SLOVENSKI STANDARD

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Zdravljenje dihanja pri prenehanju dihanja v spanju - 2. del: Maske in oprema za nameğ¦anje (ISO 17510-2:2003)

Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510 -2:2003)

Schlafapnoe-Atemtherapie - Teil 2: Masken und Anwendungszubehör (ISO 17510-2:2003)

Thérapie respiratoire de l'apnée du sommeil - Partie 2: Masques et accessoires thérapeutiques (ISO 17510-2:2003)

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Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2003)

Thérapie de l'apnée du sommeil - Partie 2: Masques et accessoires thérapeutiques (ISO 17510-2:2003)

Schlafapnoe-Atemtherapie - Teil 2: Masken und Anwendungszubehör (ISO 17510-2:2003)

This European Standard was approved by CEN on 9 September 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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of an identical text or by endorsement, at the latest by July 2003, and conflicting national standards shall be withdrawn at the latest by July 2003.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).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

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.

A risk analysis shall be performed in accordance with EN ISO 14971.

5.3 Re-breathing

Means shall be provided to minimize the risk of re-breathing during normal use and single fault condition.

NOTE The design of the mask and application accessories can be such that this requirement is already satisfied and no additional protection is required.

6 Methods of test

6.1 Test to determine the sound pressure level of the gas exhaust port

6.1.1 Principle

The noise emission from the gas exhaust port of a mask is measured. This mask is fitted on a dummy head simulating the reception of the operating noise at the patient's ears.

6.1.2 Apparatus

6.1.2.1 Sound pressure measuring device, in accordance with EN 60651 and EN 60804 type 1.

6.1.2.2 Dummy head, in accordance with IEC/TR 60959.

6.1.3 Procedure

6.1.3.1 For a face mask with integral exhaust port, fit the mask to the dummy head (6.1.2.2) as specified by the manufacturer, ensuring a gas-tight seal. For a stand-alone gas exhaust port, position it relative to the dummy head as specified by the manufacturer for normal use, with the outlet port sealed.

6.1.3.2 Connect a breathing tube and ensure that no leakage occurs.

6.1.3.3 By appropriate measures, acoustically isolate the tubing systems in such a manner that the noise caused or conducted by the tubing system does not affect the sound level measurement at the gas exhaust port.

6.1.3.4 Apply a constant gas pressure of 1 kPa to the appropriate inlet port.

6.1.3.5 Position the microphone etc. for measurement according to IEC/TR 60959 and corresponding to the person's left and right ears.

6.1.3.6 At each position of the microphone determine the time average sound pressure level L_{eq} (i.e. the energy averaged A-frequency weighted and F-time weighted sound pressure level) for the noise level during use and the background noise. Duration of each measurement is at least 10 s.

6.1.3.7 The measurement shall be in accordance with accuracy class 2 according to EN ISO 3744, in particular the environmental conditions apply with: $K_2 \leq 2$ dB and the difference between the measured noise level and the environmental noise level shall be $\Delta L \geq 6$ dB and $K_1 \leq 1{,}3$ dB.

6.1.3.8 The measurement shall be in accordance with provisions specified in EN ISO 3744. i.e. acoustic environment, measuring devices, mounting and operation etc.

6.1.4 Expression of results

Express the sound levels L_{eq} measured according to EN ISO 3744, at the left-hand and right-hand measuring positions, free of the influence of the external noise as well as the measuring environment.