# DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-69

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on: **2019-07-25** 

Voting terminates on:

2019-10-17

## Medical electrical equipment —

Part 2-69:

## Particular requirements for 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

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Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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## ISO/CEN PARALLEL PROCESSING



Reference number ISO/DIS 80601-2-69:2019(E)

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Published in Switzerland

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56	INTERNATIONAL ORGANIZATION for STANDARDISATION
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62	essential performance of oxygen concentrator equipment
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64	THE SHOELS
65	FOREWORD Still Back
66	ISO (the International Organization for Standardization) is a worldwide federation of national
67	standards bodies (ISO member bodies). The work of preparing International Standards is
68	normally carried out through ISO technical committees. Each member body interested in a subject
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71	also take part in the work. ISO collaborates closely with the International Electrotechnical
72	Commission (IEC) on all matters of electrotechnical standardization.
73	The procedures used to develop this document and those intended for its further maintenance are
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75	the different types of ISO documents should be noted. This document was drafted in accordance
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81	Any trade name used in this document is information given for the convenience of users and does
82	not constitute an endorsement.
83	ISO 80601-2-69 was prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory
84	equipment, Subcommittee SC 3, Lung ventilators and related equipment, and Technical Committee
85	$\label{eq:lectrical} \mbox{IEC/TC 62, } \textit{Electrical equipment in medical practice, } \mbox{Subcommittee SC D, } \textit{Electrical equipment.} \mbox{ The } \mbox{The } The$
86	draft was circulated for voting to the national bodies of both ISO and IEC.
87	This second edition of ISO 80601-2-69 cancels and replaces the first edition of
00	ISO 80601-2-60-2014. This adition of ISO 80601-2-69 constitutes a technical revision of

- ISO 80601-2-69:2014 and includes an alignment with the fourth edition of IEC 60601-1-2, the 89
- third edition of IEC 60601-1-6, including its Amendment 1, the second edition of IEC 60601-1-8, 90
- including its Amendment 1, and the second edition of IEC 60601-1-11. 91
- The most significant changes are the following modifications: 92
- changes to the low oxygen concentration alarm condition; 93
- changes to the gas outlet connector; 94
- changes to the test method for the filter for the delivered gas; and 95
- reformatted to provide a unique identifier for each requirement. 96

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#### INTRODUCTION 98

Oxygen supplementation can be part of management of patients with chronic, acute-on-chronic or acute respiratory disorders. The amount of supplemental oxygen depends on the individual patient's needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate. 103

- 104 The goal of long-term oxygen therapy is to keep the oxygen saturation above 90 % in patients that require supplemental oxygen. The flowrate should be adjusted for rest, exertion, and sleep to meet 105 the individual patient's needs under these various conditions. Ideally, the resting flowrate is 106 adjusted to maintain  $SpO_2 > 90$  % as indicated by pulse oximetry. 107
- 108 Supplemental oxygen is supplied by various sources: medical gas pipeline systems, oxygen concentrators, compressed gas cylinders and liquid oxygen reservoirs. This document covers the 109 particular requirements for basic safety and essential performance of oxygen concentrators. Oxygen 110 concentrators produce oxygen-enriched air from room air for delivery to a patient requiring 111 oxygen therapy. The most common oxygen concentrator uses molecular sieve beds to filter and 112 concentrate oxygen molecules from the ambient ail, generating oxygen concentrations of typically 113 82 % to 96 %. The main component of this type of oxygen concentrator is the molecular sieve, 114 which adsorbs nitrogen from air to produce a product gas, which is a mixture of typically up to 115 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred 116 to as the pressure swing adsorption process. 117
- Long-term oxygen therapy has been demonstrated in randomized, controlled clinical trials to 118 prolong survival in patients with chronic respiratory disease and documented hypoxemia. Typical 119 sources of therapeutic long-term oxygen therapy include gaseous oxygen from cylinders or from 120 liquid oxygen and oxygen from an oxygen concentrator. 121
- This publication has been drafted in accordance with the ISO/IEC Directives, Part 2. 122
- In this document, the following print types are used: 123
- requirements and definitions: roman type; 124
- test specifications and terms defined in Clause 3 of the general standard, in this document or as 125 noted: italic type; and 126
- 127 informative material appearing outside of tables, such as notes, examples and references: in smaller type. 128 Normative text of tables is also in a smaller type.
- In referring to the structure of this document, the term 129
- "clause" means one of the three numbered divisions within the table of contents, inclusive of 130 all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.); and 131
- 132 "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201). 133
- References to clauses within this document are preceded by the term "Clause" followed by the 134 135 clause number. References to subclauses within this document are by number only.

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- In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any
- combination of the conditions is true.
- The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2.
- For the purposes of this document, the auxiliary verb:
- "shall" means that conformance with a requirement or a test is mandatory for conformance
   with this document;
- "should" means that conformance with a requirement or a test is recommended but is not
   mandatory for conformance with this document;
- "may" is used to describe a permission (e.g., a permissible way to achieve conformance with a
   requirement or test);
- "can" is used to describe a possibility or capability; and
- 147 "must" is used express an external constraint.
- Annex C contains a guide to the marking and labelling requirements in this document.
- Annex D contains a summary of the symbols referenced in this document.
- An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title
- indicates that there is guidance or rationale related to that item in Annex AA.
- This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of standards.

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#### **MEDICAL ELECTRICAL EQUIPMENT -**154 155 Part 2-69: Particular requirements for the basic safety and 156 essential performance of oxygen concentrator equipment 157 \* Scope, object and related standards 201.1 158 159 IEC 60601-1:2005+A1:2012<sup>1</sup>, Clause 1 applies, except as follows: 201.1.1 160 Scope IEC 60601-1:2005+Amendment 1:2012, 1.1 is replaced by: 161 This document specifies requirements for the basic safety and essential performance of an oxygen 162 concentrator in combination with its accessories, hereafter referred to as ME equipment, intended 163 to increase the oxygen concentration of gas intended to be delivered to a single patient. Such 164 oxygen concentrators are typically intended for use in the home healthcare environment, including 165 transit-operable use by a single patient in various environments including any private and public 166 transportation as well as in commercial aircraft. 167 Such an oxygen concentrator can also be used in professional healthcare facilities. 168 This document is applicable to a transit-operable and non-transit-operable oxygen concentrator. 169 This document is applicable to an oxygen concentrator integrated into or used with other medical 170 devices, ME equipment or ME systems? 171 EXAMPLE 1 An oxygen concentrator with integrated oxygen conserving equipment [1] 2 function or humidifier 172 function. 173 EXAMPLE 2 An oxygen concentrator used with a flowmeter stand. EXAMPLE 3 An oxygen concentrator as part of an anaesthetic system for use in areas with limited logistical supplies 175 176 of electricity and anaesthetic gases [2] EXAMPLE 4 An oxygen concentrator with an integrated liquid reservoir function or gas cylinder filling system 177 178 function. This document is also applicable to those accessories intended by their manufacturer to be 179 connected to an oxygen concentrator, where the characteristics of those accessories can affect the 180 181 basic safety or essential performance of the oxygen concentrator.

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

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

the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

The general standard is IEC 60601-1:2005 +AMD1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

<sup>&</sup>lt;sup>2</sup> Figures in square brackets refer to the Bibliography.

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- 187 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the
- scope of this document are not covered by specific requirements in this document except in 7.2.13
- and 8.4.1 of the general standard.
- 190 NOTE 2 See also 4.2 of the General Standard.
- This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of standards.
- 192 **201.1.2 Object**
- 193 IEC 60601-1:2005, 1.2 is replaced by:
- The object of this document is to establish particular basic safety and essential performance
- requirements for an *oxygen concentrator* [as defined in 201.3.202] and its *accessories*.
- 196 NOTE 1 Accessories are included because the combination of the oxygen concentrator and the accessories needs to be
- 197 adequately safe. Accessories can have a significant impact on the basic safety or essential performance of an oxygen
- 198 concentrator.
- 199 NOTE 2 This document has been prepared to address the relevant essential principles of safety and
- 200 performance of ISO 16142-1:2016 as indicated in Annex BB
- 201 NOTE 3 This document has been prepared to address the relevant general safety and performance
- requirements of European regulation (EU) 2017/745 as indicated in Annex CC.
- 203 201.1.3 Collateral standards
- 204 IEC 60601-1:2005+AMD 1:2012, 1.3 applies with the following addition:
- 205 IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013+AMD2:— and IEC 60601-1-11:2015
- apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3  $^{[3]}$  does not apply. All
- other published collateral standards in the IEC 60601-1 series apply as published.
- 208 **201.1.4** Particular standards
- 209 Replacement:
- In the IEC 60601 series, particular standards may modify, replace or delete requirements
- 211 contained in the general standard and collateral standards as appropriate for the particular
- 212 ME equipment under consideration, and may add other basic safety and essential performance
- 213 requirements.
- A requirement of a particular standard takes priority over the general standard.
- For brevity, IEC 60601-1 is referred to in this document as the general standard. Collateral
- standards are referred to by their document number.
- 217 The numbering of clauses and subclauses of this document corresponds to that of the general
- standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of
- the general standard) or applicable collateral standard with the prefix "20x", where x is the final
- digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the
- content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the
- content of Clause 4 of the IEC 60601-1-3 [3] collateral standard, etc.). The changes to the text of the
- general standard are specified by the use of the following words:

- 11 -

- "Replacement" means that the clause or subclause of the general standard or applicable collateral
- standard is replaced completely by the text of this document.
- 226 "Addition" means that the text of this document is additional to the requirements of the general
- 227 standard or applicable collateral standard.
- "Amendment" means that the clause or subclause of the general standard or applicable collateral
- standard is amended as indicated by the text of this document.
- Subclauses, figures or tables which are additional to those of the general standard are numbered
- starting from 201.101. However, due to the fact that definitions in the general standard are
- numbered 3.1 through 3.147, additional definitions in this document are numbered beginning
- from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.
- 234 Subclauses, figures or tables which are additional to those of a collateral standard are numbered
- starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2,
- 236 203 for IEC 6060-1-3 [3], etc.
- The term "this document" is used to make reference to the general standard, any applicable
- collateral standards and this particular document taken together.
- Where there is no corresponding clause or subclause in this document, the clause or subclause of
- the general standard or applicable collateral standard, although possibly not relevant, applies
- 241 without modification; where it is intended that any part of the general standard or applicable
- collateral standard, although possibly relevant is not to be applied, a statement to that effect is
- given in this document.

### 244 **201.2 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.
- 247 For undated references, the latest edition of the referenced document (including any
- 248 amendments) applies.
- 249 NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent
- 250 (in whole or in part) to which they apply.
- NOTE 2 Informative references are listed in the Bibliography.
- 252 IEC 60601-1:2005+AMD 1:2012, Clause 2 applies, except as follows:
- 253 Replacement:
- 254 ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014
- 255 +AMD6:2014+AMD7:2016, Graphical symbols -- Safety colours and safety signs -- Registered
- 256 safety signs
- 257 IEC 60601-1-2:2014, Medical electrical equipment Part 1-2: General requirements for basic
- 258 safety and essential performance Collateral standard: Electromagnetic disturbances —
- 259 Requirements and tests

- 12 -

- IEC 60601-1-6:2010+AMD1:2013, Medical electrical equipment Part 1-6: General requirements
- 261 for basic safety and essential performance Collateral standard: Usability
- IEC 60601-1-8:2006+AMD1:2012, Medical electrical equipment Part 1-8: General requirements
- 263 for basic safety and essential performance Collateral Standard: General requirements, tests and
- 264 guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2015, Medical electrical equipment Part 1-11: General requirements for basic
- 266 safety and essential performance Collateral Standard: Requirements for medical electrical
- 267 equipment and medical electrical systems used in the home healthcare environment
- 268 IEC 61672:2013, Electroacoustics Sound level meters Part 1: Specifications
- 269 Addition:
- 270 ISO 3744:2010, Acoustics -- Determination of sound power levels and sound energy levels of noise
- 271 sources using sound pressure -- Engineering methods for an essentially free field over a reflecting
- 272 plane
- 273 ISO 7396-1:2016, Medical gas pipeline systems -- Part 1: Pipeline systems for compressed medical
- 274 gases and vacuum
- 275 ISO 9000:2015, Quality management systems Fundamentals and vocabulary
- 276 ISO 14937:2009, Sterilization of health care products General requirements for characterization
- of a sterilizing agent and the development, validation and routine control of a sterilization process
- 278 for medical devices
- 279 ISO 15223-1:2016, Medical devices Symbols to be used with medical device labels, labelling and
- information to be supplied Part 1: General requirements
- 281 ISO 16142-1:2016, Medical devices -- Recognized essential principles of safety and performance of
- medical devices -- Part 1: General essential principles and additional specific essential principles for
- all non-IVD medical devices and guidance on the selection of standards
- 284 ISO 17664:2017, Processing of health care products -- Information to be provided by the medical
- 285 device manufacturer for the processing of medical devices
- 286 ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare
- 287 applications -- Part 1: Evaluation and testing within a risk management process
- 288 ISO 19223-1:2019, Lung ventilators and related equipment -- Vocabulary and semantics
- ISO 80601-2-74:2017, Medical electrical equipment Part 2-74: Particular requirements for basic
- 290 safety and essential performance of respiratory humidifying equipment
- ISO 80601-2-67:—<sup>3</sup>, Medical Electrical Equipment Part 2-67: Particular requirements for basic
- 292 safety and essential performance of oxygen conserving equipment
- IEC 60601-1:2005+AMD1:2012, Medical electrical equipment Part 1: General requirements for
- basic safety and essential performance

To be published. Stage at time of publication ISO/DIS 80601-2-67:2019.

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- IEC 62366-1:2015, Medical devices Application of usability engineering to medical devices 295
- EN 13544-2:2002+AMD1:2009, Respiratory therapy equipment Part 2: Tubing and connectors 296
- EN 15986:2011, Symbol for use in the labelling of medical devices Requirements for labelling of 297
- 298 medical devices containing phthalates

#### 201.3 Terms and definitions 299

- For the purposes of this document, the terms and definitions given in ISO 3744:2010, 300
- ISO 7396-1:2016, ISO 9000:2015, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, 301
- 302 ISO 19223:2019, ISO 80601-2-67:—, ISO 80601-2-74:2017, IEC 60601-1:2005+AMD 1:2012,
- IEC 60601-1-2:2014, IEC 60601-1-8:2006+AMD 1:2012, IEC 60601-1-11:2015. 303
- IEC 62366-1:2015 and the following apply. 304
- 305 An index of defined terms is found in Annex DD.
- Addition: 306
- 307 201.3.201
- flow-direction-sensitive component 308
- component or accessory through which gas flow has to be in one direction only for proper 309
- functioning or patient safety 310
- [ISO 4135:2001 [4], definition 3.1.7, modified Added or accessory and replaced 'must' with 'has 311
- 312
- 201.3.202 313
- 314
- oxygen concentrator

  ME equipment, which by selective removal of constituents of ambient air, increases the 315
- concentration of oxygen in the output gas 316
- General requirements M 201.4 317
- IEC 60601-1:2005+AMD 1:2012, Clause 4 applies, except as follows: 318
- 319 201.4.3 Essential performance
- IEC 60601-1:2005+AMD 1:2012, 4.3 applies, except as follows: 320
- Additional subclause: 321
- 201.4.3.101 \* Additional requirements for essential performance 322
- Additional essential performance requirements are found in the subclauses listed in 323
- Table 201.101. 324