INTERNATIONAL STANDARD

ISO 80601-2-70

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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

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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

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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[1].

Hypopnoea refers to a transient reduction of airflow, often while the PATIENT is asleep, that lasts for at least 10 s, shallow breathing, or an abnormally low respiratory rate. Hypopnoea is less severe than apnoea. It also results in decreased air movement into the lungs and can cause oxygen levels in the blood to drop. It is commonly due to partial obstruction of the upper airway. [16] [2]

Awareness of the RISKS associated with sleep apnoea has grown significantly. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to treat both sleep apnoea and hypopnoea has become common.

This document covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements needed to protect PATIENTS in the use of this ME EQUIPMENT.

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] Figures in square brackets refer to the Bibliography.

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 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.

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.

This particular standard is not applicable to ME EQUIPMENT or an ME SYSTEM intended for those PATIENTS who are 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 are additionally addressed by ISO 17510. [3] Refer to Figure AA.1 for items covered further 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.

3) To be published.

This particular standard is not applicable to high-frequency jet ventilators (HFJVs) or high-frequency oscillatory ventilators (HFOVs).[16]

This particular standard 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.

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

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for home care ventilators for ventilator-dependent PATIENTS which are given in ISO 10651-2[4] .

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for emergency and transport which are given in ISO 10651-3[5] .

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for home-care ventilatory support devices which are given in ISO 10651-6[6] .

This particular standard is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by:

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

201.1.3 Collateral standards

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

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

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

201.1.4 Particular standards

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

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

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

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.

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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.

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 particular 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 2xx, where “xx” 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 41.

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility – Requirements and tests*

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 1:2013

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 1:2012

IEC 60601-1-11:—[7] (Ed 2), *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*

IEC 61672-1:2013, *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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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 8185:2007[8], 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:—[9], *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*

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

IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*
+Amendment 1:2014

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

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[7] To be published.

[8] 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 80601-2-74.

[9] To be published.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8185:2007, ISO 23328-2:2002, IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+A1:2013, IEC 62366:2007+A1:2014, ISO 4135:2001 and the following apply.

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

Addition:

201.3.201
AIRWAY PRESSURE
P_{aw}
pressure at the PATIENT-CONNECTION PORT

201.3.202
AIRWAY PRESSURE ACCURACY
degree of correspondence between the pressure set on the SLEEP APNOEA BREATHING THERAPY EQUIPMENT and the actual (true) AIRWAY PRESSURE

201.3.203
BI-LEVEL PAP
BI-LEVEL POSITIVE AIRWAY PRESSURE
two therapeutic positive pressure levels at the PATIENT-CONNECTION PORT during the respiratory cycle

201.3.204
BREATHING GAS PATHWAY
pathway through which gas flows at respiratory pressures between the gas INTAKE PORT and the PATIENT-CONNECTION PORT

201.3.205
CPAP
CONTINUOUS POSITIVE AIRWAY PRESSURE
therapeutic CONTINUOUS POSITIVE AIRWAY PRESSURE during the respiratory cycle

201.3.206
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 4135:2001, definitions 3.1.7, modified–Added 'or ACCESSORY' and replaced 'must' with 'has to'.]

201.3.207
INTAKE PORT
port through which gas is drawn by SLEEP APNOEA BREATHING THERAPY EQUIPMENT

[SOURCE: ISO 4135:2001, definitions 3.2.11, modified–Replaced a ventilator or by a PATIENT with SLEEP APNOEA BREATHING THERAPY EQUIPMENT.]

201.3.208
MAXIMUM LIMITED PRESSURE
$P_{LIM\,max}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

201.3.209
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and continuously or continually or on OPERATOR-demand indicates the value of a variable to the OPERATOR

201.3.210
PROTECTION DEVICE
part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

201.3.211
SELF-ADJUSTING
automatically adjusting the pressure in the BREATHING GAS PATHWAY according to the PATIENT'S needs during use

201.3.212
SLEEP APNOEA BREATHING THERAPY EQUIPMENT
ME EQUIPMENT intended to alleviate the symptoms of a PATIENT who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the PATIENT

Note 1 to entry: SLEEP APNOEA BREATHING THERAPY EQUIPMENT is primarily used in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR without direct professional supervision.

201.4 General requirements

IEC 60601-1:2005+A1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+A1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

For the purposes of this standard, SLEEP APNOEA BREATHING THERAPY EQUIPMENT is considered to not have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this standard refers to ESSENTIAL PERFORMANCE as acceptance criteria, the static pressure shall be evaluated. The method of subclause 202.6.2.1.10 may be used to evaluate static pressure as an acceptance criterion following specific tests required by this standard.

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

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

The BREATHING GAS PATHWAY, its parts and ACCESSORIES shall be subject to the requirements for APPLIED PARTS according to subclause 201.11.6.4. The SLEEP APNOEA BREATHING THERAPY EQUIPMENT parts or ACCESSORIES that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS according to this subclause.

NOTE The ACCESSORIES that can come into contact with the PATIENT also are subject to ISO 17510:—.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT

201.5.101.1 Gas flowrate and pressure specifications

In this standard, requirements for the flowrate and pressure are expressed as if tested under STPD (standard temperature and pressure dry) conditions.

NOTE For the purposes of this standard, STPD is 101,3 kPa at an operating temperature of 20 °C, dry.

Correct all test measurements to STPD, as appropriate.

201.5.101.2 * SLEEP APNOEA BREATHING THERAPY EQUIPMENT testing errors

For the purposes of this standard, tolerances declared in the ACCOMPANYING DOCUMENTS shall include the uncertainty of the measurement used to determine the specification.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+A1:2012, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+A1:2012, 7.1.2 applies, except as follows:

Replacement (at the end of the second sentence of the second paragraph of the compliance check):

Replace ‘1 m’ with ‘0,5 m’

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101 and shall be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, if applicable. If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.13.101 Additional requirements for physiological effects

All natural rubber latex-containing components in the BREATHING GAS PATHWAYS or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.4.5 from ISO 15223-1:2012, (Table 201.D.1.101, symbol 4) may be used. The instructions for use shall disclose all natural rubber latex-containing components.