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Date: 03 May 2013

Origin: European

Latest date for receipt of comments: 22 July 2013

Project No. 2011/02696

Responsible committee: CH/121/5 Lung ventilators, tracheal tubes and related equipment

Interested committees:

Title: Draft BS ISO 80601-2-70 Medical Electrical Equipment

Part 2-70: Particular requirements for 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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- iii) requires additional national guidance or information

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Introduction

This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

Submission of Comments

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**
- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**
- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at:
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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	Comment (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.	

March 2013

ICS 11.040.10

Will supersede EN ISO 17510-1:2009

English Version

**Medical Electrical Equipment - Part 2-70: Particular
requirements for basic safety and essential performance of
sleep apnoea breathing therapy equipment (ISO/DIS 80601-2-
70:2013)**

Appareils électromédicaux - Partie 2-70: Exigences
particulières pour la sécurité de base et les performances
essentiels de l'équipement de thérapie respiratoire pour
l'apnée du sommeil (ISO/DIS 80601-2-70:2013)

Medizinische elektrische Geräte - Teil 2-70: Besondere
Festlegungen für die Sicherheit und die wesentlichen
Leistungsmerkmale von Schlafapnoe-Atemtherapiegeräten
(ISO/DIS 80601-2-70:2013)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (prEN ISO 80601-2-70:2013) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 17510-1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 80601-2-70:2013 has been approved by CEN as prEN ISO 80601-2-70:2013 without any modification.



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

[Revision of second edition (ISO 17510-1:2007)]

ICS 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO/IEC 80601-2-70 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This first edition of ISO 80601-2-70 cancels and replaces the second edition of ISO 17510-1:2007. This edition of ISO 80601-2-70 constitutes a technical revision of ISO 17510-1:2007 and includes an alignment with third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

- identification of ESSENTIAL PERFORMANCE for SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its ACCESSORIES;

and the following additions:

- tests for therapy performance; and
- new symbols.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*

- Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

- 140 — "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all
141 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 142 — "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all
143 subclauses of Clause 201.7).
- 144 References to clauses within this standard are preceded by the term "Clause" followed by the clause number.
145 References to subclauses within this particular standard are by number only.
- 146 In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of
147 the conditions is true.
- 148 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part
149 2. For the purposes of this standard, the auxiliary verb:
- 150 — "shall" means that compliance with a requirement or a test is mandatory for compliance with this
151 standard;
- 152 — "should" means that compliance with a requirement or a test is recommended but is not mandatory for
153 compliance with this standard;
- 154 — "may" is used to describe a permissible way to achieve compliance with a requirement or test.
- 155 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that
156 there is guidance or rationale related to that item in Annex AA.
- 157 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers
158 and testing organizations may need a transitional period following publication of a new, amended or revised
159 ISO or IEC publication in which to make products in accordance with the new requirements and to equip
160 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of
161 this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of
162 publication for equipment newly designed and not earlier than 5 years from the date of publication for
163 equipment already in production.

Introduction

Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep. The awareness of the RISKS associated with sleep apnoea has grown significantly in recent years. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT has become common. This document covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements needed to protect PATIENTS in the use of this ME EQUIPMENT. SLEEP APNOEA BREATHING THERAPY EQUIPMENT is commonly used to treat both sleep apnoea and hypopnoea.

Sleep apnoea is a chronic medical condition where the affected person repeatedly stops breathing during sleep. These episodes last 10 seconds or more and cause oxygen levels in the blood to drop. It can be caused by obstruction of the upper airway, resulting in obstructive sleep apnoea (OSA), or by a failure of the brain to initiate a breath, called central sleep apnoea and is typically associated with heart failure PATIENTS. Often, co-morbidities are present in PATIENTS with OSA which can contribute to their earlier onset including hypertension, heart failure, and diabetes if left untreated. It can cause and worsen other medical conditions, including hypertension, heart failure, and diabetes.¹

NOTE SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended for the treatment of obstructive sleep apnoea and not central sleep apnoea.

Hypopnoea refers to a transient reduction of airflow (often while asleep) that lasts for at least 10 seconds, shallow breathing, or an abnormally low respiratory rate. Hypopnoea is less severe than apnoea (which is a more complete loss of airflow). It can likewise result in a decreased amount of air movement into the lungs and can cause oxygen levels in the blood to drop. It is more commonly due to partial obstruction of the upper airway.²

ISO 80601-2-70 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.

¹ source: http://sleepdisorders.about.com/od/glossary/g/Sleep_Apnea.htm

² source: <http://sleepdisorders.about.com/od/glossary/g/Hypopnea.htm>

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

201.1 Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies, except as follows:

201.1.1 * Scope

IEC 60601-1:2005+A1:2012, 1.1 is replaced by:

This **particular** standard 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 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.

This **particular** standard excludes SLEEP APNOEA BREATHING THERAPY EQUIPMENT intended for use with neonates.

This **particular** standard is applicable to ME EQUIPMENT or an ME SYSTEM intended for those PATIENTS who are not dependent on mechanical ventilation **such as PATIENTS with central sleep apnoea**.

This **particular** standard 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 also are addressed by ISO 17510.³⁾ Refer to Figure AA.1 for items covered under this standard.

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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 4 See also 4.2 of the General Standard.

This **particular** standard is not applicable to HOME HEALTHCARE ENVIRONMENT ventilators, ventilatory support ME EQUIPMENT, emergency and transport ventilators, anaesthetic ventilators, high-frequency jet ventilators (HFJVs), critical care ventilators or high-frequency oscillatory ventilators (HFOVs).^[15] This **particular** standard

3) To be published.

219 does not specify the requirements for ME EQUIPMENT that is intended solely to augment the ventilation of
220 spontaneously breathing PATIENTS.

221 | This **particular** standard does not specify the requirements for ventilators or ACCESSORIES intended for critical
222 care ventilators for ventilator-dependent PATIENTS which are given in ISO 80601-2-12.

223 | This **particular** standard does not specify the requirements for ventilators or ACCESSORIES intended for
224 anaesthetic applications which are given in IEC 80601-2-13.

225 | This **particular** standard does not specify the requirements for ventilators or ACCESSORIES intended for home
226 care ventilators for ventilator-dependent PATIENTS which are given in ISO 10651-2⁴⁾.

227 | This **particular** standard does not specify the requirements for ventilators or ACCESSORIES intended for
228 emergency and transport which are given in ISO 10651-3⁵⁾.

229 | This **particular** standard does not specify the requirements for ventilators or ACCESSORIES intended for home-
230 care ventilatory support devices which are given in ISO 10651-6⁶⁾.

231 | This **particular** standard is a particular standard in the 60601-1 series of standards.

232 **201.1.2 Object**

233 | *IEC 60601-1:2005, 1.2 is replaced by:*

234 The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE
235 requirements for SLEEP APNOEA BREATHING THERAPY EQUIPMENT [as defined in 201.3.212].

236 **201.1.3 Collateral standards**

237 | *IEC 60601-1:2005+A1:2012, 1.3 applies with the following addition:*

238 This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the
239 general standard and 201.2 of this particular standard.

240 IEC 60601-1-3:2008 does not apply.

241 **201.1.4 Particular standards**

242 | *IEC 60601-1:2005+A1:2012, 1.4 is replaced by:*

243 In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the
244 general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under
245 consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

246 A requirement of a particular standard takes priority over the general standard or the collateral standards.

4) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-xx.

5) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 at which time it will be replaced by ISO 80601-2-xx.

6) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-xx.

For brevity, IEC 60601-1:2005+A 1:2012 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

"Addition" means that the text of this particular standard 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 particular standard.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that 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 standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the section, 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 particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography beginning on page 42.

IEC 60601-1:2005+A1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*
+Amendment 1:2012

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

- IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
+Amendment 1:—⁷⁾
- IEC 60601-1-8:2006, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+Amendment 1:2011
- IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
+Amendment 1:—⁸⁾
- IEC 61672-1:2002, *Electroacoustics - Sound level meters - Part 1: Specifications*
- 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 5356-1:2004, *Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets*
- ISO 7000:2012, *Graphical symbols for use on equipment -- Registered symbols*
- ISO 8185:2007⁹⁾, *Humidifiers for medical use -- General requirements for humidification systems*
- ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
- EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*
- ISO 17510:—¹⁰⁾, *Sleep apnoea breathing therapy masks and application accessories*
- 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*

⁷⁾ To be published.

⁸⁾ To be published.

⁹⁾ In the future, this standard is expected to be harmonized with the IEC 60601-1:2005+A1:2012 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-xx.

¹⁰⁾ To be published.

315 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential*
 316 *performance*
 317 *Amendment 1:2012*

318 IEC 62304:2006, *Medical device software – Software life cycle processes*

319 IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
 320 [+Amendment 1:—^{11\)}](#)

321 ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General*
 322 *requirements*

323 ISO 80369-2:—¹²⁾, *Small bore connectors for liquids and gases in healthcare applications -- Part 2:*
 324 *Connectors for breathing systems and driving gases applications*

325 **201.3 Terms and definitions**

326 For the purposes of this document, the terms and definitions given in ISO 8185:2007, ISO 23328-2:2002,
 327 IEC 60601-1:2005[+A1:2012](#), IEC 60601-1-2:2007, IEC 60601-1-6:2010[+A1:—](#), IEC 62366:2007[+A1:—](#),
 328 ISO 4135:2001 and the following apply.

329 NOTE An index of defined terms is found beginning on page 43.

330 *Addition:*

331 **201.3.201**

332 **AIRWAY PRESSURE**

333 P_{aw}

334 pressure at the PATIENT-CONNECTION PORT

335 **201.3.202**

336 **AIRWAY PRESSURE ACCURACY**

337 difference between the pressure set on the SLEEP APNOEA BREATHING THERAPY EQUIPMENT and the measured
 338 AIRWAY PRESSURE

339 **201.3.203**

340 **BPAP**

341 **BI-LEVEL POSITIVE AIRWAY PRESSURE**

342 two therapeutic positive pressure levels at the PATIENT-CONNECTION PORT during the respiratory cycle

343 **201.3.204**

344 **BREATHING GAS PATHWAY**

345 pathway through which gas flows at respiratory pressures between the gas INTAKE PORT and the PATIENT-
 346 CONNECTION PORT

¹¹⁾ To be published.

¹²⁾ To be published.