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Medicinska električna oprema - 2-70. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za zdravljenje prenehanja dihanja v spanju (ISO/DIS 80601-2-70:2013)

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

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

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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/DIS 80601-2-70:2013)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-70**

ICS:

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

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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/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.

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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.

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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

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.

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ISO/TC **121**/SC **3** Secretariat: **ANSI**

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Medical electrical equipment —

Part 2-70:
Particular requirements for basic safety and essential performance of sleep apneoa 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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[Revision of second edition (ISO 17510-1:2007)]

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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.

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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.*

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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.

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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

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— "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.

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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.

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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]

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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.

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

[2] source: http://sleepdisorders.about.com/od/glossary/g/Hypopnea.htm

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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.

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

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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.

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