International Standard

ISO 17510

Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

Dispositifs médicaux — Thérapie respiratoire de l'apnée du sommeil — Masques et accessoires d'application

Second edition
2025-11

Reference number
ISO 17510:2025(en)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17510:2015), which has been technically revised.

The main changes are as follows:

— harmonization with IEC 60050-880 sources, where appropriate;

— adding disclosure requirements for magnets in *headgear*;

— updated *processing* requirements;

— updated noise requirements;

— referencing ISO 18562-1, for *biocompatibility* of *gas pathways*;

— harmonization with ISO 20417, where appropriate.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 for *masks* and other application *accessories* needed to protect *patients* during use of this equipment.

Sleep apnoea breathing therapy equipment is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this document together with the *sleep apnoea breathing therapy equipment* of ISO 80601-2-70 that form a sleep apnoea breathing system.

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text of tables is also in a smaller type.

— *Terms defined in Clause 3 in this document or as noted: italics.*

In referring to the structure of this document, the term:

— "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes 5.1, 5.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 5.1, 5.2, and 5.3.1 are all subclauses of Clause 5).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission; and

— "can" is used to describe a possibility or capability.