



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 17510:2025**  
**01-februar-2025**

---

**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)

**Ta slovenski standard je istoveten z: prEN ISO 17510**

[oSIST prEN ISO 17510:2025](https://standards.iteh.ai/catalog/standards/sist/c26a1e47-184c-4dad-b9752b3-100d/osist-pr-en-iso-17510-2025)

**ICS:**

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

**oSIST prEN ISO 17510:2025**

**en,fr,de**





# DRAFT International Standard

## 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*

ICS: 11.040.10

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:  
**2024-12-09**

Voting terminates on:  
**2025-03-03**

ITh Standards  
(<https://standards.iteh.ai>)  
Document Preview

[oSIST prEN ISO 17510:2025](https://standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/c20a4eaf-af34-4bac-8daf-fb9752b3400d/osist-pren-iso-17510-2025>

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

**ISO/CEN PARALLEL PROCESSING**

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

## ISO/DIS 17510:2024(en)

# iTeh Standards (<https://standards.iteh.ai>) Document Preview

[oSIST prEN ISO 17510:2025](https://standards.iteh.ai/catalog/standards/sist/c20a4eaf-af34-4bac-8daf-fb9752b3400d/osist-pren-iso-17510-2025)

<https://standards.iteh.ai/catalog/standards/sist/c20a4eaf-af34-4bac-8daf-fb9752b3400d/osist-pren-iso-17510-2025>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

1	<b>Contents</b>	Page
2	<b>Foreword</b> .....	6
3	<b>Introduction</b> .....	7
4	<b>1 Scope</b> .....	1
5	<b>2 Normative references</b> .....	1
6	<b>3 Terms and definitions</b> .....	2
7	<b>4 Information supplied by the manufacturer</b> .....	4
8	<b>4.1 General</b> .....	4
9	<b>4.2 Accompanying information</b> .....	4
10	<b>5 Construction requirements</b> .....	6
11	<b>5.1 Mask connectors</b> .....	6
12	<b>5.2 Biocompatibility</b> .....	6
13	<b>5.2.1 Patient contacting</b> .....	6
14	<b>5.2.2 Gas pathway contacting</b> .....	7
15	<b>5.3 Protection against rebreathing</b> .....	7
16	<b>5.3.1 Normal condition protection</b> .....	7
17	<b>5.3.2 Single fault condition protection</b> .....	8
18	<b>5.4 Cleaning, disinfection, and sterilization</b> .....	8
19	<b>5.4.1 Single patient multiple use</b> .....	8
20	<b>5.4.2 Multiple patient multiple use</b> .....	9
21	<b>5.5 Breathing during single fault condition</b> .....	10
22	<b>5.6 Breathing system filter</b> .....	10
23	<b>6 Audible acoustic energy</b> .....	10
24	<b>7 Measurement uncertainty</b> .....	11
25	<b>Annex A (informative) Particular guidance and rationale</b> .....	12
26	<b>A.1 General guidance</b> .....	12
27	<b>A.2 Rationale for particular clauses and subclauses</b> .....	13
28	<b>Annex B (normative) Exhaust flow test procedure</b> .....	17
29	<b>B.1 Principle</b> .....	17
30	<b>B.2 Apparatus</b> .....	17
31	<b>B.3 Procedure</b> .....	17
32	<b>Annex C (normative) Resistance to flow (pressure drop)</b> .....	19
33	<b>C.1 Principle</b> .....	19
34	<b>C.2 Apparatus</b> .....	19
35	<b>C.3 Procedure</b> .....	19
36	<b>Annex D (normative) Anti-asphyxia valve pressure testing</b> .....	21
37	<b>D.1 Principle</b> .....	21
38	<b>D.2 Apparatus</b> .....	21

39	<b>D.3</b>	<b><i>Procedure for determining the opening pressure</i></b> .....	<b>22</b>
40	<b>D.4</b>	<b><i>Procedure for determining the closing pressure</i></b> .....	<b>22</b>
41	<b>Annex E</b> (normative)	<b>Determination of the inspiratory and expiratory pressure</b>	
42		<b>drop under <i>single fault condition</i></b> .....	<b>23</b>
43	<b>E.1</b>	<b>Principle</b> .....	<b>23</b>
44	<b>E.2</b>	<b>Apparatus</b> .....	<b>23</b>
45	<b>E.3</b>	<b><i>Procedure</i></b> .....	<b>24</b>
46	<b>Annex F</b> (normative)	<b>Carbon Dioxide <i>rebreathing</i></b> .....	<b>25</b>
47	<b>F.1</b>	<b>Principle</b> .....	<b>25</b>
48	<b>F.2</b>	<b>Apparatus</b> .....	<b>25</b>
49	<b>F.3</b>	<b><i>Procedure</i></b> .....	<b>25</b>
50	<b>Annex G</b> (normative)	<b>Audible acoustic energy</b> .....	<b>28</b>
51	<b>G.1</b>	<b>Principle</b> .....	<b>28</b>
52	<b>G.2</b>	<b>Apparatus</b> .....	<b>28</b>
53	<b>G.3</b>	<b><i>Procedure</i></b> .....	<b>28</b>
54	<b>Annex H</b> (informative)	<b>Guide to <i>information supplied by the manufacturer</i></b> .....	<b>30</b>
55	<b>H.1</b>	<b><i>Accompanying information for mask or accessory</i></b> .....	<b>30</b>
56	<b>Annex I</b> (informative)	<b>Reference to the IMDRF essential principles and</b>	
57		<b>labelling guidances</b> .....	<b>31</b>
58	<b>Annex J</b> (informative)	<b>Terminology — alphabetized index of defined terms</b> .....	<b>34</b>
59	<b>Bibliography</b> .....		<b>36</b>
60			

# ISO 17510

## 61 Foreword

62 ISO (the International Organization for Standardization) is a worldwide federation of national standards  
63 bodies (ISO member bodies). The work of preparing International Standards is normally carried out  
64 through ISO technical committees. Each member body interested in a subject for which a technical  
65 committee has been established has the right to be represented on that committee. International  
66 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO  
67 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of  
68 electrotechnical standardization.

69 The procedures used to develop this document and those intended for its further maintenance are  
70 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the  
71 different types of ISO documents should be noted. This document was drafted in accordance with the  
72 editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

73 Attention is drawn to the possibility that some of the elements of this document may be the subject of  
74 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any  
75 patent rights identified during the development of the document will be in the Introduction and/or on  
76 the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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

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

82 The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*,  
83 Subcommittee SC 3, *Respiratory devices and related equipment for patient care*.

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

- 86 — harmonization with IEC 60050-880, where appropriate ;
- 87 — adding disclosure requirements for magnets in *headgear*;
- 88 — updated *processing* requirements;
- 89 — updated vibration and noise requirements;
- 90 — referencing ISO 18562-1, for *biocompatibility of gas pathways*; and
- 91 — harmonization with ISO 20417, where appropriate.

## 92 Introduction

93 Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during  
94 sleep. The awareness of the *risks* associated with sleep apnoea has grown significantly in recent years. As  
95 a result, the use of *sleep apnoea breathing therapy equipment* has become common. This document covers  
96 basic safety and essential performance requirements for *masks* and other application *accessories* needed  
97 to protect *patients* during use of this equipment.

98 In this document, the following print types are used:

99 — requirements and definitions: roman type;

100 — informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text  
101 of tables is also in a smaller type;

102 — *Terms defined in Clause 3 in this document or as noted: italics.*

103 In referring to the structure of this document, the term

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

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

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

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

112 In this document, the following verbal forms are used:

113 — “shall” indicates a requirement;

114 — “should” indicates a recommendation;

115 — “may” indicates a permission; and

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





# 117 **Medical devices — Sleep apnoea breathing therapy — Masks and** 118 **application accessories**

## 119 **1 Scope**

120 This document applies to *masks* and their *accessories* used to connect *sleep apnoea breathing therapy*  
121 *equipment* to the *patient*. It specifies requirements for *masks* and *accessories*, including any connecting  
122 element, that are required to connect the *patient-connection port* of *sleep apnoea breathing therapy*  
123 *equipment* to a *patient* for the application of sleep apnoea breathing therapy (e.g. nasal masks, exhaust  
124 *ports* and *headgear*).

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

128 This document does not cover *oral appliances*.

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

## 131 **2 Normative references**

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

135 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources*  
136 *using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

137 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and*  
138 *equipment*

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

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

143 ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk*  
144 *management process*

145 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*  
146 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*  
147 *devices*

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

**ISO 17510**

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

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

154 ISO 20417:—<sup>1</sup>, *Medical devices — Information to be supplied by the manufacturer*

155 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method*  
 156 *to assess filtration performance*

157 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration*  
 158 *aspects*

159 IEC 60050-880:—<sup>2</sup>, *International Electrotechnical Vocabulary (IEV) – Part 880: Electrical equipment,*  
 160 *electrical systems and software used in healthcare*

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

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

### 164 **3 Terms and definitions**

165 For the purposes of this document, the terms and definitions given in IEC 60050-880:— as indicated in  
 166 Annex J and the following apply.

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

#### 168 **3.1**

##### 169 **anti-asphyxia valve**

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

172 [SOURCE: ISO 4135:2022, 3.6.3.7]

#### 173 **3.2**

##### 174 **breathing system filter**

##### 175 **BSF**

176 device intended to reduce transmission of particulates, including microorganisms, in a breathing system

177 [SOURCE: ISO 4135:2022, 3.6.1.5]

#### 178 **3.3**

##### 179 **breathing tube**

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

181 [SOURCE: ISO 4135:2022, 3.1.4.4, modified —deleted note.]

<sup>1</sup> Under preparation. Stage at the time of publication: ISO/DIS 20417:2024.

<sup>2</sup> Under preparation. Stage at the time of publication: IEC/CDV 60050-880:2024.

182 **3.4**183 **exhaust flow**

184 flow from the *mask* or application *accessory* to atmosphere other than the leak due to improper seal to  
185 the face

186 Note 1 to entry: The *exhaust flow* can pass through openings in the *mask*, the connecting element and the *mask* or  
187 through the *anti-asphyxia valve*.

188 Note 2 to entry: The *exhaust flow* discharges exhaled gases to atmosphere to reduce *rebreathing* of CO<sub>2</sub>.

189 [SOURCE: ISO 4135:2022, 3.8.1.3]

190 **3.5**191 **exhaust port**

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

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

194 **3.6**195 **gas output port**

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

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

199 **3.7**200 **headgear**

201 part that is used to fix the *mask* to the *patient*

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

203 **3.8**204 **mask**

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

207 [SOURCE: ISO 4135:2022, 3.8.6.4]

208 **3.9**209 **oral appliance**

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

212 **3.10**213 **patient-connection port**

214 port of a breathing system intended for connection to an airway device

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

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

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