Second edition
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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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 27427 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This second edition cancels and replaces the first edition (ISO 27427:2009), of which it constitutes a minor revision.

The following changes were made:

— a new subclause 4.1.2 (Clinical evaluation) was added;

— a new subclause 4.8 (Usability) was added and, as a result, two new references were added in Clause 2;

— 5.1.2 a) was updated;

— a new item 5.1.2 d) was added and the subsequent items were renumbered;

— in 5.1.2, a new item (o) was added;

— in 5.3.2, two new items (u and v) were added;

— a note was added to 6.1.2.

In addition, several minor editorial changes were made.

Introduction

Nebulizers are widely used to deliver drugs, in an **aerosol** form, to humans through the respiratory system. These drugs may be in the form of a solution, suspension or emulsion. **Aerosol** inhalation is the preferred route of administration of some drugs. Some drugs are intended for treatment of systemic disease and other drugs are intended to treat respiratory diseases. To achieve the intended treatment, **aerosol** particles may need 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** must be defined by the manufacturer and specified in the accompanying documentation. **Nebulizers** are also used for diagnostic purposes using radioisotopes, and for lung challenge tests and the delivery of vaccines.

This International Standard is based on the European Standard EN 13544-1:2007. This International Standard was developed to cover “general purpose” **nebulizers**. It was specifically written to ensure that the results of the various tests declared by the manufacturer were meaningful to the users and buyers of **nebulizers**.

The objectives of this International Standard are to ensure:

— the 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;

— 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 document are set in **bold type**.

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