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Third edition  
2013-12-15

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# Anaesthetic and respiratory equipment — Nebulizing systems and components

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



Reference number  
ISO 27427:2013(E)

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Published in Switzerland

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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](http://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](http://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.

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## 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.<sup>[29]</sup> 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 (\*).