SLOVENSKI STANDARD
oSIST prEN ISO 5366:2015

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Anestezijska in dihalna oprema - Traheostomske cevke - 1. del: Cevke in priključki za odrasle (ISO/DIS 5366:2015)

Anaesthetic and respiratory equipment - Tracheostomy tubes (ISO/DIS 5366:2015)

Anästhesie- und Beatmungsgeräte - Tracheotomietuben (ISO/DIS 5366:2015)

Matériel d'anesthésie et de réanimation respiratoire - Tubes de trachéostomie (ISO/DIS 5366:2015)

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ICS:

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

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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part :
Tubes and connectors for use in adults

Matériel d'anesthésie et de réanimation respiratoire — Tubes de trachéostomie —

Partie : Tubes et raccords pour utilisation chez les adultes

ICS: 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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

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 fifth edition cancels and replaces the fourth edition, ISO 5366-1:2000, which has been technically revised.

The requirements of ISO 5366-3:2001 and ISO 5366-3 Corr:2003, *Tracheostomy tubes – Part 3: Paediatric tracheostomy tubes,* have been included in this fifth edition.

Throughout this International Standard the following print types are used:

— Requirements and definitions: roman type;

— *Test specifications: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— TERMS DEFINED IN CLAUSE 3: SMALL CAPS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new

requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

This standard provides the essential requirements for the design of cuffed and uncuffed TRACHEOSTOMY TUBES and connectors. These devices are intended to be inserted through a stoma in the trachea to convey gases and vapours to and from the trachea. Cuffed devices are designed to seal and protect the trachea from aspiration and to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation for short or prolonged durations. Specialized tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases, and the many other types of TRACHEOSTOMY TUBES devised for specialized applications are included in this specification, as many specialized TRACHEOSTOMY TUBES are now commonly used, and all share similar essential requirements defined in this International Standard.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable tube for a particular patient's anatomy. Size is designated by the internal dimension, which is important because of its relationship to resistance to gas flow. Because stoma and tracheal sizes are also an important factor when selecting a TRACHEOSTOMY TUBE it is considered essential that the outside dimension for each size of tube is also made known to the user.

Cuffed TRACHEOSTOMY TUBES can be characterized by a combination of the tube inside and outside dimensions and by the diameter of the CUFF to be marked.

A variety of CUFF designs are available to meet particular clinical requirements. CUFF performance requirements with associated test methods, which are aligned with the requirements in ISO 5361, *Tracheal tubes and connectors* have been added to this fifth edition.

Requirements for paediatric TRACHEOSTOMY TUBES have been included in this fifth edition because they share many common requirements that can be standardized and which are important for patient safety. An infant or child differs from an adult, not only in size but also with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults, both in size and in basic design. It does not require the connector to be permanently attached to the tube, as this can be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this standard makes provision for them. This standard does not limit the range of tube designs needed to match the variations in paediatric anatomy, lesions and space limitations encountered.

Kink resistance requirements with associated test methods have also been added to this fifth edition to measure the ability of the shaft of the TRACHEOSTOMY TUBE to resist collapse and increased breathing resistance when bent or curved. These new requirements are aligned with the requirements in ISO 5361, *Tracheal tubes and connectors* (under development).

Requirements for TRACHEOSTOMY TUBES that are common to other airway and related devices have been removed from this fifth edition as these are now included in ISO 18190 *General requirements for airways and related equipment*, which is cross referenced where appropriate.

Anaesthetic and respiratory equipment – Tracheostomy tubes

1 *Scope

This International standard specifies requirements for adult and paediatric TRACHEOSTOMY TUBES and connectors. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support.

This International standard is also applicable to specialized TRACHEOSTOMY TUBES that share common attributes , for example those without a connector at the MACHINE END intended for spontaneously breathing patients and those with reinforced walls or tubes made of metal or tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases.

Flammability of TRACHEOSTOMY TUBES is a well-recognized hazard (for example when electrosurgical units or lasers are used with flammable anaesthetic agents in oxidant-enriched atmospheres) that is addressed by appropriate clinical management and is outside the scope of this International standard.

NOTE ISO/TR 11991 gives guidance on avoidance of airway fires.

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 4135, *Anaesthetic and respiratory equipment — Vocabulary.*

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

ISO/DIS 18190, *General requirements for airways and related equipment* (under development)

ISO/DIS 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications* (under development)

ASTM F 640-12, *Standard Test Methods for Determining Radiopacity for Medical Use*

ASTM F 2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F 2503. *Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

NOTE See Figure 1 for illustrations of typical TRACHEOSTOMY TUBES and associated nomenclature.

3.1
ANGLE OF BEVEL
angle between the plane of the BEVEL and the longitudinal axis of a TRACHEOSTOMY TUBE

