



**International
Standard**

ISO 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*

**Second edition
2025-11**

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

ISO 17510:2025

<https://standards.iteh.ai/catalog/standards/iec/f273e2c4-3167-4008-bc24-3457d475aa35/iso-17510-2025>

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

ISO 17510:2025

<https://standards.itih.ai/catalog/standards/iec/f273e2c4-3167-4008-bc24-3457d475aa35/iso-17510-2025>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

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
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Information supplied by the manufacturer	8
4.1 General	8
4.2 Accompanying information	8
5 Construction requirements	10
5.1 Mask connectors	10
5.2 Biocompatibility	10
5.2.1 Patient contacting	10
5.2.2 Gas pathway contacting	10
5.3 Protection against rebreathing	10
5.3.1 Normal condition protection	11
5.3.2 Single fault condition protection	11
5.4 Cleaning, disinfection, and sterilization	11
5.4.1 Single patient multiple use	11
5.4.2 Multiple patient multiple use	12
5.5 Breathing during single fault condition	12
5.6 Breathing system filter	13
6 Audible acoustic energy	13
7 Measurement uncertainty	13
Annex A (informative) Particular guidance and rationale	14
Annex B (normative) Exhaust flow test procedure	18
Annex C (normative) Resistance to flow (pressure drop)	20
Annex D (normative) Anti-asphyxia valve pressure testing	22
Annex E (normative) Determination of the inspiratory and expiratory pressure drop under single fault condition	24
Annex F (normative) Carbon dioxide rebreathing	26
Annex G (normative) Audible acoustic energy	29
Annex H (informative) Guide to information supplied by the manufacturer	31
Annex I (informative) Reference to the IMDRF essential principles and labelling principles	32
Annex J (informative) Terminology — Alphabetized index of defined terms	34
Bibliography	36

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

