INTERNATIONAL STANDARD

ISO 17510-1

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Sleep apnoea breathing therapy —

Part 1:
Sleep apnoea breathing therapy devices

Thérapie respiratoire de l'apnée du sommeil —

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

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 3.

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 part of ISO 17510 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 17510 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

ISO 17510 consists of the following parts, under the general title *Sleep apnoea breathing therapy*:

— *Part 1: Sleep apnoea breathing therapy devices*

— *Part 2: Masks and application accessories*

Annexes AA and BB of this part of ISO 17510 are for information only.

For the purposes of this part of ISO 17510, the CEN annex regarding fulfilment of European Council Directives has been removed.

Contents

Foreword

The text of EN ISO 17510-1:2002 has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Annexes AA and BB are for information only.

EN ISO 17510 consists of the following parts under the general title *Sleep apnoea breathing therapy.*

— Part 1: *Sleep apnoea breathing therapy devices*

— Part 2: *Masks and application accessories.*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This particular standard amends and supplements EN 60601-1 (see the exact references with amendments in clause 2).

The requirements are followed by specifications for the relevant tests.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of EN 60601-1. The changes to the text of EN 60601-1 are specified by the use of the following words.

"Replacement" means that the clause or subclause of EN 60601-1:1990 + A1:1993 and A12:1993 is replaced completely by the text of this particular standard.

"Addition" means that the clause or subclause of this particular standard is additional to the requirements of EN 60601-1.

"Amendment" means that the clause or subclause of EN 60601-1:1990 + A1:1993 and A12:1993 is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of EN 60601-1:1990 + A1:1993 and A12:1993 are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Annex AA contains rationales for this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with **R)** after their number.

Section one General

1 Scope

The scope given in clause 1 of EN 60601-1:1990 + A1:1993 and A12:1993 applies with the following addition.

This European Standard specifies requirements for devices intended for sleep apnoea breathing therapy for domiciliary use and for use in healthcare institutions.

Jet and very high frequency ventilation and oscillation are not considered in this part of the European Standard.

This European standard does not apply to devices covered by the scope of the EN 794 series.

Masks and application accessories are adressed in Part 2 of this Standard (in preparation).

This European Standard does not cover external body ventilators as defined in EN ISO 4135.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 550, *Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*.

EN 552, *Sterilization of medical devices - Validation and routine control of sterilization by irradiation*.

EN 554, *Sterilization of medical devices - Validation and routine control of sterilization by moist heat.*

EN 556, *Sterilization of medical devices - Requirements for medical devices to be labelled "STERILE".*

prEN 737-6:1998, *Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum*.

EN 739, *Low-pressure flexible hose assemblies for use with medical gases*.

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1281-1, *Anaesthetic and respiratory equipment - Conical connectors - Part 1 : Cones and sockets*.

EN 1281-2, *Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors. (ISO 5356-2:1987 modified)*

EN ISO 4135:1996, *Anaesthesiology – Vocabulary (ISO 4135:1995)*.

EN ISO 8185, *Humidifiers for medical use - General requirements for humidification systems*.

EN 60601-1:1990 + A1:1993, A2:1995, A12:1993 and A13:1996, *Medical electrical equipment - Part 1: General requirements for safety (includes amendments A1:1993, A2:1995, A12:1993 and A13:1996) (IEC 60601-1:1988 + A1:1991 + A2:1995 + corrigendum 1995 mod).*

EN 60601-1-2, *Medical electrical equipment – Part 1: General requirements for safety – 2: Collateral Standard: electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:1993)*

ISO 32, *Gas cylinders for medical use- Marking for identification of content*.

ISO 3744, *Acoustics - Determination of sound power levels of noise sources - Engineering methods for free-field conditions over a reflecting plane*[1] .

EN ISO 9360-1, *Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans – Part 1 : HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1 :2000).*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres - Part 4: Method of test for ignition temperature.*

IEC 60651:1979, *Sound level meters.*

3 Terms and definitions

For the purposes of this Standard, EN 60601-1:1990, clause 2 + A1:1993 and A12:1993 applies with the terms and definitions of EN IS0 4135:1996 and the following:

2.1.5 R) applied part: Add the following item

— all parts of the device intended to be connected to the patient or to the breathing system.

3.1
bi-level positive airway pressure device
device intended to generate two positive pressure levels at the patient connection port during the respiratory cycle

3.2
breathing system

sleep apnoea therapy[2] device breathing system bounded by the low pressure gas input port(s), the gas intake port(s) and the patient connection port together with the fresh-gas inlet and exhaust port(s), if these are provided

NOTE Valves can be placed anywhere in relation to ports and, indeed, anywhere in the breathing system, provided the requirements of this standard are met.

3.3
continuous positive airway pressure device ; CPAP device
device intended to generate continuous positive airway pressure at the patient connection port throughout the respiratory cycle

3.4
fresh-gas
gas supplied to the breathing system

It excludes the following :

a) air drawn through the emergency air intake port ;

b) air drawn through leaks in the breathing system ;

c) expired gas from the patient.

3.5
fresh-gas intake port
gas intake port, other than the emergency air intake port, through which fresh-gas can be drawn into the equipment breathing system by the equipment or the patient (see note to 3.2)

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1) This reference will be replaced when EN 21201 is published by reference to EN 21201 "Acoustics – Noise emitted by machinery and equipment – Measurement of emission sound pressure levels at the work station and at other specific positions – Engineering method in an essentially free field over a reflecting plane".

2) See the glossary for these terms (in Annex BB)

3.6
gas exhaust port
port of the equipment from which gas is discharged to the atmosphere under normal operating conditions either directly or via an anaesthetic gas scavenging system.

3.7
gas output port
port of the equipment through which gas is delivered at respiratory pressures through an operator-detachable part of the breathing system to the patient connection port

3.8
gas return port
port of the equipment through which gas is returned at respiratory pressures through an operator-detachable part of the breathing system from the patient connection port

3.9
high pressure gas input port
gas input port to which gas is supplied at a pressure greater than 100 kPa

3.10
label
printed or graphic information applied to a medical device or any of its containers or wrappers

3.11
low pressure gas input port
gas input port to which gas is supplied at a pressure not exceeding 100 kPa

3.12
marking
inscription in writing or as a symbol applied on a medical device from which the inscription is not dissociable

3.13
maximum limited pressure ($P_{lim\ max}$)
highest pressure measured at the patient connection port under normal and single fault conditions

3.14
microbial filter
device intended to remove bacteria other microorganisms and particles from the gas stream

3.15
patient connection port
port of the breathing system to which the patient can be connected

3.16
self-adjusting sleep apnoea breathing therapy devices
device which automatically adjusts the pressure in the breathing system according to the patient's needs during use.

Note This device may adjust to one or more pressure levels.

3.17
sleep apnoea breathing therapy device
breathing therapy device intended to alleviate the symptoms of patients who suffer from sleep apnoea[3)] , suitable for healthcare institution and domiciliary use, primarily without professional supervision

3.18
stability of the respiratory pressure
change of the respiratory pressure set value with regard to time and change in the environmental conditions (e.g. temperature and ageing)

3) See the glossary for these terms (in Annex BB)

3.19
variation of the respiratory pressure
difference between actual reading of the respiratory pressure and set value during the respiratory cycle

4 General requirements and general requirements for test

4.1 Clause 3 of EN 60601-1:1990 + A1:1993 and A12:1993

Clause 3 of EN 60601-1:1990 + A1:1993 and A12:1993 applies.

4.2 Clause 4 of EN 60601-1:1990 + A1:1993 and A12:1993

Clause 4 of EN 60601-1:1990 + A1:1993 and A12:1993 applies.

5 Classification

Clause 5 of EN 60601-1:1990 + A1:1993 and A12:1993 applies.

NOTE A device can have applied parts of different types.

6 Identification, marking and documents

Clause 6 of EN 60601-1:1990 + A1:1993 and A12:1993 applies with the following additions and modifications :

In 6.1 (marking on the outside of equipment or equipment parts) add the following to item e) (identification of the origin).

If imported from outside the EU, the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the EU shall be provided with the label or the accompanying documents.

In 6.1 j) (power input) replace the first paragraph by the following :

The rated input shall be given in amperes.

In addition, add the following items to 6.1.

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

bb) Any high pressure gas input port shall be marked on or in the vicinity with the name or symbol of the gas as given in EN 739 with the range of supply pressures in kPa and with the maximum flow requirement in l/min.

cc) If operator accessible ports are provided, they shall be marked.

The following terms may be used :

— fresh-gas intake port: “FRESH-GAS INTAKE” ;

— gas output port: “GAS OUTPUT” ;

— gas return port: “GAS RETURN” ;

— gas exhaust port: “EXHAUST”.

If an optional port is dedicated for a probe, it shall be marked accordingly.