INTERNATIONAL STANDARD

ISO 17510

First edition
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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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*

ISO 80601-2-70:2015, *Medical Electrical Equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 17664:2004, ISO 23328-2:2002, ISO 80601-2-70:2015, IEC 60601-1:2005+A1:2012 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 MASK, which covers the mouth and is opened to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not providing adequate pressure at the MASK, and that is closed to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is providing adequate pressure at the MASK

3.2
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.

3.3
EXPECTED USEFUL LIFE
time period specified by the MANUFACTURER during which the MEDICAL DEVICE or ACCESSORY is expected to remain suitable for use under the conditions specified by the MANUFACTURER

Note 1 to entry: CLEANING and other PROCESSING can be necessary during the EXPECTED USEFUL LIFE.

3.4
HEADGEAR
part that is used to fix the MASK to the PATIENT

3.5
MASK
part which provides the interface between the PATIENT and the PATIENT-CONNECTION PORT

Note 1 to entry: According to their application, MASKS are divided into nasal MASKS, oral MASKS, or nasal-oral MASKS.

3.6
MULTI-PATIENT REUSE
capable of being re-used multiple times on multiple PATIENTS

3.7
ORAL APPLIANCE
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of SLEEP APNOEA BREATHING THERAPY EQUIPMENT

3.8
SINGLE FAULT CONDITION
condition of ME EQUIPMENT or ACCESSORY in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+A1:2012, 3.116, modified—added 'or ACCESSORY' and deleted note.]

3.9
SINGLE-PATIENT REUSE
capable of being used multiple times on the same PATIENT

4 Information to be supplied by the MANUFACTURER

4.1 General

MASKS, HEADGEAR and other ACCESSORIES shall be provided with an ACCOMPANYING DOCUMENT. The ACCOMPANYING DOCUMENT shall be regarded as a part of MASKS, HEADGEAR and the ACCESSORIES.

NOTE 1 The purpose of an ACCOMPANYING DOCUMENT is to promote the safe use of a MASK, HEADGEAR or other ACCESSORY during the EXPECTED USEFUL LIFE.

NOTE 2 Annex H contains a guide to assist the reader in locating the marking and labelling requirements contained in other clauses of ISO 17510.

4.2 Marking on the protective packaging

Packages of MASKS, HEADGEAR and other ACCESSORIES shall be marked with:

a) name or trade name and address of
   - the MANUFACTURER, and
   - where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

   to which the OPERATOR or RESPONSIBLE ORGANIZATION can refer;

b) the details strictly necessary to identify the device and the contents of the packaging especially for the OPERATOR or RESPONSIBLE ORGANIZATION;

c) the identity and intended purpose of the MASK and any application ACCESSORIES;

d) any special storage and/or handling conditions;

e) any special operating instructions;

f) any special warnings and/or precautions to be taken;

g) if applicable, symbol from ISO 15223-1:2012, 5.1.4 indicating the latest date by which the MASK and any application ACCESSORIES can be used safely (i.e. shelf life), expressed as the year, month and day;

h) identification reference to the batch, type or serial number with symbol from ISO 15223-1:2012, 5.1.7 with an accompanying serialization or symbol from ISO 15223-1:2012, 5.1.5 with an accompanying lot or batch identifier; and

i) for sterile items, with symbol ISO 15223-1:2012, 5.2.1, symbol ISO 15223-1:2012, 5.2.2, symbol ISO 15223-1:2012, 5.2.3 or symbol ISO 15223-1:2012, 5.2.4, as appropriate.

Packaging for single use MASKS, HEADGEAR and other ACCESSORIES shall be marked accordingly and shall be consistent for a MODEL OR TYPE REFERENCE.

Check compliance by inspection without opening the packaging.

4.3 ACCOMPANYING DOCUMENT

The ACCOMPANYING DOCUMENT of the MASK, HEADGEAR, or other ACCESSORY shall contain the following information:

a) name or trade name and address of

- the MANUFACTURER; and
- where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the OPERATOR or RESPONSIBLE ORGANIZATION can refer;

b) the identity and the intended purpose of the MASK and any application ACCESSORIES;

c) the details of any treatment or handling needed before the MASK or ACCESSORY can be used;

d) if provided sterile,

- an indication of the method of sterilization using symbol ISO 15223-1:2012, 5.2.1, symbol ISO 15223-1:2012, 5.2.2, symbol ISO 15223-1:2012, 5.2.3 or symbol ISO 15223-1:2012, 5.2.4, as appropriate;
- instructions necessary in the event of damage to the sterile packaging and details of appropriate methods of resterilization;

e) if the packaging contains more than one component information necessary for correct assembly of the components;

f) information necessary to verify whether the MASK or ACCESSORY is properly installed and can operate correctly and safely;

g) if the MASK or ACCESSORY includes an EXHAUST PORT, a warning statement to the effect that: "WARNING: Occlusion of the exhaust needs to be prevented to avoid having an adverse effect on the safety and quality of the therapy";

h) a statement to the effect that combination with other medical devices not intended to be combined with the mask can decrease the safety or alter the performance of the mask (e.g. in combination with a humidifier for medical use, nebulizer, heat and moisture exchanger (HME), filters, bi-level positive airway pressure equipment, self-adjusting equipment, or additional oxygen supply or any exhaust port);

i) if applicable, information about the means provided to minimize REBREATHING (see 5.3);

j) the RATED pressure range of the MASK including any connecting element;

k) information to enable the RESPONSIBLE ORGANIZATION (prescriber) to inform the PATIENT of

- any potential contraindications and any precautions that might need to be taken,
- any precautions to be taken in the event of changes in performance, and
- any precautions to be taken regarding to risks associated with disposal;

l) if specified for reuse:

- the information specified in ISO 17664:2004, 3.9, if sterilizable;
- a warning statement to the effect that: "WARNING: frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents, or

exceeding the number of PROCESSING cycles can have an adverse effect on the [place name of component here] and consequently the safety or the quality of the therapy";

m) information about the nature and frequency of regular and preventative maintenance of the MASK or ACCESSORY, including information about the replacement of consumable components during the EXPECTED USEFUL LIFE of the MASK or ACCESSORY;

n) information for the OPERATOR to identify parameters or criteria that could indicate a safety or efficacy change in the MASK or ACCESSORY (e.g. visual inspection criteria); as well as the course of action to follow as a result of this identification (e.g. disposal or component replacement procedure);

o) the EXPECTED USEFUL LIFE of MASKS and any ACCESSORIES;

p) * the resistance, derived from pressure drop, between the MASK and the PATIENT-CONNECTION PORT at flowrates of 50 l/min and 100 l/min, as determined in Annex C;

q) * for MASKS that cover the nose and the mouth, the inspiratory, and expiratory resistance of the MASK in combination with the ANTI-ASPHYXIA VALVE open to atmosphere, as determined in Annex E;

r) * the pressure-flow curve of the EXHAUST FLOW throughout the working pressure range as determined in Annex B;

s) * the date of issue or revision level of the ACCOMPANYING DOCUMENT.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

5 Construction requirements

5.1 MASK connectors

MASK connectors, if conical, shall be 15 mm or 22 mm size male connectors conforming to ISO 5356-1:2015 or ISO 5356-2:2012.

Non-conical MASK connectors shall not engage with conical connectors conforming to ISO 5356-1:2015 or ISO 5356-2:2012, unless they comply with the engagement, disengagement, and leakage requirements of ISO 5356-1:2015 or ISO 5356-2:2012.

Check compliance by inspection and functional testing.

5.2 Biocompatibility

Parts or materials that are intended to be in contact with the PATIENT or PATIENT gas pathway during NORMAL USE shall be evaluated according to ISO 10993-1:2009.

NOTE 1 The gas pathways should be evaluated to ISO 18562-1:—, upon its publication.

Parts or materials that are intended to be inserted into the nares or the mouth shall be evaluated as mucosal membrane contact.

For parts or materials not intended to be inserted into the nares or mouth (e.g. MASK elbows, tubing, cushions, and faceplates), the gas pathway materials shall be evaluated as skin contact.

For MASK materials, including HEADGEAR, intended to contact the PATIENT's head, the materials shall be evaluated as skin contact.

All materials shall be considered as for permanent duration contact as categorized in ISO 10993-1:2009.

NOTE 2 Permanent duration contact is required because SLEEP APNOEA BREATHING THERAPY EQUIPMENT and ACCESSORIES have cumulative usage that is greater than 30 d.

Natural rubber latex shall not be used in the MASK or ACCESSORIES.

The MANUFACTURER of a MASK or ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway. Special attention shall be given to substances which are carcinogenic, mutagenic, or toxic to reproduction.

A MASK or ACCESSORY that contains phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked on the MASK or ACCESSORY itself or on the packaging that it contains phthalates. If the INTENDED USE of a MASK or ACCESSORY includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The ACCOMPANYING DOCUMENT of a MASK or ACCESSORY that contains such phthalates shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by the application of ISO 10993-1:2009, inspection of the ACCOMPANYING DOCUMENT and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

5.3 * Protection against REBREATHING

5.3.1 NORMAL CONDITION protection

Means shall be provided to minimize the RISK of REBREATHING during NORMAL CONDITION. The means may be integral to the MASK or other application ACCESSORY or located in the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

Under NORMAL CONDITION, the relative CO_2 increase shall not exceed 20 % when tested at

— the minimum RATED pressure,

— a pressure of 5 hPa (5 cmH_2O), and

— a pressure of 10 hPa (10 cmH_2O).

Check compliance by the tests described in Annex F.

5.3.2 SINGLE FAULT CONDITION PROTECTION

MASKS that cover the mouth shall be designed to minimize REBREATHING during SINGLE FAULT CONDITION.

Under SINGLE FAULT CONDITION, the relative CO_2 increase shall not exceed 60 % when tested

— with blockage of the BREATHING TUBE, and

— at the equipment-end of the BREATHING TUBE open to atmosphere.

NOTE PATIENTS can open their mouth and breathe normally under SINGLE FAULT CONDITION for a MASK that only covers the nose.

Check compliance by the tests described in Annex F.

5.4 CLEANING, DISINFECTION, and sterilization

The MASK and any ACCESSORIES, whether for SINGLE-PATIENT REUSE or MULTI-PATIENT REUSE, shall be designed so that contaminant-trapping features are minimized and can be easily cleaned by the OPERATOR.

The MASK and any ACCESSORIES and their parts intended for MULTI-PATIENT REUSE shall be so constructed that they can be cleaned and disinfected or cleaned and sterilized.

