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Medical electrical equipment —

Part 2-74:

Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Appareils électromédicaux —

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

ISO/FDIS 80601-2-74

<https://standards.iteh.ai/catalog/standards/sist/cf24a4f5-493e-4a79-88a9-b7a7ac7d3a58/iso-fdis-80601-2-74>

This draft is submitted to a parallel vote in ISO and in IEC.

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Contents	Page
Foreword.....	v
Introduction.....	vii
201.1 Scope, object and related standards.....	1
201.2 Normative references	3
201.3 Terms and definitions	5
201.4 General requirements	8
201.5 General requirements for testing of <i>ME equipment</i>	11
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	12
201.7 <i>ME equipment</i> identification, marking and documents.....	13
201.8 Protection against electrical hazards form <i>ME equipment</i>	20
201.9 Protection against mechanical hazards of <i>ME equipment</i> and <i>ME systems</i>	20
201.10 Protection against unwanted and excessive radiation hazards.....	21
201.11 Protection against excessive temperatures and other hazards	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs	24
201.13 Hazardous situations and fault conditions for <i>ME Equipment</i>	30
201.14 Programmable electrical/medical systems (PEMS)	31
201.15 Construction of <i>ME equipment</i>	32
201.16 <i>ME systems</i>	32
201.16.2 Accompanying documents of an <i>ME system</i>	32
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	32
201.101 Breathing system connectors and ports.....	33
201.102 Requirements for the breathing system and accessories.....	35
201.103 Liquid container	36
201.104 Functional connection	36
202 Electromagnetic disturbances — Requirements and tests.....	37
206 Usability	38
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	39
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	39
Annex C (informative) Guide to marking and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	40
Annex D (informative) Symbols on marking	45
Annex AA (informative) Particular guidance and rationale	47
Annex BB (normative) * Determination of the accuracy of the displayed measured gas temperature.....	64
Annex CC (normative) * Determination of the humidification output	66
Annex DD (normative) * Specific enthalpy calculations	71
Annex EE (normative) Removable temperature sensors and mating ports.....	73
Annex FF (normative) * Reference temperature sensor	77

Annex GG (informative) Saturation vapour pressure	80
Annex HH (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	81
Annex II (informative) Reference to the <i>essential principles of safety and performance of medical devices</i> in accordance with ISO 16142-1:2016	85
Annex JJ (informative) Reference to the general safety and performance requirements	88
Annex KK (informative) Terminology — Alphabetized index of defined terms	91
Bibliography	95

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ISO/FDIS 80601-2-74
<https://standards.iteh.ai/catalog/standards/sist/cf24a4f5-493e-4a79-88a9-b7a7ac7d3a58/iso-fdis-80601-2-74>

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 ØW 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 website.

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.

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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.

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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*. (standards.iteh.ai)

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

<https://standards.iteh.ai/catalog/standards/sist/cf24a4f5-493e-4a79-88a9-b7a71c743a58/iso-80601-2-74>

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 as indicated in Annex KK and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE An 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*

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[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