Uneapnoe hingamisteraapia. Osa 2: Maskid ja lisatarvikud

Sleep apnoea breathing therapy - Part 2: Masks and application accessories

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 17510-2:2009 sisaldab Euroopa standardi EN ISO 17510-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 17510-2:2009 consists of the English text of the European standard EN ISO 17510-2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 11.03.2009.	Date of Availability of the European standard text 11.03.2009.
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Võtmesõnad: artificial breathing apparatus, hospitals, inha, marking, masks, medical equipment, medical products, medical technology, medicine, noise level, nursing, patients, respiratory standstill, snore illness, sound pressure level, testing, therapeutics, therapy equipment

EUROPEAN STANDARD

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English Version

Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 2: Masques et accessoires d'application (ISO 17510-2:2007)

Schlafapnoe-Atemtherapie - Teil 2: Masken und Anwendungszubehör (ISO 17510-2:2007)

This European Standard was approved by CEN on 24 February 2009.

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Ref. No. EN ISO 17510-2:2009: E

Foreword

The text of ISO 17510-2:2007 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17510-2:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17510-2:2007.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 17510-2:2007 has been approved by CEN as a EN ISO 17510-2:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
4	13.1, 13.6 a)	
4	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
4	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
4	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
4	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
4.1 a)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
4.1 b)	13.3 b)	

4.1 c)	9.1, 13.6 b) , 13.6 c)	
4.1 d)	9.1, 13.6 b)	
4.1 e)	8.6, 13.6 h)	
4.1 f)	13.3 i)	
4.1 g)	13.3 j)	
4.1 h)	13.3 k)	
4.1 i)	13.3 b), 13.6 i)	
4.1 j)	13.6 k)	
4.1 l)	9.1, 13.6 b)	
4.1 o)	9.1, 13.6 b)	
4.1 m)	13.6 c)	
4.1 n)	13.6 n)	
4.1 q)	13.6 i)	
4.1 r), s)	13.6 d)	
4.2 a)	13.2, 13.3 d), 13.5	
4.2 b)	13.2, 13.3 e), 13.4	
4.2 c)	9.1	
4.2 d)	8.7, 13.2, 13.3 c), 13.3 m)	
4.2 e)	13.6 g)	
5	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5	4, 7.2, 7.5, 7.6	
5.1	12.7.4	
5.2	7.1, 7.3	
5.3	9.2, 12.8.2	
5.4	7.1, 7.3, 8.1, 8.3, 8.4, 8.5	
5.5	9.2, 12.8.1, 12.8.2	
5.6	8.1	
6	12.7.2, 12.7.3	

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

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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*