



SLOVENSKI STANDARD SIST EN ISO 27427:2019

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Nadomešča:

SIST EN 13544-1:2007+A1:2009

Anestezijska in dihalna oprema - Razprševalni sistemi in sestavni deli (ISO 27427:2013)

Anaesthetic and respiratory equipment - Nebulizing systems and components (ISO 27427:2013)

Atemtherapiegeräte - Verneblersysteme und deren Bauteile (ISO 27427:2013)

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Matériel d'anesthésie et de réanimation respiratoire - Systèmes de nébulisation et ses composants (ISO 27427:2013)

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

EN ISO 27427

NORME EUROPÉENNE

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English Version

Anaesthetic and respiratory equipment - Nebulizing systems and components (ISO 27427:2013)

Matériel d'anesthésie et de réanimation respiratoire -
Systèmes de nébulisation et ses composants (ISO
27427:2013)

Atemtherapiegeräte - Verneblersysteme und deren
Bauteile (ISO 27427:2013)

This European Standard was approved by CEN on 28 July 2019.

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European foreword

The text of ISO 27427:2013 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 27427:2019 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of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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INTERNATIONAL
STANDARD

ISO
27427

Third edition
2013-12-15

**Anaesthetic and respiratory
equipment — Nebulizing systems and
components**

*Matériel d'anesthésie et de réanimation respiratoire — Systèmes de
nébulisation et ses composants*

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ISO 27427:2013(E)**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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

This third edition cancels and replaces the second edition (ISO 27427:2010), of which it constitutes a major revision.

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 International Standard is based on Reference.[29] This International Standard 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 International Standard 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.

Important changes were made to the original EN standard in recognition of the advances in test devices such as lasers and low-flow impactors that allow manufacturers to use different test methods, provided these alternate methods are validated against the methods specified in this International Standard.

Terms defined in this International Standard are set in **bold type**.

Throughout this International Standard, text for which rationale is provided in [Annex A](#) is indicated by an asterisk (*).

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Anaesthetic and respiratory equipment — Nebulizing systems and components

1 Scope

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

*This International Standard does not apply to devices intended for nasal deposition.

This International Standard does not apply to devices intended solely to provide humidification or hydration by providing water in **aerosol** form.

NOTE ISO 8185 covers this.^[3]

*This International Standard 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 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

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*

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*

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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*

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 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 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*

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 outlet port**

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

3.3***aerosol output**

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

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 E](#).

3.6**continuous nebulizer**

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

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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