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Medical devices - Sleep apnoea breathing therapy - Masks and application accessories (ISO 17510:2025)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 17510:2025 sisaldab Euroopa standardi EN ISO 17510:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 17510:2025 consists of the English text of the European standard EN ISO 17510:2025.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 10.12.2025.	Date of Availability of the European standard is 10.12.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.10

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17510

December 2025

ICS 11.040.10

Supersedes EN ISO 17510:2020

English Version

Medical devices - Sleep apnoea breathing therapy - Masks and application accessories (ISO 17510:2025)

Dispositifs médicaux - Thérapie respiratoire de l'apnée du sommeil - Masques et accessoires d'application (ISO 17510:2025)

Medizinische Geräte - Schlafapnoe-Atemtherapie - Masken und Anwendungszubehör (ISO 17510:2025)

This European Standard was approved by CEN on 4 December 2025.

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Ref. No. EN ISO 17510:2025 E

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European foreword

This document (EN ISO 17510:2025) 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 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of an identical text or by endorsement, at the latest by June 2026, and conflicting national standards shall be withdrawn at the latest by June 2026.

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 17510:2020.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 17510:2025 has been approved by CEN as EN ISO 17510:2025 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 document 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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17510:2015), which has been technically revised.

The main changes are as follows:

— harmonization with IEC 60050-880 sources, where appropriate;

— adding disclosure requirements for magnets in *headgear*;

— updated *processing* requirements;

— updated noise requirements;

— referencing ISO 18562-1, for *biocompatibility* of *gas pathways*;

— harmonization with ISO 20417, where appropriate.

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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 for *masks* and other application *accessories* needed to protect *patients* during use of this equipment.

Sleep apnoea breathing therapy equipment is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this document together with the *sleep apnoea breathing therapy equipment* of ISO 80601-2-70 that form a sleep apnoea breathing system.

In this document, the following print types are used:

— Requirements and definitions: roman 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 document or as noted: italics.*

In referring to the structure of this document, 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.);

— “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 document are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular document are by number only.

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

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” is used to describe a possibility or capability.

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

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1 Scope

This document 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*).

This document applies to *masks* and their *accessories* used to connect *sleep apnoea breathing therapy equipment* to the *patient*.

The requirements in this document take priority over the requirements in ISO 18190.

This document does not cover *oral appliances*.

NOTE This document has been prepared to address the relevant *essential principles*[14] and labelling principles[15] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex I.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 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 5356-2:2012/Amd 1:2019, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors — Amendment 1*

ISO 10993-1:2018, *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 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:—[1)], *Medical devices — Information to be supplied by the manufacturer*

1) Under preparation. Stage at the time of publication: ISO/DIS 20417:2025.

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

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20417:— and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

3.1
anti-asphyxia valve
valve used on a breathing *mask* intended to allow spontaneous breathing when the lung ventilator or breathing therapy equipment is not providing adequate pressure or flow

[SOURCE: ISO 4135:2022, 3.6.3.7]

3.2
biocompatibility
ability of a *medical device*, *accessory* or material to perform with an appropriate host response in a specific application

Note 1 to entry: A *medical device* or *accessory* can produce some level of adverse effect, but that level can be determined to be acceptable when considering the *benefit* provided.

[SOURCE: ISO 18562-1:2024, 3.6]

3.3
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in a breathing system

[SOURCE: ISO 4135:2022, 3.6.1.5]

3.4
breathing tube
non-rigid tube used to convey gases or vapours within the *user*-detachable section of a breathing system

[SOURCE: ISO 4135:2022, 3.1.4.4, modified — Deleted Note 1 to entry.]

3.5
cleaning
process to remove contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* of a used *product* consists of the removal of adherent soil (e.g. blood, protein substances and other debris) from the surfaces, crevices, serrations, joints and lumens of a *medical device* by a manual or automated *process* that prepares the items for safe handling or further *processing*.

Note 2 to entry: *Cleaning* of a new *product* can occur before initial use or during production before release for distribution.

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