
**Suction catheters for use in the
respiratory tract**

Sondes d'aspiration pour les voies respiratoires



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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. 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. www.iso.org/patents

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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 fourth edition of ISO 8836 cancels and replaces the third edition (ISO 8836:2007), of which it constitutes a technical revision.

Introduction

This International Standard specifies dimensions and requirements for **suction catheters** for use in the respiratory tract. It is concerned with the basic requirements and method of size designation of both **open** and **closed suction catheters** made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable **suction catheter** for a particular patient. Size is designated by outside diameter which is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a **tracheal** or **tracheostomy tube**.^{[2][3][4]}

Revisions in this fourth edition are intended to harmonize this International Standard with recent amendments in the European Medical Device Directive.

Major technical revisions in this edition include requirements for **closed suction catheters**, new requirements to harmonize this International Standard with requirements for critical care **ventilators**, and **risk management**.

Terms defined in [Clause 3](#) of this International Standard or in ISO 4135^[1] appear in **bold** type.

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

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for **suction catheters**, including **closed suction catheters**, made of flexible materials and intended for use in suctioning of the respiratory tract.

Angled-**tip suction catheters** (e.g. Coudé catheters) and **suction catheters** with aspirator collectors are not considered to be specialized and are therefore included in the scope of this International Standard.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this International Standard.

NOTE See ISO/TR 11991 for guidance on airway management during laser surgery of the upper airway.^[6]

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

*ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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

ISO 5367:—¹⁾, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*²⁾

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the 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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

1) To be published. (Revision of ISO 5367:2000)

2) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.