Doc No: MHD 11 (24987) WC
April 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

एनेस्थेटिक और श्वशन उपस्कर श्वासनली ट्यूब और कनेक्टर

(पहला पुनरीक्षण)

Draft Indian Standard

Anaesthetic and respiratory equipment Tracheal tubes and connectors

(First Revision)

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11	Last date for comments: 9 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard supersedes IS 4154: 1967 “Specification for endotracheal connections”, IS 6581: 1972 “Specification for endotracheal tubes (Rubber)” and IS 6807: 1972 “Reinforced (Flexo-metallic) Magill's Endotracheal Tube”. The ISO standard has been revised in 2023. This standard is an identical adoption of ISO 5361: 2023.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 4135, Anaesthetic and respiratory equipment — Vocabulary	IS 13200: 2023/ ISO 4135:2022 Anaesthetic and Respiratory Equipment Vocabulary Second Revision	Identical
ISO 5356-1, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets	IS/ISO 5356-1: 2015 Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (First Revision)	Identical
ISO 14971, Medical devices — Application of risk management to medical devices	IS/ISO 14971: 2019 Medical devices - Application of risk management to medical devices First Revision	Identical
ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7: 2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 18190:2016	Anaesthetic and respiratory equipment — General requirements for airways and related equipment
ISO 18562 (all parts)	Biocompatibility evaluation of breathing gas pathways in healthcare applications
ASTM F640-20	Standard test methods for determining radiopacity for medical use

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (revised)’.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex I.

NATIONAL ANNEX I
(National Foreword)

I-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to **ISO 5361:2023** or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in; hmhd@bis.gov.in

ANNEX J

J-1 LIST OF TECHNICAL DEVIATIONS

J-1.1 Reference to clause 9.3.1 of ISO 5361: 2023,

h) a glottis depth mark(s);

NOTE 3 Glottic depth marks are optional for cuffed *tracheal tubes*.

The "NOTE 3 Glottic depth marks are optional for cuffed *tracheal tubes*" is deleted in the Indian Standard.

Introduction

This document provides the essential performance and safety requirements of tracheal tubes and tracheal tube connectors. Tracheal tubes are intended to be inserted orally or nasally through the larynx into the trachea to convey gases and vapours to and from a patient's lungs during spontaneous, assisted or controlled ventilation for short or prolonged durations.

In addition, tracheal tubes with cuffs are intended to seal and protect the trachea from aspiration.

A variety of cuff designs are available to meet particular clinical requirements. Cuff performance requirements with associated test methods remain unchanged from the second edition.

Requirements for paediatric tracheal tubes, with and without cuffs, have been updated from the third edition to include new guidance on the design of tracheal tubes used in paediatric and neonatal patients. The maximum distance from the patient end of the tracheal tube to the machine end of the inflatable length of the cuff has been revised in this edition to minimise the risk of the inflatable length of the cuff aligning with the larynx of neonatal and paediatric patients.

Clinical considerations have also dictated the historical maximum distance from the patient end of the tracheal tube to the machine end of the inflatable length of the cuff be maintained for tracheal tubes designed for the general population. Anatomical abnormalities or disease states can require smaller tracheal tube sizes to be used in adult patients than would typically be appropriate. Because long tracheal tubes, sometimes of relatively narrow diameter, can be required, tracheal tubes designed to the historical specification should be readily available.

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

Kink resistance requirements with associated test methods to measure the ability of the shaft of the tracheal tube to resist collapse and avoid increased breathing resistance when bent or curved remain unchanged from the second edition.

Radiopacity requirements and test methods to characterize the visibility of tracheal tubes in X-rays used to determine proper placement of the tube remain unchanged from the second edition.

Where applicable a rationale for some of the requirements in this document are included in Annex A

The requirements of this document were developed using the hazard identification for risk assessment in Annex G.

Throughout this document the following print types are used:

- — Requirements and definitions: roman 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: italics.

Scope

This document provides specific requirements for the basic safety and essential performance for oro-tracheal and naso-tracheal tubes and tracheal tube connectors, tracheal tubes with walls reinforced with metal or plastic, tracheal tubes with shoulders, tapered tracheal tubes, tracheal tubes with means for suctioning, monitoring or delivery of drugs or other gases, and the many other types of tracheal tubes devised for specialized applications.

Tracheobronchial (including endobronchial) tubes (see ISO 16628), tracheostomy tubes (see ISO 5366), and supralaryngeal airways (see ISO 11712) are excluded from the scope of this document.

Tracheal tubes intended for use with flammable anaesthetic gases or agents, lasers, or electrosurgical equipment are outside the scope of this document.

NOTE 1 There is guidance or rationale for this clause contained in Annex A.2.

NOTE 2 ISO 11990-1, ISO 11990-2, and ISO 14408 deal with laser surgery of the airway.