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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: Systemes de nébulisation et leurs composants

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

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

This European Standard was approved by CEN on 29 June 2001.

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Foreword

This European Standard 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of an identical text or by endorsement, at the latest by February 2002, and conflicting national standards shall be withdrawn at the latest by February 2002.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.

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.

Annex CC is normative and forms part of this European Standard. Annexes AA, BB, DD, EE and ZA are for information only.

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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is based on European Standard 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 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) or manually-powered nebulizers.

NOTE Requirements for nebulizers having also a humidification function are specified in EN ISO 8185 “Humidifiers”.

This European Standard does not include nebulizers precharged with a specific medicinal product and not for universal application.

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 the 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).

Appendix L of EN 60601-1:1990 applies with the following additions:

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 556:1994+A1:1998, *Sterilization of medical devices - Requirements for medical devices to be labelled “Sterile”.*

EN 737-3, *Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum.*

EN 738-1, *Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices.*

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

EN 1041, *Information supplied by the manufacturer with 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 4135:1995, *Anaesthesiology - Vocabulary (ISO 4135:1995).*

EN ISO 8185, *Humidifiers for medical use – General requirements for humidification systems (ISO 8185:1997).*

EN 60601-1:1990, *Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988).*

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

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

IEC 60651, *Sound level meters; amendment 1.*

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

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*[1)].

European Pharmacopoeia, Monograph on preparations for inhalation (3rd edition).

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN ISO 4135:1995, 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)

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1) This reference will be replaced, when EN 31201 is published, by reference to EN 31201 “Acoustics - Noise emitted by machinery and equipment - Measurement of emission sound pressure levels at the work station and at other specified positions - Engineering method in an essentially free field over a reflecting plane (ISO/DIS 11201:1993)”.

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

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 additions.

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)** an oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

4.2 Clause 4 of EN 60601-1:1990

Clause 4 of EN 60601-1:1990 applies.

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) :

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 or of the authorised representative of the manufacturer or the importer established within the European Community shall be provided with the device or with the accompanying document.

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 etc.) 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 6.8.2dd)) ;

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 ;

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

— the expiry date, if the device is sensitive to storage or shelf life in accordance with EN 980 ;

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

— any special storage and/or handling conditions ;

— any warning and/or precaution to take ;

— for active medical devices the year of manufacture except for those covered by 6.1 cc) 5th dash) ;

NOTE This indication can be the batch or serial number.

— if appropriate, the recommended method(s) of cleaning, disinfection and sterilization ;

— device packaging and/or labelling shall differentiate between the same or similar products both sterile and non-sterile placed on the market by the same manufacturer ;

— if appropriate, packages containing parts made of antistatic or conductive material shall be clearly marked with the word “ANTISTATIC” or “CONDUCTIVE” ;

— the liquid container of the nebulizer shall be marked at the maximum filling level. This shall be defined in the instruction for use (see 6.8.2 aa) 9th dash).

6.3 Marking of controls and instruments

6.3 of EN 60601-1:1990 applies with the following addition :

aa) units

— gas supply pressures shall be displayed in kPa.

NOTE 1 Additional units e.g. bar can be used.

— pressures in breathing systems shall be displayed in Pa times 100.

NOTE 2 Additional units e.g. cm H_2O can be used.

— flows shall be displayed in L/min.

6.4 Symbols

EN 980 and 6.4 of EN 60601-1:1990 apply.

6.8.2 Instructions for use

In 6.8.2 add the following items :

aa) as far as applicable the following information shall be provided with the nebulizing system, its parts or the packages thereof, and EN 1041 shall apply ;

— the purpose and intended use of the nebulizing system and/or its parts ;

— a list of the necessary parts which are not an integral part of the nebulizing system;

— a statement that the parts listed in 6.8.2 aa) 2nd dash are required for correct function and that they have to be in compliance with this European Standard ;

— the minimum and maximum recommended driving-gas flows and the corresponding pressures for gas-powered nebulizers ;

— **R) -** the particle size distribution curve, measured as described in annex CC, Figure CC.3, under the normal operating conditions for maximum and minimum, if applicable, pressures and flows ;

— the aerosol output and aerosol output rate at the manufacturer's stated minimum and maximum driving-gas flows and corresponding pressures in the testing conditions defined in annex CC ;

— whether the nebulizer is suitable for use in anaesthetic breathing systems or lung ventilator breathing systems ;

— the maximum temperature, if above ambient, reached in the nebulizing chamber for the maximum recommended fill volume of the solution in normal use conditions ;

— the maximum and minimum recommended fill volume as declared by the manufacturer ;

— details of recommended power or control devices and accessories for use with the nebulizer ;

— the maximum A-weighted sound pressure level as measured in clause 26 ;

— a statement that performance information provided by the manufacturer in accordance with this standard may not apply to drugs supplied in suspension or high viscosity form. In such cases, information should be sought from the drug supplier ;

— the recommended driving gases ;

bb) as far as applicable the following information shall be provided with the power and/or control device, its parts or the packages thereof :

— the recommended range of gas flows and the corresponding pressures ;

— the recommended gas(es) or gas mixture (s) ;

— details of recommended nebulizers and accessories for use with the power or control device ;

cc) the instructions for use shall contain information on methods of cleaning and/or sterilization prior to use and the number of cycles of cleanings and/or sterilizations the nebulizing system will withstand. These instructions shall contain procedures for reassembly (see 6.8.2 dd) ;

dd) dismantling and reassembly

The manufacturer shall recommend a functional test of operation to be carried out after reassembly and before use.

NOTE A nebulizing system intended to be dismantled by the user, e.g. for cleaning/sterilization, should be designed so as to minimize the risk of incorrect reassembly when all parts are mated.

ee) information about monitoring, alarm and protection modules

As far as applicable the instructions for use shall contain :

— a description of the methods of verifying alarm functions ;

— details of any pressure relief valves fitted.

ff) information about electromagnetic compatibility

If applicable the instructions for use shall include a warning statement to the effect that the functioning of this nebulizer may be adversely affected by electromagnetic interference exceeding the levels specified in EN 60601-1-2 ;

gg) information about disposal

The instructions for use shall include information about any precautions to be taken if there is a specific unusual risk associated with the disposal of a device.

6.8.3 Technical description

6.8.3 of EN 60601-1:1990 applies with the following addition :

In 6.8.3a) add the following :

The technical description shall additionally include the following information :

— interdependence of controls, if applicable ;

— the pressure and flow characteristics of any gas power outlet under worst case conditions stated by the manufacturer ;

— the specified range of flows required from any gas source, if applicable ;

— if relevant, a statement of the composition and dryness specification for all gases to be supplied to the nebulizer ;

— details of non-return valves and pressure relief valves and their characteristics if fitted ;

— lifetime of the reusable parts.

7 Power input

Clause 7 of EN 60601-1:1990 applies.