
**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, *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.

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

1 Scope

This International Standard 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 International Standard together with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT of ISO 80601-2-70 that form a sleep apnoea breathing system.

This International Standard does not cover ORAL APPLIANCES.

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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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 10993-1:2009, *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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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*