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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

*Matériel d'anesthésie et de réanimation respiratoire — Sondes
trachéales et raccords*



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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.

This second edition cancels and replaces the first edition (ISO 5361:1999), which has been technically revised.

The requirements of ISO 5361-4, **Tracheal tubes** — *Part 4: Cole type*, have been included in this second edition because **Cole type tracheal tubes** are specialized tubes, and as such, are now included in the scope of this International Standard.

Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135 appear in **bold** type.

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

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Introduction

This International Standard provides the essential performance and safety requirements for the design of **tracheal tubes** and **tracheal tube connectors**. **Tracheal tubes** are intended to be inserted through the larynx into the trachea to convey gases and vapours to and from the trachea.

Tracheal tubes with **cuffs** are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation for short or prolonged durations.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods have been added to this second edition.

Requirements for paediatric **tracheal tubes** with **cuffs** have been added because these are commercially available and in common use.

Tracheal tubes are also intended to conform as closely as possible to human anatomy when in position.

Clinical considerations have also dictated the specified length of **tracheal tubes** because long **tracheal tubes**, sometimes of relatively narrow diameter, may be required and therefore should be readily available. Provision has also been included for pre-cut **tracheal tubes**.

Kink resistance requirements with associated test methods have also been added to the second edition to measure the ability of the shaft of the **tracheal tube** to resist collapse and increased breathing resistance when bent or curved.

Radiopacity requirements and test methods have been added to this second edition to characterize the visibility of **tracheal tubes** in X-rays used to determine proper placement of the tube. The requirements of this International Standard were developed using the hazard identification for **risk assessment** in Annex F.