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Interested committees:

Title: Draft BS EN ISO 18777-1 Transportable liquid oxygen systems for medical use. Part 1: Common requirements and particular requirements for base units.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 18777-1.2

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*

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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63 **Foreword**

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

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

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 85 expressions related to conformity assessment, as well as information about ISO's adherence to the World
 86 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see
 87 www.iso.org/iso/foreword.html.

88 .

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

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

96 The main changes are as follows:

- 97 — ISO 18777:2005 has been split into two parts:
 - 98 • Part 1 Common requirements and particular requirements for *base units*; and
 - 99 • Part 2 Particular requirements for *Portable units*.
- 100 — part 1 includes requirements that are common to both *base units* and *portable units*. Part 2 cross
 101 references these common requirements as appropriate;
- 102 — requirements for the *transfilling device* have been included.

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

104 Any feedback or questions on this document should be directed to the user's national standards body. A
 105 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 $-180\text{ }^{\circ}\text{C}$;
- 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.

In this document, the following verbal forms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" is used to describe a possibility or capability.

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 17256:202X¹, *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 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 -21029-1:3.17 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 to entry: *transfilling devices* can also be used as the means to fill *base units* from liquid oxygen sources.