



SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-69:2024
01-november-2024

Medicinska električna oprema - 2-69. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za koncentriranje kisika (ISO/DIS 80601-2-69:2024)

Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (ISO/DIS 80601-2-69:2024)

Medizinische elektrische Geräte - Teil 2-69: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO/DIS 80601-2-69:2024)

Appareils électromédicaux - Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO/DIS 80601-2-69:2024)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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oSIST prEN ISO 80601-2-69:2024 **en,fr,de**



DRAFT International Standard

ISO/DIS 80601-2-69

Medical electrical equipment —

Part 2-69:

Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

*Partie 2-69: Exigences particulières pour la sécurité de base
et les performances essentielles des dispositifs concentrateurs
d'oxygène*

ICS: 11.040.10

ISO/TC 121/SC 3

Secretariat: **ANSI**

Voting begins on:
2024-09-16

Voting terminates on:
2024-12-09

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

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Published in Switzerland

ISO/DIS 80601-2-69:2024(en)

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45 Foreword

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

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

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

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

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

67 This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
68 *equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and
69 Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular*
70 *medical equipment, software, and systems*, in collaboration with the European Committee for
71 Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in
72 accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

73 This third edition cancels and replaces the second edition (ISO 80601-2-69:2020), which has been
74 technically revised.

75 The main changes compared to the previous edition are as follows:

- 76 — updated references, where appropriate;
- 77 — harmonization with ISO 20417, where appropriate;
- 78 — updated uncertainty of measurement requirements;
- 79 — added *marking* requirements for *gas intake port*, external gas sources and MR compatibility;
- 80 — requirements for *processing* of the *enclosure*;
- 81 — added *cybersecurity* recommendations; and
- 82 — updated *connector* requirements.

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- 83 A list of all parts in the ISO and IEC 80601 series can be found on the ISO and IEC websites.
- 84 Any feedback or questions on this document should be directed to the user's national standards body. A
- 85 complete listing of these bodies can be found at www.iso.org/members.html.

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86 Introduction

87 Oxygen supplementation can be part of management of *patients* with chronic, acute-on-chronic or acute
88 respiratory disorders. The amount of supplemental oxygen depends on the individual *patient's* needs
89 under various conditions. The managing healthcare team typically prescribes the endpoint of treatment,
90 for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled
91 by the flowrate.

92 The goal of long-term oxygen therapy is to keep the oxygen saturation above a target value in *patients*
93 that require supplemental oxygen. The flowrate should be adjusted for rest, exertion and sleep to meet
94 the individual *patient's* needs under these various conditions. Ideally, the resting flowrate is adjusted to
95 maintain SpO₂ greater than the target value as indicated by pulse oximetry.

96 Supplemental oxygen is supplied by various sources: *medical gas pipeline systems, oxygen concentrators,*
97 *compressed gas cylinders and liquid oxygen reservoirs. Oxygen concentrators* produce oxygen-enriched
98 air from room air for delivery to a *patient* requiring oxygen therapy. The most common *oxygen*
99 *concentrator* uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air,
100 generating oxygen concentrations of typically 90 % to 96 %. The main component of this type of *oxygen*
101 *concentrator* is the molecular sieve, which adsorbs nitrogen from air to produce a product gas, which is a
102 mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of
103 nitrogen is referred to as the pressure swing adsorption *process*.

104 Long-term oxygen therapy has been demonstrated in randomized, controlled clinical trials to prolong
105 survival in *patients* with chronic respiratory disease and documented hypoxemia. Typical sources of
106 therapeutic long-term oxygen therapy include gaseous oxygen from cylinders or from liquid oxygen and
107 oxygen from an *oxygen concentrator*.

108 In this document, the following print types are used:

- 109 — requirements and definitions: roman type;
- 110 — *test specifications and terms defined in Clause 3 of the general standard, in this particular document or*
111 *as noted: italic type; and*
- 112 — informative material appearing outside of tables, such as notes, examples and references: in smaller type.
113 Normative text of tables is also in a smaller type.

114 In referring to the structure of this document, the term.

- 115 — “clause” means one of the three numbered divisions within the table of contents, inclusive of all
116 subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.); and
- 117 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses
118 of Clause 201).

119 References to clauses within this document are preceded by the term “Clause” followed by the clause
120 number. References to subclauses within this particular document are by number only.

121 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
122 of the conditions is true.

123 For the purposes of this document, the auxiliary verb:

- 124 — “shall” indicates a requirement;

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125 — "should" indicates a requirement;

126 — "may" indicates a permission;

127 — "can" indicates a possibility or capability; and

128 — "must" is used to express an external constraint.

129 Annex C contains a guide to the *marking* and labelling requirements in this document.

130 Annex D contains a summary of the *symbols* referenced in this document.

131 Requirements in this document have been decomposed so that each requirement is uniquely delineated.

132 This is done to support automated requirements tracking .

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134 Medical electrical equipment

135 Part 2-69:

136 Particular requirements for the basic safety and 137 essential performance of oxygen concentrator equipment

138 201.1 Scope, object and related standards

139 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

140 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

141 NOTE 2 The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

142 201.1.1 Scope

143 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.1 is replaced by:

144 This document specifies requirements for the *basic safety* and *essential performance* of an *oxygen*
145 *concentrator* in combination with its *accessories*, hereafter referred to as *ME equipment*, intended to
146 increase the oxygen concentration of gas intended to be delivered to a single *patient*. Such *oxygen*
147 *concentrators* are typically intended for use in the *home healthcare environment* by a single *patient* in
148 various environments including any private and public transportation as well as in commercial aircraft.

149 NOTE 1 Such *oxygen concentrators* can also be used in professional healthcare facilities.

150 This document is applicable to a *transit-operable* and *non-transit-operable oxygen concentrator*. This
151 document is applicable to an *oxygen concentrator* integrated into or used with other medical devices,
152 *ME equipment* or *ME systems*.

153 EXAMPLE 1 An *oxygen concentrator* with integrated *oxygen conserving equipment* function or *humidifier* function.

154 EXAMPLE 2 An *oxygen concentrator* used with a flowmeter stand.

155 EXAMPLE 3 An *oxygen concentrator* as part of an anaesthetic system for use in areas with limited logistical supplies
156 of electricity and anaesthetic gases^[2].

157 EXAMPLE 4 An *oxygen concentrator* with an integrated liquid reservoir function or gas cylinder filling system
158 function.

159 This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to
160 an *oxygen concentrator*, where the characteristics of those *accessories* can affect the *basic safety* or
161 *essential performance* of the *oxygen concentrator*.

162 NOTE 2 Such *accessories* can include, but are not limited to, *masks*, *cannulae*, *extension tubing*, *humidifiers*, *carts*,
163 *carrying cases*, *external power sources* and *oxygen conserving equipment*.

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164 This document does not specify requirements for *oxygen concentrators* for use with a *medical gas pipeline*
165 *system*.

166 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems*
167 *only*, the title and content of that clause or subclause will say so. If that is not the case, the clause or
168 subclause applies both to *ME equipment* and to *ME systems*, as relevant.

169 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope
170 of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of
171 the general standard.

172 NOTE 3 See also 4.2 of the general standard.

173 201.1.2 Object

174 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.2 is replaced by:

175 The object of this document is to establish particular *basic safety* and *essential performance* requirements
176 for an *oxygen concentrator* (as defined in 201.3.238) and its *accessories*.

177 NOTE 1 *Accessories* are included because the combination of the *oxygen concentrator* and the *accessories* needs to
178 be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *oxygen*
179 *concentrator*.

180 NOTE 2 This document has been prepared to address the relevant *essential principles*^[11] and labelling
181 principles^[12] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex BB.

182 NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of
183 ISO 16142-1:2016 as indicated in Annex CC.

184 NOTE 4 This document has been prepared to address the relevant general safety and performance requirements
185 of European regulation (EU) 2017/745^[10] as indicated in Annex DD.

186 201.1.3 Collateral standards

187 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

188 IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and
189 IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206 and 211 respectively.
190 IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published collateral standards in the
191 IEC 60601-1 series apply as published.

192 201.1.4 Particular standards

193 *Replacement:*

194 In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements,
195 and may modify, replace or delete requirements contained in the general standard and collateral
196 standards as appropriate for the particular *ME equipment* under consideration.

197 A requirement of a particular standard takes priority over the general standard.

198 For brevity, IEC 60601-1+AMD1:2012+AMD2:2020 is referred to in this document as the general
199 standard. Collateral standards are referred to by their document number.

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200 The numbering of clauses and subclauses of this document corresponds to that of the general standard
 201 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general
 202 standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the
 203 collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of
 204 the IEC 60601-1-2 collateral standard, 211.4 in this document addresses the content of Clause 4 of the
 205 IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by
 206 the use of the following words.

207 — "Replacement" means that the clause or subclause of the general standard or applicable collateral
 208 standard is replaced completely by the text of this document.

209 — "Addition" means that the text of this document is additional to the requirements of the general
 210 standard or applicable collateral standard.

211 — "Amendment" means that the clause or subclause of the general standard or applicable collateral
 212 standard is amended as indicated by the text of this document.

213 Clauses, subclauses, figures or tables which are additional to those of the general standard are numbered
 214 starting from 201.101. However, due to the fact that definitions in the general standard are numbered
 215 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201.
 216 Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

217 Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting
 218 from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 211 for
 219 IEC 60601-1-11, etc.

220 The term "this document" is used to make reference to the general standard, any applicable collateral
 221 standards and this particular document taken together.

222 Where there is no corresponding clause or subclause in this document, the clause or subclause of the
 223 general standard or applicable collateral standard, although possibly not relevant, applies without
 224 modification; where it is intended that any part of the general standard or applicable collateral standard,
 225 although possibly relevant, is not to be applied, a statement to that effect is given in this document.

226 **201.2 Normative references**

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

230 IEC 60601-1:2005+AMD1:2012+AMD2: 2020, Clause 2 applies, except as follows:

231 *Replacement:*

232 ISO 15223-1:2021, *Medical devices — Symbols to be used with medical device labels, labelling and*
 233 *information to be supplied — Part 1: General requirements*

234 IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

235 *Addition:*

236 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources*
 237 *using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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- 238 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and*
239 *equipment*
- 240 ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
241 *medical gases and vacuum*
- 242 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
243 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
244 *devices*
- 245 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device*
246 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*
- 247 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*
248 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*
- 249 ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
250 *Part 1: Evaluation and testing within a risk management process*
- 251 ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*
- 252 ISO 80601-2-67:—¹, *Medical Electrical Equipment — Part 2-67: Particular requirements for basic safety*
253 *and essential performance of oxygen conserving equipment*
- 254 IEC 60601-1:2005+AMD1:2012+AMD2: 2020, *Medical electrical equipment — Part 1: General*
255 *requirements for basic safety and essential performance*
- 256 IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for*
257 *basic safety and essential performance — Collateral Standard: Electromagnetic disturbances —*
258 *Requirements and tests*
- 259 IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1-8: General*
260 *requirements for basic safety and essential performance — Collateral Standard: General requirements,*
261 *tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
- 262 IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for*
263 *basic safety and essential performance — Collateral standard: Requirements for medical electrical*
264 *equipment and medical electrical systems used in the home healthcare environment*
- 265 IEC 62366-1:2015+AMD1:2020, *Medical devices – Application of usability engineering to medical devices*
- 266 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic*
267 *resonance environment*
- 268 IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the*
269 *electrotechnical sector*
- 270 EN 13544-2:2002+AMD1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

¹ Under preparation. Stage at the time of publication: ISO/DIS 80601-2-67:2024.