



DPC: 24 / 30475056 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 12 March 2024

Origin: International

Latest date for receipt of comments: 3 April 2024

Project No. 2023/01239

Responsible committee: CH/121/9 Lung Ventilators & Related Equipment

Interested committees:

Title: BS EN ISO 80601-2-69 Medical electrical equipment

Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 3 April 2024**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Responsible Committee Secretary: Ms Allie Ives (BSI)

Direct tel:

E-mail: allie.ives@bsigroup.com

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2122/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

ISO 80601-2-69 ED3

DATE OF CIRCULATION:

2024-03-08

CLOSING DATE FOR COMMENTS:

2024-05-03

SUPERSEDES DOCUMENTS:

62D/2054/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

NOTE FROM TC/SC OFFICERS:

This is a joint project with ISO/TC 121/SC 3.

Copyright © 2024 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

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

CD stage

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

© ISO 2024, Published in Switzerland

All rights reserved. Unless otherwise specified, 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
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

1	Contents	
2		
3	Foreword	v
4	Introduction	vii
5	201.1 Scope, object and related standards	1
6	201.2 Normative references	3
7	201.3 Terms and definitions	5
8	201.4 General requirements	17
9	201.5 General requirements for testing of <i>ME equipment</i>	18
10	201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	19
11	201.7 <i>ME equipment</i> identification, <i>marking</i> and documents	19
12	201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	26
13	201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	26
14	201.10 Protection against unwanted and excessive radiation <i>hazards</i>	29
15	201.11 Protection against excessive temperatures and other <i>hazards</i>	29
16	201.12 Accuracy of controls and instruments and protection against hazardous outputs	33
17	201.13 Hazardous situations and fault conditions for <i>ME equipment</i>	39
18	201.14 Programmable electrical medical systems (PEMS)	39
19	201.15 Construction of <i>ME equipment</i>	40
20	201.16 <i>ME systems</i>	40
21	201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	40
22	201.101 Outlet connector	41
23	201.102 Requirements for parts and accessories	41
24	201.103 Functional connection	43
25	201.104 Indication of duration of operation	43
26	201.105 Integrated conserving equipment function	44
27	202 Electromagnetic disturbances – Requirements and tests	44
28	202.4.3.1 Configurations	44
29	206 Usability	45
30	211 Requirements for medical electrical equipment and medical electrical systems used	
31	in the home healthcare environment	46
32	211.4.2.2 Environmental operating conditions	46
33	Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and	
34	<i>ME systems</i>	47
35	Annex D (informative) <i>Symbols on marking</i>	52

36 **Annex AA (informative) Particular guidance and rationale..... 54**

37 **Annex BB (informative) Reference to the IMDRF *essential principles* and labelling**

38 **guidances 63**

39 **Annex CC (informative) Reference to the *essential principles* 68**

40 **Annex DD (informative) Reference to the general safety and performance requirements..... 72**

41 **Annex EE (informative) Terminology — alphabetized index of defined terms..... 76**

42 **Bibliography..... 80**

43

44 **Foreword**

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

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

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

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

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

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

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

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

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

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

Introduction

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.

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

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

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

In this document, the following print types are used:

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

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

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

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

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.

For the purposes of this document, the auxiliary verb:

- “shall” **indicates** a requirement;

- 124 — "should" **indicates** a requirement;
 - 125 — "may" **indicates** a permission;
 - 126 — "can" **indicates** a possibility or capability; and
 - 127 — "must" is used to express an external constraint.
- 128 Annex C contains a guide to the *marking* and labelling requirements in this document.
- 129 Annex D contains a summary of the *symbols* referenced in this document.
- 130 **Requirements in this document have been decomposed so that each requirement is uniquely delineated.**
- 131 **This is done to support automated requirements tracking .**
- 132

Medical electrical equipment

Part 2-69:

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

201.1 Scope, object and related standards

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

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

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

201.1.1 Scope

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

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

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

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

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

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 of electricity and anaesthetic gases^[2].

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

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

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

This document does not specify 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.

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.

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 201.3.220) and its *accessories*.

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

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

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

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

201.1.3 Collateral standards

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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, 211.4 in this document addresses the content of Clause 4 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words.

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

— “Addition” means that the text of this document is additional to the requirements of the general 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.

Clauses, 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.

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, 211 for IEC 60601-1-11, 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 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.

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. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Replacement:

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

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

Addition:

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

- 237 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and*
238 *equipment*
- 239 ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
240 *medical gases and vacuum*
- 241 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
242 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
243 *devices*
- 244 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device*
245 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*
- 246 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*
247 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*
- 248 ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
249 *Part 1: Evaluation and testing within a risk management process*
- 250 ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*
- 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/CD 80601-2-67:2024.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

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

NOTE An index of defined terms is found in Annex EE.

Addition:

201.3.201

accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202

alarm condition delay

time from the occurrence of a triggering event either in the patient, for physiological alarm conditions, or in the equipment, for technical alarm conditions, to when the alarm system determines that an alarm condition exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.203

alarm limit

threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.204

alarm setting

alarm system configuration, including but not limited to:

- *alarm limits*;
- the characteristics of any *alarm signal* inactivation states; and
- the values of variables or parameters that determine the function of the *alarm system*

Note 1 to entry: Some algorithmically-determined *alarm settings* can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.8]

201.3.205

attack

attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset

[SOURCE: IEC 81001-5-1:2021, 3.5]

201.3.206

biocompatibility

ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.

[SOURCE: ISO 18562-1:2024, 3.6]

201.3.207

cleaning

removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]

201.3.208

connector

fitting to join two or more components

EXAMPLE *Connectors for low-pressure hose assembly* are any of a range of mating components intended to maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.209

conserving equipment

ME equipment intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle

Note 1 to entry: *Conserving equipment* can be electrically or pneumatically powered.

[SOURCE: ISO 80601-2-67:2024, 201.3.207]

201.3.210**continuous flow**

gas flowing continuously through the *breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's* inspiratory effort

Note 1 to entry: For the purposes of this document, *ventilator* is taken to include *oxygen concentrator*.

[SOURCE: ISO 19223:2019, 3.7.8, modified — deleted notes and added note 1.]

201.3.211**cybersecurity**

state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1:2021, 3.30]

201.3.212**disinfection**

process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-1:2021, 3.3]

201.3.213**distributed alarm system**

alarm system that involves more than one item of equipment of a *me system* intended for delivery of *alarm conditions* with technical confirmation

Note 1 to entry: The parts of a *distributed alarm system* can be widely separated in distance.

Note 2 to entry: A *distributed alarm system* is intended to notify *operators* of the existence of an *alarm condition*.

Note 3 to entry: Technical confirmation means that each element of a *distributed alarm system* confirms or guarantees the successful delivery of the *alarm condition* to the next element or appropriate *technical alarm conditions* are created.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.17]

201.3.214**emergency medical services environment****EMS environment**

actual conditions and settings, in which *operators* interact with the *ME equipment* or *ME system*, in and around the scene of an emergency outside of a professional healthcare facility where a *patient* can be given medical care, basic or advanced life support as well as during professional transport to a professional healthcare facility or between professional healthcare facilities

EXAMPLE 1 Responding to and providing life support at the scene of an emergency to a *patient* reported as experiencing injury or illness in a pre-hospital setting, and transporting the *patient*, while continuing such life support care, to an appropriate professional healthcare facility for further care.

EXAMPLE 2 Providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

Note 1 to entry: The *EMS environment* is not considered to be part of the *professional healthcare environment*.

Note 2 to entry: Use of equipment intended for the *EMS environment* and temporarily used in the *home healthcare environment* by emergency medical personnel is considered use in the *EMS environment*.

Note 3 to entry: The *operators* of equipment intended for the *EMS environment* are presumed to be *healthcare professional operators*.

Note 4 to entry: Emergency medical services are known by various names in different countries and regions.

Note 5 to entry: Transport includes road, rotary and fixed-wing ambulances.

[SOURCE: IEC 60601-1-12:2014, 3.1, modified —replaced “professional medical personnel or personnel with relevant specialized training” with “*healthcare professional operators*” and replaced original note 3 with new note 1.]

201.3.215 essential function

function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the *manufacturer*, and operational availability for the medical device

Note 1 to entry: *Essential functions* include, but are not limited to, the *safety* instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the *medical device* safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.216 essential principles essential principles of safety and performance

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

201.3.217 exhaust port

port through which exhaust gas is discharged to the atmosphere or to an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.218**firecall**

method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a *firecall* is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as "break glass" feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

201.3.219**flow-direction-sensitive component**

component or *accessory* through which gas flow is in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:—, definition 3.1.7, modified — Added 'or *accessory*' and replaced 'must' with 'is']

201.3.220**gas intake port**

port through which gas is drawn for use by the *patient*

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in opposition to an *inlet*, at which gas is provided by a medical gas supply system.

[SOURCE: ISO 4135:2022, 3.1.4.21, modified — replaced "apposition" with "opposition".]

201.3.221**gas output port**

port of the *ventilator* through which gas is delivered at respiratory pressures to an *operator*-detachable part of a *breathing system*

Note 1 to entry: For the purposes of this document, *ventilator* is taken to include *respiratory high-flow therapy equipment*.

[SOURCE: ISO 19223:2019, 3.14.3, modified — added note.]

201.3.222**gas pathway**

interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

EXAMPLE 1 The *breathing system*, *inlet* filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or *masks* and mouthpieces.

Note 1 to entry: The *gas pathway* is bounded by the fluid ports through which gases or liquids enter the medical device or *accessory*. This can include the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.

Note 3 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

[SOURCE: ISO 18562-1:2024, 3.11, modified — replaced “ports” with “fluid ports”.]

201.3.223

home healthcare environment

dwelling place in which a *patient* lives or other places where *patients* are present, excluding the *professional healthcare environment* and the *EMS environment*

EXAMPLE Other places include in a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Nursing homes are considered *home healthcare environments*.

Note 2 to entry: In some countries, nursing homes are considered *professional healthcare facilities*.

[SOURCE: IEC 60601-1-11:2015, 3.1, modified — deleted notes 1 and 3, modified note 2 as new note 1 and added note 2.]

201.3.224

humidifier

device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, bubble-through and ultrasonic *humidifiers* and active heat and moisture exchangers (HMEs).

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.225

immunity

the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.226

information for safety

information provided to the *operator* or the *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for use* of a medical device or *accessory* to prevent use error or avoid a *hazardous situation*.

EXAMPLE 3 Explanation of a safety feature of a medical device or *accessory*.

Note 1 to entry: *Information for safety* may be included in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a medical device.

[SOURCE: ISO 20417:2021, 3.9, modified — replaced “user” with “operator”.]

201.3.227

information supplied by the manufacturer

information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the user or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

201.3.228

inlet

opening through which gas or other material is pushed by an elevated upstream pressure

[SOURCE: ISO 4135:2022, 3.1.4.26, modified — deleted note.]

201.3.229

inlet connector

connector on an *inlet*

EXAMPLE Connection on a low-flow nasal cannula that connects to the *outlet* of oxygen therapy tubing.

Note 1 to entry: An *inlet connector* can be gas-specific, but this should be indicated with the post-coordinated term gas-specific *inlet connector*.

[SOURCE: ISO 4135:2022, 3.1.4.26.1]

201.3.230

instructions for use

IFU

portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a user can be either a *lay* user or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 4 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 5.]

201.3.231

lay

lay person

<adj> term referring to non-professional or professional without relevant specialized training

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.2]

201.3.232

marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

201.3.233

mask

device which provides a non-invasive interface between the *patient's* airway and a *patient*-connection port or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.234

maximum limited pressure

$P_{lim,max}$

highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 4135:2022, 3.1.4.41.3]

201.3.235

outlet

opening through which gas leaves a device or component

552 [SOURCE: ISO 4135:2022, 3.1.4.40]

553 **201.3.236**

554 **medical gas pipeline system**

555 combination of a supply system, monitoring and *alarm system* and a pipeline distribution system with
556 terminal units for provision of medical gases or vacuum

557 [SOURCE: ISO 4135:2022, 3.2.1.1]

558 **201.3.237**

559 **outlet**

560 opening through which gas leaves a device or component

561 [SOURCE: ISO 4135:2022, 3.1.4.40]

562 **201.3.238**

563 **oxygen concentrator**

564 *ME equipment*, which by selective removal of constituents of ambient air, increases the concentration of
565 oxygen in the output gas

566 **201.3.239**

567 **physiological alarm condition**

568 *alarm condition* arising from a monitored *patient*-related variable

569 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.31]

570 **201.3.240**

571 **processing**

572 activity to prepare a new or used healthcare product for its *intended use*

573 Note 1 to entry: *Processing* includes *cleaning*, *disinfection* and *sterilization*.

574 Note 2 to entry: Healthcare products include medical devices and *accessories*.

575 [SOURCE: ISO 17664-2:2021, 3.10, modified — deleted “(if necessary and applicable)” and added note 2.]

576 **201.3.241**

577 **relative humidity**

578 water vapour pressure, expressed as a percentage of the saturation vapour pressure, at a particular
579 temperature

580 Note 1 to entry: See also *absolute humidity*.

581 [SOURCE: ISO 4135:2022, 3.1.2.4]

201.3.242**security level**

level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]

201.3.243**single use**

intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

[SOURCE: ISO 20417:2021, 3.26]

201.3.244**sound power level**

L_W

ten times the logarithm to the base 10 of the ratio of the sound power of a source, P , to a reference value, P_0 , expressed in decibels

$$L_W = 10 \lg \frac{P}{P_0} \text{ dB} \quad (201.3.1)$$

where the reference value, P_0 , is 1 pW

Note 1 to entry: If a specific frequency weighting as specified in IEC 61672-1 or specific frequency bands are applied, this is indicated by appropriate subscripts; e.g. L_{WA} denotes the A-weighted *sound power level*.

[SOURCE: ISO 3744:2010, 3.21, modified —deleted note 2.]

201.3.245**sound pressure level**

L_P

ten times the logarithm to the base 10 of the square of the sound pressure, p , to the square of a reference value, p_0 , expressed in decibels

$$L_P = 10 \lg \frac{p^2}{p_0^2} \text{ dB} \quad (201.3.2)$$

where the reference value, p_0 , is 20 µPa

Note 1 to entry: If a specific frequency weighting as specified in IEC 61672-1 or specific frequency bands are applied, this is indicated by appropriate subscripts; e.g. L_{pA} denotes the A-weighted *sound power level*.

[SOURCE: ISO 3744:2010, 3.2, modified —deleted note 2.]

201.3.246**standard temperature and pressure, dry****STPD**

pressure of 101,325 kPa at an operating temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.247**sterile**

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.248**sterilization***process* used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 17664-1:2021, 3.17]

201.3.249**symbol**

graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.30]

201.3.250**system recovery**

method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.251**technical alarm condition***alarm condition* arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artefact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.36]

201.3.252 technical description

portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing* transport or storage for the expected lifetime of a medical device

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified — deleted note 2.]

201.3.253 transit-operable

term referring to transportable equipment whose *intended use* includes operation while it is being moved

EXAMPLE Transportable *ME equipment* that is *body-worn*, hand-held, attached to a wheelchair, or used in a car, bus, train, boat or plane.

Note 1 to entry: For the purpose of this document, *transit-operable* use in the *home healthcare environment* can include use indoors, outdoors and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.4]

201.3.254 use specification

summary of the important characteristics related to the context of use of the medical device

Note 1 to entry: The intended medical indication, *patient* population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the *use specification*.

Note 2 to entry: The summary of the medical device *use specification* is referred to by some authorities having jurisdiction as the 'statement of intended use'.

Note 3 to entry: The *use specification* is an input to determining the *intended use* of ISO 14971:2019.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.23]

201.3.255 validation

confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or application have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The term "*validated*" is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 4 applies, except as follows:

201.4.3 Essential performance

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 Additional requirements for essential performance

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

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed essential performance requirements

Requirement	Subclause
The oxygen concentration in the delivered gas, in both <i>normal condition</i> and <i>single fault condition</i> , within the performance levels as indicated in the <i>instructions for use</i>	201.12.1.101 ^a 201.12.1.102 201.12.1.103
or generation of an <i>alarm condition</i>	
power supply failure <i>technical alarm condition</i>	201.11.8.101.1
<i>internal electrical power source</i> nears depletion <i>technical alarm condition</i>	201.11.8.101.2
low oxygen concentration <i>technical alarm condition</i>	201.12.4.102
malfunction <i>technical alarm condition</i>	201.13.2.101
start-up period <i>technical alarm condition</i>	201.12.4.4.101.2
^a Subclause 202.8.1.101 indicates methods of evaluating delivered oxygen concentration as acceptance criteria following specific tests required by this document.	

201.4.3.102 System recovery

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

a) Following a malfunction, the *oxygen concentrator* shall perform a *system recovery* to attempt to restore *essential performance* of the *oxygen concentrator*.

NOTE 2 *Oxygen concentrator* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *oxygen concentrator*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of therapy. Therapy would thus be interrupted until an alternative means of therapy is connected. *System recovery*, as specified in this subclause, attempts to automatically re-establish therapy in a shorter period. If necessary, the *oxygen concentrator* can be replaced later when it is less consequential for the *patient's* therapy.