Uneapnoe hingamisteraapia. Osa 1: Uneapnoe hingamisteraapia seadmed

Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA	NATIONAL FOREWORD
Käesolev Eesti standard EVS-EN ISO 17510-1:2009 sisaldab Euroopa standardi EN ISO 17510-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 17510-1:2009 consists of the English text of the European standard EN ISO 17510-1:2009.
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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ICS 11.040.10

Võtmesõnad: apnoea, breathing equipment, breathing therapy, electrical safety, medical equipment, medical technology, medicine, respiratory standstill, snore illness, therapeutics, therapy equipment

EUROPEAN STANDARD

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English Version

Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 1: Équipement de thérapie respiratoire de l'apnée du sommeil (ISO 17510-1:2007)

Schlafapnoe-Atemtherapie - Teil 1: Schlafapnoe-Atemtherapiegeräte (ISO 17510-1:2007)

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

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Ref. No. EN ISO 17510-1:2009: E

Foreword

The text of ISO 17510-1:2007 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 17510-1:2009 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 17510-1:2007.

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 17510-1:2007 has been approved by CEN as a EN ISO 17510-1:2009 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	
4	6, 12.6	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
6	13	
6	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
6.1	2, 13.3 a)	
6.1 aa) to cc)	13.6 c), d)	
6.1 dd)	8.7, 9.1, 13.3, 13.4, 13.5	
6.1 dd) 7th dash	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 e)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.3	10.2, 10.3, 12.9	

6.8.2	13.6 b), c), h), i), l)	
6.8.3	13.6 c), d), p), n)	
10.1	8.3	
10.101, 10.102	4	
13, 15, 17, 18,19, 20	12.6	
21	5, 9.2, 12.7.1	
23	4, 9.2	
24	4, 12.7.1	
26	12.7.2, 12.7.3	
36	4, 9.2, 11.3.1, 12.5	
38	13.2, 13.4	
39, 40, 41	9.3	
42	9.2, 12.7.5	
43	7.1, 7.2, 9.3	
43.101	7.1, 9.3	
44	4, 7.2, 7.3, 7.5, 7.6, 8.1, 8.6	
44.6	7.6	
44.7	8.3, 8.5	
46	9.2, 10.2, 12.8.2, 12.9	
48	7.2, 7.5	
49	4	
49.101	12.8.1, 12.8.2	
51	12.8.1, 12.8.2	
51.5	2, 12.8.2, 12.9	
51.101	12.8.2	
51.102	10.1, 10.2, 12.8.2	
51.103	10.1, 10.2, 12.8.2	
51.104	4, 12.8.1, 12.8.2	
51.105	4, 12.8.2	
52	12.1	

54	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
54	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
54.1	12.1, 12.9	
54.101	7.5	
56.3	9.1, 12.7.4	
56.10	12.9	
56.101.1	7.3, 8.1, 8.4	
56.101.2	7.3, 8.1, 8.6	
56.102	9.1	

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR o 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
6.8.2, 56	1.5.4	This relevant EHSR is not fully addressed in this European Standard
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

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

Contents

Page

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 in the use of this equipment.

This document 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 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.

To facilitate the use of this document, the following drafting conventions have been applied.

This document uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this document.

— “Addition” means that the relevant text of this document is supplementary to the requirements of the General Standard.

— “Amendment” means that existing text of the General Standard is modified as indicated by the text of this document.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this document: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc., and additional annexes are lettered AA, BB, etc.

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

Sleep apnoea breathing therapy —

Part 1:
Sleep apnoea breathing therapy equipment

1 * Scope

IEC 60601-1:1988, Clause 1 applies, except as follows.

Amendment (add at the end of the Subclause 1.1):

This part of ISO 17510 specifies requirements for equipment intended for sleep apnoea breathing therapy for domiciliary use, ships, aircraft and other transport vehicles and for use in healthcare institutions.

This part of ISO 17510 applies to equipment intended for use with adults and children, and excludes equipment intended for use with neonates.

Jet and very high frequency ventilation and oscillation are not considered in this part of ISO 17510.

This part of ISO 17510 does not apply to equipment covered by the scope of the ISO 10651 series, including:

— ISO 10651-2:2004;

— ISO 10651-3:1997;

— ISO 10651-4:2002;

— ISO 10651-5:2006;

— ISO 10651-6:2004.

This part of ISO 17510 does not apply to equipment covered by the scope of IEC 60601-2-12.

ISO 17510 covers sleep apnoea breathing therapy equipment for patient use. ISO 17510-2 applies to masks and accessories used to connect sleep apnoea breathing therapy equipment to the patient. See also Figure AA.1.

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 32, *Gas cylinders — Colour coding*

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 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 8185:2007, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 11135 (both parts), *Sterilization of health care products — Ethylene oxide*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

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;* Amendment 1, 2003

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/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

ISO 17510-2:2007, *Sleep apnoea breathing therapy — Part 2: Masks and application accessories*

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

ISO 17665 (both parts), *Sterilization of health care products — Moist heat*

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 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature;* Amendment 1, 1995

IEC 60529, *Degrees of protection provided by enclosures (IP Code);* Amendment 1:1999

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for 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 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*