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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

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|---|---|
| See Eesti standard EVS-EN ISO 17510:2020 sisaldab Euroopa standardi EN ISO 17510:2020 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 17510:2020 consists of the English text of the European standard EN ISO 17510:2020. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.02.2020. | Date of Availability of the European standard is 19.02.2020. |
| Standard on kättesaadav Eesti Standardikeskusest. | The standard is available from the Estonian Centre for Standardisation. |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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# EN ISO 17510

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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.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

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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.

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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition cancels and replaces the second edition of ISO 17510-2:2007 which has been technically revised with the following changes:

— removing the SINGLE FAULT CONDITION testing for REBREATHING for nasal-only MASKS as PATIENTS can breathe through their mouth in that circumstance;

— referencing ISO 80601-2-70 for SLEEP APNOEA THERAPY EQUIPMENT.

NOTE ISO 17510-1 was replaced by ISO 80601-2-70.



 

# 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