.201), modified — “equipment/ME equipment” replaced with “device” and “intended to conserve supplemental oxygen” replaced with “amount of oxygen consumed”.]

3.3
flow control device
FCD
device that indicates the selected flow of a specific gas

[SOURCE: ISO 15002:2023, 3.1[9], modified — Note 1 to entry deleted.]

3.4
maximum allowable working pressure
MAWP
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:—[1)], 3.17, modified — "*Ps*" deleted and 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 1 to entry: *transfilling devices* can also be used as the means to fill *base units* from 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.

1) Under preparation. Stage at the time of publication: ISO/DIS 21029-1:2026.

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 D lists known hazards for use as guidance 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[6] and IEC 62366-1[7]), 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.1.

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 in accordance with ISO 15001:2010;

c) conform with 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 potential source of ignition at an expected pressure and temperature.

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 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 15001:2010.

Check conformance by inspection of the technical file.

4.3.2 Components which come in contact with breathing gas pathways shall be evaluated for biocompatibility in accordance with 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 units or their components during normal use.

Check conformance by inspection of the technical file.

4.4 Environmental conditions

4.4.1 Transport and storage

Units shall conform to the performance requirements of this document after being exposed to the environmental conditions stated by the manufacturer in their instructions for use [see 7.3.1 c)].