



DPC: 24 / 30489408 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: 19 March 2024

Origin: International

Latest date for receipt of comments: 10 April 2024

Project No. 2023/01226

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

Interested committees:

Title: BS EN ISO 80601-2-90 Medical electrical equipment

Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy 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 10 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/2126/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

ISO 80601-2-90 ED2

DATE OF CIRCULATION:

2024-03-15

CLOSING DATE FOR COMMENTS:

2024-05-10

SUPERSEDES DOCUMENTS:

62D/2058/CD, 62D/2089A/CC

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](#)).

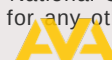
TITLE:

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

NOTE FROM TC/SC OFFICERS:

Second Committee Draft. Joint 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.



Documents

Document Sharing Hub

ISO 80601-2-90:2024(E)

ISO/TC 121/SC 3/ **N3066**

ISO 80601-2-90:2024(E)

ISO/TC 121/SC 3—IEC/62D JWG 12

Secretariat: ANSI

2024-03-05

**Medical Electrical Equipment — Part 2-90: Particular requirements for
basic safety and essential performance of respiratory high-flow therapy
equipment**

*Appareils électromédicaux — Partie 2-90: Exigences particulières pour la sécurité de base
et les performances essentielles des équipements de thérapie respiratoire à haut débit*

CD2 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

Contents.....	iii
Introduction.....	viii
201.1 Scope, object and related standards.....	1
201.1.1 Scope.....	1
201.1.2 Object.....	2
201.1.3 Collateral standards.....	3
201.1.4 Particular standards.....	3
201.2 Normative references.....	4
201.3 Terms and definitions.....	5
201.4 General requirements.....	21
201.4.3 <i>Essential performance</i>	21
201.4.3.101 Additional requirements for <i>essential performance</i>	21
201.4.5 <i>Alternative risk control measures or test methods for ME equipment or ME system</i>	22
201.4.6 <i>ME equipment or ME system parts that contact the patient</i>	23
201.4.11.101 Additional requirements for pressurized gas input.....	23
201.4.11.101.1 Overpressure requirement.....	23
201.4.11.101.2 Compatibility requirement.....	23
201.5 General requirements for testing of <i>ME equipment</i>	24
201.5.101 Additional requirements for the general requirements for testing of <i>ME equipment</i>	24
201.5.101.1 <i>Respiratory high-flow therapy equipment</i> test conditions.....	24
201.5.101.2 Gas flowrate specifications.....	24
201.5.101.3 <i>Respiratory high-flow therapy equipment</i> testing errors.....	25
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	25
201.7 <i>ME equipment</i> identification, marking and documents.....	25
201.7.1.101 <i>Information supplied by the manufacturer</i>	25
201.7.2.4.101 Additional requirements for <i>accessories</i>	26
201.7.2.18 External gas source.....	26
201.7.4.3 Units of measurement.....	27
201.7.9.2.1 General.....	27
201.7.9.2.1.101 Additional general requirements.....	27
201.7.9.2.2.101 Additional requirements for warnings and safety notices.....	28
201.7.9.2.8.101 Additional requirements for start-up <i>procedure</i>	29
201.7.9.2.9.101 Additional requirements for operating instructions.....	30
201.7.9.2.9.101.1 <i>Lay operator</i> operating instructions.....	30
201.7.9.2.9.101.2 <i>Healthcare professional operator</i> operating instructions.....	31
201.7.9.2.12 <i>Cleaning, disinfection and sterilization</i>	31
201.7.9.2.13.101 Additional requirements for maintenance.....	32
201.7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	32
201.7.9.3.1.101 Additional general requirements.....	32
201.7.9.3.101 Additional requirements for the <i>technical description</i>	33
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	33
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	33
201.9.4.3.101 Additional requirements for instability from unwanted lateral movement.....	33

48	201.9.6.2.1.101	Additional requirements for audible acoustic energy.....	33
49	201.10	Protection against unwanted and excessive radiation <i>hazards</i>	34
50	201.11	Protection against excessive temperatures and other <i>hazards</i>	35
51	201.11.1.2.2	<i>Applied parts</i> not intended to supply heat to a <i>patient</i>	35
52	201.11.6.6	<i>Cleaning and disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	35
53	201.11.6.7	<i>Sterilization</i> of <i>ME equipment</i> or <i>ME system</i>	36
54	201.11.7	<i>Biocompatibility</i> of <i>ME equipment</i> and <i>ME systems</i>	36
55	201.11.8.101	Additional requirements for interruption of the power supply/ <i>supply mains</i> to <i>ME equipment alarm condition</i>	37
57	201.11.8.101.1	<i>Alarm conditions</i>	37
58	201.11.8.101.2	Alternative power supply/ <i>supply mains</i>	38
59	201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	39
60	201.12.1	Accuracy of controls and instruments.....	39
61	201.12.1.101	<i>Continuous flow breathing-therapy mode</i>	39
62	201.12.1.101.1	Flowrate accuracy.....	39
63	201.12.1.101.2	Accuracy of delivered oxygen concentration.....	41
64	201.12.2.101	<i>Usability</i> of <i>ME equipment</i>	43
65	201.12.4	Protection against hazardous output.....	43
66	201.12.4.101	Oxygen monitor.....	43
67	201.12.4.102	<i>Maximum limited pressure protection device</i>	44
68	201.12.4.103	Flowrate monitoring.....	44
69	201.12.4.104	<i>Obstruction alarm condition</i>	45
70	201.12.4.105	<i>SpO₂ monitoring equipment</i>	45
71	201.12.101	Protection against accidental adjustments.....	46
72	201.13	<i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	47
73	201.13.2.101	Additional specific <i>single fault conditions</i>	47
74	201.13.101	Failure of one gas supply to <i>respiratory high-flow therapy equipment</i>	47
75	201.13.102	Independence of delivery control function and related <i>risk control</i> measures.....	48
76	201.14	<i>Programmable electrical medical systems (PEMS)</i>	48
77	201.15	Construction of <i>ME equipment</i>	49
78	201.15.101	Mode of operation.....	49
79	201.15.102	Delivered oxygen concentration.....	49
80	201.15.103	Pre-use check.....	50
81	201.16	<i>ME systems</i>	50
82	201.16.1.101	Additional general requirements for <i>ME systems</i>	50
83	201.16.2	<i>Accompanying documents</i> of an <i>ME system</i>	51
84	201.17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	51
85	201.101	Gas connections.....	51
86	201.101.1	Connections to an inlet.....	51
87	201.101.1.1	<i>Low-pressure hose assembly</i>	51
88	201.101.2	<i>Breathing system connectors</i>	51
89	201.101.2.1	General.....	51
90	201.101.2.2	Other named ports.....	52
91	201.101.2.2.1	General.....	52
92	201.101.2.2.2	<i>Patient-connection port</i>	52
93	201.101.2.2.6	<i>Gas pathway connection port</i>	53
94	201.101.2.2.7	Monitoring probe port.....	54
95	201.101.2.2.8	Temperature sensor port.....	54
96	201.101.2.2.9	Nebulization port.....	54

97	201.101.3	Oxygen inlet connector.....	54
98	201.101.4	Gas intake port.....	55
99	201.102	Requirements for the <i>breathing system</i> and accessories	55
100	201.102.1	General	55
101	201.102.2	Labelling	55
102	201.102.3	Breathing sets	55
103	201.102.4	Humidification system	56
104	201.102.5	Breathing system filter (BSF)	56
105	201.102.6	Airway devices.....	56
106	201.103	Indication of duration of operation	56
107	201.104	Functional connection	57
108	201.104.1	General	57
109	201.104.2	Connection to an electronic health record.....	57
110	201.104.3	Connection to a <i>distributed alarm system</i>	57
111	201.104.4	Connection for remote control	57
112	201.105	Power supply cords.....	57
113	201.106	Respiratory high-flow therapy equipment security	58
114	202	Electromagnetic disturbances — Requirements and tests	58
115	202.4.3.1	Compliance criteria	58
116	202.5.2.2.1	Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i>	58
117	202.8.1.101	Additional general requirements.....	58
118	206	Usability	59
119	208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	61
121	208.6.5.4.2	Selection of <i>default alarm preset</i>	61
122	208.6.12.2	Operator alarm system logging.....	61
123	211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	63
125	211.7.4.7	Additional requirements for <i>cleaning, disinfection</i> and <i>sterilization</i>	63
126	211.10.1.1	General requirements for mechanical strength.....	63
127	Annexes		63
128	Annex C (informative)	Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	64
130	Annex D (informative)	<i>Symbols on marking</i>	72
131	Annex AA (informative)	Particular guidance and rationale	74
132	AA.1	General guidance	74
133	AA.2	Rationale for particular clauses and subclauses.....	74
134	Annex BB (informative)	Data interface requirements.....	92
135	BB.1	Background and purpose.....	92
136	BB.2	Data definition	93
137	Annex CC (informative)	Reference to the IMDRF <i>essential principles</i> and labelling guidances	96
138	Annex DD (informative)	Terminology — Alphabetized index of defined terms	100
139			

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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

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

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

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

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

This second edition cancels and replaces the first edition (ISO 80601-2-90:2021), which has been technically revised.

The main changes are as follows:

- updated normative references;
- clarified *system recovery* requirements;
- added requirements for *SpO₂ monitoring equipment*; and
- corrected intended tidal volume to intended delivered flowrate.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC websites.

179 Any feedback or questions on this document should be directed to the user's national standards body. A
180 complete listing of these bodies can be found at www.iso.org/members.html and [www.iec.ch/national-](http://www.iec.ch/national-committees)
181 [committees](http://www.iec.ch/national-committees).

Introduction

Respiratory high-flow therapy equipment has been used successfully for years with neonatal patients. In recent years there is more information about treating adults with *respiratory high-flow therapy equipment* when it is used as an intermediate therapy to improve oxygenation in adult critical care patients, respiratory care units and for palliative care. *High-flow therapy equipment* is also used in the treatment of chronic respiratory disease to reduce exacerbation, improve physiological outcomes and quality of life^{[32][45][46][49]} ¹. The use of *respiratory high-flow therapy equipment* continues to increase as it is easily set up and is well tolerated by patients.

Since the outbreak of COVID-19 in January of 2020, its spread has been rapid and fierce. In hospitals across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. In general, there is a trend to use more non-invasive respiratory therapy. More and more new *manufacturers* of *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor national standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic globally, the demand for this document is clear and very urgent.

The first *respiratory high-flow therapy equipment* was constructed by the connection of a *humidifier*, air/oxygen mixer/blender, flowmeter, breathing tube and cannula. Based on the improvement in technical integration in recent years, there are several technical routes for *respiratory high-flow therapy equipment* on the market. *Respiratory high-flow therapy equipment* is not fully covered by the existing standards for *humidifiers*, gas mixers for medical use, flowmeters or *ventilators*.

This document addresses the *basic safety* and *essential performance* requirements of *respiratory high-flow therapy equipment*, including *risks* related to oxygen (e.g., fires, incorrect oxygen concentration, incorrect flow delivery, etc.).

Specifically, the following *risks* and related requirements were considered in the development of this document.

- Contaminated air entering the *gas intake port* of the *respiratory high-flow therapy equipment*.
- Instability of gas supply from a *high-pressure inlet*.
- Insufficient pressure from a *high-pressure inlet*, and subsequent effects on oxygen delivered to the patient.
- Insufficient oxygen being delivered to the patient, and related *alarm condition*.
- *Usability* by operators wearing personal protective equipment (such as gloves and blurred visors), when setting up equipment, or viewing or changing settings.
- Instability of output delivered to patients, necessitating frequent operator adjustment.
- *Processing* of equipment, including the surface of the *enclosure* and internal *gas pathways*, particularly after use on infectious patients.
- Infectious exhaled gas.
- Overheating of *respiratory high-flow therapy equipment*.
- Insufficient flow capability from a *medical gas pipeline system*, and subsequent effects on oxygen supply to other patients in a care area.

In this document, the following print types are used:

- requirements and definitions: roman type;

¹ Numbers in square brackets refer to the Bibliography.

- 222 — *terms defined in Clause 3 of the general standard, in this document or as noted: italic type;*
- 223 — informative material appearing outside of tables, such as notes, examples and references: in smaller type.
- 224 Normative text of tables is also in a smaller type.
- 225 In referring to the structure of this document, the term:
- 226 — “clause” means one of the five numbered divisions within the table of contents, inclusive of all
- 227 subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- 228 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses
- 229 of Clause 201).
- 230 References to clauses within this document are preceded by the term “Clause” followed by the clause
- 231 number. References to subclauses within this particular document are by number only.
- 232 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
- 233 of the conditions is true.
- 234 For the purposes of this document, the auxiliary verb:
- 235 — “shall” indicates a requirement;
- 236 — “should” indicates a recommendation;
- 237 — “may” indicates a permission;
- 238 — “can” is used to describe a possibility or capability; and
- 239 — “must” is used express an external constraint.
- 240

Medical electrical equipment —

Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

201.1 Scope, object and related standards

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

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

201.1.1 Scope

Replacement:

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

This document applies to the *basic safety* and *essential performance* of *respiratory high-flow therapy equipment*, as defined in 201.3.262, hereafter also referred to as *ME equipment* or *ME system*, in combination with its *accessories*:

— intended for use with *patients* who can breathe spontaneously; and

— intended for *patients* who would benefit from improved alveolar gas exchange; and who would benefit from receiving high-flow humidified respiratory gases, which can include a *patient* whose upper airway is bypassed.

EXAMPLE 1 *Patients* with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation.

EXAMPLE 2 *Patients* who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial carbon dioxide is high.

EXAMPLE 3 *Patients* requiring humidification to improve mucociliary clearance.

Respiratory high-flow therapy equipment can be intended for use in the *home healthcare environment* or intended for use in professional healthcare facilities.

NOTE 2 In the *home healthcare environment*, the *supply mains* is often not reliable.

Respiratory high-flow therapy equipment can be:

— fully integrated *ME equipment*; or

— a combination of separate items forming a *ME system*.

This document also applies to other types of respiratory equipment when that equipment includes a respiratory high-flow therapy mode.

NOTE 3 This document and ISO 80601-2-12 are applicable to a critical care *ventilator* with a high-flow therapy mode.

272 *Respiratory high-flow therapy equipment can be transit-operable.*

273 This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to
274 the *respiratory high-flow therapy equipment*, where the characteristics of those *accessories* can affect the
275 *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

276 EXAMPLE 4 Breathing sets, *connectors*, *humidifier*, *breathing system filter*, external electrical power source,
277 *distributed alarm system*, *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supra-laryngeal
278 airway.

279 NOTE 4 *Accessories* are assessed with the relevant clauses of this document when configured as part of
280 *respiratory high-flow therapy equipment*.

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

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

287 NOTE 5 Additional information can be found in the general standard, 4.2.

288 This document does not specify the requirements for:

- 289 — *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications,
290 which are given in ISO 80601-2-12;
- 291 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;
- 292 — *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given
293 in ISO 80601-2-84;
- 294 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare*
295 *environment*, which are given in ISO 80601-2-72;
- 296 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment,
297 which are given in ISO 80601-2-79;
- 298 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency,
299 which are given in ISO 80601-2-80;
- 300 — sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;
- 301 — continuous positive airway pressure (CPAP) *ME equipment*;
- 302 — high-frequency jet *ventilators* (HFJVs)^[33], which are given in ISO 80601-2-87;
- 303 — gas mixers for medical use, which are given in ISO 11195;
- 304 — flowmeters, which are given in ISO 15002;
- 305 — high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87; and
- 306 — cuirass or “iron-lung” ventilation equipment.

307 This document is a particular standard in the IEC 60601 series, the IEC 80601 series and the ISO 80601
308 series.

309 **201.1.2 Object**

310 *Replacement:*

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *respiratory high-flow therapy equipment*, as defined in 201.3.220, and its *accessories*.

NOTE 1 *Accessories* are included because the combination of the *respiratory high-flow therapy equipment* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

NOTE 2 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles* and labelling guidances as indicated in Annex CC.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[28].

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020+AMD2:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 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, including the 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 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular 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 "2xx", where xx is the final digits 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, 211.10 in this document addresses the content of Clause 10 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.

Subclauses, figures or tables that 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 3.154, 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, 203 for IEC 60601-1-3, 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 particular 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.

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

Replacement:

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

Addition:

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

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*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

- ISO 18562-1:2024⁴, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*
- ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*
- ISO 20417:2021², *Medical devices — Information to be supplied by the manufacturer*
- ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*
- ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*
- ISO 80369-1:2018³, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*
- ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*
- ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
- ISO 80601-2-61:—², *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*
- ISO 80601-2-74:—³, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*
- IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*
- IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*
- IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*
- IEC Guide 115:2023³, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

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, as indicated in Annex DD and the following apply.

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

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

² Under preparation. Stage at the time of publication: ISO/DIS 80601-2-61:2024.

³ Under preparation. Stage at the time of publication: ISO/CD 80601-2-74:2024.

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

NOTE An alphabetized index of defined terms is found Annex DD.

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

acknowledged

state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: *Acknowledged* only affects *alarm signals* that are active at the time of the *operator* action.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37]

201.3.203

airway device

device intended to provide a *gas pathway* to and from the *patient's* airway

[SOURCE: ISO 4135:2022, 3.8.1.2]

201.3.204

airway pressure

P_{aw}

pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.205

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]

201.3.206**alarm off**

state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.4]

201.3.207**alarm paused**

state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.208**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]

201.3.209**artificial ventilation**

intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

EXAMPLE Means used to provide *artificial ventilation* are manual resuscitation; mouth-to-mouth resuscitation; automatic *ventilation*; mechanical *ventilation*.

Note 1 to entry: Common classifications of areas of application of *artificial ventilation* are: emergency; transport; home-care; anaesthesia; critical care; rehabilitation.

Note 2 to entry: Classifications used to denote means used for *artificial ventilation* include: positive-pressure; negative-pressure; gas-powered; *operator*-powered; electrically-powered.

Note 3 to entry: Negative-pressure *ventilation* elevates the relative pressure in the airway by intermittently lowering the pressure in the *lungs*.

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.210**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]

201.3.211**audio off**

state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

496 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.12]

497 **201.3.212**

498 **audio paused**

499 state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an
500 auditory *alarm signal*

501 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

502 **201.3.213**

503 **biocompatibility**

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

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

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

508 **201.3.214**

509 **body temperature and pressure, saturated**

510 **BTPS**

511 ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity of 100 %

512 [SOURCE: ISO 4135:2022, 3.1.1.7]

513 **201.3.215**

514 **breathing system**

515 pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or
516 intermittently in fluid communication with the *patient's* respiratory tract during any form of *artificial*
517 *ventilation* or respiratory therapy

518 [SOURCE: ISO 4135:2022, 3.6.1.1, modified —notes deleted.]

519 **201.3.216**

520 **breathing system filter**

521 **BSF**

522 device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

523 [SOURCE: ISO 23328-2:2002, 3.1]

524 **201.3.217**

525 **breathing therapy mode**

526 respiratory mode of a device that delivers a respirable gas at therapeutic breathing pressures to the
527 *patient's* airway with a primary intention other than to support a proportion of the *patient's* work of
528 breathing

529 EXAMPLE 1 Sleep-apnoea therapy.

530 EXAMPLE 2 CPAP.

531 EXAMPLE 3 High flow oxygen therapy.

532 EXAMPLE 4 Bi-level PAP.

533 [SOURCE: ISO 19223:2019, 3.11.22, modified — deleted note.]

201.3.218**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'.]

201.3.219**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]

201.3.220**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 *respiratory high-flow therapy equipment*.

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

201.3.221**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]

201.3.222**default alarm preset**

alarm preset that can be activated by an *alarm system* without *operator* action

EXAMPLE *Default alarm preset* configured by the *manufacturer* or the *responsible organization*.

[SOURCE: IEC 60601-1-8:2006, 3.16]

201.3.223**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]

201.3.224

distributed alarm system

DAS

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]

201.3.225

distributed alarm system with user confirmation

CDAS

distributed alarm system that includes the capability to receive an *operator* response

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.47]

201.3.226

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.]

201.3.227**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]

201.3.228**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]

201.3.229**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]

201.3.230**false positive alarm condition**

presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

Note 1 to entry: A *false positive alarm condition* can be caused by spurious information produced by the *patient*, the *patient*-equipment interface, other equipment or the *alarm system* itself.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.21]

201.3.231**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]

201.3.232

flow-direction-sensitive component

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

[SOURCE: ISO 4135:2022, 3.1.4.15]

201.3.233

fresh gas

respirable gas delivered to a *breathing system*

[SOURCE: ISO 4135:2022, 3.1.1.16, modified —notes deleted.]

201.3.234

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”.]

201.3.235

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.]

201.3.236

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”.]

201.3.237**healthcare professional**

<adj> appropriately trained, knowledgeable and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

EXAMPLE *Healthcare professional operator, healthcare professional responsible organization.*

Note 1 to entry: The *healthcare professional operator* is the supervising clinician or the *healthcare professional* responsible for the treatment of a *patient* on *respiratory high-flow therapy equipment*.

201.3.238**high-flow nasal cannula**

patient interface comprising nasal prongs designed for the administration of oxygen or *fresh gas* above an appropriate threshold for the *patient* size

Note 1 to entry: A flow of greater than 6 l/min is considered as high flow for adults. For paediatric *patients*, a lower threshold might be applicable^{[38][51]}.

[SOURCE: ISO 4135:2022, 3.8.6.3, modified — added cross references.]

201.3.239**high-pressure inlet**

inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 600 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.1.4.24]

201.3.240**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.]

201.3.241**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]

722 **201.3.242**
 723 **immunity**
 724 the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an
 725 electromagnetic disturbance

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

727 **201.3.243**
 728 **information for safety**
 729 information provided to the *operator* or the *responsible organization* as a *risk control* measure

730 EXAMPLE 1 Warnings, precautions or contraindications.

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

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

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

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

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

738 **201.3.244**
 739 **information supplied by the manufacturer**
 740 information related to the identification and use of a medical device or *accessory*, in whatever form
 741 provided, intended to ensure the safe and effective use of the medical device or *accessory*

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

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

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

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

751 **201.3.245**
 752 **inlet**
 753 opening through which gas or other material is pushed by an elevated upstream pressure

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

755 **201.3.246**
 756 **inlet connector**
 757 connector on an *inlet*

758 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]

201.3.247 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.]

201.3.248 intelligent alarm system

alarm system that makes logical decisions based on monitored information without *operator* intervention

EXAMPLE 1 An *alarm system* that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An *alarm system* that suppresses an *alarm condition* when a related *alarm condition* of higher priority has recently generated an *alarm signal*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.24]

201.3.249 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]

201.3.250 low pressure hose assembly

assembly consisting of a flexible hose with permanently attached gas-specific *inlet* and *outlet connectors* and designed to conduct a medical gas at pressures less than 1 400 kPa

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including breathing system pressures (typically less than 10 kPa), terminal outlet pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.2.3.1]

797 **201.3.251**

798 **lung**

799 each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and
800 the visceral pleura, which during *ventilation* provide gas/blood interfaces that enable oxygen from the
801 gas to pass into the blood and carbon dioxide to be removed

802 [SOURCE: ISO 19223:2019, 3.1.16, modified — deleted notes.]

803 **201.3.252**

804 **marking**

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

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

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

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

812 **201.3.253**

813 **mask**

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

816 [SOURCE: ISO 4135:2022, 3.8.6.4]

817 **201.3.254**

818 **maximum limited pressure**

819 $P_{lim,max}$

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

821 [SOURCE: ISO 4135:2022, 3.1.4.41.3]

822 **201.3.255**

823 **medical gas pipeline system**

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

826 [SOURCE: ISO 4135:2022, 3.2.1.1]

827 **201.3.256**

828 **monitoring equipment**

829 equipment or component part that measures and indicates the value of a variable to the *operator*

830 Note 1 to entry: *Monitoring equipment* is not always electrical in operation, such as a pressure gauge.

831 Note 2 to entry: The value can be displayed continually or intermittently.

832 Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for
833 external communication.

834 [SOURCE: ISO 4135:2022, 3.11.1.3, modified — replaced “part” with “**component**” and “includes devices
835 that are not” with “is not always”.]

201.3.257**operator interface**

means by which the *operator* and the *ME equipment* interact

Note 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.

Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this document, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

Note 4 to entry: See IEC 62366-1:2015+AMD1:2020, 3.26.

[SOURCE: IEC 60601-1-6:2010+AMD2:2020, 3.1]

201.3.258**outlet**

opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.259**patient-connection port**

port of a *breathing system* intended for connection to an *airway device*

EXAMPLE A *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supralaryngeal airway are all *airway devices*.

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a *connector* suitable for connection to an *airway device* such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized *connectors*, for example, a *connector* conforming to ISO 5356-1.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified —deleted note 4.]

201.3.260**processing**

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

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

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

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

201.3.261**protection device**

part or function of medical device or *accessory* that, without intervention by the *operator*, protects against hazardous output

872 Note 1 to entry: Hazardous output can include incorrect delivery of energy or substances or can relate to mechanical
873 or thermal *hazards*.

874 **201.3.262**

875 **respiratory high-flow therapy equipment**

876 *ME equipment* or *ME system* intended to provide a *continuous flow* of heated and humidified gas that
877 exceeds the *patient's* inspiratory flow to a spontaneously breathing *patient*

878 Note 1 to entry: *Respiratory high-flow therapy equipment* is intended for a spontaneous breathing *patient* who
879 would benefit from improved alveolar gas exchange and who would benefit from receiving high-flow humidified
880 respiratory gases, including a *patient* whose upper airway is bypassed.

881 Note 2 to entry: *Respiratory high-flow therapy equipment* is intended to provide a sufficiently high flow to minimize
882 the *patient's* entrainment of room air.

883 Note 3 to entry: *Respiratory high-flow therapy equipment* typically connects to a *patient* with a non-sealing, *high-*
884 *flow nasal cannula*, a tracheostomy tube with *mask* or a face *mask* or helmet with large *exhaust ports*.

885 **201.3.263**

886 **responsibility accepted**

887 state created by an *operator* response accepting ownership for addressing an *alarm condition*

888 Note 1 to entry: A *responsibility accepted* can be used to initiate an *alarm signal* inactivation state.

889 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.52]

890 **201.3.264**

891 **responsibility rejected**

892 state created by an *operator* response rejecting ownership for addressing an *alarm condition*

893 Note 1 to entry: A *responsibility rejected* can be used to initiate an alarm escalation or redirection.

894 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.53]

895 **201.3.265**

896 **security level**

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

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

900 **201.3.266**

901 **single use**

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

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

906 [SOURCE: ISO 20417:2021, 3.26]

907 [SOURCE: ISO 19223:2019, 3.5.1.3, modified — deleted notes.]

908 **201.3.267**
 909 **standard temperature and pressure, dry**
 910 **STPD**
 911 pressure of 101,325 kPa at an operating temperature of 20 °C, dry

912 [SOURCE: ISO 4135:2022, 3.1.1.8]

913 **201.3.268**
 914 **sterile**
 915 free from viable microorganisms

916 [SOURCE: ISO 20417:2021, 3.29]

917 **201.3.269**
 918 **sterilization**
 919 *process* used to render product free from viable microorganisms

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

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

924 **201.3.270**
 925 **symbol**
 926 graphical representation appearing on the label or associated documentation of a medical device that
 927 communicates characteristic information without the need for the supplier or receiver of the information
 928 to have knowledge of the language of a particular nation or people

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

931 [SOURCE: ISO 20417:2021, 3.30]

932 **201.3.271**
 933 **system recovery**
 934 method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the
 935 complete *ME equipment*

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

937 **201.3.272**
 938 **technical alarm condition**
 939 *alarm condition* arising from a monitored equipment-related or *alarm system*-related variable

940 EXAMPLE 1 An electrical, mechanical or other failure.

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

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

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

201.3.273

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.]

201.3.274

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]

201.3.275

use scenario

specific sequence of tasks performed by a specific *operator* in a specific use environment and any resulting response of the *ME equipment*

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.22, modified — replaced "user" with "*operator*" and "medical device" with "*ME equipment*".]

201.3.276

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]

201.3.277

ventilator

medical device or *medical electrical equipment* intended to provide *artificial ventilation*

[SOURCE: ISO 19223:2019, 3.1.1, modified — deleted notes.]

201.3.278

ventilator-dependent

dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood.

EXAMPLE *Patients* with Duchennes Muscular Dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

[SOURCE: ISO 4135:2022, 3.1.5.18]

201.4 General requirements

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

201.4.3 Essential performance

Additional subclause:

201.4.3.101 Additional requirements for essential performance

NOTE 1 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.

NOTE 2 The *essential performance* requirements of the *humidifier* used with *respiratory high flow-therapy equipment* are found in ISO 80601-2-74.

Table 201.101 — Distributed essential performance requirements

Requirement	Subclause
Delivery of a <i>continuous flow</i> of humidified gas and oxygen concentration at the <i>patient-connection port</i> within the disclosed accuracy or	^a
generation of an <i>alarm condition</i>	
flowrate, if equipped	201.12.4.103
gas supply failure	201.13.2.101
<i>internal electrical power source</i> failure, if equipped	201.11.8.101.1
<i>internal electrical power source</i> nears depletion, if equipped	201.11.8.101.1
obstruction	201.12.4.104
oxygen level, if equipped	201.12.4.101
<i>system recovery</i>	201.4.3.102
^a Subclause 202.8.1.101 indicates methods of evaluating delivery of therapy 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 *respiratory high flow-therapy equipment* shall perform a *system recovery* to attempt to restore essential performance of the *respiratory high flow-therapy equipment*.

NOTE 2 *Respiratory high flow-therapy equipment* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *respiratory high flow-therapy equipment*. 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 *respiratory high flow-therapy equipment* can be replaced later when it is less consequential for the *patient's* therapy.

b) *System recovery* may result in the temporary:

1) cessation in the therapy of the *patient*; or

2) reduction in the function of *respiratory high flow-therapy equipment* subassemblies without impacting the therapy of the *patient*.

EXAMPLE The temporary blanking of the display.

c) During a *system recovery* with a cessation of therapy the *respiratory high flow-therapy equipment* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of therapy.

1) The *system recovery* with a cessation of therapy *alarm condition* shall be at least *medium* priority.

d) During a *system recovery* without a cessation of therapy, the *respiratory high flow-therapy equipment* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of therapy.

1) The *system recovery* without a cessation of therapy *alarm condition* shall be at least *low* priority.

2) A *low priority system recovery* without a cessation of therapy *alarm condition* need not have an auditory *alarm signal*.

e) Following a *system recovery* without *operator* intervention, the *respiratory high flow-therapy equipment* shall attempt to operate with the same system configuration settings, therapy settings and *alarm settings* as before the *system recovery*.

1) If the system configuration settings, therapy settings or *alarm settings* are different after the *system recovery*, the *respiratory high flow-therapy equipment* shall be equipped with an *alarm system* to indicate any change in settings.

2) The change in settings *alarm condition* shall be at least *medium* priority.

f) The duration of a *system recovery* with a cessation of therapy should be as short as practicable to avoid an unacceptable *risk* to the *patient*.

g) The maximum duration of a *system recovery* shall be disclosed in the *instructions for use*.

Check conformity by inspection of the *instructions for use* and functional testing.

201.4.5 Alternative risk control measures or test methods for ME equipment or ME system

Amendment (add prior to the compliance check):

aa) Subsequent revisions of dated references (new editions or amendments) may be used in substitution of a referenced document provided the *manufacturer* can demonstrate the *hazard* or *hazardous situation* addressed in the dated normative reference is adequately resolved in the subsequent revision.

201.4.6 *ME equipment or ME system parts that contact the patient*

Amendment (add at end of 4.6 prior to the compliance check):

NOTE 101 There is guidance or rationale for this subclause contained in Clause AA.2.

aa) The *breathing system* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause (i.e., 4.6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020).

Additional subclauses:

201.4.11.101 **Additional requirements for pressurized gas input**

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

201.4.11.101.1 **Overpressure requirement**

a) *Respiratory high-flow therapy equipment* with a *high-pressure inlet* shall:

- 1) operate and meet the requirements of this document throughout its *rated* range of input pressure, and
- 2) not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.

NOTE 1 Internal pressure regulators can be needed to accommodate the *single fault condition* of maximum input pressure, as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *breathing system*. Under this condition, the flowrate from the *respiratory high-flow therapy equipment* is likely to be outside of its specification.

b) If the *respiratory high-flow therapy equipment* has a maximum *rated* input pressure in excess of 600 kPa, the *respiratory high-flow therapy equipment* shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings, by functional testing in *single fault condition* and, if applicable, inspection of the *risk management file* for unacceptable *risks* from input pressures in excess of 600 kPa.

201.4.11.101.2 **Compatibility requirement**

If the *respiratory high-flow therapy equipment* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017, then

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016+AMD1:2017, and

NOTE Taking account of requirements for over-pressure and under-pressure, this corresponds to a range 280 kPa to 600 kPa.

b) under *normal condition*,

- 1) the maximum 10 s average input flowrate required by the *respiratory high-flow therapy equipment* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *high-pressure inlet*, and

2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s.

or

3) the *accompanying documents* shall disclose the following:

- i) the maximum 10 s average input flowrate required by the *respiratory high-flow therapy equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*;
- ii) the maximum transient input flowrate averaged for 3 s required by the *respiratory high-flow therapy equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*;
- iii) a warning to the effect that this equipment is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flowrate at a specified number of terminal *outlets*, in order to avoid exceeding the pipeline design flowrate, thereby minimizing the risk that the equipment interferes with the operation of adjacent equipment.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings and by inspection of the *accompanying documents*.

201.5 General requirements for testing of *ME equipment*

Clause 5 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.5.101 Additional requirements for the general requirements for testing of *ME equipment*

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

201.5.101.1 *Respiratory high-flow therapy equipment test conditions*

a) For testing, the *respiratory high-flow therapy equipment*:

- 1) shall be connected to gas supplies as specified for *normal use*;
- 2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

NOTE This subclause is only applicable to *respiratory high-flow therapy equipment* intended to be connected to a gas supply (e.g. *medical gas pipeline system* or medical gas cylinder) in *normal use*.

201.5.101.2 Gas flowrate specifications

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

All requirements for the flowrate, volume and leakage in this document,

- a) are expressed at *STPD*,
- b) except for those associated with the *breathing system*, which are expressed at *BTPS*.