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*

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*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 61672 (all parts), *Electroacoustics — Sound level meters*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 17510-2, ISO 23328-2, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and the following apply.

NOTE For convenience, the sources of all defined terms used in this document are given in Annex FF.

3.1
*** applied part**
part of the equipment which in normal use:

— necessarily comes into physical contact with the patient for the equipment to perform its function or

— can be brought into contact with the patient or

— needs to be touched by the patient or

— is intended to be connected to the patient connection port of the sleep apnoea breathing therapy equipment

[Modified from IEC 60601-1/A2:1995, definition 2.1.5]

3.2
bi-level positive airway pressure
two therapeutic positive pressure levels at the patient connection port during the respiratory cycle

3.3
breathing gas pathway
pathway through which gas flows at respiratory pressures between the fresh-gas intake port and the patient connection port

3.4
continuous positive airway pressure
CPAP
therapeutic continuous positive airway pressure at the patient connection port during the respiratory cycle

3.5
pressure accuracy
difference between the pressure set on the sleep apnoea breathing therapy equipment and the pressure measured at the patient connection port

3.6
self-adjusting
automatically adjusting the pressure in the breathing gas pathway according to the patient's needs during use

3.7
sleep apnoea breathing therapy equipment
equipment intended to alleviate the symptoms of patients who suffer from sleep apnoea by delivering a therapeutic breathing pressure to the patient

NOTE Sleep apnoea breathing therapy equipment is primarily used without direct professional supervision when a patient is at home.

4 Requirements

IEC 60601-1:1988, Clauses 3 and 4 apply.

5 Classification and designation

IEC 60601-1:1988, Clause 5 applies.

6 Marking, labelling and packaging

IEC 60601-1:1988, Clause 6 applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

e) Identification of the origin

Replacement:

The address and name or trade-mark of the manufacturer or supplier or of the authorized representative of the manufacturer who claims that the equipment complies with this document.

Addition:

aa) Flow-direction sensitive components

All operator-interchangeable flow-direction sensitive components shall be permanently marked with a clearly legible arrow indicating the correct direction of flow.

bb) High-pressure input port

Any high-pressure input port shall be marked on or in the vicinity with the name or symbol of the gas as given in ISO 5359 with the rated range of supply pressures in kilopascals and with the maximum flowrate requirement in litres per minute.

cc) Operator-accessible ports

If an operator-accessible port is provided, it shall be marked. Appropriate pictograms or symbols may be used.

dd) * Label of the equipment or detachable parts

The label shall contain the following:

— if the intended purpose of the equipment is not obvious to the operator, the detachable part or its package shall be provided with an instruction leaflet or operating instructions;

— the name or trade name and address of the manufacturer and the name and address of the person responsible or of the authorized representative of the manufacturer or importer;

— equipment identification and content information;

— where appropriate, symbols 5.20 to 5.24 from ISO 15223-1:2007;

— where appropriate, an identification reference to the batch or serial number, or symbols 5.14 or 5.16 from ISO 15223-1:2007;

— where appropriate, an indication of the latest date by which the equipment can be used, expressed as the year and month;

— where appropriate, an indication that the equipment is for single or multiple patient use only;

— any special storage and/or handling conditions;

— any warning and/or precaution to take;

— equipment which is considered to constitute active medical devices, year of manufacture or symbol 5.13 from ISO 15223-1:2007, except those covered by 6.1 dd) 6th dash;

NOTE This indication can be included in the batch code or serial number.

— where applicable, recommended methods of cleaning and disinfection or cleaning and sterilization shall be specified;

— where applicable, use of an appropriate breathing system filter shall be specified;

— where applicable, methods of cleaning the breathing system filter shall be specified;

— equipment packaging and/or labelling shall differentiate between the same or similar products placed on the market, both sterile and non-sterile;

— for equipment and its parts, marking regarding their proper disposal;

— if provided, gas-specific colour-coding of flowrate controls and flexible hoses in accordance with ISO 32.

6.2 Marking of controls and instruments

g)

Amendment (add at the end of the list):

Airway pressures shall be marked in both an SI unit and centimetre water (cm H_2O). The units of measure may be selectable.

6.8.2 Instructions for use

Amendment (add at the end of the list item):

d) * Cleaning, disinfection and sterilization of parts in contact with the patient

If applicable, the instructions for use shall contain:

— information about cleaning and disinfection or sterilization of equipment and accessories prior to first use;

— information about cleaning and disinfection or cleaning and sterilization and any restriction concerning re-use, including any specific procedure(s) necessary before the equipment and accessories are transferred to another patient;

— instructions that indicate the maximum number of reprocessing cycles of cleaning, disinfection and sterilization before a component can no longer be used, or instructions that indicate the visual or functional pass/fail criteria to be used in determining when a component can no longer be used after reprocessing.

Addition:

aa) The instructions for use shall additionally include the following:

— the form and the dimensions of the patient connection port [see 56.3 ee)];

— * the maximum flowrate at pressures of the minimum, ¼, ½, ¾ and the maximum of adjustable pressure (rounded up to the next whole integer) under the conditions specified in Annex CC, expressed in tabular form (see Table CC.1);

— pressure accuracy under the static long-term and dynamic short-term conditions derived from the tests as specified in BB.1 and BB.2;

NOTE This information is expressed in tabular form.

  — for equipment with an integrated humidifier, all results shall be given with the humidifier filled halfway between the minimum and maximum and operating in normal use;

  — for equipment that is recommended for use with a humidifier, all results shall be given without a humidifier as well as with any humidifier recommended in the instructions for use, filled halfway between the minimum and maximum and operating in normal use.

— unless not applicable, a warning to the effect that appropriate masks and accessories must be used with the equipment to ensure the delivery of the therapeutic pressure and to minimize CO_2 rebreathing;

— information concerning the disposal of the equipment and components (e.g. battery).

bb) The maximum achievable pressure at the patient connection port under normal and single fault conditions (see 51.101).

cc) If there is no respiratory pressure measuring device, the manufacturer shall declare the stability of pressure control between recommended maintenance times.

NOTE This requirement applies whether or not the respiratory pressures are adjustable by the patient.

dd) The maximum A-weighted sound pressure level and sound power level measured as described in Clause 26.

ee) The extreme conditions of operation (see 10.102).

ff) The humidification system output if the sleep apnoea breathing therapy equipment contains an integral humidifier.

gg) For equipment not intended for use in conjunction with oxidants (see Clause 43), a warning to the effect that sources of oxygen should be located more than 1 m from the equipment.

hh) If provided, the exchange interval of the air inlet filter.

ii) Information about the nature and frequency of regular and preventative maintenance of the equipment, including information about the replacement of consumable components of the equipment during its intended life.

6.8.3 Technical description

Addition:

aa) Additional general information:

The technical description shall include the following:

— all information necessary to check that the equipment is installed correctly and is in safe and correct working order;

— the maximum steady limiting pressure ($P_{lim,\ max}$) when tested as described in 51.101;

— if appropriate, the means of triggering;

— the purpose, type, range and sensing position of all measuring and display devices, either incorporated into the equipment or recommended by the manufacturer for use with the equipment including the description(s) of the interface(s) necessary for equipment set-up and safe operation;

— unless measured or displayed parameters are expressed under ATPD[1)] conditions, the conditions under which they are expressed (e.g. BTPS[2)]);

— description of operator-detachable breathing gas pathway components including breathing system filters;

— functional diagram of the pneumatic flow path through the equipment;

— details of any restrictions on the sequence of components within the breathing gas pathway, e.g. where such components are flow-direction sensitive;

— interdependence of controls;

— accuracies and ranges of displayed values and calibrated controls;

NOTE The accuracy could be expressed in the form of maximum zero error (bias) quoted in appropriate units plus a sensitivity error, e.g. quoted as percentage of the reading.

— if applicable, battery life and description of battery replacement and charging;

— equipment function after interruption and restoration of the power supply;

bb) if appropriate, a statement to the effect that combinations with other medical devices can alter the performance of the equipment, e.g. combinations with humidifier, filters, heat and moisture exchangers, breathing system filters or exhaust ports other than recommended.

cc) A statement on proper disposal at the end of the equipment's life.

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1) ATPD: Ambient Temperature and Pressure, Dry.

2) BTPS: Body Temperature and Pressure, Saturated.