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Endoscopes - Medical endoscopes and endotherapy devices —

Part 2: Particular requirements for rigid bronchoscopes

Endoscopes - Endoscopes médicaux et dispositifs d'endothérapie — Partie 2: Exigences particulières pour bronchoscopes rigides

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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 (see 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 (see 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 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This second edition cancels and replaces the first edition (ISO 8600-2:2002), of which it constitutes a minor revision.

ISO 8600 consists of the following parts, under the general title *Endoscopes — Medical endoscopes and endoscopic accessories*:

— *Part 1: General requirements*

— *Part 2: Particular requirements for rigid bronchoscopes*

— *Part 3: Determination of field of view and direction of view of endoscopes with optics*

— *Part 4: Determination of maximum width of insertion portion*

— *Part 5: Determination of optical resolution of rigid endoscopes with optics*

— *Part 6: Vocabulary*

— *Part 7: Basic requirements for medical endoscopes of water-resistant type*

Introduction

Rigid bronchoscopes need to serve three simultaneous functions during endoscopic procedures

— as an endoscope with distal illumination to allow visualization of the larynx, trachea and bronchi, and views into the bronchial trees,

— as a sheath for a flexible or rigid endoscope, aspirator (suction channel), biopsy forceps, scissors, etc., and

— as a gas passage (airway) for the terminal part of an anaesthesia ventilation system or the upper respiratory tract.

Rigid bronchoscopes, therefore, are to have sufficiently large channels with low gas-flow resistance and an adequate gas supply from the breathing system of an anaesthetic and/or breathing machine, or from compressed air/oxygen gas sources. Particular attention therefore is paid to the life-sustaining ventilatory aspects of this part of ISO 8600.

Ideally, all rigid bronchoscopes are to be usable to ventilate the patient whenever clinically necessary either under general anaesthesia or not, by means of a ventilation connector and an end-cap for assisted/controlled ventilation or by means of a jet-injector for intermittent jet ventilation. In addition to the general features of rigid bronchoscopes, the ventilatory aspects of both rigid ventilation bronchoscopes and rigid jet-ventilation bronchoscopes are especially included in this part of ISO 8600.

Test methods other than those specified in this part of ISO 8600, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this part of ISO 8600 are to be used as the reference methods.

A rationale for the most important requirements is given in Annex A. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 8600, but will expedite any subsequent revision.

Endoscopes - Medical endoscopes and endotherapy devices —

Part 2:
Particular requirements for rigid bronchoscopes

1 Scope

This part of ISO 8600 specifies requirements for rigid bronchoscopes and their endoscopic accessories used in the practice of anaesthesia and medical endoscopy.

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 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 8600-1:2013, *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-1 and the following apply.

3.1
rigid bronchoscope
open straight tube-type rigid endoscope fitted with a means of illumination through the distal end and intended to be introduced into the tracheobronchial airway, having an internal lumen sufficiently large to permit free respiration of the patient

3.2
rigid ventilation bronchoscope
rigid bronchoscope, fitted with a removable end-cap at the proximal end of the open straight tube and having an internal lumen sufficiently large to permit ventilation of the patient through an integral ventilation connector

3.3
rigid jet ventilation bronchoscope
rigid bronchoscope provided with a jet-injector

Note 1 to entry: Rigid bronchoscopes provided with only a gas nipple should not be included within the category of jet-ventilation bronchoscopes, because the Venturi principle does not necessarily function sufficiently to ventilate the patient.

3.4
ventilation connector
breathing system connector
integral part of a rigid-ventilation bronchoscope that permits connection to a breathing system of an anaesthetic or breathing machine