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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

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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.

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Submission of Comments

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- 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/2060/CD

COMMITTEE DRAFT (CD)

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62D/2056/RR

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

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:

☐

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

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

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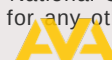
TITLE:

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

NOTE FROM TC/SC OFFICERS:

Joint project with ISO/TC121/SC3.

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Documents

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ISO 80601-2-74:2023 (Ed3)

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

2023-06-29

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

CD stage

Warning for WDs and CDs

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Foreword

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

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 ISO documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO 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).

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.

This document was prepared jointly 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 62D, *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 **third** edition cancels and replaces the **second** edition (ISO 80601-2-74:2021), which has been technically revised.

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

- harmonization with the 'A2 project' of the general standard;
- harmonization with ISO 20417;
- addition of category 3 for respiratory high-flow therapy equipment;
- modification of requirements for *humidification output* of category 2 humidifiers;
- addition of requirements for maximum temperature in *normal use*;
- addition of requirements for static and dynamic temperature stability;
- addition of requirements for low *humidification output alarm condition*;

- modification of audible acoustic energy test *procedure*;
- modification of thermal requirements for *applied parts*;
- modification of *measured gas temperature* test *procedure*;
- enlarged the $\varnothing W$ dimension of the temperature sensor port; and
- modification of *humidification output* test *procedure*.

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

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

98 Introduction

99 This document specifies requirements for respiratory humidifying equipment intended for use on
 100 *patients in home healthcare environment* and in healthcare facilities. *Humidifiers* are used to raise the
 101 water content of gases delivered to *patients*. Gases available for medical use do not contain sufficient
 102 moisture and can damage or irritate the respiratory tract or desiccate secretions of *patients* whose upper
 103 airways have been bypassed. Inadequate humidity in the inspired gas can cause drying of the upper
 104 airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can
 105 cause narrowing or even obstruction of the airway^{[30] [44]}. Heat is employed to increase the water output
 106 of the *humidifier*.

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

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

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

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

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

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

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

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

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

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

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

For the purposes of this document, the auxiliary verb:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” is used to describe a possibility or capability; and;
- “must” is used to express an external constraint.

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

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

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.

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 201.3.214, 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 HH.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016.

NOTE 3 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 does 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*

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

ISO 5367:2014, *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 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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 18562-1:2023, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-19:2020, *Medical electrical equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*

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 115:2021, *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 60601-1-8:2006+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 KK.

201.3.201

absolute humidity

mass of water vapour present in a unit volume of moist 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 *BPTS* 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.

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.207

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]

201.3.208

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]

201.3.209

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 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]

201.3.212

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.]

201.3.213

body temperature pressure, saturated

BTPS

ambient atmospheric pressure, at a temperature of 37 °C, and at a *relative humidity* (201.3.222) of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.214**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.]

201.3.215**breathing system filter****BSF**

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

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

201.3.216**breathing tube**

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

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

201.3.217**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'.]

201.3.218**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]

201.3.219**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

Note 1 to entry: *CPAP* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of breathing to a greater extent than could be experienced during natural breathing.

Note 2 to entry: This definition excludes the use of the term to describe *ventilation-modes* where spontaneous inspirations are supported by intermittently elevated pressures other than with the intention to compensate for any actual or perceived imposed work of breathing.

Note 3 to entry: Because, as used for this *ventilation-mode*, the concept of a *CPAP* level coincides with that of a baseline *airway pressure* the setting could be designated as for either concept but as the intention of the *operator* selecting this *ventilation-mode* will be to achieve a specific *CPAP* level, this becomes an acceptable admitted term to designate the set quantity.

Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation-mode*, *CPAP* is included in this document because it is commonly made available on typical critical care *ventilators* for use as part of a continuum of a *patient's* treatment without the necessity to change to another device.

Note 5 to entry: It is possible for a *ventilation-mode* resembling *CPAP* to be realized on a *ventilator* by the use of CSV (continuous spontaneous *ventilation*) with the pressure-support (PS) set to 'zero' or 'none' but CSV set in this way is not equivalent to *CPAP* if its performance in response to a spontaneous inspiration is dependent on the setting of an appropriate trigger level.

Note 6 to entry: On *ventilators* equipped with ACAP, this adjunct will enable unrestricted breathing whenever *CPAP* is selected.

Note 7 to entry: *CPAP* is a Group 4b *ventilation-mode*. Because no *inflation-type* is selected this *ventilation-mode* is identical to its *ventilation-pattern* and there is no necessity to distinguish between them. The systematic *ventilation-mode* name becomes, therefore, simply, *CPAP*. On *ventilators* where *CPAP* is enabled by means of an ACAP adjunct the systematic code is *CPAP <ACAP>*.

Note 8 to entry: When used for sleep-apnoea *breathing-therapy*, *CPAP* is not classed as a *ventilation-mode* – it becomes a sleep-apnoea *breathing-therapy mode*. Although the principle clinical intention of such a therapy mode is to maintain a positive pressure in the *patient's* airway during sleep in order prevent airway obstruction by the soft tissues in the throat it has become a common practice to reduce this pressure during expiration, principally to improve *patient* acceptability. *Ventilation-modes* with this feature are typically identified with names that allude to this use of two levels of positive *airway pressure*. The generic name adopted for the designation of such a breathing-therapy mode in this document is bi-level PAP.

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted note 9.]

201.3.220 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]

201.3.221 delivered gas temperature

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

[SOURCE: ISO 4135:2022, 3.1.1.13]

201.3.222 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]

201.3.223**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: For the purposes of this document, 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 as described in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.11.2.2.1.

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

201.3.224**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]

201.3.225**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]

201.3.226**expiratory phase**

interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

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

201.3.227**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]

201.3.228

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]

201.3.229

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']

201.3.230

gas pathway

interior surfaces, over which gases or liquids that can be inspired

EXAMPLE 1 The *ventilator 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 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 18562-1:2023, 3.11]

201.3.231

healthcare professional

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.

201.3.232

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]

201.3.233**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*.

201.3.234**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.]

201.3.235**humidification chamber**

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

[SOURCE: ISO 4135:2022, 3.7.2.5]

201.3.236**humidification output**

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

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

[SOURCE: ISO 4135:2022, 3.7.2.6]

201.3.237**humidifier**

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

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

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

201.3.238**I:E ratio**

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

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

201.3.239**immunity**

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

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

201.3.240

inflation

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

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

201.3.241

inflation-type

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

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

201.3.242

information supplied by the manufacturer

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

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

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

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

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

201.3.243

inspiratory time

t_i

duration of an *inflation phase* or inspiratory phase

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

201.3.244

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.]

201.3.245**lay**

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.]

201.3.246**liquid container**

part of a vaporizer, nebulizer or *humidifier* (xxx) 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]

201.3.247**liquid reservoir**

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

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

201.3.248**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.]

201.3.249**mask**

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

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.250**maximum limited pressure**

$P_{lim,max}$

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

[SOURCE: ISO 4135:2022, 3.1.4.41.3]

201.3.251

maximum operating pressure

maximum *rated* pressure in the *humidification chamber* (xxx) during *normal use*

201.3.252

measured gas temperature

temperature of the gas that the *ME system* is measuring and, if applicable, displaying

201.3.253

medical gas pipeline system

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

[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.254

monitoring equipment

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

[SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced 'part' with 'component part' 'user' with 'operator'.]

201.3.255

patient-connection port

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

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.]

201.3.256

pressure-control

inflation-type that acts to generate a constant inspiratory pressure at a set level, after a set rise time

[SOURCE: ISO 19223:2019, 3.3.4, modified — deleted notes.]

201.3.257

processing

<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

201.3.258

protection device

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

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

201.3.259**relative humidity**

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

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

[SOURCE: ISO 4135:2022, 3.1.2.4]

201.3.260**respiratory cycle**

complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease, of gas volume in the lung regardless of how it is generated

[SOURCE: ISO 19223:2019, 3.4.16, modified — deleted notes.]

201.3.261**security level**

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

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

201.3.262**set rate**

number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]

201.3.263**set temperature**

temperature at which the *humidifier* (xxx) attempts to maintain *measured gas temperature* (xxx)

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

201.3.264**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]

201.3.265**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]

201.3.266

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.267

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]

201.3.268

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]

201.3.269

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.

201.3.270

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.]

201.3.271

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.]

201.3.272

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]

201.3.273

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]

201.3.274

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]

201.3.275

ventilator

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

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

201.3.276

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.]

201.3.277

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, 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, if equipped</i>	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, which causes loss or degradation of *essential performance*, the *humidifier* should attempt to perform a *system recovery* with the intention of restoring 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*.

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*:

- 1) the *humidifier* shall allow spontaneous *patient* breathing in accordance with 201.103; and

2) the *humidifier* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of *humidification output*.

i) The *system recovery* with a cessation of *humidification output alarm condition* shall be *high 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 *gas intake port*, 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 *gas intake port*;

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 *gas intake port*;

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 labelled 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 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) *procedure 1 (calculation of uncertainty of measurement)* from IEC Guide 115, 4.4.2; or
- 2) *procedure 2 (accuracy method)* from IEC Guide 115:2021, 4.4.3.

- b) Test equipment and methods shall be selected and controlled to ensure that the 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:

- 988 1) category 1;
- 989 2) category 2; or
- 990 3) category 3.
- 991 b) A *humidifier* may be classified as different categories over specified ranges of flowrates and
- 992 temperatures as well as *intended use*.

993 **201.7 ME equipment identification, marking and documents**

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

995 *Additional subclauses:*

996 **201.7.1.101 Information to be supplied by the manufacturer**

- 997 a) The *information supplied by the manufacturer* of a *humidifier* and its *accessories* shall conform with
- 998 ISO 20417:2021.
- 999 b) In applying ISO 20417:2021, the terms in this document and those in
- 1000 IEC 60601-1:2005+A1:2012+A2:2020 shall be used as follows.
- 1001 1) The term "*accompanying information*" shall assume the same meaning as *accompanying*
- 1002 *documents*.
- 1003 2) The term "*medical device*" shall assume the same meaning as *ME equipment*.
- 1004 3) The term "*user*" shall assume the same meaning as *operator*.
- 1005 4) The term "*patient*" shall include animals.

1006 Check conformity by application of ISO 20417:2021.

1007 **201.7.2.4.101 Additional requirements for accessories**

1008 *Accessories* supplied separately shall:

- 1009 a) fulfil the requirements of 201.7.2.101; and
- 1010 b) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety*
- 1011 or *essential performance* of the *humidifier*, if applicable.
- 1012 1) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for*
- 1013 *use*.

1014 NOTE Additional requirements are found in 201.102.

1015 Check conformity by inspection and inspection of the *risk management file* for any limitations or adverse

1016 effects of the *accessory*.

1017 **201.7.2.5 ME equipment intended to receive power from other equipment**

1018 *Amendment (add before the last paragraph):*

1019 NOTE For a heated *breathing tube*, the *connector* to the *humidifier* or *heated breathing tube controller* is a

1020 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.

Additional subclauses:

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

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

- 1) be clearly legible; and
- 2) include the following, if necessary to maintain basic safety or essential performance of the humidifier:
 - i) the minimum liquid level;
 - ii) the maximum liquid level.

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

- 1) an arrow indicating the direction of the flow for flow-direction-sensitive components that are operator-removable without the use of a tool;
- 2) if a pressure-relief protection device is provided, the pressure at which it opens;
 - i) This marking shall be on or near the pressure-relief protection device.

c) For a 'humidifier intended to be used in the magnetic resonance (MR) environment, the humidifier, its parts and accessories shall have clearly legible markings in conformity with:

- 1) symbol 7.3.1-1 of IEC 62570 (Table 201.D.2.101, symbol 2) if 'MR Safe';
- 2) symbol 7.3.1-2 of IEC 62570 (Table 201.D.2.101, symbol 3) if 'MR Safe'; or
- 3) symbol 7.3.2 of IEC 62570 (Table 201.D.2.101, symbol 4) if 'MR Conditional'.

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

Check conformity by inspection.

201.7.4.3 Units of measurement

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

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

aa) All gas volume, flowrate and leakage specifications:

- 1) shall be expressed at STPD; except

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

201.7.9.2.1 General

Amendment (add as third bullet following the first paragraph):

— the intended position of the *operator*;

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 intended range of *tidal volume*.

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.”

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

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

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

1) See also 201.16.2.

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

201.7.9.2.6 Installation

Amendment (add at the end of the subclause):

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

Additional subclauses:

201.7.9.2.8.101 Additional requirements for start-up procedure

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

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

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

b) Portions of this test method may:

1) be performed automatically by the *humidifier*; or

2) require *operator* action.

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

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

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

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

201.7.9.2.9.101 Additional requirements for operating instructions

201.7.9.2.9.101.1 Lay operator operating instructions

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

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

EXAMPLE 1 Acceptable range of water level.

EXAMPLE 2 Interval of calibration of a sensor.

- b) the maximum volume of water, expressed in ml, available for vaporization contained in the *liquid container* and, if provided, in the *liquid reservoir*;

- c) an indication of the expected duration of operation between refills, under specified operating conditions;

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

201.7.9.2.9.101.2 Healthcare professional operator operating instructions

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

- a) The *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall include:

- 1) the *maximum limited pressure* of:

- i) the *humidifier*, and

- ii) the *accessories*;

- 2) the *maximum operating pressure*;

- 3) the minimum operating pressure of the *humification chamber*, if applicable;

- 4) the *rated* range of environmental operating conditions (temperature and altitude) of *normal use*;

- 5) the maximum *delivered gas temperature*, if the *humidifier* is not provided with a means of continuously indicating the *measured gas temperature*;

- 6) the location in the *humidifier* or *accessories* to which the displayed *measured gas temperature* is referenced;

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

- 7) the gas leakage of the *humidifier* or individual components, as appropriate, at the maximum *rated* pressure. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method. The gas leakage for an *active HME* should be determined in accordance with ISO 9360-1 or ISO 9360-2;

- 8) unless the *humidifier* is integrated into other equipment,