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Date: 12 March 2024

Origin: International

Latest date for receipt of comments: 3 April 2024

Project No. 2023/01235

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

Interested committees:

Title: BS EN ISO 80601-2-70 Medical electrical equipment

Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

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Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2124/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

ISO 80601-2-70 ED3

DATE OF CIRCULATION:

2024-03-08

CLOSING DATE FOR COMMENTS:

2024-05-03

SUPERSEDES DOCUMENTS:

62D/2119/RR

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

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:

☐

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

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

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TITLE:

Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment

NOTE FROM TC/SC OFFICERS:

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ISO/TC 121/SC 3/ **N3062**

ISO 80601-2-70:2023(E)

Date: 2024-03-05

ISO 80601-2-70 (Ed 3)

ISO/TC 121/SC 3/JWG 12

Secretariat: ANSI

Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

Appareils électromédicaux — Partie 2-70: Exigences particulières pour la sécurité de base et les performances essentielles de l'équipement de thérapie respiratoire pour l'apnée du sommeil

CD stage

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Foreword

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

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

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

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

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

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

This third edition cancels and replaces the second edition (ISO 80601-2-70:2020), which has been technically revised.

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

- updated references;
- updated the audible acoustic energy requirements; and
- updated the maximum flowrate test method.

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.

Introduction

Sleep apnoea is a chronic medical condition where the *patient* repeatedly stops breathing during sleep. These episodes typically last 10 s or more and cause the oxygen levels in the blood to drop. It can be caused by obstruction of the upper airway (obstructive sleep apnoea or OSA) or by a failure of the brain to initiate a breath (central sleep apnoea).

NOTE *Sleep apnoea breathing therapy equipment* is intended for the treatment of obstructive sleep apnoea and not central sleep apnoea.

Sleep apnoea, if untreated, can cause and worsen other medical conditions, including hypertension, heart failure and diabetes^[22].

Hypopnoea refers to a transient reduction of airflow, often while the *patient* is asleep, that lasts for at least 10 s, shallow breathing. It also results in arousal or can cause oxygen saturation to drop. Hypopnoea is less severe than apnoea. It is commonly due to partial obstruction of the upper airway^[20].

Awareness of the *risks* associated with obstructive sleep apnoea has grown significantly. As a result, the use of *sleep apnoea breathing therapy equipment* to treat obstructive sleep apnoea has become common.

This document covers *basic safety* and *essential performance* requirements needed to protect *patients* in the use of this *ME equipment*.

This document covers *sleep apnoea breathing therapy equipment* for *patient* use. ISO 17510 applies to *masks* and *accessories* used to connect *sleep apnoea breathing therapy equipment* to the *patient*. Figure AA.1 shows this diagrammatically.

In this document, the following print types are used:

— Requirements and definitions: roman type

— *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 four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.1, 201.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.101, 201.102 and 201.102.1 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” indicates a requirement;

- 178 – “should” indicates a recommendation;
179 – “may” indicates a permission;
180 – “can” is used to describe a possibility or capability; and
181 – “must” is used to express an external constraint.
182 Annex C contains a guide to the *marking* and labelling requirements in this document.

183

Medical electrical equipment —

Part 2-70:

Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment

201.1 Scope, object and related standards

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

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

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

201.1.1 Scope

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.1 is replaced by:

This document is applicable to the *basic safety* and *essential performance* of *sleep apnoea breathing therapy equipment*, hereafter referred to as *ME equipment*, intended to alleviate the symptoms of *patients* who suffer from obstructive sleep apnoea by delivering a therapeutic breathing pressure to the respiratory tract of the *patient*. *Sleep apnoea breathing therapy equipment* is intended for use in the *home healthcare environment* by *lay operators* as well as in professional healthcare institutions.

Sleep apnoea breathing therapy equipment is not considered to utilize a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the therapy settings.

This document excludes *sleep apnoea breathing therapy equipment* intended for use with neonates.

This document is applicable to *ME equipment* or an *ME system* intended for those *patients* who are not dependent on *artificial ventilation*.

This document is not applicable to *ME equipment* or an *ME system* intended for those *patients* who are dependent on *artificial ventilation* such as *patients* with central sleep apnoea.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to *sleep apnoea breathing therapy equipment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *sleep apnoea breathing therapy equipment*.

Masks and application *accessories* intended for use during sleep apnoea breathing therapy are additionally addressed by ISO 17510. Refer to Figure AA.1 for items covered further under this document.

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.

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

218 NOTE 2 See also 4.2 of the general standard.

219 This document does not specify the requirements for:

- 220 – ventilators or *accessories* intended for critical care ventilators for ventilator-dependent *patients*,
221 which are given in ISO 80601-2-12.
- 222 – ventilators or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13.
- 223 – ventilators or *accessories* intended for home care ventilators for ventilator-dependent *patients*, which
224 are given in ISO 80601-2-72.
- 225 – ventilators or *accessories* intended for emergency and transport, which are given in ISO 80601-2-84.
- 226 – ventilators or *accessories* intended for home-care ventilatory support, which are given in
227 ISO 80601-2-79 and ISO 80601-2-80.
- 228 – high-frequency jet ventilators (HFJVs) or high-frequency oscillatory ventilators (HFOVs), which are
229 given in ISO 80601-2-87.
- 230 – high-frequency oscillatory *ventilators* (HFOVs)^[23];
- 231 – respiratory high flow equipment, which are given in ISO 80601-2-90;
- 232 NOTE 3 ISO 80601-2-80 *ventilatory support equipment* can incorporate high-flow therapy operational mode,
233 but such a mode is only for spontaneously breathing *patients*.
- 234 – user-powered resuscitators, which are given in ISO 10651-4;
- 235 – gas-powered emergency resuscitators, which are given in ISO 10651-5;
- 236 – oxygen therapy constant flow *ME equipment*; and
- 237 – cuirass or “iron-lung” *ventilation equipment*.

238 201.1.2 Object

239 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.2 is replaced by:

240 The object of this document is to establish particular *basic safety* and *essential performance* requirements
241 for *sleep apnoea breathing therapy equipment* (as defined in 201.3.215).

242 NOTE 1 This document has been prepared to address the relevant *essential principles*^[17] and labelling^[18] guidances of the
243 International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

244 NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of
245 European regulation (EU) 2017/745^[16].

246 201.1.3 Collateral standards

247 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

248 IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 apply as modified
249 in Clauses 202 and 206 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published
250 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+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, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables 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 3.139, 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 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.

- 289 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:
- 290 *Addition:*
- 291 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources*
292 *using sound pressure — Engineering methods for an essentially free field over a reflecting plane*
- 293 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and*
294 *equipment*
- 295 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Cones and sockets*
- 296 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
297 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
298 *devices*
- 299 ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*
- 300 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device*
301 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*
- 302 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*
303 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*
- 304 ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
305 *Part 1: Evaluation and testing within a risk management process*
- 306 ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*
- 307 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method*
308 *to assess filtration performance*
- 309 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration*
310 *aspects*
- 311 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications —*
312 *Part 1: General requirements*
- 313 ISO 80601-2-74:—¹, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety*
314 *and essential performance of respiratory humidifying equipment*
- 315 IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1:*
316 *Security — Activities in the product life cycle*
- 317 IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the*
318 *electrotechnical sector*

¹ xxx

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, and the following apply.

ISO and IEC maintain terminology 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 index of defined terms is found in Annex FF.

Addition:

201.3.201

accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202

airway

connected, gas-containing cavities and passages within the respiratory system, that conduct gas between the alveoli and the oral and nasal orifices on the surface of the face, or the *patient-connection port* if an airway device is used

Note 1 to entry: This is a well-established term that is commonly used in isolation in references to the *airway* of a *patient*. Depending on the context, it is sometimes more helpful to use the qualified term, *patient's airway*.

[SOURCE: ISO 19223:2019, 3.1.2, modified — deleted note 2.]

201.3.203

airway pressure

P_{aw}

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

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

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.204

airway pressure accuracy

degree of correspondence between the pressure set on the *sleep apnoea breathing therapy equipment* and the actual (true) *airway pressure*

201.3.205

artificial ventilation

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

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

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

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

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

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.206

attack

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

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

201.3.207

auto CPAP

operating mode in which the *sleep apnoea breathing therapy equipment* automatically adjusts the applied gas pressure level within a clinically predetermined range to prevent disturbances of the *patient's* breathing at the lowest necessary pressure

Note 1 to entry: These disturbances are typically obstructive apnoea (cessation of air flow) or hypopnoea (shallow breathing) events.

Note 2 to entry: An *auto CPAP* mode may be bi-level.

Note 3 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.208

automatic start/stop function

feature by which the *sleep apnoea breathing therapy equipment* automatically starts or stops the therapy based on whether the *patient* is connected or disconnected from the equipment

389 Note 1 to entry: *Sleep apnoea breathing therapy equipment* may provide an *automatic start* function, an *automatic*
 390 *stop* function, or both.

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

392 **201.3.209**

393 **bi-level PAP**

394 **bi-level positive airway pressure**

395 *sleep-apnoea breathing-therapy mode in which there are two therapeutic positive pressure levels at the*
 396 *patient-connection port during the respiratory cycle*

397 Note 1 to entry: The two levels of positive *airway pressure* (PAP) invoked by the various names that have been given
 398 to this breathing-therapy mode are typically identified by the terms IPAP (inspiratory positive *airway pressure*) and
 399 EPAP (expiratory positive *airway pressure*), with IPAP representing the set inspiratory pressure level during the
 400 *patient's* inspiratory phase and EPAP the set baseline airway pressure (BAP) during the *patient's* expiratory phase.

401 [SOURCE: ISO 19223:2019, 3.12.5, modified — deleted notes 2 to 4.]

402 **201.3.210**

403 **biocompatibility**

404 *ability of a medical device, accessory or material to perform with an appropriate host response in a*
 405 *specific application*

406 Note 1 to entry: A medical device or *accessory* may produce some level of adverse effect, but that level may be
 407 determined to be acceptable when considering the benefits provided by the medical device or *accessory*.

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

409 **201.3.211**

410 **body temperature and pressure saturated**

411 **BTPS**

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

413 [SOURCE: ISO 4135:2022, 3.1.1.7]

414 **201.3.212**

415 **breathing gas pathway**

416 *gas pathways* through which gas flows at respiratory pressures between the *gas intake port* and the
 417 *patient-connection port*

418 **201.3.213**

419 **breathing system filter**

420 **BSF**

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

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

- 423 **201.3.214**
 424 **breathing tube**
 425 non-rigid tube used to convey gases between components of a breathing system
- 426 **201.3.215**
 427 **cleaning**
 428 removal of contaminants to the extent necessary for further *processing* or for *intended use*
- 429 Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris)
 430 from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that
 431 prepares the items for safe handling or further *processing*.
- 432 [SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]
- 433 **201.3.216**
 434 **connector**
 435 fitting to join two or more components
- 436 EXAMPLE *Connectors for low-pressure hose assembly* are any of a range of mating components intended to
 437 maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular
 438 gas.
- 439 [SOURCE: ISO 4135:2022, 3.1.4.5]
- 440 **201.3.217**
 441 **CPAP**
 442 **continuous positive airway pressure**
 443 *ventilation-mode* or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at
 444 a set *airway-pressure* level, above ambient pressure
- 445 Note 1 to entry: *CPAP* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor
 446 deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable
 447 levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of
 448 breathing to a greater extent than could be experienced during natural breathing.
- 449 Note 2 to entry: This definition excludes the use of the term to describe *ventilation-modes* where spontaneous
 450 inspirations are supported by intermittently elevated pressures other than with the intention to compensate for
 451 any actual or perceived imposed work of breathing.
- 452 Note 3 to entry: Because, as used for this *ventilation-mode*, the concept of a *CPAP* level coincides with that of a
 453 baseline *airway pressure* the setting could be designated as for either concept but as the intention of the *operator*
 454 selecting this *ventilation-mode* will be to achieve a specific *CPAP* level, this becomes an acceptable admitted term to
 455 designate the set quantity.
- 456 Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation-mode*, *CPAP* is included
 457 in this document because it is commonly made available on typical critical care *ventilators* for use as part of a
 458 continuum of a *patient's* treatment without the necessity to change to another device.
- 459 Note 5 to entry: It is possible for a *ventilation-mode* resembling *CPAP* to be realized on a *ventilator* by the use of CSV
 460 (continuous spontaneous *ventilation*) with the pressure-support (PS) *set* to 'zero' or 'none' but CSV set in this way
 461 is not equivalent to *CPAP* if its performance in response to a spontaneous inspiration is dependent on the setting of
 462 an appropriate trigger level.

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

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

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

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

201.3.218 cybersecurity

state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1:2021, 3.30]

201.3.219 diagnostic apnoea

A_d

decrease in *airway* flow greater than ≥ 90 % of pre-event baseline for at least 10 s

Note 1 to entry: Airflow is typically measured by oronasal thermal airflow sensor or nasal pressure transducer normally determined using full polysomnography in an attended sleep study or home sleep test.

Note 2 to entry: Reference [19] was used to determine this definition.

201.3.220 diagnostic apnoea-hypopnoea index

AHI_d

average number of *diagnostic apnoea* events and *diagnostic hypopnoea* events occurring per hour of sleep

$$AHI_d = \frac{(A_d + H_d) \cdot 60}{t_s}$$

where

A_d is the total number of diagnostic apnoea events

H_d is the total number of diagnostic hypopnoea events

t_s is the total sleep time in minutes

496 Note 1 to entry: A *diagnostic apnoea-hypopnoea index* is normally determined using full polysomnography in an
497 attended sleep study or home sleep test.

498 **201.3.221**
499 **diagnostic hypopnoea**

500 H_d
501 decrease in *airway* flow of at least 30 % of the pre-event baseline for at least 10 s; and at least 3 % oxygen
502 desaturation from pre-event baseline or an arousal event, excluding *diagnostic apnoea*

503 Note 1 to entry: For monitoring oxygen saturation, a pulse oximeter should have a maximum signal averaging time
504 of ≤ 3 s.

505 Note 2 to entry: An oxygen desaturation of 4 % from pre-event baseline is also used.

506 Note 3 to entry: Airflow is typically measured by oronasal thermal airflow sensor or nasal pressure transducer
507 normally determined using full polysomnography in an attended sleep study or home sleep test.

508 Note 4 to entry: Reference [19] was used to determine this definition.

509 **201.3.222**
510 **disinfection**

511 *process to inactivate* viable microorganisms to a level previously specified as being appropriate for a
512 defined purpose

513 [SOURCE: ISO 17664-2:2021, 3.5]

514 **201.3.223**
515 **equipment apnoea**

516 A_{flow}
517 diagnostic apnoea as estimated by sleep apnoea breathing therapy equipment

518 **201.3.224**
519 **equipment apnoea-hypopnoea index**

520 AHI_{flow}
521 average number of residual *equipment apnoea* and *equipment hypopnoea* events occurring per hour of
522 the therapy session

523 Note 1 to entry: References [19] and [23] were used to determine this definition.

524 **201.3.225**
525 **equipment hypopnoea**

526 H_{flow}
527 diagnostic hypopnoea as estimated by sleep apnoea breathing therapy equipment

528 Note 1 to entry: *Sleep apnoea breathing therapy equipment* without oximetry cannot monitor oxygen saturation.
529 Therefore, *sleep apnoea breathing therapy equipment* without the oxygen saturation information, can only provide
530 an estimate of hypopnoea events.

201.3.226**essential function**

function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the manufacturer, and operational availability for the *medical device*

Note 1 to entry: *Essential functions* include, but are not limited to, the *safety* instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the *medical device* safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.227**essential principles****essential principles of safety and performance**

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

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

201.3.228**exhaust port**

port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.229**firecall**

method established to provide emergency access to a secure medical device

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

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

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

201.3.230**flow-direction-sensitive component**

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

[SOURCE: ISO 4135:2022, definition 3.1.4.15]

- 568 **201.3.231**
 569 **gas intake port**
 570 port through which gas is drawn for use by the *patient*
- 571 Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in opposition to an *inlet*, at which gas
 572 is provided by a medical gas supply system.
- 573 [SOURCE: ISO 4135:2022, 3.1.4.21 modified — replaced “apposition” with “opposition”.]
- 574 **201.3.232**
 575 **gas output port**
 576 port through which gas is delivered at respiratory pressures through a tube to the *patient-connection port*
- 577 **201.3.233**
 578 **gas pathway**
 579 interior surfaces, over which gases or liquids that can be inspired *pass*
- 580 EXAMPLE 1 The *ventilator breathing system*, *inlet* filter, gas mixer, blower and internal piping.
- 581 EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.
- 582 EXAMPLE 3 The inner surfaces of *breathing tubes*, tracheal tubes or *masks* and mouthpieces.
- 583 Note 1 to entry: The *gas pathway* is bounded by the *fluid* ports through which gases or liquids enter the *medical*
 584 *device* or *accessory*. This can include the *patient* interface or the interior surfaces of enclosures that are in contact
 585 with gases or liquids that can be inspired.
- 586 Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.
- 587 Note 3 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are
 588 evaluated according to the ISO 10993 series.
- 589 [SOURCE: ISO 18562-1:2024, 3.11, modified — replaced “ports” with “fluid ports”.]
- 590 **201.3.234**
 591 **healthcare professional**
 592 <adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative,
 593 promotional or rehabilitative healthcare services
- 594 **201.3.235**
 595 **home healthcare environment**
 596 dwelling place in which a *patient* lives or other places where *patients* are present, excluding the
 597 professional healthcare environment and the *emergency medical services* (EMS) environment
- 598 EXAMPLE Other places include in a car, bus, train, boat or plane, in a wheelchair or walking outdoors.
- 599 Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres,
 600 dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple
 601 treatment facilities and emergency medical services.
- 602 Note 2 to entry: Nursing homes are considered *home healthcare environments*.

603 Note 3 to entry: Other places where a *patient* is present include the outdoor environment, while working and in
 604 vehicles.

605 [SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1, modified —deleted “For the purpose of this collateral
 606 standard,” and replaced “EMS” with “emergency medical services (EMS)”.]

607 **201.3.236**

608 **humidifier**

609 **device** that adds water in the form of droplets or vapour, or both, to the inspired gas

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

612 [SOURCE: ISO 4135:2022, 3.7.2.1]

613 **201.3.237**

614 **I:E ratio**

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

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

617 **201.3.238**

618 **inflation-type**

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

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

621 **201.3.239**

622 **information supplied by the manufacturer**

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

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

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

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

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

634 **201.3.240**

635 **inlet**

636 **opening** through which gas or other material is pushed by an elevated upstream pressure

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

201.3.241

inspiratory pressure

airway pressure during an inspiratory or inflation phase

[SOURCE: ISO 19223:2019, 3.6.2, modified — deleted notes.]

201.3.242

instructions for use

IFU

portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a user can be either a *lay* user or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 5 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 6.]

201.3.243

lay

lay person

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

EXAMPLE *Lay operator, lay responsible organization.*

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

201.3.244

lung

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

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

671 **201.3.245**
 672 **marking**
 673 information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical
 674 device or *accessory*

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

676 Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly
 677 described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of
 678 *marking*.

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

680 **201.3.246**
 681 **mask**
 682 device which provides a non-invasive interface between the *patient's* airway and a *patient-connection*
 683 *port* or other connection to a source of respirable gas

684 [SOURCE: ISO 4135:2022, 3.8.6.4]

685 **201.3.247**
 686 **maximum limited pressure**
 687 $P_{lim,max}$
 688 highest *airway pressure* that can occur during *normal use* or under *single fault condition*

689 [SOURCE: ISO 19223:2019, 3.13.3, modified — deleted notes.]

690 **201.3.248**
 691 **monitoring equipment**
 692 equipment or component part that measures and indicates the value of a variable to the *operator*

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

695 **201.3.249**
 696 **operator interface**
 697 means by which the *operator* and the *ME equipment* interact

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

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

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

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

705 [SOURCE: IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, 3.1]

706 **201.3.250**
 707 **outlet**
 708 opening through which gas leaves a device or component

709 [SOURCE: ISO 4135:2022, 3.1.4.40]

710 **201.3.251**
 711 **patient-connection port**
 712 port of a *breathing system* intended for connection to an *airway device*

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

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

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

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

719 **201.3.252**
 720 **physiologic closed-loop control system**
 721 part of *ME equipment* or *ME system* used to adjust a physiologic variable relative to a command variable
 722 using a feedback variable

723 [SOURCE: IEC 60601-1-10:2007+AMD1:2013+AMD2:2020, 3.19]

724 **201.3.253**
 725 **processing**
 726 <preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory*
 727 for its *intended use*

728 [SOURCE: ISO 20417:2021, 3.20]

729 **201.3.254**
 730 **protection device**
 731 part or function of medical device or *accessory* that, without intervention by the *operator*, protects against
 732 hazardous output

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

735 **201.3.255**
 736 **ramp mode**
 737 operating mode in which the *sleep apnoea breathing therapy equipment* automatically increases the
 738 applied pressure level from an initial level to the clinically predetermined therapeutic level in a
 739 predetermined profile, or decreases the applied pressure level from the therapeutic level to a lower level
 740 in a predetermined profile