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.

1) ATPD: Ambient Temperature and Pressure, Dry.

2) BTPS: Body Temperature and Pressure, Saturated.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows.

10.1 Transport and storage

Amendment (add at end of paragraph):

Packaging of sterile equipment or equipment parts shall ensure sterile conditions until opened or damaged or until its expiration date is reached.

Consideration should be given to the disposal of packaging waste.

Addition:

10.101 Electrical and pneumatic driving power supplies

The equipment shall continue to function within the specified tolerances throughout the range of supply variation specified by the manufacturer.

10.102 * Operation under extreme conditions

Outside the environmental and supply conditions specified in IEC 60601-1:1988, 10.2, but within the limits stated below, the equipment shall not cause a safety hazard to the patient or operator.

— ambient temperature range of 5 °C to 40 °C;

— ambient relative humidity range of 15 % RH to 95 % RH;

— AC supply voltage range of −15 % to +10 % of declared nominal value;

— DC supply voltage range of −15 % to +25 % of declared nominal value.

NOTE The equipment might continue to function but not within the specified pressure accuracy requirements.

11 Not used

12 Not used

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies, except as follows.

14.1 Class I equipment

Replacement:

Sleep apnoea breathing therapy equipment shall not be class I.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies, except as follows.

19.4 Tests

h) Measurement of the patient leakage current

Addition:

101 * The patient leakage current shall be measured from those applied parts classified as the same type (see IEC 60601-1:1988, 14.6). Such applied parts shall be connected together electrically. Applied parts connected to the protective earth terminal shall be tested separately.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 * Vibration and noise

IEC 60601-1:1988, Clause 26 applies, except as follows.

Replacement:

The A-weighted sound power level caused by the equipment shall be measured and disclosed in the instructions for use in accordance to ISO 4871 and ISO 3744 using engineering method grade 2. The A-weighted sound pressure level in accordance with ISO 4871 and ISO 3744 at a distance of 1 m shall also be disclosed in the instructions for use.

Check compliance with the following test.

Place the equipment on the sound-reflecting plane and fit the breathing tubes as provided or recommended by the manufacturer.

If a humidifier is provided with the equipment, include the humidifier in the test.

Connect the standard resistance with 4 mm internal diameter, 40 mm length and outlet angle of 45° (see Figure 101) to the patient connection port.

Acoustically insulate the breathing tubes and the gas leaving at the resistance placed at the patient connection port by a suitable means, outside the testing area so that the noise caused by the breathing tube and the gas flow does not interfere with the sound measurement of the equipment.

Dimensions in millimetres

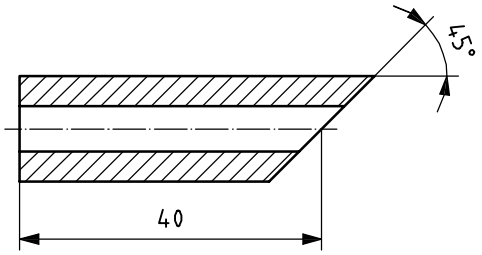


Figure 101 — Standard resistance

Set the equipment to achieve a continuous pressure of 10 hPa (10 cm H_2O) at the patient connection port.

Using the microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672, measure the sound pressure levels at 10 positions in a hemisphere with a radius of 1m to the geometric centre of the equipment as specified in ISO 3744:1994, 7.2.

Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with ISO 3744:1994, 8.1.

Calculate the A-weighted sound power level in accordance with ISO 3744:1994, 8.6.

Ensure that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.

Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

33 Infra-red radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultra-violet radiation

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultra-sonics)

IEC 60601-1:1988, Clause 35 applies.

36 Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies except as follows.

Replacement:

Sleep apnoea breathing therapy equipment shall meet the requirements of IEC 60601-1-2:2007. Sleep apnoea breathing therapy equipment shall be Class B according to IEC 60601-1-2:2007, 36.201.1 a).

NOTE Sleep apnoea breathing therapy equipment is not considered as life-supporting equipment or system as defined in IEC 60601-1-2.

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 applies.

38 Marking, accompanying documents

IEC 60601-1:1988, Clause 38 applies.

39 Common requirements for Category AP and Category APG equipment

IEC 60601-1:1988, Clause 39 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 applies.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

43 Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows.

Addition:

43.101 * Sleep apnoea breathing therapy equipment used in conjunction with oxidants

43.101.1 Ignitable material

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, shall not be subjected at the same time to conditions in which:

— the temperature of the material is raised to its minimum ignition temperature;

— an oxidant is present.

Determine the minimum ignition temperature in accordance with IEC 60079-4 using the oxidizing conditions present under the normal and single fault condition.

Check compliance by determining the temperature the material is raised to under the normal and single fault condition.

43.101.2 Sparking

If sparking can occur under normal or single fault conditions, the materials subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Check compliance by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault condition.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

IEC 60601-1:1988, Clause 44 applies, except as follows.

44.6 Ingress of liquids

Amendment:

Add (as 2nd sentence, first paragraph):

Sleep apnoea breathing therapy equipment shall not cause a safety hazard and shall function normally after the following tests:

— the tests in IEC 60529 for IPX2 or

— the tests in IEC 60529 for IPX1 and the spillage test of 44.3 in IEC 60601-1:1988.

Add to test requirement last sentence:

and the sleep apnoea breathing therapy equipment continues to function normally.

44.7 * Cleaning, sterilization and disinfection

Amendment (add before the compliance test):

The equipment shall be designed so that the exterior is easily cleaned and the use of contaminant trapping features is minimized.

Any breathing system filter shall comply with ISO 23328-1 and ISO 23328-2.

Accessories of sleep apnoea breathing therapy equipment and parts not intended for single patient use shall be so constructed that the gas pathways can be dismantled for cleaning and disinfection or cleaning and sterilization. Processing or (re)processing instructions for the equipment and their parts shall comply with ISO 17664 and ISO 14937.

Sleep apnoea breathing therapy equipment or accessories labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Non-sterile device packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of contamination.

Amendment (add at the end of the compliance test):

If a sterility claim is made, review the accompanying documents for methods of sterilization and disinfection and comparison to the relevant validation reports.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies, except as follows.

Amendment (add after the first sentence):

This Clause does not apply to sleep apnoea breathing therapy equipment breathing gas pathways.

46 Human errors

IEC 60601-1:1988, Clause 46 applies, except as follows.

Replacement:

The requirements of IEC 60601-1-6 apply.

47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48, except as follows.

Amendment (add between “fluids”, and “shall”):

or patient gas pathway,

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, except as follows.

Addition:

49.101 Spontaneous breathing during power failure

The sleep apnoea breathing therapy equipment shall incorporate a means of allowing spontaneous breathing of the patient when the electrical or pneumatic power supply fails or falls outside the range for normal operation. This means may be provided by the masks and accessories specified in ISO 17510-2 (i.e., anti-asphyxiation valves).

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows.

51.5 Incorrect output

Replacement:

Means of protection against accidental adjustment of controls that can create a hazardous output shall be provided.

NOTE Mechanical control techniques such as locks, shielding, friction-loading and detents are considered as suitable. For pressure-sensitive finger pads, capacitive finger switches and microprocessor-based “soft” controls, a specific sequence of key or switch operations is considered suitable.

Check compliance by visual inspection following the instructions for use.

51.101 * Maximum steady limiting pressure

The maximum steady limiting pressure at the patient connection port shall not exceed:

— for CPAP and self-adjusting equipment, 20 hPa (20 cm H_2O) + pressure stability under normal use and 30 hPa (30 cm H_2O) under single fault condition;

— for bi-level positive airway pressure equipment, 30 hPa (30 cm H_2O) + pressure stability under normal use and 40 hPa (40 cm H_2O) under single fault condition.

Check compliance by functional testing under normal use and single fault condition.

51.102 Measuring device for respiratory pressure

If a measuring device is provided for the respiratory pressure, the actual display reading shall indicate the pressure at the patient connection port with a pressure accuracy of ± (2 % of the full scale reading + 4 % of the actual reading). The full-scale reading shall not exceed the maximum value that can be achieved under single fault conditions (see 51.101).

Check compliance by functional testing.

51.103 Measuring device for expiratory volume

If a measuring device for the expiratory tidal volume or minute volume is provided, the accuracy of the reading for the range specified shall be given by the manufacturer.

Check compliance by functional testing.

51.104 * CO_2 rebreathing

Sleep apnoea breathing therapy equipment shall be designed so that excessive rebreathing of carbon dioxide does not occur. Use of sleep apnoea breathing therapy equipment with a designated mask or accessory that complies with ISO 17510-2 may be used to comply with this requirement. In such a case, the accompanying documents shall include the list of designated masks or accessories.

NOTE The design of the sleep apnoea breathing therapy equipment can be such that this requirement is satisfied without a designated mask or accessory.

Check compliance by the tests in Annex F of ISO 17510-2:2007.

51.105 Temperature at the patient connection port

The maximum air temperature under normal or single fault conditions measured at the patient connection port shall not exceed 43 °C for all settings.

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies, except as follows.

Amendment (add at the end of Clause 54):

Planning and design of products applying to this International Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex DD.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

Addition:

54.101 * Leaching of substances

All parts of the equipment shall be designed and manufactured to minimize health risks due to substances leached or leaking from the equipment during normal use and under single fault conditions.

NOTE It is recommended that the conducting pathway for respiratory gases be separate from those used for ventilation, for example, of the electronic compartment.

Check compliance by inspection of the risk management file.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies, except as follows.

56.3 Connections — General

Addition:

aa) High-pressure input ports

If a high-pressure input port is provided for the input of high-pressure respiratory gases, it shall be either the body of an NIST fitting complying with the requirements of ISO 5359 or the male part of a quick connector complying with the requirements of ISO 9170-1.

Check compliance by application of the requirements of ISO 5359 and ISO 9170-1.

bb) Breathing gas pathway connectors

Breathing gas pathway connectors, if conical, shall be 15 mm or 22 mm size connectors complying with ISO 5356-1 and ISO 5356-2.

Non-conical connectors shall not engage with conical connectors complying with ISO 5356-1 or ISO 5356-2, unless they comply with the engagement, disengagement and leakage requirements of ISO 5356-1 or ISO 5356-2.

Check compliance by application of the requirements of ISO 5356-1 or ISO 5356-2.

cc) Fresh-gas intake port

A fresh-gas intake port, if provided, shall not be compatible with connectors complying with ISO 5356-1.

Check compliance by application of the requirements of ISO 5356-1.

dd) Gas output and gas return port connectors (inspiratory and expiratory port connectors)

If a gas output or gas return port is provided, it shall, if conical [see 6.8.2 aa) 1st dash] be one of the following:

— a 22 mm conical connector complying with ISO 5356-1 or ISO 5356-2 or

— a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by application of the requirements of ISO 5356-1 or ISO 5356-2.

ee) Patient connection port connector

The patient connection port connector, if conical, shall be a coaxial 15 mm/22 mm connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by application of the requirements of ISO 5356-1 or ISO 5356-2.

ff) Flow-direction-sensitive component connectors

Any flow-direction-sensitive, operator-detachable component shall be designed so that it cannot be fitted in such a way as to present a safety hazard to the patient.

Check compliance by inspection.

gg) Accessory port

If an accessory port is provided, it shall not be compatible with connectors specified in ISO 5356-1 or ISO 5356-2 and shall be provided with a means to secure engagement and closure.

NOTE This port is generally used for sampling of gases or for introduction of therapeutic aerosols.

Check compliance by inspection.

hh) Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall not be compatible with connectors specified in ISO 5356-1 or ISO 5356-2, and it shall be provided with a means to secure the probe in position and with a means to secure closure after removal of the probe.

Check compliance by inspection.

ii) Exhaust port connector

If provided and if conical, an exhaust port connector shall be a 30 mm male connector complying with ISO 5356-1.

NOTE The exhaust port is often located in the mask (see ISO 17510-2).

Check compliance by application of the requirements of ISO 5356-1.

56.10 Actuating parts of controls

Addition:

aa) Consistency of movement

The manufacturer should ensure consistency regarding direction of movement of rotary controls of the equipment.

Addition:

56.101 Respiratory gas-conducting components (packaging and decontamination)

56.101.1 Sterilization

If a claim is made in the accompanying documents that equipment or equipment parts are sterile, they shall have been sterilized using an appropriate, validated method described in ISO 11135, ISO 11137, ISO 14937 or ISO 17665.

Check compliance by inspection.

56.101.2 Packaging systems

Non-sterile packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

Check compliance by inspection of the risk management file.

56.102 Humidifiers

Any heated humidifier shall comply with ISO 8185.

Check compliance by application of the requirements of ISO 8185.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

Annexes

IEC 60601-1:1988, appendices apply, except as follows.

Addition:

Annexes AA to FF are added.

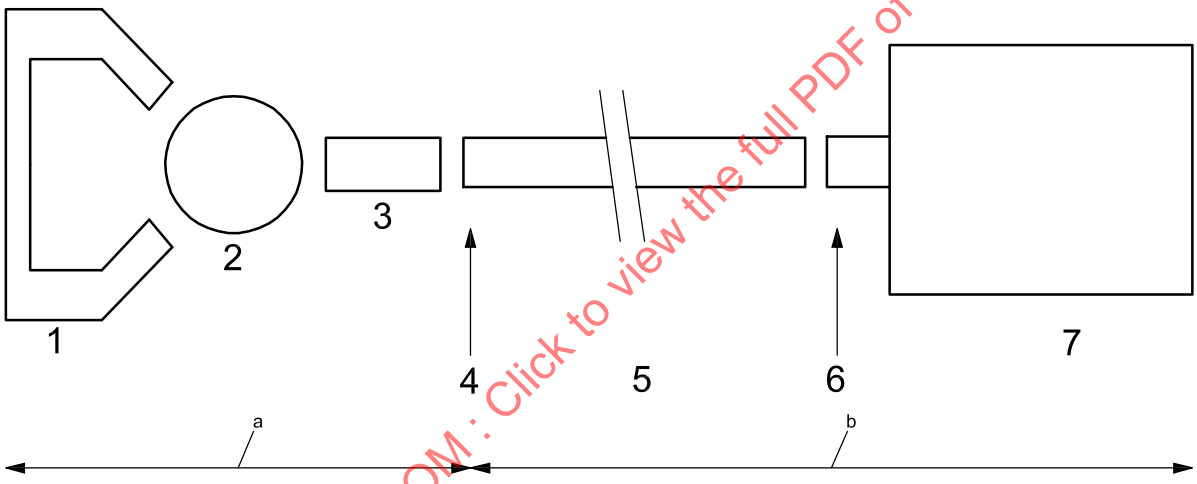
Annex AA
(informative)

Rationale

AA.1 Introduction

This annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

Figure AA.1 is a typical example of a series of component arrangements of the ISO 17510 series. It is intended to enhance comprehension of the combination of sleep apnoea breathing therapy equipment and masks and application accessories, as well as to clarify the scope of the parts of ISO 17510 series.



Key

1 headgear
2 mask
3 connecting element (optional)
4 patient connection port
5 breathing tube
6 gas output port connector
7 sleep apnoea breathing therapy equipment with or without humidifier

[a] Scope of ISO 17510-2.
[b] Scope of ISO 17510-1.

NOTE The exhaust port can be located in the connecting element (3) or the mask (2).

Figure AA.1 – Relationship of the components of sleep apnoea breathing therapy equipment and masks and application accessories and the parts of ISO 17510

The clauses in this annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

1 Scope

The field of application encompasses CPAP equipment, bi-level positive airway pressure equipment, and self-adjusting positive airway pressure equipment intended for sleep apnoea breathing therapy. Sleep apnoea breathing therapy equipment relies on both the design of the sleep apnoea breathing therapy equipment to minimize risk of asphyxia and the defence mechanism of the patient to respond to single fault conditions and arouse the patient from sleep, thereby allowing the patient to remove himself from potential harm. Therefore this part of ISO 17510 deals extensively with the performance standard for sleep apnoea breathing therapy equipment to ensure the delivery of the therapeutic pressure and prevent asphyxia.

This equipment can be used in hospitals, at home, in ships, in aircraft or in other transport situations.

3.1 Applied part

The definition of “applied part” in this part of ISO 17510 is the basis for clarification of requirements for, and measurement of, patient leakage current.

It cannot be excluded that antistatic tubing or other tubing which should be considered as electrically conductive can be used in the breathing gas pathway of equipment.

It is not possible, however, to include any requirements in this document on leakage currents from electrically-operated attachments, such as humidifiers and heating elements, which may be connected in the breathing gas pathway, because the types of such attachments which will be used in clinical work with a type of equipment cannot be anticipated by a manufacturer or test house.

6.1 Marking on the outside of equipment or equipment parts

dd) Label of the equipment or detachable parts

The indication for single patient use or multiple patient use shall be provided because sleep apnoea breathing therapy equipment is used in the sleep lab, by rental companies with many clients and healthcare facilities.

The use of a breathing system filter is not intended to guarantee the prevention of cross contamination. A breathing system filter placed on the gas output port should be used to minimize the occurrence of cross contamination via the breathing gas pathway.

6.8.2 Instructions for use

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

In order to avoid any risks to the patient resulting from contamination, this part of ISO 17510 requires the manufacturer to give appropriate information in the instructions for use.

aa)

To ensure the therapeutic efficiency, the following parameters should be observed:

— stability of the respiratory pressure should be adequate in all specified operating modes (e.g. with or without humidification of breathing air) and operating ranges (e.g. adjustable pressure and flowrate ranges);

— sufficient delivery of breathing air in the specified operating modes and operating ranges;

— low operating noise level of the entire set up, e.g. noise emitted directly from the device as well as noise transmitted via the breathing tube;

— adequate humidification system output in the specified operating modes and operating ranges, if applicable.

10.102 Operation outside specified conditions

IEC 60601-1:1988, 10.2, specifies a set of ambient conditions (temperature, relative humidity, barometric pressure, power supply, etc.) under which equipment is required to comply with the requirements of the document. These conditions apply to the environmental conditions within a healthcare institution. This document includes equipment intended for home use and the environmental conditions in the home are typically wider than those of a healthcare institution.

To meet all the likely extremes, even when considering only the most probable combinations of conditions for one type (one design and construction) of equipment will undoubtedly lead to quite expensive equipment for which there is hardly any place in a market which has more constraints than that of the healthcare institution market.

There was a consensus that equipment ought not to cause a safety hazard to the patient or operator if used outside the environmental conditions specified in 10.2.1 of IEC 60601-1:1988, and that all safety mechanisms ought to remain functional but the performance parameters could degrade below their specified values.

There will nevertheless be a point where the degradation of performance reaches a level where the risks posed by the continued use of the equipment will outweigh its benefits.

This part of ISO 17510 specifies a set of likely extreme conditions for a particular use, e.g. home-care, that are outside those specified in IEC 60601-1:1988, 10.2.1.

The manufacturer is to declare how the performance of the equipment is affected when subjected to one of these extreme conditions at a time, while maintaining the other parameters within reasonable limits.

If necessary, certain critical combinations of extreme conditions could be specified.

It is felt that this information will enable the user to make an appropriate selection of equipment to suit a particular situation or to take necessary precautions to correct the conditions, e.g. install an air conditioner to control the room temperature in extremely hot climates.

This approach is consistent with current product liability case law where any warning statement has to be explained, indicating the potential consequences of not abiding by the warning.

19.101 Patient leakage current

Since equipment might have multiple applied parts connected to the same patient and patient leakage current is cumulative (but not directly additive), it is important to measure all the patient leakage current of the applied parts of the same type, concurrently. See also 3.1.

26 Vibration and noise

Noise emissions are especially disturbing if the noise includes tonal components. Therefore, it is recommended that the tonal components of noise be determined additionally (see e.g. DIN 45681).

For undisturbed sleep, the World Health Organization recommends that the sound pressure level should not exceed 30 dB(A). Manufacturers are encouraged to strive for lower sound pressure levels.

43.101

Reports of fire caused by medical devices are unusual. However, when such fires occur in the environment of a healthcare facility they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

— ignitable material (fuel);

— temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of IEC 60601-1, the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these can be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that may accumulate during prolonged use, e.g., airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical devices, as a temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, e.g. ignition tests, may be necessary to assure safety under these conditions.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton, 100 % oxygen which is given in the America NFPA publication 53 M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical devices with oxygen enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published documents. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either overly restrictive or potentially hazardous, depending on the manner in which the power can be dissipated and the proximity and type of any “fuel” present.

It is now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant with regard to its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit, the possible number of failure models is very high. In this case, full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a single fault condition.

The particular combination of material, oxidant and temperature, not a single value of any one of these variables, determines whether a fire will occur.

44.7 Cleaning, sterilization and disinfection

Any part of the gas pathways of sleep apnoea breathing therapy equipment and accessories that are not intended for single patient use should be provided with means to prevent cross contamination.

If the gas pathways cannot be cleaned and disinfected or cleaned and sterilized and if the equipment is intended to be re-used by multiple patients, a breathing system filter placed in line with the gas output port that can only be removed with the use of a tool might be necessary to minimize the potential for cross contamination.

51.101 Maximum steady limiting pressure

Pressures above 20 cm H_2O present the known risk of swallowing of air and subsequent regurgitation. Laryngeal reflexes decrease drastically with increasing age.

51.104 CO_2 rebreathing

Sleep apnoea therapy breathing gas pathways differ from most other breathing gas pathways in the design of the inspiratory and expiratory breathing pathways such that they share a common conduit, namely the breathing tube connecting the sleep apnoea flow generator to the patient connection port. The breathing tube contains an admixture of fresh and expired gases. This design has important consequences to the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration. Therefore the design and configuration of sleep apnoea breathing therapy equipment and its masks and accessories has a major impact on the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration.

54.101 Leaching of substances

The recommendation that the airway should be separated from control elements is intended to minimize the risk of leaching of substances during malfunction of e.g. electronic parts, main parts.

Information about the maximum working place concentration should be considered during risk assessment.

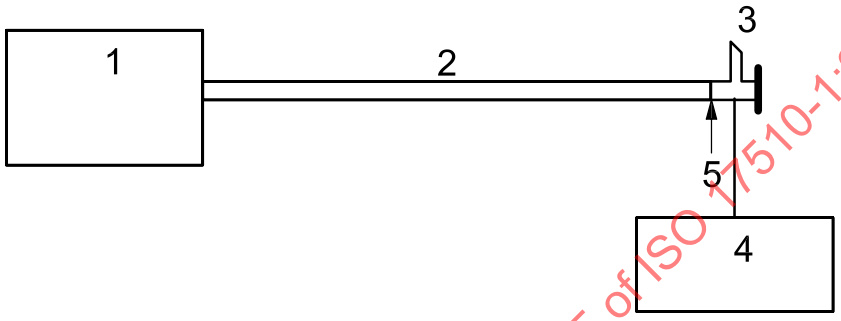
Annex BB Pressure accuracy in normal use test methods

Pressure stability is one of the key parameters that effects the efficiency of the sleep apnoea therapy. Development of the sleep apnoea breathing therapy equipment design should ensure that pressure variations are minimized.

Annex BB
(normative)

* Pressure accuracy in normal use test methods

BB.1 Static pressure stability measurement (long-term accuracy)



Key

1 – sleep apnoea breathing therapy equipment
2 – 1,9 m ± 0,15 m breathing tube
3 – standard resistance (see Figure 101)
4 – pressure meter
5 – patient connection port

Figure BB.1 — Test set-up for static pressure accuracy in normal use

Check static pressure stability by:

a) Set up the equipment according to the instructions for use and Figure BB.1 with the pressure set to 10 hPa (10 cm H_2O). Place the standard resistance (see Figure BB.1) at the patient connection port.

b) Using a pressure-measuring device, measure the pressure at least once per second at the patient connection port of the breathing tube and record, each minute, the average pressure over each averaging interval of 1 min for a period of 8 h.

c) Calculate the most positive and most negative pressure difference (if applicable) with reference to the set value on the sleep apnoea breathing therapy equipment.

d) Verify that the average measured static pressure is within the static pressure accuracy limit.

BB.2 Dynamic pressure stability measurement (short-term accuracy)

To check dynamic pressure stability:

a) Connect the patient connection port to a pressure meter and a pump that produces a sinusoidal cycle with I:E = 1:1 according to Figure BB.2. Monitor and measure the flowrate and pressure using a pressure- and flowrate-measuring device at the patient connection port.

The deadspace of the test lung should be less than the tidal volume used.

All measurement uncertainty of the test apparatus used for these tests [specified in a.) and b.)] shall be included in the calculation of the results, i.e. uncertainties are to be added to the differences measured.

b) Set the pressure to the minimum pressure setting.

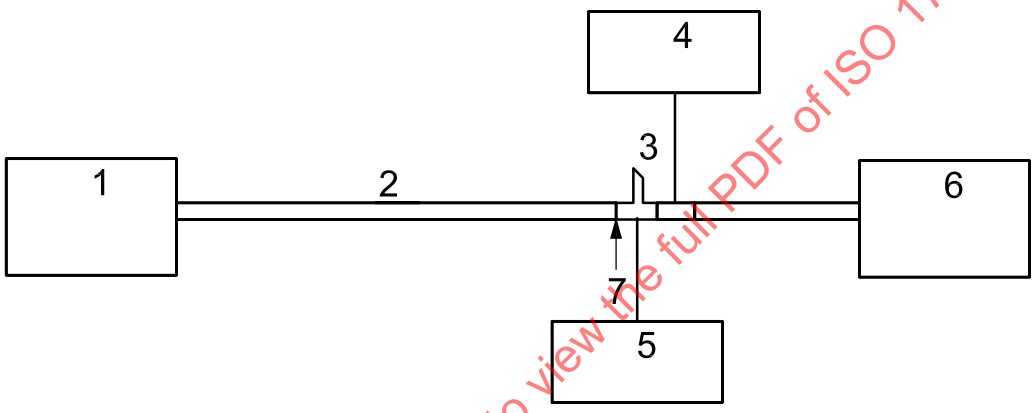
c) Set lung parameters according to Figure BB.2.

d) For each cycle, calculate the most positive and negative pressure difference from the set value. Average these results over a period of 5 min.

e) Record the pressure and flowrate waveforms. If necessary adjust settings until breath rate and stroke volume match desired settings.

f) Record the dynamic high and low pressure measurements as peak to peak values. Subtract the recorded dynamic low pressure from the recorded dynamic high pressure.

g) Repeat steps c) to f) for the test values in Table BB.1.



Key

1 – sleep apnoea breathing therapy equipment
2 – 1,9 m ± 0,15 m breathing tube
3 – standard resistance (see Figure 101)
4 – flow meter
5 – pressure meter
6 – pump that produces a sinusoidal cycle
7 – patient connection port

Figure BB.2 — Test set-up for dynamic pressure accuracy in normal use

Table BB.1 — Parameters for testing

Parameter	Fraction of the maximum adjustable pressure				
P[a]	P_{min}	P_{min} + ¼ ($P_{max} - P_{min}$)	P_{min} + ½ ($P_{max} - P_{min}$)	P_{min} + ¾ ($P_{max} - P_{min}$)	P_{max}
f (breaths/min)	10, 15, and 20				
V_t (ml)	500				

[a] Rounded to the nearest whole integer.

Annex CC
(normative)

Maximum flowrate test method

CC.1 Procedure

To check maximum flowrate

a) set up sleep apnoea equipment with 1,9 m ± 0,15 m breathing tubing,

b) apply a pressure-measuring device and flowrate meter to the patient connection port,

c) apply an adjustable valve at the patient connection port,

d) set the pressure to the minimum setting and open the adjustable valve until the actual measured pressure is reduced by 1 hPa ± 0,1 hPa (1 cm H_2O ± 0,1 cm H_2O) below the pressure setting. Read the corresponding measured pressure and flowrate value,

e) repeat step d) 10 times and record the average value of these 10 measurements,

f) repeat step e) with pressures indicated in Table CC.1,

g) record the results in Table CC.1.

Table CC.1 — Sleep apnoea breathing therapy equipment performance at set pressures

	Test pressures				
	P_{min}	P_{min} + ¼ ($P_{max} - P_{min}$)	P_{min} + ½ ($P_{max} - P_{min}$)	P_{min} + ¾ ($P_{max} - P_{min}$)	P_{max}
Measured pressure at the patient connection port (hPa)					
Average flow at the patient connection port (l/min)					