SLOVENSKI STANDARD
oSIST prEN ISO 17510:2025

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Medicinski pripomočki - Zdravljenje dihanja pri spalni apneji - Maske in oprema za nameščanje (ISO/DIS 17510:2024)

Medical devices - Sleep apnoea breathing therapy - Masks and application accessories (ISO/DIS 17510:2024)

Medizinische Geräte - Schlafapnoe-Atemtherapie - Masken und Anwendungszubehör (ISO/DIS 17510:2024)

Dispositifs médicaux - Thérapie respiratoire de l'apnée du sommeil - Masques et accessoires d'application (ISO/DIS 17510:2024)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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ISO/DIS 17510

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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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, *Respiratory devices and related equipment for patient care*.

This second edition cancels and replaces the first edition of ISO 17510:2015 which has been technically revised with the following changes:

— harmonization with IEC 60050-880, where appropriate ;

— adding disclosure requirements for magnets in *headgear*;

— updated *processing* requirements;

— updated vibration and noise requirements;

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

— harmonization with ISO 20417, where appropriate.

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.

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.), 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 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.

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

1 Scope

This document 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 document together with the *sleep apnoea breathing therapy equipment* of ISO 80601-2-70 that form a sleep apnoea breathing system.

This document does not cover *oral appliances*.

NOTE This document has been prepared to address the relevant *essential principles*[8] and labelling[9] principles guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex BB.

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 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 10993-1:2018, *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*

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 60050-880:—[2], *International Electrotechnical Vocabulary (IEV) – Part 880: Electrical equipment, electrical systems and software used in healthcare*

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 IEC 60050-880:— as indicated in Annex J 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 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
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]

3.3
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] Under preparation. Stage at the time of publication: ISO/DIS 20417:2024.

[2] Under preparation. Stage at the time of publication: IEC/CDV 60050-880:2024.

3.4
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.

[SOURCE: ISO 4135:2022, 3.8.1.3]

3.5
exhaust port
port through which gas is discharged to the atmosphere or to an anaesthetic gas scavenging system

[SOURCE: ISO 4135:2022, 3.1.4.11, modified —deleted notes.]

3.6
gas output port
port of the device through which gas is delivered at respiratory pressures to a *user*-detachable part of a breathing system

[SOURCE: ISO 4135:2022, 3.1.4.22, modified —deleted note.]

3.7
headgear
part that is used to fix the *mask* to the *patient*

Note 1 to entry: The *headgear* may be an integral part of the *mask*.

3.8
mask
device which provides a non-invasive interface between the *patient's* airway and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

3.9
oral appliance
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of *sleep apnoea breathing therapy equipment*

3.10
patient-connection port
port of a breathing system intended for connection to an airway device

Note 1 to entry: The *patient-connection port* is the end of the breathing system proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a connector suitable for connection to an airway device such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized connectors, for example, a connector conforming to ISO 5356-1.