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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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ISO/DIS 18777-1

Transportable liquid oxygen systems for medical use —

Part 1: Common requirements and particular requirements for base units

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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

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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 documents 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).

75 Attention is drawn to the possibility that some of the elements of this document may be the subject of
76 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any
77 patent rights identified during the development of the document will be in the Introduction and/or on
78 the ISO list of patent declarations received (see www.iso.org/patents).

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

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

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

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

92 The main changes are as follows:

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

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

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

ISO/DIS 18777-1:2024(en)**103 Introduction**

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

110 *Base units* comprise:

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

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

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

122 **1 Scope**

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

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

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

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

132 **2 Normative references**

133 The following documents are referred to in the text in such a way that some or all of their content
 134 constitutes requirements of this document. For dated references, only the edition cited applies.
 135 For undated references, the latest edition of the referenced document (including any
 136 amendments) applies.

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

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

139 ISO 17256:202X¹, *Anaesthetic and respiratory equipment — Respiratory therapy tubing and*
 140 *connectors*

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

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

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

146 ISO 21029-2, *Cryogenic vessels — Transportable vacuum insulated vessels of not more than 1*
 147 *000 litres volume — Part 2: Operational requirements*

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

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

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

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

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155 3 Terms and definitions

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

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

159 — ISO Online browsing platform: available at <https://www.iso.org/obp>

160 — IEC Electropedia: available at <https://www.electropedia.org/>

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

162 3.1

163 base unit

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

166 3.2

167 conserving device

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

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

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

173 3.3

174 flow control

175 means for setting and indicating the flow

176 3.4

177 maximum allowable working pressure

178 MAWP

179 Ps

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

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

183 3.5

184 portable unit

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

187 3.6

188 transfilling device

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

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

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192 4 General requirements

193 4.1 Risk management

194 **4.1.1** Manufacturers shall assess the risks, in accordance with ISO 14971, when the
195 units are transported, stored, installed and operated under normal and single fault conditions
196 and maintained according to the manufacturer's instructions.

197 Check conformance by inspection of the risk management file.

198 **4.1.2** Any risks identified shall be reduced to an acceptable level.

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

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

201 Check conformance by inspection of the risk management file.

202 4.2 Usability

203 Manufacturers shall apply a usability engineering process, (e.g. IEC 60601-1-6 and IEC
204 62366), to assess and mitigate any risks caused by usability problems associated with
205 correct use (i.e. normal use) and use errors.

206 Check conformance by inspection of the usability engineering file.

207 4.3 Materials

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

209 **4.3.1** Materials, which come in contact with liquid or gaseous oxygen under normal or
210 single fault conditions, shall:

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

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

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

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

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

226 Check conformance by inspection of the technical documentation.

227 **4.3.2** Components with breathing gas pathways shall be evaluated for biocompatibility
228 according to ISO 18562-1. Any identified risks shall be reduced to an acceptable level.

229 **4.3.3** Units and parts thereof shall be designed and manufactured to minimize health
230 risks due to substances leached from the unit or its components during normal use.

231 Check conformance by inspection of the technical documentation.