Irish Standard
I.S. EN ISO 17510-1:2009

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

I.S. EN ISO 17510-1:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
I.S. EN ISO 17510-1:2007	EN ISO 17510-1:2009 EN ISO 17510-1:2007	11 March, 2009 30 October, 2007

This document was published under the authority of the NSAI and comes into effect on:
11 May, 2009

ICS number:
11.040.10

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Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN ISO 17510-1:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17510-1

March 2009

ICS 11.040.10

Supersedes EN ISO 17510-1:2007

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)

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

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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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

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I.S. EN ISO 17510-1:2009

INTERNATIONAL STANDARD

ISO 17510-1

Second edition
2007-10-01

Sleep apnoea breathing therapy —

Part 1: Sleep apnoea breathing therapy equipment

Thérapie respiratoire de l'apnée du sommeil —

Partie 1: Équipement de thérapie respiratoire de l'apnée du sommeil

Reference number
ISO 17510-1:2007(E)

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Published in Switzerland

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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 17510-1 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 17510-1:2002) 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 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*