Transportable liquid oxygen systems for medical use - Part 1: Common requirements and particular requirements for base units (ISO 18777-1:2026)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18777-1:2026 sisaldab Euroopa standardi EN ISO 18777-1:2026 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18777-1:2026 consists of the English text of the European standard EN ISO 18777-1:2026.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.03.2026.	Date of Availability of the European standard is 04.03.2026.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Transportable liquid oxygen systems for medical use - Part 1: Common requirements and particular requirements for base units (ISO 18777-1:2026)

Systèmes transportables d'oxygène liquide à usage médical - Partie 1: Exigences communes et exigences particulières s'appliquant aux unités de base (ISO 18777-1:2025)

Flüssigsauerstoffsysteme für medizinische Anwendungen - Teil 1: Allgemeine Anforderungen und besondere Anforderungen für Basiseinheiten (ISO 18777-1:2025)

This European Standard was approved by CEN on 3 January 2026.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 18777-1:2026) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 2026, and conflicting national standards shall be withdrawn at the latest by September 2026.

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

This document supersedes EN ISO 18777:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 18777-1:2026 has been approved by CEN as EN ISO 18777-1:2026 without any modification.

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

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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 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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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.

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.