SLOVENSKI STANDARD

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Zdravljenje dihanja pri prenehanju dihanja v spanju - 1. del: Oprema za zdravljenje prenehanja dihanja v spanju (ISO 17510-1:2002)

Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy devices (ISO 17510-1:2002)

Schlafapoe-Atemtherapie - Teil 1: Schlafapoe-Atemtherapiegeräte (ISO 17510-1:2002)

Thérapie respiratoire de l'apnée du sommeil - Partie 1 : Dispositifs de thérapie respiratoire de l'apnée du sommeil (ISO 17510-1:2002)

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This European Standard was approved by CEN on 15 April 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

Annex AA, BB and ZA 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)

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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.

Alternatively, other terms, pictograms or symbols may be used, in which case they shall be explained and referred to in the above terms.

dd)R) Label of the device and accessories (e.g. breathing system attachments)

The label shall contain the following :

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

— the name or tradename and address of the manufacturer and additionally for accessories imported from outside the EU the name and address of the person responsible or of the authorised representative of the manufacturer or the importer established within the EU ;

— device identification and content information ;

— where appropriate, the symbol STERILE in accordance with EN 980 and the method of sterilization ;

— where appropriate, the batch code preceded by the symbol LOT in accordance with EN 980 or serial number ;

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

— where appropriate, an indication that the device is for single use only ;

NOTE Symbol ISO 7000-1051 can be used (see EN 980).

— any special storage and/or handling conditions ;

— any warning and/or precaution to take ;

— devices which are considered as active medical devices, year of manufacture, except those covered by 6.1dd) 6th dash ;

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

— where applicable, recommended methods of cleaning, disinfection and sterilization.

Device packaging and/or labelling shall differentiate between the same or similar products placed on the market both sterile and non-sterile.

Packages containing breathing attachments made of conductive materials shall be clearly marked with the word “CONDUCTIVE” or “ANTISTATIC”.

ee) If gas-specific colour-coding of flow controls and flexible hoses is provided, it shall be in accordance with ISO 32.

In 6.8.2 add the following items.

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

— The form and the dimensions of the patient connection port (see 56 ee)) ;

— cleaning requirements for components, if applicable.

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

For expiratory tidal volume, or minute volume, measurement, the range and the accuracy of the actual reading, if a measuring device is provided.

cc) A warning statement to the effect that, for protection class 1 equipment, it is essential that the protective earth of the domiciliary electrical installation be checked for safe and effective operation.