SLOVENSKI STANDARD
oSIST prEN ISO 27427:2021

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Anestezijska in dihalna oprema - Razprševalni sistemi in sestavni deli (ISO/DIS 27427:2021)

Anaesthetic and respiratory equipment - Nebulizing systems and components (ISO/DIS 27427:2021)

Atemtherapiegeräte - Verneblersysteme und deren Bauteile (ISO/DIS 27427:2021)

Matériel d'anesthésie et de réanimation respiratoire - Systèmes de nébulisation et ses composants (ISO/DIS 27427:2021)

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Anaesthetic and respiratory equipment — Nebulizing systems and components

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This document is written following the format of ISO 18190, *General standard for airways and related equipment.* The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard.

This fourth edition cancels and replaces the third edition (ISO 27427:2013), of which it constitutes a major revision. The main changes compared to the previous edition are as follows:

— Alignment with the general standard for airway devices, ISO 18190;

— updating of references.

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— Test specifications: italic type;

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *terms defined in clause 3: italics*

— Throughout this document, text for which rationale is provided in Annex A is indicated by an asterisk (*).

Introduction

Nebulizers are widely used to deliver drugs and vaccines in an aerosol form to humans through the respiratory system. *Nebulizers* are also used for diagnostic purposes using radioisotopes for lung challenge tests. These drugs can be in the form of a solution, suspension or emulsion. *Aerosol* inhalation is the preferred route of administration for some drugs. Some drugs are intended for treatment of systemic diseases and other drugs are intended to treat respiratory diseases. To achieve the intended treatment, *aerosol* particles have to be deposited in specific parts of the respiratory tract. Different size particles tend to deposit in different parts of the respiratory system; therefore, the performance profile and the intended use of the *nebulizer* have to be defined by the manufacturer and specified in the accompanying documentation.

This document was developed to cover "general purpose" *nebulizers* and is based on adult test parameters which are likely to be different than stated when testing for paediatric or infant patient populations. It was specifically written to ensure that the results of the various tests declared by the manufacturer are meaningful to the users and buyers of *nebulizers*.

The objectives of this document are to ensure

— suitability of the *nebulizers* for the intended use as disclosed by the manufacturer;

— safety, particularly for *electrically powered nebulizers*;

— compatibility between the materials of the components and the dispensed liquid; and

— biocompatibility of the materials of the components that come into contact with the human body.

Anaesthetic and respiratory equipment — Nebulizing systems and components

1 Scope

*This document specifies requirements for the safety and performance testing of general-purpose *nebulizing systems* intended for continuous or breath-actuated delivery of liquids, in *aerosol* form, to humans through the respiratory system.

This document includes *gas-powered nebulizers* which can be powered by, e.g., compressors, pipeline systems, cylinders, etc., and *electrically powered nebulizers* [e.g., spinning disc, ultrasonic, vibrating mesh (active and passive), and capillary devices] or *manually powered nebulizers*.

This document does not specify the minimum performance of *nebulizing systems*.

*This document does not apply to:

a) devices intended for nasal deposition;

b) devices intended solely to provide humidification or hydration by providing water in *aerosol* form.

NOTE ISO 80601-2-74[3] and ISO 20789[4] cover these devices.

*This document does not apply to drug-specific *nebulizers* or their components (e.g., metered dose inhalers, metered liquid inhalers, dry powder inhalers).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

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

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 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 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17256, *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

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 18082, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

ISO 18190, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 23328-1, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ISO 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2006+A1:2012, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 13544-2, *Respiratory therapy equipment — Part 2: Tubing and connectors*

EN 15908, *Anaesthetic and respiratory equipment. Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

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

CGA V-5-2005, *Diameter Index Safety System — Noninterchangeable Low Pressure Connections for Medical Gas Applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
aerosol
suspension of particles in gas

Note 1 to entry: Particles can be liquid or solid.

Note 2 to entry: The gas can be the driving gas or ambient air.

3.2
***aerosol output**
mass or volume of *aerosol* emitted by the *nebulizing system* at the *aerosol outlet port* for the given fill volume

3.2.1
aerosol outlet port
outlet of the *nebulizing system* through which the *aerosol* is emitted

3.3
aerosol outlet port
outlet of the *nebulizing system* through which the *aerosol* is emitted

3.4
***aerosol output rate**
mass or volume of *aerosol* emitted by the *nebulizing system* per unit of time

3.5
breath-actuated nebulizer
nebulizer triggered by a respiratory parameter

Note 1 to entry: Examples of this classification are found in Annex F.

3.6
continuous nebulizer
nebulizer in which *aerosol* is delivered continuously over multiple inhalation/exhalation breathing cycles or over long periods

3.7
electrically-powered nebulizer
nebulizer that operates by means of electrical power

Note 1 to entry: *Electrically powered nebulizers* include ultrasonic, vibrating mesh and capillary-type devices.

3.8
gas-powered nebulizer
nebulizer in which the *aerosol* is generated by compressed gas

3.9
liquid container
part of the *nebulizer* that contains the liquid for nebulization

3.10
manually powered nebulizer
nebulizer that operates by means of human power

3.11
mass median aerodynamic diameter
MMAD
particle size at which 50 % of the mass of the active component are contained in droplets of smaller or equal aerodynamic diameter

3.12
maximum fill volume
maximum volume of liquid, expressed in millilitres, in the *liquid container* when the *nebulizer* is filled to its maximum filling level

3.13
nebulizer
device that converts a liquid to an *aerosol*

Note 1 to entry: A *nebulizer* is also known as an *aerosol* generator.

3.14
nebulizing system
device, including the *nebulizer* and all other components, up to and including the *aerosol outlet port*, required to make the *aerosol* available for inhalation

Note 1 to entry: Airway devices (e.g., masks, tracheal and tracheostomy tubes, supralaryngeal airways) and breathing systems are not part of the *nebulizing system*.

3.15
***percentage of fill volume emitted**
aerosol output expressed as a percentage of the fill volume recommended by the manufacturer that is emitted by the *nebulizer*

3.16
***residual volume**
estimated volume of liquid remaining in the *nebulizing system* when the *nebulizer* stops generating an *aerosol*

3.17
***respirable fraction**
fraction of *aerosol* droplets below 5 µm in diameter expressed as a percentage of the total *aerosol distribution*

Note 1 to entry: The *respirable fraction* can be converted to a percentage (%) by multiplying by 100.

3.18
***test solution**
aqueous solution used for the type-tests to characterize *aerosol output*, *aerosol output rate*, and particle sizing

Note 1 to entry: See 4.2.1.2, 5.4.2 j) and k), Annex C, and Annex D.

3.19
test substance
active ingredient contained in the test solution

4 General requirements and requirements for test

4.1 General

The requirements of ISO 18190:2016 Clause 4 shall apply.

4.2 Test methods and alternatives

4.2.1 Test methods for *aerosol output*, *aerosol output rate*, and particle sizing

The type-test methods for *aerosol output*, *aerosol output rate*, and particle sizing in air are specified in Annexes C and D.

4.2.1.1 *All type-test methods shall be performed on at least three representative devices of the same type.

Check conformance by inspection of the technical file/documentation.

4.2.1.2 *The type-test methods shall use a test solution of albuterol 0,1 % (mass/mass or volume/volume (m/m OR V/V)) concentration in 0,9 % sodium chloride solution or 2,5 % (m/m OR V/V) sodium fluoride in distilled water with the provision that its use is declared in the accompanying documents. See **9.3.2** j).

Check conformance by inspection of the technical file/documentation and the accompanying documents.

4.2.2 *Alternative test methods

The manufacturer can use type-test methods for *aerosol output*, *aerosol output rate*, and particle sizing different from those specified in Annexes C and D, provided that any:

a) alternative test methods are validated against the test methods in Annexes C and D to demonstrate equivalency and that

b) the demonstration of equivalency is included in the technical documentation of the manufacturer.

Check conformance by inspection of the technical file/documentation.

4.2.3 Calibration and setup

To establish confidence in the test method, it is recommended that mass balance procedures be incorporated during initial determinations. It is also recommended that occasional checks for system leaks and overall efficiency of analysis be performed.

5 Materials

5.1 General

The applicable requirements of ISO 18190:2016 Clause 5 shall apply.

5.2 Biocompatibility

Materials used to manufacture *nebulizers, nebulizing systems*, and their components shall be evaluated for biocompatibility. The breathing gas pathways shall be evaluated for biocopmatilibyt as specified in ISO 18562-1:2017 and tested as appropriate.

Check conformance by inspection of the technical file/documentation.