



SLOVENSKI STANDARD

SIST EN ISO 17510:2020

01-april-2020

Nadomešča:

SIST EN ISO 17510-2:2009

Medicinski pripomočki - Zdravljenje dihanja pri spalni apneji - Maske in oprema za nameščanje (ISO 17510:2015)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 17510:2020

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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SIST EN ISO 17510:2020

en

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EUROPEAN STANDARD

EN ISO 17510

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2020

ICS 11.040.10

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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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INTERNATIONAL STANDARD

ISO 17510

First edition
2015-08-01

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

*Dispositifs médicaux — Thérapie respiratoire de l'apnée du sommeil
— Masques et accessoires d'application*

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ISO 17510:2015(E)

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

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