INTERNATIONAL STANDARD

ISO 17510-2

Second edition
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Sleep apnoea breathing therapy —

Part 2: Masks and application accessories

Thérapie respiratoire de l'apnée du sommeil —

Partie 2: Masques et accessoires d'application

Reference number
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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 17510-2 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 17510-2:2003) 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 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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 17510-1, ISO 17664, ISO 23328-2, IEC 60601-1, IEC 60601-1-1 and the following apply.

NOTE For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex K.

3.1
anti-asphyxia valve
valve used on a naso-oral mask, which is open to atmosphere when the sleep apnoea breathing therapy equipment is not providing adequate pressure at the mask and that is closed to atmosphere when the sleep apnoea breathing therapy equipment is providing adequate pressure at the mask

3.2
exhaust flow
flow from the mask or application accessories to atmosphere other than the leak due to improper seal to the face

NOTE 1 The exhaust flow can pass through openings in the mask, the connecting element and the mask, or through the anti-asphyxia valve.

NOTE 2 The exhaust flow discharges exhaled gases to atmosphere to reduce rebreathing of CO_2.

3.3
headgear
part that is used to fix the mask to the patient

3.4
mask
part which provides the interface between the patient and the patient connection port

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

3.5
multi-patient re-use
capable of being re-used multiple times on multiple patients

3.6
oral appliance
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of sleep apnoea breathing therapy equipment