



DPC: 24 / 30489449 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. 2023/01230

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

Interested committees:

Title: BS EN ISO 80601-2-74 Medical electrical equipment

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying 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/2127/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

ISO 80601-2-74 ED3

DATE OF CIRCULATION:

2024-03-15

CLOSING DATE FOR COMMENTS:

2024-05-10

SUPERSEDES DOCUMENTS:

62D/2060/CD, 62D/2094A/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](#)).

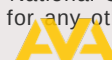
TITLE:

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

NOTE FROM TC/SC OFFICERS:

Second Committee Draft. 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.



Documents

Document Sharing Hub

IEC/62D-ISO/TC 121/SC 3/ **N3064**

ISO 80601-2-74:2024 (Ed3)

IEC/62D-ISO/TC 121/SC 3/JWG 12

2024-03-05

Secretariat: ANSI

Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Appareils électromédicaux — Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire

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

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

Case postale 56 • CH-1211 Geneva 20

Tel. + 41 22 749 01 11

Fax + 41 22 749 09 47

E-mail copyright@iso.org

Web www.iso.org

Published in Switzerland.

1	Contents	Page
2	Foreword.....	v
3	Introduction.....	vi
4	201.1 Scope, object and related standards.....	1
5	201.2 Normative references.....	3
6	201.3 Terms and definitions	4
7	201.4 General requirements	19
8	201.5 General requirements for testing of <i>ME equipment</i>	23
9	201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	24
10	201.7 <i>ME equipment</i> identification, <i>marking</i> and documents.....	25
11	201.8 Protection against electrical <i>hazards</i> form <i>ME equipment</i>	32
12	201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	32
13	201.10 Protection against unwanted and excessive radiation <i>hazards</i>	33
14	201.11 Protection against excessive temperatures and other <i>hazards</i>	34
15	201.12 Accuracy of controls and instruments and protection against	
16	hazardous outputs	36
17	201.13 Hazardous situations and fault conditions for <i>ME Equipment</i>	45
18	201.14 Programmable electrical medical systems (PEMS)	46
19	201.15 Construction of <i>ME equipment</i>	47
20	201.16 <i>ME systems</i>	47
21	201.16.2 Accompanying documents of an <i>ME system</i>	47
22	201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	48
23	201.101 Breathing system connectors and ports.....	48
24	201.102 Requirements for the <i>breathing system</i> and <i>accessories</i>	51
25	201.103 Liquid container	52
26	201.104 Functional connection	52
27	202 Electromagnetic disturbances — Requirements and tests	53
28	206 Usability	54
29	208 General requirements, tests and guidance for alarm systems in medical	
30	electrical equipment and medical electrical systems	55
31	211 Requirements for medical electrical equipment and medical	
32	electrical systems used in the home healthcare environment	55
33	Annex C (informative) Guide to <i>marking</i> and labelling requirements	
34	for <i>ME equipment</i> and <i>ME systems</i>	56
35	Annex D (informative) Symbols on <i>marking</i>	61
36	Annex AA (informative) Particular guidance and rationale	63
37	Annex BB (normative) Determination of the accuracy of the displayed	
38	measured gas temperature	84
39	Annex CC (normative) Determination of the <i>humidification output</i>	86
40	Annex DD (normative) Specific enthalpy calculations	91
41	Annex EE (normative) Removable temperature sensors and mating ports.....	93
42	Annex FF (normative) Reference temperature sensor	97

43 **FF.1 Test preparation 97**

44 **Annex GG (informative) Saturation vapour pressure 100**

45 **Annex HH (informative) Liquid fill port..... 101**

46 **Annex II (informative) Reference to the IMDRF *essential principles* and labelling**

47 **guidances 105**

48 **Annex JJ (informative) Terminology — Alphabetized index of defined terms 109**

49 **Bibliography..... 114**

50

51 Foreword

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

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

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

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

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

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

79 This third edition cancels and replaces the second edition (ISO 80601-2-74:2021), which has been
80 technically revised.

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

- 82 — [updated normative references](#);
- 83 — [added requirements for the fill connector](#); and
- 84 — [clarified system recovery requirements](#).

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

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

89 Introduction

90 This document specifies requirements for respiratory humidifying equipment intended for use on
 91 *patients in home healthcare environment* and in healthcare facilities. *Humidifiers* are used to raise the
 92 water content of gases delivered to *patients*. Gases available for medical use do not contain sufficient
 93 moisture and can damage or irritate the respiratory tract or desiccate secretions of *patients* whose upper
 94 airways have been bypassed. Inadequate humidity in the inspired gas can cause drying of the upper
 95 airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can
 96 cause narrowing or even obstruction of the airway^{[32] [46]}. Heat is employed to increase the water output
 97 of the *humidifier*.

98 In addition, many *humidifiers* utilize heated *breathing tubes* in order to increase operating efficiency and
 99 reduce water loss (condensate) as well as heat loss in the *breathing tube*. *Ventilator* and anaesthesia
 100 *breathing tubes* in common use might not withstand the heat generated by *humidifiers* and *breathing tube*
 101 heating mechanisms.

102 Many *humidifier manufacturers* use off-the-shelf electrical *connectors* for their electrically heated
 103 *breathing tubes*. However, since different *manufacturers* have used the same electrical *connector* for
 104 different power outputs, electrically heated *breathing tubes* can be physically, but not electrically,
 105 interchangeable. Use of improper electrically heated *breathing tubes* has caused overheating, circuit
 106 melting, *patient* and *operator* burns and fires. It was not found practical to specify the interface
 107 requirements for electrical *connectors* to ensure compatibility between *humidifiers* and *breathing tubes*
 108 produced by different *manufacturers*.

109 Since the safe use of a *humidifier* depends on the interaction of the *humidifier* with its many *accessories*,
 110 this document sets total system performance requirements up to the *patient-connection port*. These
 111 requirements are applicable to *accessories* such as *breathing tubes* (both heated and non-heated),
 112 temperature sensors and equipment intended to control the environment within these *breathing tubes*.

113 Humidification can also be used by respiratory support *ME equipment* to increase *patient* comfort and
 114 compliance with the therapy. Examples are obstructive sleep apnoea and nasal high-flow therapy
 115 equipment. The *humidification output* requirements of such *ME equipment* is less demanding as the
 116 *patient's* upper airway is not bypassed.

117 *Humidifiers* are commonly used with air and air-oxygen mixtures and any *humidifier* should be able to
 118 operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures,
 119 as the different physical and thermal properties of these gases may disturb the operation of the
 120 *humidifier*.

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

- 122 — Requirements and definitions: roman type;
- 123 — *Test specifications and terms defined in Clause 3 of the general standard, in this document or as noted:*
 124 *italic type*;
- 125 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 126 Normative text of tables is also in a smaller type;

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

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

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

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

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

137 — “shall” indicates a requirement;

138 — “should” indicates a recommendation;

139 — “may” indicates a permission;

140 — “can” is used to describe a possibility or capability; and;

141 — “must” is used to express an external constraint.

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

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

144

145

Medical electrical equipment —

Part 2-74:

Particular requirements for basic safety and essential performance of respiratory humidifying 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 a *humidifier*, also hereafter referred to as *ME equipment*, in combination with its *accessories*, the combination also hereafter referred to as *ME system*.

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

EXAMPLE 1 Heated *breathing tubes* (heated-wire *breathing tubes*) or *ME equipment* intended to control these heated *breathing tubes* (heated *breathing tube controllers*).

NOTE 2 Heated *breathing tubes* and their controllers are *ME equipment* and are subject to the requirements of IEC 60601-1.

NOTE 3 ISO 5367 specifies other safety and performance requirements for *breathing tubes*.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy *patients*.

NOTE 4 A *humidifier* can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the *humidifier*.

EXAMPLE 2 Heated *humidifier* incorporated into a critical care *ventilator* where ISO 80601-2-12 also applies.

EXAMPLE 3 Heated *humidifier* incorporated into a homecare *ventilator* for dependent *patients* where ISO 80601-2-72 also applies.

EXAMPLE 4 Heated *humidifier* incorporated into sleep apnoea therapy equipment where ISO 80601-2-70 also applies.

EXAMPLE 5 Heated *humidifier* incorporated into ventilatory support equipment where either ISO 80601-2-79 or ISO 80601-2-80 also apply.

EXAMPLE 6 Heated *humidifier* incorporated into respiratory high-flow therapy equipment where ISO 80601-2-90 also applies.

This document also includes requirements for an *active HME* (*heat and moisture exchanger*), *ME equipment* which actively adds heat and moisture to increase the humidity level of the gas delivered from the *HME* to the *patient*. This document is not applicable to a passive *HME*, which returns a portion of the expired moisture and heat of the *patient* to the respiratory tract during inspiration without adding heat or moisture.

NOTE 5 ISO 9360-1 and ISO 9360-2 specify safety and performance requirements for a passive *HME*.

NOTE 6 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 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 7 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for cold pass-over or cold bubble-through humidification devices, the requirements for which are given in ISO 20789.

This document is not applicable to equipment commonly referred to as “room humidifiers” or humidifiers used in heating, ventilation and air conditioning systems, or *humidifiers* incorporated into infant incubators to humidify the chamber air (i.e., are not directly connected to the *patient*).

This document is not applicable to nebulizers used for the delivery of a drug to *patients*.

NOTE 8 ISO 27427 specifies the safety and performance requirements for nebulizers and ISO 80601-2-94 for [inhalational therapy nebulizer equipment](#).

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *humidifier*, as defined in 201.3.239, and its *accessories*.

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

NOTE 1 This document has been prepared to address the relevant *essential principles* and labelling guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex II.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.

201.1.3 Collateral standards

Addition (add after existing text):

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

IEC 60601-1-2:2014+AMD1:2020, 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 60601-1-3:2008+AMD1:2013+[AMD2:2021](#) and [IEC 60601-1-9:2007+AMD1:2013+AMD2:2020](#) 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 60601-1:2005+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, 208.6 in this document addresses the content of Clause 6 of the IEC 60601-1-8 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 3.154, 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, 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.

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

Replacement:

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*

- 265 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and*
 266 *sockets*
- 267 ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for*
 268 *use with medical gases*
- 269 ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*
- 270 ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
 271 *medical gases and vacuum*
- 272 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
 273 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
 274 *devices*
- 275 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device*
 276 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*
- 277 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*
 278 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*
- 279 ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
 280 *Part 1: Evaluation and testing within a risk management process*
- 281 ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*
- 282 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1:*
 283 *General requirements*
- 284 ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7:*
 285 *Connectors for intravascular or hypodermic applications*
- 286 IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General*
 287 *requirements for basic safety and essential performance*
- 288 IEC 60601-2-19:2020, *Medical electrical equipment — Part 2-19: Particular requirements for the basic*
 289 *safety and essential performance of infant incubators*
- 290 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic*
 291 *resonance environment*
- 292 IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1:*
 293 *Security — Activities in the product life cycle*
- 294 IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the*
 295 *electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1-8:2006+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 <https://www.electropedia.org/>

NOTE An alphabetized index of defined terms is found in Annex JJ.

201.3.201

absolute humidity

mass of water vapour present in a unit volume of gas

Note 1 to entry: In respiratory applications *absolute humidity* is commonly represented in units of milligrams per litre or grams per cubic metre, with volume expressed at *BTPS* condition.

Note 2 to entry: See also *relative humidity*.

[SOURCE: ISO 4135:2022, 3.1.1.1]

201.3.202

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.]

201.3.203

active HME

humidifier where water, water vapour or heat is actively added to the *HME* to increase the humidity level of the gas delivered from the *HME* to the *patient*

[SOURCE: ISO 4135:2022, 3.7.2.3, modified —replaced 'device' with '*humidifier*'.]

201.3.204

aerosol

suspension of liquid or solid particles in a gas

[SOURCE: ISO 4135:2022, 3.1.1.3]

201.3.205

airway device

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

[SOURCE: ISO 4135:2022, 3.8.1.2]

201.3.206

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.

341 [SOURCE: ISO 4135:2022, 3.1.4.41.1]

342 **201.3.207**

343 **alarm limit**

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

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

346 **201.3.208**

347 **alarm paused**

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

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

351 **201.3.209**

352 **alarm setting**

353 *alarm system* configuration, including but not limited to:

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

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

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

360 **201.3.210**

361 **artificial ventilation**

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

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

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

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

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

372 [SOURCE: ISO 19223:2019, 3.1.10]

373 **201.3.211**

374 **attack**

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

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

201.3.212**audio paused**

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

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

201.3.213**BAP**

quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

201.3.214**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]

201.3.215**body temperature and pressure, saturated****BTPS**

ambient atmospheric pressure, at a temperature of 37 °C, and at a *relative humidity* (201.3.215) of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.216**breathing system**

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

[SOURCE: ISO 4135:2022, 3.6.1.1, modified —deleted the notes to entry.]

201.3.217**breathing system filter****BSF**

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

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

201.3.218**breathing tube**

non-rigid tube used to convey gases or vapours within the *operator-detachable* section of a *breathing system* (201.3.216)

[SOURCE: ISO 4135:2022, 3.1.4.4, modified —replaced “user” with “operator” deleted note.]

201.3.219**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'.]

201.3.220

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]

201.3.221

CPAP

continuous positive airway pressure

ventilation-mode or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at a set *airway-pressure* level, above ambient pressure

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted notes.]

201.3.222

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]

201.3.223

delivered gas temperature

temperature of the gas, or *aerosol* (201.3.223), or both, being delivered to a *patient*, referenced to the *patient-connection port*

[SOURCE: ISO 4135:2022, 3.1.1.13]

201.3.224

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]

201.3.225

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]

201.3.226

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]

494 **201.3.228**
 495 **essential principles**
 496 **essential principles of safety and performance**
 497 fundamental high-level requirements that when complied with ensure a medical device is safe and
 498 performs as intended

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

500 **201.3.229**
 501 **expiratory phase**
 502 interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

503 [SOURCE: ISO 19223:2019, 3.4.2, modified — deleted notes.]

504 **201.3.230**
 505 **firecall**
 506 method established to provide emergency access to a secure medical device

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

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

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

513 **201.3.231**
 514 **flow-direction-sensitive component**
 515 component or *accessory* through which gas flow has to be in one direction only for proper functioning or
 516 *patient safety*

517 [SOURCE: ISO 4135:2022, 3.1.4.15]

518 **201.3.232**
 519 **gas intake port**
 520 port through which gas is drawn for use by the *patient*

521 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
 522 is provided by a medical gas supply system.

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

524 **201.3.233**
 525 **gas pathway**
 526 interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the
 527 ports through which gases or liquids enter and leave the medical device including the *patient* interface or
 528 the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

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

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

531 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”.]

201.3.234

healthcare professional

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

Note 1 to entry: This term functions as an adjective.

201.3.235

heat and moisture exchanger

HME

device intended to retain a portion of the *patient's* expired moisture and heat, and return it to the respiratory tract during inspiration

[SOURCE: ISO 9360-1:2000, 3.1]

201.3.236

heated breathing tube controller

ME equipment which controls the temperature or the heating of a *breathing tube*

Note 1 to entry: A *heated breathing tube controller* can be either stand-alone or part of the *humidifier*.

201.3.237

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+AMD1:2020, 3.1, modified — deleted notes 1 and 3, modified note 2 as new note 1 and added note 2.]

201.3.238

humidification chamber

part of the *humidifier* (201.3.239) in which vaporization or nebulization takes place

[SOURCE: ISO 4135:2022, 3.7.2.5]

201.3.239

humidification output

total mass of water vapour per unit volume of gas at the *patient-connection port*

570 Note 1 to entry: *Humidification output* is expressed under *body temperature and pressure, saturated* conditions.

571 [SOURCE: ISO 4135:2022, 3.7.2.6]

572 **201.3.240**
573 **humidifier**

574 *ME equipment* that adds water in the form of droplets or vapour, or both, to the inspired gas

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

577 [SOURCE: ISO 4135:2022, 3.7.2.1, modified —replaced ‘device’ with ‘*ME equipment*’.]

578 **201.3.241**
579 **I:E ratio**

580 ratio of the *inspiratory time* to the expiratory time in a *respiratory cycle*

581 [SOURCE: ISO 19223:2019, 3.4.19, modified — deleted notes.]

582 **201.3.242**
583 **immunity**

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

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

587 **201.3.243**
588 **inflation**

589 *ventilator* action intended to increase the volume of gas in the *lungs* by the application of an elevated-
590 pressure waveform to the *patient-connection port* until a specified termination criterion is met

591 [SOURCE: ISO 19223:2019, 3.3.1, modified — deleted notes.]

592 **201.3.244**
593 **inflation-type**

594 *inflation* characterized by its temporal delivery pattern following initiation, and its termination criteria

595 [SOURCE: ISO 19223:2019, 3.3.2, modified — deleted notes.]

596 **201.3.245**
597 **information supplied by the manufacturer**

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

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

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

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

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

201.3.246**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.]

201.3.247**inlet connector**

connector on an *inlet* (201.3.245)

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]

201.3.248**inspiratory time**

t_i

duration of an *inflation phase* or inspiratory phase

[SOURCE: ISO 19223:2019, 3.4.8, modified — deleted notes.]

201.3.249**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.]

201.3.250**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]

201.3.251

lay

lay person

not having formal education in a relevant field of healthcare or medical discipline and, if appropriate, relevant specialized training on the use of the specific medical device

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: ISO 20417:2021, 3.13, modified — deleted “individual who does” and added the example.]

201.3.252

liquid container

part of a vaporizer, nebulizer or *humidifier* (201.3.239) that holds the liquid

Note 1 to entry: The *liquid container* can be accessible to the breathing gas.

Note 2 to entry: The *liquid container* can also be part of the *humidification chamber*.

Note 3 to entry: The *liquid container* can be detachable for filling.

[SOURCE: ISO 4135:2022, 3.1.4.28]

201.3.253

liquid reservoir

reservoir from which the *liquid container* (201.3.251) can be replenished or which, in the absence of a *liquid container*, supplies liquid directly to the *humidification chamber*

[SOURCE: ISO 4135:2022, 3.1.4.29, modified —replaced 'may' with 'can'.]

201.3.254

lung

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

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

201.3.255

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.]

201.3.256

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]

- 685 **201.3.257**
 686 **maximum limited pressure**
 687 $P_{lim,max}$
 688 highest *airway pressure* that can occur during *normal use* or under *single fault condition*
 689 [SOURCE: ISO 4135:2022, 3.1.4.41.3]
- 690 **201.3.258**
 691 **maximum operating pressure**
 692 maximum *rated pressure* in the *humidification chamber* (201.3.237) during *normal use*
- 693 **201.3.259**
 694 **measured gas temperature**
 695 temperature of the gas that the *ME system* is measuring and, if applicable, displaying
- 696 **201.3.260**
 697 **medical gas pipeline system**
 698 combination of a supply system, monitoring and *alarm system* and a pipeline distribution system with
 699 terminal units for provision of medical gases or vacuum
 700 [SOURCE: ISO 4135:2022, 3.2.1.1]
- 701 **201.3.261**
 702 **monitoring equipment**
 703 equipment or component part that measures and indicates the value of a variable to the *operator*
 704 Note 1 to entry: *Monitoring equipment* is not always electrical in operation, such as a pressure gauge.
 705 Note 2 to entry: The value can be displayed continually or intermittently.
 706 Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for
 707 external communication.
- 708 [SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced 'part' with 'component part' 'user' with
 709 'operator'.]
- 710 **201.3.262**
 711 **outlet**
 712 opening through which gas leaves a device or component
 713 [SOURCE: ISO 4135:2022, 3.1.4.40]
- 714 **201.3.263**
 715 **patient-connection port**
 716 port of a *breathing system* intended for connection to an *airway device*
 717 Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.
 718 Note 2 to entry: The *patient-connection port* is typically a *connector* suitable for connection to an *airway device* such
 719 as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.
 720 Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the
 721 form of specific standardized *connectors*, for example, a *connector* conforming to ISO 5356-1.
 722 [SOURCE: ISO 4135:2022, 3.1.4.41, modified —deleted note 4.]

- 723 **201.3.264**
 724 **pressure-control**
 725 *inflation-type* that acts to generate a constant inspiratory pressure at a set level, after a set rise time
- 726 [SOURCE: ISO 19223:2019, 3.3.4, modified — deleted notes.]
- 727 **201.3.265**
 728 **processing**
 729 <preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory*
 730 for its *intended use*
- 731 [SOURCE: ISO 20417:2021, 3.20]
- 732 **201.3.266**
 733 **protection device**
 734 part or function of medical device or *accessory* that, without intervention by the *operator*, protects against
 735 hazardous output
- 736 Note 1 to entry: Hazardous output can include incorrect delivery of energy or substances or can relate to mechanical
 737 or thermal *hazards*.
- 738 **201.3.267**
 739 **relative humidity**
 740 water vapour pressure, expressed as a percentage of the saturation vapour pressure, at a particular
 741 temperature
- 742 Note 1 to entry: See also *absolute humidity*.
- 743 [SOURCE: ISO 4135:2022, 3.1.2.4]
- 744 **201.3.268**
 745 **respiratory cycle**
 746 complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease,
 747 of gas volume in the *lung* regardless of how it is generated
- 748 [SOURCE: ISO 19223:2019, 3.4.16, modified — deleted notes.]
- 749 **201.3.269**
 750 **security level**
 751 level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of
 752 devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit
- 753 [SOURCE: IEC/TR 60601-4-5:2021, 3.23]
- 754 **201.3.270**
 755 **set rate**
 756 number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per
 757 minute
- 758 [SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]
- 759 **201.3.271**
 760 **set temperature**
 761 temperature at which the *humidifier* (201.3.239) attempts to maintain *measured gas temperature*
 762 (201.3.258)

Note 1 to entry: The *set temperature* may be *operator*-adjustable.

201.3.272

single use

<medical device, *accessory*> 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, 3.27]

201.3.273

standard temperature and pressure, dry

STPD

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

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.274

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.275

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]

201.3.276

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]

201.3.277

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.

201.3.278

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]

201.3.279

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.]

201.3.280

tidal volume

V_T

volume of gas that enters and leaves the *lung* during a breath

[SOURCE: ISO 19223:2019, 3.8.1, modified — deleted notes.]

201.3.281

transit-operable

<adj> 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 standard, *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]

201.3.282

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".]

201.3.283

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, 3.23]

201.3.284

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]

201.3.285

ventilator

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

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

201.3.286

volume targeted

automatic *inflation-to-inflation* adjustment of the *inflation* settings, with the target of achieving a set inspiratory volume for each breath

[SOURCE: ISO 19223:2019, 3.3.15, modified — deleted notes.]

201.3.287

volume-control

inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

[SOURCE: ISO 19223:2019, 3.3.3, modified — deleted notes.]

201.4 General requirements

Clause 4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 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
For category 1 or category 3 <i>humidifiers</i> , delivery of <i>humidification output</i> or generation of a <i>technical alarm condition</i> <i>low humidification output</i> <i>system recovery</i> , if equipped	201.12.1.101 ^a 201.12.4.102 201.4.3.102
For category 2 <i>humidifiers</i> for the purposes of this document, category 2 <i>humidifiers</i> are considered to not have <i>essential performance</i> . Notwithstanding this fact, when this document refers to <i>essential performance</i> as acceptance criteria, the delivery of <i>humidification output</i> is evaluated. ^a	—
^a Subclause 202.8.1.101 indicates methods of evaluating delivery of <i>humidification output</i> 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 a category 1 and category 3 humidifier shall perform a system recovery to attempt to restore the essential performance of the humidifier.

NOTE 2 A humidifier or a subassembly function can become disturbed by a malfunction that could jeopardize the essential performance of the humidifier.

- 1) A category 2 humidifier need not have system recovery function.

- b) System recovery may result in the temporary:

- 1) cessation in the humidification output to the patient; or
2) reduction in the function of humidifier subassemblies without impacting the humidification output of the patient.

EXAMPLE The temporary blanking of the display.

- c) During a system recovery with a cessation of humidification output, the humidifier shall be equipped with an alarm system to indicate system recovery with a cessation of humidification output.

- 1) The system recovery with a cessation of humidification output alarm condition shall be at least medium priority.

- d) During a system recovery without a cessation of humidification output, the humidifier shall be equipped with an alarm system to indicate system recovery without a cessation of humidification output.

- 1) The system recovery without a cessation of humidification output alarm condition shall be at least low priority.
2) A low priority system recovery without a cessation of humidification output alarm condition need not have an auditory alarm signal.

- e) Following a *system recovery* without *operator* intervention, the *humidifier* shall attempt to operate with the same system configuration settings, settings and *alarm settings* as before the *system recovery*.
- 1) If the system configuration settings, *humidifier* settings or *alarm settings* are different after the *system recovery*, the *humidifier* 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 *humidification output* should be as short as practicable to avoid an unacceptable *risk* to the *patient*.
- g) The maximum duration of a *system recovery* of *humidification output* shall be disclosed in the *instructions for use*.

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

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 *humidifier* 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.

Additional subclauses:

201.4.11.101 Additional requirements for pressurized gas input

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

201.4.11.101.1 Overpressure requirement

- a) If the *humidifier* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017, then it:

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

NOTE 1 An internal pressure regulator 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 *humidifier* is likely to be outside of its specification.

- b) If the *humidifier* has a maximum *rated* input pressure in excess of 600 kPa, the *humidifier* 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 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 *humidifier* is intended to be directly 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 *humidifier* 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:

- i) the maximum 10 s average input flowrate required by the *humidifier* 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 *humidifier* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*;

- iii) a warning to the effect that this humidifier 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-flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the humidifier 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*.

EXAMPLE Highest driving gas consumption, highest gas delivery and, if provided, the highest *rated* gas consumption at any gas power supply output.

201.4.101 Additional general requirements

Humidifiers are frequently used in combination with other respiratory *ME equipment* or medical devices. The *basic safety* and *essential performance* of both the *humidifier* and the other respiratory *ME equipment* or medical device are interdependent.

- a) Where a *humidifier* is intended to be used in combination with other respiratory *ME equipment* or medical devices as indicated in its *instructions for use*, it shall be evaluated in combination with the other respiratory *ME equipment* or medical devices when applying the requirements of this document.

- b) As appropriate, the requirements of the particular standards of the other respiratory *ME equipment* or medical devices indicated in the *instructions for use* of the *humidifier* shall also apply to the combination of the *humidifier* and other respiratory *ME equipment* or medical devices.

201.5 General requirements for testing of ME equipment

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

201.5.4 Other conditions

Amendment (add to the list):

a) Unless otherwise specified, the *liquid container* and *liquid reservoir*, if provided, shall be filled to maximum capacity, as indicated in the *instructions for use*, at the beginning of a test with distilled water at the ambient test temperature.

b) For the purpose of checking conformity with requirements of this document, the *delivered gas temperature* shall be sensed in the *breathing tube* not more than 50 mm from the *patient-connection port* (see Annex BB).

Additional subclauses:

201.5.101 Additional requirements for general requirements for testing of ME equipment

201.5.101.1 Humidifier test conditions

a) Where a *humidifier* is intended to receive a medical gas supply as specified for *normal use*:

- 1) oil-free industrial grade oxygen or air may be substituted for the equivalent medical gas; and
- 2) the moisture content shall be less than 1 mg/l.

b) Where a *humidifier* is intended to receive room air in *normal use*, such as in combination with a blower device,

- 1) the incoming air shall be at a low moisture content within the *rated* range of humidity of *normal use* appropriate to the incoming air temperature.
- 2) drier air is preferred as it provides more margin below dew point in which to demonstrate *humidification output*.

201.5.101.2 Gas flowrate and leakage specifications

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

In this document, requirements for the flowrate, volume and leakage

- a) are expressed at *standard temperature and pressure, dry (STPD)*,
- b) except for those associated with the *breathing system*, which are expressed at *body temperature and pressure, saturated (BTPS)*.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 Humidifier testing errors

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

a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use:

- 1) *evaluation* of uncertainty of measurement from IEC Guide 115:2023, 4.1.1 and 4.1.2; and
- 2) *simple acceptance* method from IEC Guide 115:2023, 4.3.

NOTE 2 Previous revisions of ISO 80601-2-74 required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

- b) Test equipment and methods shall be selected and controlled to ensure that the measurement uncertainty (with coverage factor $k = 2$, for confidence of $\sim 95\%$) is no more than 30 % of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for *set temperature* of $\pm 2^\circ\text{C}$, then the uncertainty of the measurement cannot exceed $\pm 0,6^\circ\text{C}$ of the *set temperature*.

- c) The *manufacturer* shall disclose the measurement uncertainty of each disclosed tolerance in the *technical description*.

Check conformity by inspection of the *instructions for use* and the *technical description*.

201.6 Classification of ME equipment and ME systems

Clause 6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

Additional subclause:

201.6.101 Humidifier classification

201.6.101.1 Category 1

A *humidifier* intended for use in *patients* whose upper airways have been bypassed (invasive therapy) shall be classified as category 1.

NOTE A category 1 *humidifier* can also be suitable for use in *patients* whose upper airways have not been bypassed.

201.6.101.2 Category 2

A *humidifier* intended for use in *patients* whose upper airways have not been bypassed (i.e. intended for non-invasive ventilation, sleep apnoea CPAP therapy) shall be classified as category 2 unless it is intended for use in high-flow therapy.

201.6.101.3 Category 3

A *humidifier* intended for use with non-sealed *airway devices* in high-flow therapy (i.e., constant delivered flow that is intended to exceed the inspiratory flow of the *patient*), in *patients* whose upper airways have not been bypassed, shall be classified as category 3.

NOTE Category 3 *humidifiers* are intended for use with a non-sealing *airway device* such as a high-flow nasal cannula, a *mask* or helmet with large exhaust ports.

201.6.101.4 Classification

- a) A *humidifier*, in each mode of operation, shall be classified either as:

- 1) category 1;
- 2) category 2; or
- 3) category 3.

- b) A *humidifier* may be classified as different categories over specified ranges of flowrates and temperatures as well as *intended use*.

201.7 ME equipment identification, marking and documents

Clause 7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Additional subclauses:

201.7.1.101 Information to be supplied by the manufacturer

a) The *information supplied by the manufacturer* of a *humidifier* and its *accessories* shall conform with ISO 20417:2021.

b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.

1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.

2) The term "*medical device*" shall assume the same meaning as *ME equipment*.

3) The term "*user*" shall assume the same meaning as *operator*.

4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

201.7.2.4.101 Additional requirements for accessories

Accessories supplied separately shall:

a) fulfil the requirements of 201.7.2.101; and

b) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *humidifier*, if applicable.

1) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

NOTE Additional requirements are found in 201.102.

Check conformity by inspection and inspection of the *risk management file* for any limitations or adverse effects of the *accessory*.

201.7.2.5 ME equipment intended to receive power from other equipment

Amendment (add before the last paragraph):

NOTE For a heated *breathing tube*, the *connector* to the *humidifier* or *heated breathing tube controller* is a connection to the supply that might need this *marking*.

201.7.2.8.2 Other power sources

Amendment (add at the end of the subclause):

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

NOTE 102 The *connector* on the *humidifier* or *heated breathing tube controller* for a heated *breathing tube* is a *connector* that can need this *marking*.

1077 *Additional subclauses:*

1078 **201.7.2.101 Additional requirements for marking on the outside of ME equipment or**
1079 **ME equipment parts**

1080 a) The *marking of ME equipment*, its parts or *accessories* shall:

1081 1) be *clearly legible*; and

1082 2) include the following, if necessary to maintain *basic safety* or *essential performance* of the
1083 *humidifier*:

1084 i) the minimum liquid level;

1085 ii) the maximum liquid level.

1086 b) If applicable, *marking of operator-accessible ME equipment*, its parts or *accessories* shall include the
1087 following:

1088 1) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are
1089 *operator-removable* without the use of a *tool*;

1090 2) if a pressure-relief *protection device* is provided, the pressure at which it opens;

1091 i) This *marking* shall be on or near the pressure-relief *protection device*.

1092 c) For a *category 1 and category 3 humidifier* intended to be used in the magnetic resonance (MR)
1093 environment, the *humidifier*, its parts and *accessories* shall have *clearly legible markings* in conformity
1094 with:

1095 1) *symbol 7.3.1-1* of IEC 62570 (Table 201.D.2.101, *symbol 2*) if 'MR Safe';

1096 2) *symbol 7.3.1-2* of IEC 62570 (Table 201.D.2.101, *symbol 3*) if 'MR Safe'; or

1097 3) *symbol 7.3.2* of IEC 62570 (Table 201.D.2.101, *symbol 4*) if 'MR Conditional'.

1098 d) For a *category 1 and category 3 humidifier* not intended to be used in the magnetic resonance (MR)
1099 environment, the *humidifier*, its parts and *accessories* shall have *clearly legible markings* in conformity
1100 with IEC 62570:2014 *symbol 7.3.3* (Table 201.D.2.101, *symbol 5*) for an 'MR Unsafe' *humidifier*.

1101 Check conformity by inspection.

1102 **201.7.4.3 Units of measurement**

1103 *Amendment (add to the bottom as a new row in Table 1):*

1104 NOTE 101 There is guidance or rationale for this subclause contained in Clause AA.2.

1105 aa) All gas volume, flowrate and leakage specifications:

1106 1) shall be expressed at *STPD*; except

1107 2) for those associated with the *breathing system* which shall be expressed at *BTPS*.

1108 *Additional subclauses:*

201.7.9.2.1.101 Additional general requirements

a) For a *humidifier* intended for use in the *home healthcare environment*, separate *instructions for use* shall be provided for:

1) the *lay operator*;

2) the supervising clinician or the *healthcare professional operator*.

b) Unless otherwise indicated in this document, the *manufacturer* may choose in which *instructions for use* to place the information required by this document based on *risk management* and *usability* considerations.

c) The supervising clinician or the *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

d) The *instructions for use* shall disclose the *rated* range of *gas flow through the humidifier*.

Check conformity by inspection of the *instructions for use*, the *usability engineering file* and *risk management file* for justification for the placement of information for the *instructions for use*.

201.7.9.2.1.102 Additional general requirements

The *instructions for use* shall include a statement:

a) on the quality and purity of the water to be used in the *humidifier*, and

b) that adding other substances can have adverse effects.

NOTE A nebulizer, located between the *ventilator* and the gas *inlet* port of the *humidification chamber* is a source of such substances.

Check conformity by inspection.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

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

The *instructions for use* shall include:

a) a warning statement to the effect that “WARNING: Do not add any attachments or accessories to the humidifier that contravene the instructions for use of the humidifier or accessory as the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.”

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

b) a warning statement to the effect that “WARNING: Do not use the humidifier at an altitude above [insert maximum *rated* altitude] or outside a temperature of [insert *rated* temperature range]. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.”

c) a warning statement to the effect that “WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in conformity with ISO 5367 or ISO 80601-2-74 should be used”.

d) if applicable, a warning statement to the effect that “WARNING: Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.”

- 1146 e) if applicable, a warning statement to the effect that “WARNING: The humidifier shall not be used with
1147 nitric oxide. Such use might cause the humidifier to not function correctly causing serious
1148 deterioration of health.”

1149 NOTE 3 There is guidance or rationale for this list element contained in Clause AA.2.

- 1150 f) a warning statement to the effect that “WARNING: Use of the humidifier with a gas source (e.g. a
1151 blower/turbine-based ventilator) that heats the gas provided to the humidifier above a temperature
1152 of [insert *rated* temperature limit] can result in impaired humidification output with the potential to
1153 cause severe deterioration of health.”

1154 NOTE 4 See also 201.16.2.

1155 Check conformity by inspection of the *instructions for use*.

1156 201.7.9.2.6 Installation

1157 *Amendment (add at the end of the subclause):*

1158 The *instructions for use* shall give recommended mounting methods and other relevant information for
1159 installation of the *humidifier*.

1160 *Additional subclauses:*

1161 201.7.9.2.8.101 Additional requirements for start-up procedure

1162 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

1163 NOTE 2 For the purposes of this document, a start-up *procedure* is a pre-use test that is used to determine
1164 whether the *humidifier* is ready for use.

- 1165 a) If the *humidifier* is equipped with an *alarm system*, then the *instructions for use* for the *lay operator*
1166 shall disclose a method by which the *alarm signals* can be functionally tested to determine if they are
1167 operating correctly.

- 1168 b) Portions of this test method may:

- 1169 1) be performed automatically by the *humidifier*; or
1170 2) require *operator* action.

1171 EXAMPLE 1 Combination of the power-on self-test routines and *operator* actions that functionally check the
1172 *alarm signals*.

- 1173 c) The specifications of any required *accessories* or test equipment needed to perform these tests shall
1174 be disclosed in the *instructions for use*.

1175 EXAMPLE 2 A test temperature probe that activates the *alarm condition*.

1176 Check conformity by inspection of the *instructions for use*.

1177 201.7.9.2.9.101 Additional requirements for operating instructions

1178 201.7.9.2.9.101.1 Lay operator operating instructions

1179 The *instructions for use* for the *lay operator* shall include:

- 1180 a) the conditions under which the *humidifier* maintains the accuracy of controlled and displayed
1181 variables as disclosed in the *instructions for use*;