INTERNATIONAL STANDARD

ISO 17510-2

Second edition
2007-10-01

Sleep apnoea breathing therapy —

Part 2: Masks and application accessories

Thérapie respiratoire de l'apnée du sommeil —

Partie 2: Masques et accessoires d'application

Reference number
ISO 17510-2:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 17510-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 17510-2:2003) which has been technically revised.

ISO 17510 consists of the following parts, under the general title *Sleep apnoea breathing therapy*:

— *Part 1: Sleep apnoea breathing therapy equipment*

— *Part 2: Masks and application accessories*

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 needed to protect patients during use of this equipment.

ISO 17510-2 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic document for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical electrical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Sleep apnoea breathing therapy —

Part 2:
Masks and application accessories

1 Scope

This part of ISO 17510 applies to masks, their fixing and to the accessories used to connect a 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, and are used 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 17510-1. See Figure A.1 for typical elements of the two parts of ISO 17510.

This part of ISO 17510 does not cover oral appliances.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane*

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

ISO 4871, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

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

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

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 14937, *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 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17510-1:2007, *Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment*

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

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

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*; Amendment A1:1991; Amendment A2:1995

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 61672-1, *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, ISO 17510-1, ISO 17664, ISO 23328-2, IEC 60601-1, IEC 60601-1-1 and the following apply.

NOTE For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex K.

3.1
anti-asphyxia valve
valve used on a naso-oral mask, which is open 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 accessories to atmosphere other than the leak due to improper seal to the face

NOTE 1 The exhaust flow can pass through openings in the mask, the connecting element and the mask, or through the anti-asphyxia valve.

NOTE 2 The exhaust flow discharges exhaled gases to atmosphere to reduce rebreathing of CO_2.

3.3
headgear
part that is used to fix the mask to the patient

3.4
mask
part which provides the interface between the patient and the patient connection port

NOTE According to their application, masks are divided into: nasal masks, oral masks or nasal-oral masks.

3.5
multi-patient re-use
capable of being re-used multiple times on multiple patients

3.6
oral appliance
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of sleep apnoea breathing therapy equipment

3.7
*** patient connection port**
port where the breathing gas pathway connects to the mask

3.8
single-patient reuse
capable of being used multiple times on the same patient

4 Information to be supplied by the manufacturer

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

4.1 The label of the packaging, marking on the mask or accessory, and/or the accompanying documents shall contain the following information:

a) the name or trade name and address of the manufacturer and the name and address of the person responsible or of the authorized representative of the manufacturer or importer;

b) the identity and intended purpose of the mask and any application accessories;

c) * the pressure-flow curve of the exhaust flow throughout the working pressure range as determined in Annex B;

d) the rated pressure range of the mask including any connecting element;

e) if re-usable:

— the information specified in ISO 17664:2004, 3.9, if sterilizable;

— a warning that 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 materials used or performance;

f) any special storage and/or handling conditions;

g) any special operating instructions;

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

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

j) information to enable the user (prescriber) to inform the patient of any potential contra-indications and any precautions that might need to be taken;

k) a warning statement to the effect that occlusion of any exhaust port should be prevented;

l) * the resistance, derived from pressure drop, between mask and the patient connecting port at flowrates of 50 l/min and 100 l/min, as determined in Annex C;

m) information about the means provided to minimize the risk of rebreathing (see 5.3);

n) a statement on proper disposal at end of life for the mask or accessory;

o) * the inspiratory and expiratory resistance of the mask in combination with the anti-asphyxia valve open to atmosphere, as determined in Annex E;

p) expected service life of any masks and accessories;

q) the details of any further treatment or handling needed before the mask or accessory can be used;

r) the information needed to verify whether the mask or accessory is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that it operates properly and safely at all times;

s) information about the nature and frequency of regular and preventative maintenance of the mask or accessory, including information about the replacement of consumable components of the device during the intended life of the mask or accessory.

Check compliance by inspection of the accompanying documents.

4.2 If appropriate, the label of the packaging, marking on the mask or accessory, and/or the accompanying documents shall contain the following information:

a) a serial number (or symbol 5.16 from ISO 15223-1:2007), or lot identifying number or batch identifying number (or symbol 5.14 from ISO 15223-1:2007);

b) an indication (or symbol 5.12 from ISO 15223-1:2007) of the latest date by which the mask and any application accessories can be used safely, expressed as the year and month;

c) a statement to the effect that combination with other medical devices can 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;

d) symbols 5.20 to 5.24 from ISO 15223-1:2007, if the package is sterile;

e) instructions necessary in the event of damage to the sterile packaging and details of appropriate methods of resterilization.

Check compliance by inspection of the accompanying documents.

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 or ISO 5356-2.

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

Check compliance by inspection and functional testing.

5.2 Biocompatibility

Parts and/or materials that are intended to be in contact with the patient or patient gas pathway under normal use shall comply with the ISO 10993 series. For nasal accessories intended to be inserted into the nares or parts of masks intended to be inserted into the mouth, the external materials of the nasal inserts or of the parts of the masks shall be evaluated as mucosal membrane contact. Additionally, for parts or materials not intended to be inserted into nares or mouth, the gas pathway materials shall be evaluated as externally communicating with tissue. For mask materials, including headgear, intended to contact the patient's head, the materials shall be evaluated as skin contacting.

All materials shall be considered as for permanent duration contact as categorized in ISO 10993.

NOTE Permanent duration contact is required because sleep apnoea breathing therapy equipment and accessories have cumulative usage that is greater than 30 days.

Latex shall not be used in the mask and accessories.

Check compliance by application of the ISO 10993 series.

5.3 * Protection against rebreathing

Means shall be provided to minimize the risk of rebreathing during normal condition and single fault condition.

Under normal condition, the relative CO_2 increase shall not exceed 20 % when tested at the minimum rated, 5 hPa (5 cm H_2O), and 10 hPa (10 cm H_2O) pressure.

Under single fault condition, the relative CO_2 increase shall not exceed 60 %.

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 re-use, 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 re-use shall be so constructed that they can be cleaned and disinfected or cleaned and sterilized.

Processing or (re)processing methods for cleaning and disinfection of a mask shall consist of performing the number of cleaning or cleaning and disinfection cycles that represents the expected lifetime of the mask.

Processing or (re)processing instructions disclosed in the instructions for use for the mask and any accessories and their parts shall comply with ISO 17664 and ISO 14937. The mask and any accessories labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Non-sterile device packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of contamination.

Check compliance by review of the validation of the processing methods, including the verification that the mask and any accessories and their parts comply with their specifications after re-processing and inspection of instructions for use.

5.5 * Breathing during single fault condition

Means shall be provided to limit inspiratory and expiratory resistance in single fault condition. The resistance to flow shall not exceed 10 hPa (10 cm H_2O) per l/s (measured at the patient connection port) at flowrates of 50 l/min.

If an anti-asphyxia valve is provided, the open-to-atmosphere pressure shall be less than the minimum rated pressure of the mask. The open-to-atmosphere and closed-to-atmosphere pressures shall be disclosed in the instructions for use.

Check compliance by using the tests described in Annexes D and E.

5.6 Breathing system filter

Any breathing system filter shall comply with ISO 23328-1 and ISO 23328-2.

Check compliance by application of the requirements of ISO 23328-1 and ISO 23328-2.

6 Vibration and noise

The A-weighted sound power level caused by the mask and any accessories shall be measured and disclosed in the instructions for use in accordance with ISO 4871 and ISO 3744 using engineering-method grade 2. The A-weighted sound pressure level in accordance with ISO 4871 and ISO 3744 at a distance of 1 m shall also be disclosed in the instructions for use.

NOTE Care is required in the test set-up to ensure that the sound measurement of the mask and any accessories is not interfered with by the noise emitted by the breathing tube or the equipment.

Check compliance by the tests in Annex G.