International Standard

ISO 18777-1

First edition
2026-02

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

Reference number
ISO 18777-1:2026(en)

© ISO 2026



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 General requirements **2**
4.1 Risk management 2
4.2 Usability 3
4.3 Materials 3
4.4 Environmental conditions 3
4.4.1 Transport and storage 3
4.4.2 Operational 4

5 Design requirements **4**
5.1 Cryogenic vessels 4
5.2 Contents level indication 4
5.3 *Transfilling devices* and filling port connectors 4
5.4 Interoperability between the *base unit* and the *portable unit* 6
5.5 Flow outlets 6
5.6 Oxygen temperature at the flow outlet 6
5.7 *Flow control device* 6
5.8 Pressure at the flow outlet 6
5.9 Oxygen *conserving device* 6
5.10 Venting of gaseous oxygen 6
5.11 Pressure control 7
5.12 Evaporation rate 7
5.13 Leakage 7
5.14 Excessive temperatures of accessible surfaces 7
5.15 Electrical safety 7
5.16 Protection of components and controls 7
5.17 Stability 8
5.18 Battery compartments 8

6 Construction requirements **8**

7 Information to be supplied by the manufacturer **8**
7.1 General 8
7.2 Marking 8
7.3 Instructions for use for the intended user 9
7.3.1 General information 9
7.3.2 Safety information 9
7.3.3 Pre use checks 9
7.3.4 Filling instructions 9
7.3.5 General warning statements 10

Annex A (informative) **Rationale** **11**

Annex B (Normative) **Test Methods** **13**

Annex C (Normative) **Opening sequence between the *base unit transfilling device* and the *portable unit* filling port connector** **17**

Annex D (informative) **Guidance on the requirements in IEC 60601-1 that can be applicable** **18**

Annex E (informative) **Hazard identification for risk management assessment** **21**

Bibliography **22**

© ISO 2026 – All rights reserved

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 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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:

— 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.

© ISO 2026 – All rights reserved

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.

© ISO 2026 – All rights reserved

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 2026 – All rights reserved

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.

© ISO 2026 – All rights reserved