



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-70:2025. It is identical to ISO 80601-2-70:2025. It supersedes BS EN ISO 80601-2-70:2020, which is withdrawn.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 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment (ISO 80601-2-70:2025)

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 (ISO 80601-2-70:2025)

Medizinische elektrische Geräte - Teil 2-70: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Schlafapnoe-Atemtherapiegeräten (ISO 80601-2-70:2025)

This European Standard was approved by CEN on 23 November 2025.

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European foreword

This document (EN ISO 80601-2-70:2025) 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of an identical text or by endorsement, at the latest by June 2026, and conflicting national standards shall be withdrawn at the latest by June 2026.

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 80601-2-70:2020.

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Endorsement notice

The text of ISO 80601-2-70:2025 has been approved by CEN as EN ISO 80601-2-70:2025 without any modification.

Contents

Page

Foreword	vi
Introduction	vii
201.1 Scope, object and related standards	1
201.1.1 Scope	1
201.1.2 Object	2
201.1.3 Collateral standards.....	2
201.1.4 Particular standards.....	3
201.2 Normative references	4
201.3 Terms and definitions	5
201.4 General requirements	20
201.4.3 <i>Essential performance</i>	20
201.4.3.101 Additional requirements for <i>essential performance</i>	20
201.4.6 <i>ME equipment</i> or <i>ME system</i> parts that contact the patient	21
201.5 General requirements for testing of <i>ME equipment</i>	21
201.5.101 Additional requirements for general requirements for testing of <i>ME equipment</i>	21
201.5.101.1 Gas flowrate specifications.....	21
201.5.101.2 <i>Sleep apnoea breathing therapy equipment</i> testing errors	21
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	22
201.7 <i>ME equipment</i> identification, marking and documents	22
201.7.1.2 Legibility of <i>markings</i>	22
201.7.2.4.101 Additional requirements for <i>accessories</i>	22
201.7.2.101 Additional requirements for <i>marking</i> on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts	23
201.7.4.3 Units of measurement	23
201.7.9.2 <i>Instructions for use</i>	23
201.7.9.2.1.101 Additional general requirements	24
201.7.9.2.2.101 Additional requirements for warnings and safety notices	24
201.7.9.2.5.101 Additional requirements for <i>ME equipment</i> description.....	25
201.7.9.2.9.101 Additional requirements for operating instructions.....	25
201.7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	25
201.7.9.2.13.101 Additional requirements for maintenance	25
201.7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	26
201.7.9.3.1.101 Additional general requirements	26
201.8 Protection against electrical hazards from <i>ME equipment</i>	27
201.9 Protection against mechanical hazards of <i>ME equipment</i> and <i>ME systems</i>	27
201.9.6.2.1.101 Additional requirements for audible acoustic energy	28
201.10 Protection against unwanted and excessive radiation hazards	30
201.11 Protection against excessive temperatures and other hazards	30
201.11.1.2.2 <i>Applied parts</i> not intended to supply heat to a <i>patient</i>	30
201.11.6.6 <i>Cleaning and disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	30

201.11.7	<i>Biocompatibility of ME equipment and ME systems</i>	31
201.11.8	Additional requirements for interruption of the power supply/supply mains to ME equipment.....	32
201.12	Accuracy of controls and instruments and protection against hazardous outputs	32
201.12.1	Accuracy of controls and instruments	32
201.12.1.101	Stability of static <i>airway pressure accuracy</i> (long-term accuracy).....	32
201.12.1.102	Stability of dynamic <i>airway pressure accuracy</i> (short-term accuracy)	34
201.12.1.102.1	CPAP mode.....	34
201.12.1.102.2	Bi-level positive airway pressure mode, pressure stability.....	35
201.12.1.103	Maximum flowrate.....	38
201.12.4	Protection against hazardous output.....	41
201.12.4.101	Measurement of <i>airway pressure</i>	41
201.12.4.102	Maximum limited pressure protection device	41
201.12.4.103	CO ₂ rebreathing.....	42
201.13	Hazardous situations and fault conditions	42
201.14	Programmable electrical medical systems (PEMS)	42
201.15	Construction of ME equipment	43
201.15.101	Mode of operation	43
201.16	ME systems	43
201.17	Electromagnetic compatibility of ME equipment and ME systems	43
201.101	Breathing gas pathway connectors	44
201.101.1	General.....	44
201.101.2	Other named ports.....	44
201.101.2.1	Patient-connection port.....	44
201.101.2.2	Gas output port.....	44
201.101.2.3	Flow-direction-sensitive components.....	45
201.101.2.4	Accessory access connection port	45
201.101.2.5	Oxygen inlet connector	45
201.101.2.5.1	Low pressure.....	45
201.101.2.5.2	High pressure.....	46
201.102	Requirements for the breathing gas pathway and accessories	46
201.102.1	General.....	46
201.102.2	Labelling.....	46
201.102.3	Humidification.....	47
201.102.4	Breathing system filter (BSF).....	47
201.103	Functional connection	47
201.103.1	General.....	47
201.103.2	Functional connection to support remote supervision	47
202	Electromagnetic disturbances — Requirements and tests	48
202.4.3.1	Configurations	48
202.5.2.2.1	Requirements applicable to all ME equipment and ME systems	48
202.8.1.101	Additional general requirements	48
206	Usability	48

211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	49
211.4.2.3.1	Continuous operating conditions.....	49
Annex C (informative)	Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	50
201.C.1	<i>Marking on the outside of ME equipment, ME systems or their parts.....</i>	50
201.C.2	<i>Accompanying documents, general</i>	50
201.C.3	<i>Accompanying documents, instructions for use</i>	51
201.C.4	<i>Accompanying documents, technical description.....</i>	53
Annex AA (informative)	Particular guidance and rationale.....	55
AA.1	General guidance	55
AA.2	Rationale for particular clauses and subclauses.....	56
AA.2.1 —	201.1.1 — Scope.....	56
AA.2.2 —	201.3.207 — <i>Auto CPAP</i>	57
AA.2.3 —	201.3.208 — <i>Automatic start/stop function</i>	58
AA.2.4 —	201.3.254 — <i>Ramp mode</i>	58
AA.2.5 —	201.4.3.101 — Additional requirements for <i>essential performance</i>	58
AA.2.6 —	201.4.6 — <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	59
AA.2.7 —	201.5.101.2 — <i>Sleep apnoea breathing therapy equipment</i> testing errors.....	59
AA.2.8 —	201.7.1.2 — Legibility of <i>markings</i>	59
AA.2.9 —	201.7.9.3.1.101 — Additional general requirements	59
AA.2.10 —	201.9.6.2.1.101 — Additional requirements for audible acoustic energy	60
AA.2.11 —	201.11.6 — <i>Cleaning</i> and <i>disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	60
AA.2.12 —	201.12.1 — Accuracy of controls and instruments	63
AA.2.13 —	201.12.1.102.2 — <i>Bi-level positive airway pressure</i> mode, pressure stability.....	63
AA.2.14 —	201.12.1.103 — Maximum flowrate.....	63
— c) 2)	63	
AA.2.15 —	201.12.4.102 — <i>Maximum limited pressure protection device</i>	63
Annex BB (informative)	Data interface requirements.....	65
BB.1	Background and purpose.....	65
BB.2	Data definition	66
Annex CC (informative)	Reference to the IMDRF <i>essential principles</i> and labelling guidances.....	69
Annex DD (informative)	Terminology — alphabetized index of defined terms	73
Bibliography		77

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^[25].

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*^[23].

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

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

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

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.2.1.

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.

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 7.2.13 and 8.4.1 of the general standard.

NOTE 2 See also 4.2 of the general standard.

This document does not specify the requirements for:

- ventilators or *accessories* intended for critical care ventilators for ventilator-dependent *patients*, which are given in ISO 80601-2-12.
- ventilators or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13.
- ventilators or *accessories* intended for home care ventilators for ventilator-dependent *patients*, which are given in ISO 80601-2-72.
- ventilators or *accessories* intended for emergency and transport, which are given in ISO 80601-2-84.
- ventilators or *accessories* intended for home-care ventilatory support, which are given in ISO 80601-2-79 and ISO 80601-2-80.
- high-frequency ventilators^[23], which are given in ISO 80601-2-87.
- respiratory high flow equipment, which are given in ISO 80601-2-90;

NOTE 3 ISO 80601-2-80 ventilatory support equipment can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

- user-powered resuscitators, which are given in ISO 10651-4;
- gas-powered emergency resuscitators, which are given in ISO 10651-5;
- oxygen therapy constant flow *ME equipment*; and
- cuirass or “iron-lung” *ventilation* equipment.

201.1.2 Object

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

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *sleep apnoea breathing therapy equipment* (as defined in 201.3.259).

NOTE 1 This document has been prepared to address the relevant *essential principles*^[20] and labelling principles^[21] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[19].

201.1.3 Collateral standards

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

IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards specify *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.

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

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 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

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

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 17510:—¹, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:—², *Medical devices — Information to be supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

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

ISO 80369-1:2025, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-74:—³, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

¹ Under preparation. Stage at the time of publication: ISO/FDIS 17510:2025.

² Under preparation. Stage at the time of publication: ISO/FDIS 20417:2025.

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+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/>

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:—, 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.]

³ Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-74:2025.

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, modified — added letter symbol.]

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

<sleep apnoea breathing therapy> category of operation that provides inflations

EXAMPLE invasive ventilation, non-invasive ventilation

Note 1 to entry: Invasive ventilation is the correct term when used with endotracheal tube or tracheostomy .

Note 2 to entry: Some equipment may provide inflations using a *mask*, providing a back-up safety feature, but this should not be termed invasive ventilation.

[SOURCE: ISO 19223-3:2025, 3.3.27.1]

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, intended to ensure respiratory safety by preventing apnoea and hypopnoea at the lowest necessary pressure

Note 1 to entry: An *auto CPAP* mode may be bi-level.

Note 2 to entry: *Auto CPAP* does not augment tidal volume by providing an inflation or respiratory support.

Note 3 to entry: There is guidance or rationale for this definition contained in Clause AA.2.2.

[SOURCE: ISO 19223-3:2025, 3.3.3, modified — added note 3.]

201.3.208

automatic start/stop function

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

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

Note 2 to entry: There is guidance or rationale for this definition contained in Clause AA.2.3.

[SOURCE: ISO 19223-3:2025, 3.3.3, modified — added note 2.]

201.3.209

bi-level PAP

bi-level positive airway pressure

BPAP

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

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

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

201.3.210

biocompatibility

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

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

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

201.3.211

breathing gas pathway

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

201.3.212

breathing system filter

BSF

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

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

201.3.213

breathing tube

non-rigid tube used to convey gases or vapours within the user-detachable section of a *breathing gas pathway*

[SOURCE: ISO 4135:2022, 3.1.4.5, modified — replaced “system” with “gas pathway” deleted note.]

201.3.214

cleaning

removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2021, 3.1, modified — In note 1, replaced 'and/or' with 'or'.]

201.3.215

connector

fitting to join two or more components

EXAMPLE *Connectors for low-pressure hose assembly* are any of a range of mating components intended to maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.216

CPAP

continuous positive airway pressure

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

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

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

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

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

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

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

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

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

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

201.3.217 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]

201.3.218 diagnostic apnoea

A_d

respiratory event of at least 10 s in which there is a decrease in *airway* flow of ≥ 90 % of baseline during a sleep study

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^{[22][24][26]}.

Note 2 to entry: This is distinct from and excludes *diagnostic hypopnoea*, during a sleep study.

[SOURCE: ISO 19223-3:2025, 3.3.12]

201.3.219

diagnostic apnoea-hypopnoea index

AHI_d

average number of *diagnostic apnoea* and *diagnostic hypopnoea* occurrences 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

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

[SOURCE: ISO 19223-3:2025, 3.3.13]

201.3.220

diagnostic hypopnoea

H_d

respiratory event of at least 10 s duration in which there is a decrease in *airway* flow of at least 30 % from baseline and at least 3 % decrease in SpO₂ or an arousal event

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

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

Note 3 to entry: This is distinct from and excludes *diagnostic apnoea*, during a sleep study.

Note 4 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^{[22][24][26]}.

[SOURCE: ISO 19223-3:2025, 3.3.14]

201.3.221

disinfection

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

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

201.3.222

equipment apnoea

A_{flow}

apnoea as determined by *sleep apnoea breathing therapy equipment*, during *normal use*, not during a sleep study

Note 1 to entry: This is to be distinguished from *diagnostic apnoea* which only applies during a sleep study.

[SOURCE: ISO 19223-3:2025, 3.3.15]

201.3.223

equipment apnoea-hypopnoea index

AHI_{flow}

average number of residual *equipment apnoea* and *equipment hypopnoea* events occurring per hour of the therapy session

Note 1 to entry: References [22] and [26] were used to determine this definition.

201.3.224

equipment hypopnoea

H_{flow}

hypopnoea as measured by *sleep apnoea breathing therapy equipment*

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

[SOURCE: ISO 19223-3:2025, 3.3.17]

201.3.225

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, modified — term “core function” deleted.]

201.3.226

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]

201.3.227

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]

201.3.228

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]

201.3.229

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]

201.3.230

gas intake port

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

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in opposition to an *inlet*, at which gas is provided by a medical gas supply system.

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

201.3.231

gas output port

port through which gas is delivered at respiratory pressures through a tube to the *patient-connection port*

201.3.232

gas pathway

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

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

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

EXAMPLE 3 The inner surfaces of *breathing tubes*, tracheal tubes or *masks* and mouthpieces.

Note 1 to entry: The *gas pathway* is bounded by the fluid ports through which gases or liquids enter the *medical device* or *accessory*. This can include the *patient* interface or the interior surfaces of enclosures that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.

Note 3 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

[SOURCE: ISO 18562-1:2024, 3.11, modified — replaced “ports” with “fluid ports”.]

201.3.233

healthcare professional, adj

appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

201.3.234

home healthcare environment

dwelling place in which a *patient* lives or other places where *patients* are present, excluding the professional healthcare environment and the emergency medical services environment where *operators* with medical training are continually available when *patients* are present

EXAMPLE In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: Nursing homes are considered *home healthcare environments*.

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

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1, modified — replaced “environments” with “environment and the emergency medical services environment” and in note 2, deleted “For the purpose of this collateral standard,”.]

201.3.235

humidifier

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

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

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.236

I:E ratio

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

[SOURCE: ISO 19223:2019, 3.4.19, modified — deleted term phase time ratio and notes.]

201.3.237

inflation-type

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

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

201.3.238

information supplied by the manufacturer

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

Note 1 to entry: *e-documentation* is included in the *information supplied by the manufacturer*.

Note 2 to entry: Shipping documents (e.g. packing list and customs documents) and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

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

[SOURCE: ISO 20417:—, 3.15, modified — deleted note 4.]

201.3.239

inlet

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

[SOURCE: ISO 4135:2022, 3.1.4.26, modified — deleted note and deprecated terms.]

201.3.240

inspiratory pressure

airway pressure during an inspiratory or inflation phase

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

201.3.241

instructions for use

IFU

portion of the *accompanying information* that is:

- directed to the *user*;
- essential for the safe and effective use of a medical device or *accessory*

Note 1 to entry: A user can be either a *lay* user or professional user with relevant specialized training.

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

Note 3 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 4 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

Note 5 to entry: Information indicated on a graphical user interface (GUI) is considered as appearing on the item.

[SOURCE: ISO 20417:—, 3.16, modified — replaced note 5.]

201.3.242

lay, adj

lay person, adj

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

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: ISO 20417:—, 3.19]

201.3.243

lung

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

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

201.3.244

marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

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

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

[SOURCE: ISO 20417:—, 3.22, modified — deleted note 3.]

201.3.245

mask

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

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.246

maximum limited pressure

maximum limited airway-pressure

$p_{lim,max}$

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

[SOURCE: ISO 19223:2019, 3.13.3, modified — added symbol and deleted deprecated term and notes.]

201.3.247

monitoring equipment

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

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

201.3.248

outlet

opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.249

patient-connection port

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

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

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

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

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

201.3.250

physiologic closed-loop control system

PCLCS

part of *ME equipment* or *ME system* used to adjust a physiologic variable relative to a command variable using a feedback variable

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

201.3.251

processing

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

Note 1 to entry: *Processing* includes *cleaning*, *disinfection* and *sterilization*, as appropriate.

[SOURCE: ISO 20417:—, 3.31]

201.3.252

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 4135:2022, 3.1.4.48, modified — replaced “user” with “operator”.]

201.3.253

ramp mode

operating mode in which the *sleep apnoea breathing therapy equipment* automatically increases or decreases the applied pressure level from an initial level to the clinically predetermined therapeutic level in a predetermined profile

Note 1 to entry: This function affects successive breaths rather than operating within a single breath

Note 2 to entry: There is guidance or rationale for this definition contained in Clause AA.2.4.

[SOURCE: ISO 19223-3:2025, 3.3.22, modified — added note 2.]

201.3.254

relative humidity

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

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

[SOURCE: ISO 4135:2022, 3.1.2.4]