Respiratoorse teraapia seadmed. Osa 1: Pihustussüsteemid ja nende komponendid KONSOLIDEERITUD TEKST

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13544-1:2007+A1:2009 sisaldab Euroopa standardi EN 13544-1:2007+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 13544-1:2007+A1:2009 consists of the English text of the European standard EN 13544-1:2007+A1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.08.2009.	Date of Availability of the European standard text 19.08.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13544-1:2007+A1

August 2009

ICS 11.040.10

Supersedes EN 13544-1:2007

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.

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

CEN members are the national standards bodies of 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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

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