



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-74:2021. It is identical to ISO 80601-2-74:2021. It supersedes BS EN ISO 80601-2-74:2020, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:2021)

Appareils électromédicaux - Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire (ISO 80601-2-74:2021)

Medizinische elektrische Geräte - Teil 2-74: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anfeuchtersystemen für Atemgase (ISO 80601-2-74:2021)

This European Standard was approved by CEN on 2 July 2021.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-74:2021) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80601-2-74:2020.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-74:2021 has been approved by CEN as EN ISO 80601-2-74:2021 without any modification.

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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, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-74:2017), 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 $\emptyset W$ 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.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on *patients* in *home healthcare environment* and in healthcare facilities. *Humidifiers* are used to raise the water content of gases delivered to *patients*. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of *patients* whose upper airways have been bypassed. Inadequate humidity in the inspired gas can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway^[25] [38]. Heat is employed to increase the water output of the *humidifier*.

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

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

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

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

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this 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” means that conformance with a requirement or a test is mandatory for conformance with this document;
- “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);
- “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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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:

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

NOTE 2 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 3 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^[10] also applies.

EXAMPLE 3 Heated *humidifier* incorporated into a homecare *ventilator* for dependent *patients* where ISO 80601-2-72^[12] also applies.

EXAMPLE 4 Heated *humidifier* incorporated into sleep apnoea therapy equipment where ISO 80601-2-70^[11] also applies.

EXAMPLE 5 Heated *humidifier* incorporated into ventilatory support equipment where either ISO 80601-2-79^[13] or ISO 80601-2-80^[14] also apply.

EXAMPLE 6 Heated *humidifier* incorporated into respiratory high-flow therapy equipment where ISO 80601-2-90^[15] 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 4 ISO 9360-1 and ISO 9360-2^[4] specify safety and performance requirements for a passive *HME*.

NOTE 5 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 6 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^[6].

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.

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

NOTE 7 ISO 27427^[7] 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 as indicated in Annex II.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 as indicated in Annex JJ.

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 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

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 16142-1:2016, *Medical devices -- Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

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

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

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 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1:2016, ISO 9360-1:2000, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015, IEC 62366-1:2015 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.

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

[SOURCE: ISO 4135:—^[1], 3.1.1.1]

201.3.202

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:—^[1], 3.7.2.3, modified —replaced 'device' with '*humidifier*'.]

201.3.203

aerosol

suspension of liquid or solid particles in a gas

[SOURCE: ISO 4135:—^[1], 3.1.1.3]

201.3.204

airway device

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

[SOURCE: ISO 4135:—^[1], 3.8.1.2]

201.3.205

body temperature pressure, saturated

BTPS

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

[SOURCE: ISO 4135:—^[1], 3.1.1.7]

201.3.206

breathing system

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

[SOURCE: ISO 4135:—^[1], 3.6.1.1, modified —deleted the notes to entry.]

201.3.207

breathing tube

non-rigid tube used to convey gases or vapours between components of a *breathing system* (201.3.206)

[SOURCE: ISO 4135:—^[1], 3.1.4.4, modified —deleted “and/”.]

201.3.208

delivered gas temperature

temperature of the gas, or *aerosol* (201.3.203), or both, at the *patient-connection port*

[SOURCE: ISO 4135:—^[1], 3.1.1.13]

201.3.209

flow-direction-sensitive component

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

[SOURCE: ISO 4135:—^[1], 3.1.4.15, modified —replaced “must be” with “is”.]

201.3.210

gas intake port

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

[SOURCE: ISO 4135:—^[1], 3.1.4.21]

201.3.211

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*.

201.3.212

humidification chamber

part of the *humidifier* (201.3.214) in which vaporization or nebulization takes place

[SOURCE: ISO 4135:—^[1], 3.7.2.5]

201.3.213

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 (BTPS)* conditions.

[SOURCE: ISO 4135:—^[1], 3.7.2.6]

201.3.214 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:—^[1], 3.7.2.1]

201.3.215 liquid container

part of a vaporizer, nebulizer or *humidifier* (201.3.214) which 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:—^[1], 3.1.4.28]

201.3.216 liquid reservoir

reservoir from which the *liquid container* (201.3.215) can be replenished or which, in the absence of a *liquid container* (201.3.215), supplies liquid directly to a vaporizer or *aerosol* (201.3.203) generator

[SOURCE: ISO 4135:—^[1], 3.1.4.29, modified —replaced 'may' with 'can'.]

201.3.217 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:—^[1], 3.8.6.4]

201.3.218 maximum operating pressure

maximum *rated* pressure in the *humidification chamber* (201.3.212) during *normal use*

201.3.219 measured gas temperature

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

201.3.220 monitoring equipment

ME equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*

[SOURCE: ISO 4135:—^[1], 3.11.1.3, modified —replaced 'user' with '*operator*'.]

201.3.221 protection device

part or function of medical device or *accessory* that, without intervention by the *operator*, protects the *patient*, other people or the environment from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 4135:—^[1], 3.14.48, modified —replaced 'user' with 'operator'.]

201.3.222

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:—^[1], 3.1.2.4]

201.3.223

set temperature

temperature at which the *humidifier* (201.3.214) attempts to maintain *measured gas temperature* (201.3.219)

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

201.3.224

standard temperature and pressure, dry

STPD

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

[SOURCE: ISO 4135:—^[1], 3.1.1.8]

201.3.225

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], 3.8.13]

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

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>	201.12.1.101 ^a
<i>measured gas temperature</i>	201.12.1.102
<i>low humidification output</i>	201.12.4.102
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.	

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

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

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**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 conformance 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.

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 conformance 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):

- aa) 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.
- bb) For the purpose of checking conformance 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*

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*

- a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use the type A evaluation method (statistical uncertainty) *procedure* from IEC Guide 115, 4.4.2.

NOTE This is a change from previous revisions of this document, which 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 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 ± 2 °C, then the uncertainty of the measurement cannot exceed $\pm 0,6$ °C of the *set temperature*.

- c) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.
- d) The *manufacturer* shall disclose the measurement uncertainty of each disclosed tolerance in the *technical description*.

Check conformance 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+A1:2012+A2:2020 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 conformance by application of ISO 20417:2021.

201.7.2.4.101 Additional requirements for accessories

Accessories supplied separately shall fulfil the requirements of:

- a) 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 conformance 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 The connector on the *humidifier* or *heated breathing tube controller* for a heated *breathing tube* is a connector that might 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 conforming 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'.

Check conformance by inspection.

201.7.4.3 * Units of measurement

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

All gas volume, flowrate and leakage specifications:

- aa) shall be expressed at STPD; except
- bb) 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) The *manufacturer* may choose in which *instructions for use* to place the information required by this document unless otherwise indicated in 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*.

Check conformance by inspection of the instructions for use, the risk management file and usability engineering file.

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 conformance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

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.”
- 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 conformance 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.”

- 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 conformance 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 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 conformance 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) an explanation of the meaning of the IP classification *marked* on the *ME equipment*;
- c) the maximum volume of water, expressed in ml, available for vaporization contained in the *liquid container* and, if provided, in the *liquid reservoir*;

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

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101.2 * Supervising clinician operating instructions

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

- a) the *maximum limited pressure* of:
 - 1) the *humidifier*, and
 - 2) the *accessories*;
- b) the *maximum operating pressure*;
- c) the minimum operating pressure of the *humidification chamber*, if applicable;
- d) the *rated* range of environmental operating conditions (temperature and altitude) of *normal use*;
- e) the maximum *delivered gas temperature*, if the *humidifier* is not provided with a means of continuously indicating the *measured gas temperature*;
- f) * the location in the *humidifier* or *accessories* to which the displayed *measured gas temperature* is referenced;
- g) 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^[4];
- h) unless the *humidifier* is integrated into other equipment,
 - 1) The *rated* range of the following characteristics of the assembled *operator*-detachable parts, over which the accuracies of set and monitored humidification are maintained:
 - i) flowrate;
 - ii) *gas pathway* resistance; and
 - iii) *gas pathway* compliance.
 - 2) These specifications may be presented in ranges.
 - 3) The accuracies of set and monitored values may be presented as a function of these characteristics.
 - 4) Since these values can be affected by the depletion of the liquid, the minimum and maximum values shall be disclosed.
 - 5) Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate and the maximum *rated* pressure).

- 6) The resistance and compliance should be determined in accordance with ISO 5367 or an equivalent method.
 - 7) The resistance and compliance for an *active HME* should be determined in accordance with ISO 9360-1 or ISO 9360-2^[4].
 - i) * unless the *humidifier* is integrated into other equipment, the pressure drop, as a function of flowrate, across the *humidifier* and *accessories* or individual components;
 - 1) The pressure drop should be determined in accordance with ISO 5367 or an equivalent method.
 - 2) The pressure drop for an *active HME* should be determined in accordance with ISO 9360-1 or ISO 9360-2^[4].
 - j) unless the *humidifier* is integrated into other equipment, the *rated* range of gas inlet temperature;
 - k) unless the *humidifier* is integrated into other equipment that provides control of gas flow and pressure to the *patient*, any restrictions on the ventilation modes, pressures or flow patterns applied to the *humidifier* and its *accessories* from equipment indicated in the *instructions for use*; and
- EXAMPLE A *humidifier* not qualified for use with high frequency ventilation modes, or with a 'variable flow' type infant nasal *CPAP* equipment in which the *humidifier chamber* is exposed to continuous pressure exceeding 125 hPa.
- l) the known adverse effects on the performance of the *humidifier* when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference.

If applicable, *instructions for use* shall disclose

- m) the essential technical characteristics of each recommended *breathing system filter*;

EXAMPLE Deadspace and resistance.

- n) for a *humidifier* that entrains air for the purpose of diluting oxygen:
 - 1) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the *humidifier*, e.g. when using *accessory* equipment;
 - 2) a recommendation that the oxygen concentration be measured at the point of delivery to the *patient*.

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

201.7.9.2.12 Cleaning, disinfection and sterilization

Amendment (add after normal use):

or in *single fault condition*

Amendment (add after bulleted list):

- aa) The *instructions for use* shall identify the portions of the *gas pathways* through the *humidifier* that can become contaminated with body fluids or by contaminants carried by expired breathing gases during both *normal condition* and *single fault condition*.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The *instructions for use* shall disclose

- a) a description of periodic visual safety inspections that should be performed by the *operator*,
- b) the intervals at which *cleaning procedures* need to be performed and the items required for such *cleaning*; and
- c) if applicable, the *internal electrical power source* care and maintenance *procedures*, including instructions for recharging or replacement.

Check conformance by inspection of the instructions for use.

201.7.9.2.14.101 Additional requirements for accessories, supplementary equipment, used material

The *instructions for use* of a *humidifier* shall identify:

- a) at least one set of *accessories*; and
- b) if applicable, the *ME equipment* necessary for the *humidifier's intended use*.

If applicable, the *instructions for use* shall disclose:

- c) any restrictions on the positioning of components within the *breathing system*; and

EXAMPLE Where such components are *flow-direction-sensitive components*.

- d) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *humidifier* or equipment to which it is connected.

Check conformance by inspection of the instructions for use and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1.101 Additional general requirements

The *technical description* shall disclose

- a) the interdependence of control functions, and
- b) a statement to the effect that the responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.

Check conformance by inspection of the technical description.

201.7.9.3.101 Additional requirements for the technical description

The *technical description* shall disclose:

- a) a description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during start-up; and
- b) which checks are performed automatically.

Check conformance by inspection of the technical description.

201.8 Protection against electrical hazards form *ME equipment*

Clause 8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

Additional subclause:

201.8.3.101 Additional requirements for classification of *applied parts*

The *applied parts* of a *humidifier* and its *accessories* shall be *F-type applied parts*.

Check conformance by inspection of the humidifier.

201.8.7.4.7 Measurement of the *patient leakage current*

Amendment (add to the second paragraph of e)):

Assemble the humidifier to the breathing tube and other necessary accessories. Wrap the metal foil around outside of the patient-connection port, as well as inside to depth that accessible by the relevant standard test finger, as mentioned under 8.7.4.6. The metal foil is considered as the only patient connection for the applied part concerned.

201.9 Protection against *mechanical hazards of ME equipment and ME systems*

Clause 9 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

Additional subclauses:

201.9.4.3.101 * Additional requirements for instability from unwanted lateral movement

- a) A *transit-operable humidifier* intended for use in either the *home healthcare environment* or *emergency medical services environment* shall include a means by which the *humidifier* can be easily attached without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE 1 Means to be physically restrained during transport in a personal vehicle, in an ambulance or on a wheelchair.

- 1) The means shall hold the *humidifier* to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 3 s each.

EXAMPLE 2 Attach the *humidifier* to an armature at a 1 m radius from an axis of horizontal rotation. When rotating through a circle every 2 s at constant speed, the lateral (centripetal) acceleration is approximately 1,0 g^[54].

- 2) No more liquid than is specified in 201.13.1.101 shall exit the *humidification chamber* outlet from these accelerations or decelerations.

Check conformance by functional testing and the testing of 201.13.1.101.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

The A-weighted sound pressure level emitted by the *humidifier*, not integrated into *ME equipment* that is covered by another particular standard, shall be less than 50 dB as determined by the test method of this document.

Check conformance with the following test.

- a) Place the *humidifier* on the sound-reflecting plane, fill the *humidification chamber* to the least favourable level and attach the least favourable set of *accessories* from those indicated in the instructions for use.
- b) Connect appropriate flow source to the input of the *humidifier*.

- c) *Acoustically isolate the flow source and the exhaust flow by suitable means so that any noise caused by them does not interfere with the sound measurement of the humidifier.*
- d) *Configure the flow source to worst case flow.*
- e) *Using a microphone of the sound level meter conforming with the requirements of type 1 instruments specified in IEC 61672-1 measure the maximum time-weighted sound pressure level using frequency-weighting characteristic A and the time-weighting F of the sound level meter (i.e. L_{AFmax}) at 10 positions in a hemisphere with a radius from the geometric centre of the humidifier in a free field over a reflecting plane as specified in 8.1.1. of ISO 3744:2010. Average the values in conformance with 8.2.2 of ISO 3744:2010.*
- f) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.*
- g) *Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.*
- h) *Confirm that the measured sound pressure level is less than 50 dB.*

201.9.6.2.1.102 Additional requirements for audible acoustic energy for use with an incubator

A humidifier with the *breathing tube* and other necessary *accessories* intended for use with an incubator shall conform with the sound pressure level requirements of IEC 60601-2-19:2020, 201.9.6.2.1.101.

Check conformance by application of the tests of IEC 60601-2-19:2020, 201.9.6.2.1.101.

201.10 Protection against unwanted and excessive radiation hazards

Clause 10 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.11 Protection against excessive temperatures and other hazards

Clause 11 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

201.11.1.1 Maximum temperature during normal use

Amendment (add at the end of the subclause):

- aa) The heating element of a *humidifier* shall provide means to ensure that it is unlikely to be touched while exceeding the temperature limits indicated in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table 23.
 - 1) *Safety sign 7010-W017 (Table 201.D.2.102, safety sign 1) may be used to fulfil this requirement.*
 - 2) *Symbol 60417-5041 (Table 201.D.2.101, symbol 1) in combination with a warning indicator light (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table 2) may be used to fulfil this requirement.*

NOTE ISO 13732-1:2006^[5], Annex E, provides examples of additional *risk control* (protective) measures that can be considered to fulfil this requirement.

201.11.1.2.2 * Applied parts not intended to supply heat to a patient

Amendment (add at the end of the subclause):

Notwithstanding the requirements of IEC 60601-1:2005+AMD1:2012, 11.1.2.2, the allowable maximum temperature of the *accessible part* surfaces of *breathing tubes* within 25 cm of the *patient-connection port* shall not reach the following limits:

- aa) during *thermal stability*: 44 °C; and

bb) during a change in average flow or other disturbance: 48 °C for not more than 10 min.

NOTE A disturbance could be during the start-up period or during the transition to a new state of *thermal stability* following a change in gas flowrate or change in *set temperature*.

201.11.6.2 * Overflow in ME equipment

Replacement:

- a) Liquid overflowing from the *liquid container* or *liquid reservoir* shall
 - 1) not wet any *means of protection* that is liable to be adversely affected by liquid, nor
 - 2) result in the loss of *basic safety* or *essential performance*.
- b) No *hazardous situation* (as specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 13.1 or 201.13.1.101) or unacceptable *risk* due to overflow shall be developed:
 - 1) if the *liquid container* or *liquid reservoir* is filled to its maximum capacity;
 - 2) for a *portable humidifier* (e.g. tabletop), if it is tilted through an angle of 10° from any position of *normal use* when operated under *normal condition* at the maximum flowrate of *normal use*;
 - 3) for a *mobile humidifier* (e.g. pole-mounted), if it is
 - i) tilted through an angle of 20° from any position of *normal use*, and
 - ii) moved over a threshold as described in IEC 60601-1:2005+AMD1:2012, 9.4.2.4.3, and
 - 4) for an *active HME*, in the least favourable orientation;when operated under *normal condition* at the maximum flowrate of *normal use*.

Check conformance by the following:

- c) *Fill the liquid container and liquid reservoir to the indicated maximum level. Operate the humidifier at its maximum rated flowrate.*
- d) *Portable ME equipment is subsequently tilted through an angle of 10° in the least favourable direction(s) (if necessary with refilling) starting from the position of normal use.*
- e) *Mobile ME equipment is subsequently tilted through an angle of 20° in the least favourable direction(s) (if necessary with refilling) starting from the position of normal use and is moved over a threshold as described in IEC 60601-1:2005+AMD1:2012, 9.4.2.4.3.*
- f) *Return the humidifier to normal orientation and subsequently refill the liquid container to the maximum level then add a further quantity equal to 15 % of the capacity of the liquid container, poured in steadily over a period of 1 min.*
- g) *After these procedures, the humidifier is to pass the appropriate dielectric strength and leakage current tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of basic safety or essential performance in normal condition or in combination with a single fault condition (based on a visual inspection).*
- h) *In addition, confirm that there is no more liquid than is specified in 201.13.1.101 exits the humidification chamber outlet.*

201.11.6.6 * Cleaning and disinfection of ME equipment or ME system

Amendment (add additional requirement as new first paragraph):

aa) Gas pathways through the humidifier and its accessories not intended for *single use* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* that are not *single use* shall be designed to allow for:

- 1) *cleaning and disinfection; or*
- 2) *cleaning and sterilization.*

NOTE Additional requirements are found in IEC 60601-1:2005+AMD1:2012, 11.6.7 and IEC 60601-1-11:2015, 8.2.

- 3) Dismantling may be used.

Amendment (add additional requirement and replace the compliance test):

bb) Humidifier enclosures shall be designed to allow for surface *cleaning and disinfection* to reduce to acceptable levels the *risk* of cross infection of the *operator*, other persons or next *patient*.

cc) Processing instructions for the humidifier and its accessories shall

- 1) conform to ISO 17664:2017 and ISO 14937:2009, and
- 2) be disclosed in the *instructions for use*.

NOTE 1 ISO 14159 provides guidance for the design of *enclosures*.

Check conformance by inspection of the risk management file. When conformance with this document could be affected by the cleaning or the disinfecting of the humidifier or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these procedures, confirm that basic safety and essential performance are maintained. Confirm that the manufacturer has evaluated the effects of multiple processing cycles and the effectiveness of those cycles.

NOTE 2 Additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 Sterilization of ME equipment or ME system

Amendment (add note before compliance test):

NOTE Additional requirements are found also in IEC 60601-1:2005+AMD1:2012, 11.6.6 and IEC 60601-1-11:2015+AMD1:2020, Clause 8.

201.11.7 Biocompatibility of ME equipment and ME systems

Amendment (add after existing text prior to the compliance statement):

aa) The manufacturer of a humidifier, breathing system, its parts and accessories shall address in the *risk management process* the risks associated with the leaching or leaking of substances into the *gas pathway*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

Check conformance by confirming conformity to ISO 18562-1:2017.