SLOVENSKI STANDARD
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Dihalna oprema za zdravljenje - 1. del: Razprševalni sistemi in njihovi sestavni deli

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

Matériel respiratoire thérapeutique - Partie 1: Systèmes de nébulisation et leurs composants

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English Version

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Matériel respiratoire thérapeutique - Partie 1: Systèmes de nébulisation et leurs composants

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

This European Standard was approved by CEN on 22 March 2007 and includes Amendment 1 approved by CEN on 23 July 2009.

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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 CEN Management Centre has the same status as the official versions.

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

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Foreword

This document (EN 13544-1:2007+A1:2009) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by February 2010 and conflicting national standards shall be withdrawn at the latest by March 2010.Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1, approved by CEN on 2009-07-23.

This document supersedes ▌A1⟩ EN 13544-1:2001 ⟨A1▌.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▌.

This document 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 document.

This European Standard applies to respiratory therapy equipment and has been prepared in three parts. This Part addresses nebulizing systems; Parts 2 and 3 address respectively tubing and connectors, and air entrainment devices.

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

Introduction

This European Standard is based on EN 60601-1:1990.

In EN 60601-1:1990, this type of European Standard is referred to as a “Particular Standard”. As stated in 1.3 of EN 60601-1:1990 the requirements of this European Standard take precedence over those of EN 60601-1:1990.

Clauses, subclauses, tables and figures additional to those in EN 60601-1:1990 are numbered beginning at '101'. Additional annexes are lettered beginning at 'AA' except for Annex 'ZA'.

Additional items in lettered lists are lettered beginning 'aa)'.

Rationales for some of the requirements of this European Standard are given in Annex AA. Such requirements are indicated by the letter '**R**' after the clause number.

Section one – General

1 R) Scope

The scope given in Clause 1 of EN 60601-1:1990 applies except that 1.1 is replaced by the following:

1.1 This European Standard specifies requirements for nebulizing systems used for the delivery of drugs in an aerosol form to humans through the respiratory system.

This European Standard includes gas-powered nebulizers which may be derived from e.g. compressors, pipeline systems, cylinders etc., or electrically-powered nebulizers (e.g. ultrasonic and membrane devices) or manually-powered nebulizers.

NOTE Requirements for nebulizers having also a humidification function are specified in EN ISO 8185:1997 + AC: 2002 “Humidifiers” (see 56.102).

This European Standard does not apply to nebulizers precharged with a specific medicinal product (e.g. MDI, DPI).

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.

EN 556 (all parts), *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE”*

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

ENV 737-6, *Medical gas pipeline systems — Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum*

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

EN 980, [A1⟩ *Symbols* ⟨A1] *for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer* [A1⟩ *of* ⟨A1] *medical devices*

EN 1281-2[1)], *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)*

EN 1707, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings*

EN 20594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:1988)*

[1)] Will be superseded by EN ISO 5356-2, which is currently under preparation.

EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests* [A1] *(IEC 60601-1-2:2007, modified)* [/A1]

[A1] EN 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability (IEC 60601-1-6:2006)* [/A1]

EN 61000-4-2:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge immunity test — Basic EMC publication (IEC 61000-4-2:1995)*

EN 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications (IEC 61672-1:2002)*

EN 61672-2, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests (IEC 61672-2:2003)*

[A1] EN 62304, *Medical device software — Software life-cycle processes (IEC 62304:2006)*

EN 62366, *Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)* [/A1]

EN ISO 3744, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane (ISO 3744:1994)*

EN ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)*

EN ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)*

EN ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum* [A1] *(ISO 7396-1:2007)* [/A1]

EN ISO 8185, *Humidifiers for medical use — General requirements for humidification systems* [A1] *(ISO 8185:2007)* [/A1]

EN ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)*

EN ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)*

EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)*

EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2006)*

EN ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects (ISO 11137-3:2006)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices* [A1] *(ISO 14971:2007)* [/A1]

EN ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003)*

EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 4135:2001, Clause 2 of EN 60601-1:1990 and the following apply.

2.1.5 R) applied part: Add the following item:

All parts of the nebulizer intended to be connected to the patient or to the breathing system.

3.1
aerosol
suspension of particles in gas

NOTE Particles can be liquid or solid.

3.2
aerosol output
amount of aerosol delivered by the nebulizing system for given filled volume

3.3
aerosol output rate
amount of aerosol delivered by the nebulizing system per unit of time

3.4
anatomical airways
natural pathways through which respired gases pass in either direction between the atmosphere and the alveoli (see Annex BB)

3.5
manually-powered nebulizer
nebulizer which operates by means of human power

3.6
electrically-powered nebulizer
nebulizer which operates by means of electrical power

3.7
gas-powered nebulizer (jet nebulizer)
nebulizer in which aerosol is generated by compressed gas

3.8
ultrasonic nebulizer
nebulizer in which aerosol is generated by means of ultrasound

3.9
liquid container
part of the nebulizer which contains the liquid for nebulization

3.10
maximum fill volume
maximum volume of liquid, expressed in millilitres, in the liquid container during normal operation when the nebulizer is filled to its maximum filling level

3.11
nebulizer
device which converts a liquid into an aerosol

3.12
nebulizing system
device, including all parts, required to convert a liquid into an aerosol and make it available for inhalation

3.13
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term "validated" is used to designate the corresponding status.

NOTE 2 The use conditions for validation can be real or simulated.

4 General requirements and general requirements for test

4.1 Modifications to Clause 3 of EN 60601-1:1990

Clause 3 of EN 60601-1:1990 applies with the following modifications.

Replace 3.1 with the following:

Nebulizing systems and nebulizers shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk management procedures in accordance with EN ISO 14971 and which is connected with their intended application, in normal condition and in single fault condition.

In 3.6 add the following:

aa) applicable single fault conditions are:

- short and open-circuits of components or wiring which can:
  - cause sparks to occur, or
  - increase the energy of sparks, or
  - increase temperature (see section seven);
- incorrect output resulting from software error.

NOTE See also 54.101.

bb) **R)** A situation in which a fault is not detected is considered a normal condition.

Fault conditions/hazardous situations may remain undetected over a period of time and as a consequence may lead to an unacceptable risk. In that case subsequent fault conditions need to be considered as a single fault condition.

Specific risk control measures need to be determined within the risk management process to deal with such situations.

A1 In 3.10 Clinical evaluation add the following:

A clinical evaluation shall be performed and documented in the risk management file.

Check compliance by inspection of the risk management file. A1

4.2 Clause 4 of EN 60601-1:1990

Clause 4 of EN 60601-1:1990 applies.

4.3 Alternative type-test methods

The manufacturer may use type-test methods for particle sizing, different from those specified in Annex CC.

Validation of alternative type-test methods shall be performed against the reference method in Annex CC to demonstrate that an equivalent particle size distribution curve and derived results are obtained.

Demonstration shall be circulated in the technical documentation of the manufacturer.

Evidence shall be provided upon request e.g. to Regulatory Authorities.

5 Classification

Clause 5 of EN 60601-1:1990 applies.

NOTE A nebulizing system can have applied parts of different types.

6 Identification, marking and documents

Clause 6 of EN 60601-1:1990 applies with the following additions and modifications.

6.1 Marking on the outside of equipment or equipment parts

In 6.1 add the following to item e):

A1 The name or trademark and address of the manufacturer. For devices imported into the European Union the following applies: the name and address of the person responsible and of the authorised representative of the manufacturer established within the European Community shall be provided with the device or with the accompanying document. A1

In 6.1 add the following additional items:

aa) all flow-direction sensitive components, breathing attachments or parts (e.g. face mask or mouth piece one-way valve) shall be either clearly and durably marked with an arrow showing direction of gas flow if operator-detachable, or shall be permanently attached (see note of 6.8.2 dd));

bb) if gas-specific, the inlet and outlet shall be identified by clear and durable marking;

cc) marking of devices, labels and packaging.

Devices, labels and/or packaging shall contain the following:

— device identification and content information;

— if appropriate, the symbol STERILE in accordance with EN 980 together with the method of sterilization;