INTERNATIONAL STANDARD

ISO 17510-2

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Sleep apnoea breathing therapy —

Part 2:
Masks and application accessories

Thérapie de l'apnée du sommeil —

Partie 2: Masques et accessoires thérapeutiques

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Foreword

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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 the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

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

— *Part 1: Sleep apnoea breathing therapy devices*

— *Part 2: Masks and application accessories*

For the purposes of this part of ISO 17510, the CEN annex regarding fulfilment of European Council Directives has been removed.

Annex ZZ provides a list of corresponding International and European Standards for which equivalents are not given in the text.

Contents

Foreword

This document (EN ISO 17510-2:2003) has been prepared by Technical Committee CEN /TC 215, "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with ISO/TC 121 "Anaesthetic and respiratory equipment".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2003, and conflicting national standards shall be withdrawn at the latest by July 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN ISO 17510 covers sleep apnoea breathing therapy products for patients to use in the home. Part 1 applies to the sleep apnoea breathing therapy devices. This part 2 applies to masks, their fixing and to the accessories used to connect a sleep apnoea breathing therapy device to the patient.

Annex A is informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This part of the European Standard specifies requirements for masks and accessories which are required to connect the patient connection port to a sleep apnoea breathing therapy device and the mask to a patient, and are used for the application of sleep apnoea breathing therapy e.g. nasal masks, gas exhaust ports, connecting element and headgear.

This part of EN ISO 17510 does not cover oral appliances.

NOTE 1 Sleep apnoea breathing therapy devices are covered by EN ISO 17510-1 (see Figure A.1 for typical elements of the two parts of EN ISO 17510).

NOTE 2 Annex A contains rationale statements for this Part of EN ISO 17510.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1281-1, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.*

EN 1281-2, *Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)*

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

EN ISO 4135:2001, *Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2001).*

EN ISO 10993 series, *Biological evaluation of medical devices.*

EN ISO 14971, *Medical devices - Application of risk management to medical devices (ISO 14971:2000).*

EN ISO 17510-1:2002, *Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy devices (ISO 17510-1:2002).*

EN 60651, *Sound level meters (IEC 60651:1993)*

EN 60804, *Integrating-averaging sound level meters (IEC 60804:2000)*

IEC/TR 60959, *Provisional head and torso simulator for acoustic measurements on air conduction hearing aids.*

3 Terms and definitions

For the purposes of this part of the European Standard, the terms and definitions given in EN ISO 4135:2001, EN ISO 17510-1:2002 and the following apply.

3.1
oral appliance
device intended to maintain the oral airway by mechanical means which achieves its purpose independently of a sleep apnoea breathing therapy device

3.2
headgear
part that is used to fix the mask in the appropriate position on the patient

3.3
mask
part which provides the interface between the patient and the patient connection port or the connecting element

NOTE 1 According to their application, masks are divided into nasal masks, oral masks or nasal-oral masks.

NOTE 2 A mask can additionally include specific facilities, e.g. supplementary gas connector, gas exhaust port, monitoring connector, means to minimize re-breathing.

3.4
connecting element
part connecting the patient connection port and the mask

NOTE A connecting element can include specific facilities, e.g. supplementary gas connector, gas exhaust port, monitoring connector, means to minimize re-breathing.

4 Information to be supplied by the manufacturer

The label of the packaging and/or the instructions for use shall contain the following information:

4.1 if imported into the EU, the name and address of the person responsible or the authorized representative of the manufacturer or the importer established within the EU;

4.2 the intended purpose of the mask and application accessories;

4.3 the pressure-flow curve of any gas exhaust port throughout the working pressure range (see A.3);

4.4 the working pressure range of the mask and/or the connecting element;

4.5 the sound pressure level of any gas exhaust port measured according to 6.1 (see A.4);

4.6 if appropriate, the symbol STERILE in accordance with EN 980 and the method of sterilization;

4.7 if appropriate, the symbol LOT in accordance with EN 980 or serial number;

4.8 if appropriate, an indication of the date by which the mask and application accessories can be used safely, expressed as the year and month;

4.9 if appropriate, an indication that the mask and application accessories are not for re-use;

4.10 if re-usable:

- information necessary for cleaning, disinfection and/or sterilisation, including information about the frequency, methods and agents to be utilized, and number of re-uses of the device;
- a warning that inappropriate frequency or method or agent can have an adverse effect on the materials used and their performance;

4.11 any special storage and/or handling conditions;

4.12 any special operating instructions;

4.13 any special warnings and/or precautions to be taken (see A.5), including the use of a separate exhalation valve when using a non-valved mask;

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

4.15 if appropriate, a statement to the effect that combinations with other medical devices can alter the performance of the device, e.g. combinations with humidifier for medical use, nebulizer, heat and moisture exchanger (HME), filters, bi-level positive airway pressure device, self-adjusting sleep apnoea breathing therapy device, additional oxygen supply any gas exhaust port;

4.16 instructions necessary in the event of damage to the sterile packaging and, if appropriate, details of appropriate methods of re-sterilisation;

4.17 information to enable medical staff to brief the patient on any potential contra-indications and any precautions that may need to be taken, particularly in the event of changes in the performance of the device or when external sources of heat are located in the vicinity of the device;

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

4.19 instructions for the correct disposal of the mask and application accessories;

4.20 a warning statement to the effect that electrically conductive breathing tubes should not be used;

4.21 the resistance to flow, at 50 l/min and 100 l/min, of the mask and/or components of any connecting element when measured in accordance with 6.2, expressed as pressure drop in kPa (cmH_20) (see A.6);

4.22 information relating to the means provided to minimize the risk of re-breathing (see 5.3).

5 Construction requirements

5.1 Face mask connectors

Face mask connectors, if conical, shall be 15 mm or 22 mm size connectors conforming to EN 1281-1 or EN 1281-2.

Non-conical connectors shall not engage with conical connectors conforming to EN 1281-1 or EN 1281-2 unless they comply with the engagement, disengagement and leakage requirements of EN 1281-1 or 1281-2.

5.2 Compatibility

Parts and/or materials which are intended to be in contact with the patient under normal use conditions shall be tested in accordance with EN ISO 10993 series.