SVENSK STANDARD
SS-EN ISO 17510:2020

Medicintekniska produkter – Respirationsbehandling av sömnapné – Masker och tillbehör (ISO 17510:2015)

Medical devices – Sleep apnoea breathing therapy – Masks and application accessories (ISO 17510:2015)

Svenska Institutet för Standarder

Language: engelska/English

Edition: 4

Svenska Institutet för Standarder

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Fastställd: 2020-02-25
ICS: 11.040.10

Svenska Institutet för Standarder

Europastandarden EN ISO 17510:2020 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 17510:2020.

Denna standard ersätter SS-EN ISO 17510-2:2009, utgåva 3

The European Standard EN ISO 17510:2020 has the status of a Swedish Standard. This document contains the official version of EN ISO 17510:2020.

This standard supersedes the SS-EN ISO 17510-2:2009, edition 3

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17510

February 2020

ICS 11.040.10

Supersedes EN ISO 17510-2:2009

English Version

Medical devices - Sleep apnoea breathing therapy - Masks and application accessories (ISO 17510:2015)

Dispositifs médicaux - Thérapie respiratoire de l'apnée du sommeil - Masques et accessoires d'application (ISO 17510:2015)

Medizinische Geräte - Schlafapnoe-Atemtherapie - Masken und Anwendungszubehör (ISO 17510:2015)

This European Standard was approved by CEN on 11 November 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 17510:2020: E

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European foreword

The text of ISO 17510:2015 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17510:2020 by 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of an identical text or by endorsement, at the latest by August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.

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 17510-2:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17510:2015 has been approved by CEN as EN ISO 17510:2020 without any modification.

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 International Standard covers basic safety and essential performance requirements for MASKS and other application ACCESSORIES needed to protect PATIENTS during use of this equipment.

In this International 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: in smaller type. Normative text of tables is also in a smaller type;

— TERMS DEFINED IN CLAUSE 3 IN THIS INTERNATIONAL STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this International Standard, the term

— "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes 5.1, 5.2, etc.), and

— "subclause" means a numbered subdivision of a clause (e.g. 5.1, 5.2, and 5.3.1 are all subclauses of Clause 5).

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

In this International 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 International Standard conform to usage described in ISO/IEC Directives Part 2, Annex H. For the purposes of this International Standard, the auxiliary verb:

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

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International 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 A.

The attention of Member Bodies 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 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 three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

1 Scope

This International Standard applies to MASKS and their ACCESSORIES used to connect SLEEP APNOEA BREATHING THERAPY EQUIPMENT to the PATIENT. It specifies requirements for MASKS and ACCESSORIES, including any connecting element, that are required to connect the PATIENT-CONNECTION PORT of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to a PATIENT for the application of sleep apnoea breathing therapy (e.g. nasal MASKS, EXHAUST PORTS and HEADGEAR).

SLEEP APNOEA BREATHING THERAPY EQUIPMENT is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this International Standard together with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT of ISO 80601-2-70 that form a sleep apnoea breathing system.

This International Standard does not cover ORAL APPLIANCES.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 5356-2:2012, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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 80601-2-70:2015, *Medical Electrical Equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 17664:2004, ISO 23328-2:2002, ISO 80601-2-70:2015, IEC 60601-1:2005+A1:2012 and the following apply.

NOTE An alphabetical index of defined terms is found in Annex J.

3.1
ANTI-ASPHYXIA VALVE
valve used on a MASK, which covers the mouth and is opened to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not providing adequate pressure at the MASK, and that is closed to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is providing adequate pressure at the MASK

3.2
EXHAUST FLOW
flow from the MASK or application ACCESSORY to atmosphere other than the leak due to improper seal to the face

Note 1 to entry: The EXHAUST FLOW can pass through openings in the MASK, the connecting element and the MASK, or through the ANTI-ASPHYXIA VALVE.

Note 2 to entry: The EXHAUST FLOW discharges exhaled gases to atmosphere to reduce REBREATHING of CO_2.

3.3
EXPECTED USEFUL LIFE
time period specified by the MANUFACTURER during which the MEDICAL DEVICE or ACCESSORY is expected to remain suitable for use under the conditions specified by the MANUFACTURER

Note 1 to entry: CLEANING and other PROCESSING can be necessary during the EXPECTED USEFUL LIFE.

3.4
HEADGEAR
part that is used to fix the MASK to the PATIENT

3.5
MASK
part which provides the interface between the PATIENT and the PATIENT-CONNECTION PORT

Note 1 to entry: According to their application, MASKS are divided into nasal MASKS, oral MASKS, or nasal-oral MASKS.

3.6
MULTI-PATIENT REUSE
capable of being re-used multiple times on multiple PATIENTS

3.7
ORAL APPLIANCE
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of SLEEP APNOEA BREATHING THERAPY EQUIPMENT

3.8
SINGLE FAULT CONDITION
condition of ME EQUIPMENT or ACCESSORY in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+A1:2012, 3.116, modified—added 'or ACCESSORY' and deleted note.]

3.9
SINGLE-PATIENT REUSE
capable of being used multiple times on the same PATIENT

4 Information to be supplied by the MANUFACTURER

4.1 General

MASKS, HEADGEAR and other ACCESSORIES shall be provided with an ACCOMPANYING DOCUMENT. The ACCOMPANYING DOCUMENT shall be regarded as a part of MASKS, HEADGEAR and the ACCESSORIES.

NOTE 1 The purpose of an ACCOMPANYING DOCUMENT is to promote the safe use of a MASK, HEADGEAR or other ACCESSORY during the EXPECTED USEFUL LIFE.

NOTE 2 Annex H contains a guide to assist the reader in locating the marking and labelling requirements contained in other clauses of ISO 17510.

4.2 Marking on the protective packaging

Packages of MASKS, HEADGEAR and other ACCESSORIES shall be marked with:

a) name or trade name and address of

   — the MANUFACTURER, and

   — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

   to which the OPERATOR or RESPONSIBLE ORGANIZATION can refer;

b) the details strictly necessary to identify the device and the contents of the packaging especially for the OPERATOR or RESPONSIBLE ORGANIZATION;

c) the identity and intended purpose of the MASK and any application ACCESSORIES;

d) any special storage and/or handling conditions;

e) any special operating instructions;

f) any special warnings and/or precautions to be taken;

g) if applicable, symbol from ISO 15223-1:2012, 5.1.4 indicating the latest date by which the MASK and any application ACCESSORIES can be used safely (i.e. shelf life), expressed as the year, month and day;

h) identification reference to the batch, type or serial number with symbol from ISO 15223-1:2012, 5.1.7 with an accompanying serialization or symbol from ISO 15223-1:2012, 5.1.5 with an accompanying lot or batch identifier; and

i) for sterile items, with symbol ISO 15223-1:2012, 5.2.1, symbol ISO 15223-1:2012, 5.2.2, symbol ISO 15223-1:2012, 5.2.3 or symbol ISO 15223-1:2012, 5.2.4, as appropriate.

Packaging for single use MASKS, HEADGEAR and other ACCESSORIES shall be marked accordingly and shall be consistent for a MODEL OR TYPE REFERENCE.