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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

3.5
end-cap
removable fitting at the proximal end of a rigid-ventilation bronchoscope to seal its lumen

3.6
jet-injector
narrow-lumen tubular device utilizing compressed gases (often using the Venturi principle) to provide intermittent positive gas pressure to the lungs of a patient

Note 1 to entry: Gases selected may include air, oxygen and/or other gases.

3.7
jet ventilation
artificial inflation of the lungs by intermittent release of compressed gases by means of a jet-injector within or towards the trachea and bronchi of a patient

3.8
maximum insertion portion width
maximum external width of an endoscope or endotherapy device throughout the length of the insertion portion to be inserted

Note 1 to entry: The maximum width of any expandable or transformable portion of the insertion portion is not considered as a maximum insertion portion width, such as balloons, controllable parts, jaws and the like having variable insertion portion widths.

Note 2 to entry: See also ISO 8600-6.

[SOURCE: ISO 8600-1:2013, definition 3.10]

3.9
total length
distance between the proximal and distal ends of a rigid bronchoscope

4 Requirements

4.1 General

Rigid bronchoscopes shall comply with the requirements specified in ISO 8600-1. In addition, rigid bronchoscopes shall also comply with the requirements specified in 4.2 and 4.5; rigid-ventilation bronchoscopes shall also comply with the requirements specified in 4.3 and rigid jet-ventilation bronchoscopes shall also comply with the requirements specified in 4.4.

4.2 Dimensions

4.2.1 Working length

The actual working length of a rigid bronchoscope shall be at least as long as, and not more than, 10 mm longer than the working length stated in the instructions for use provided by the manufacturer.

4.2.2 Total length

The total length shall be in the range ±10 mm to the length stated in instructions for use.

4.2.3 Maximum insertion portion width

The maximum insertion portion width shall be in the range ±1 mm stated in the instructions for use provided by the manufacturer.

4.3 Rigid ventilation bronchoscopes

4.3.1 A rigid ventilation bronchoscope shall be provided with an integral ventilation connector and an end-cap at its proximal end. Provision shall be made for insertion of endoscopes and endoscopic accessories through the end-cap. The end-cap shall not accidentally detach at an airway pressure of less than 4,0 kPa (40 cmH_2O).

An end-cap may incorporate a transparent window and/or may permit the insertion of an endoscope or endoscopic accessory through the opening or an airtight gasket. Removal or opening of the end-cap for accessory insertion may be achieved by the detachment, rotation or sliding of the end-cap.

4.3.2 A rigid ventilation bronchoscope shall be provided, in a side-arm, either with an integral ventilation connector or shall be provided with a detachable adapter which shall meet the requirements for 15 mm male conical connectors specified in ISO 5356-1 (see Figure 1). This shall not be a connector in which the internal lumen has been reduced. The ventilation connector, when fitted to the rigid ventilation bronchoscope, shall permit to-and-fro ventilation of the patient.

Adding a smaller connector to a 15 mm adapter creates a low dead-space connector. Users should be aware of the danger of using two connected low dead-space connectors, which may cause excessive flow resistance.

A ventilation connector may be located at either side of the rigid bronchoscope (see Figure 1) and may swivel around the shaft of the rigid bronchoscope.

4.4 Rigid jet-ventilation bronchoscopes

4.4.1 Rigid jet-ventilation bronchoscopes shall be provided with a jet-injector intended for jet ventilation.

Jet ventilation through a rigid bronchoscope is usually possible without a separate jet-injector port. Figure 2 gives examples of different bronchoscopes where jet injection is possible.

4.4.2 When tested in accordance with 5.3, a jet-injector supplied with a bronchoscope shall withstand a minimum force of 20 N without becoming detached.

4.4.3 When tested in accordance with 5.4, the container pressure generated by a rigid jet-ventilation bronchoscope with any jet-injector provided by the manufacturer shall not exceed 6,0 kPa (60 cmH_2O).

If the bronchoscopist uses jet-injectors other than those provided by the manufacturer, he/she is responsible for its function and performance.

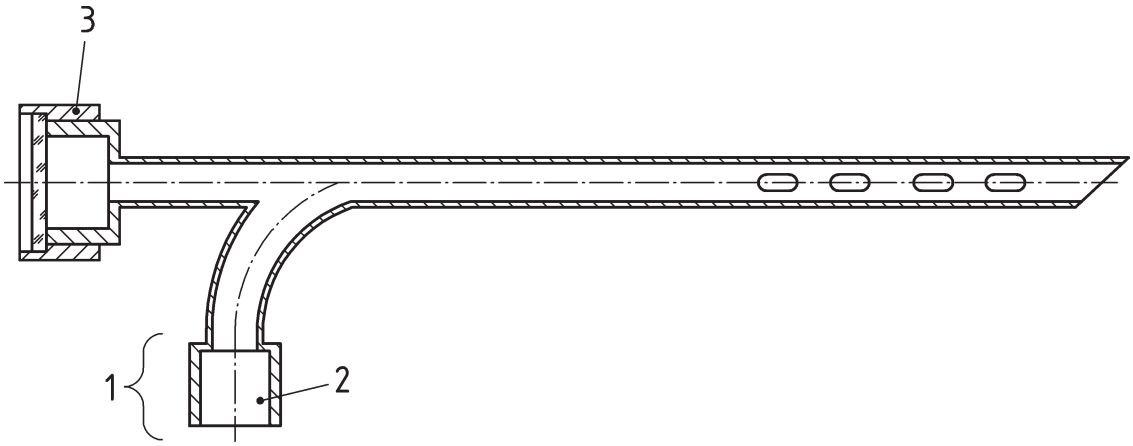
The ventilation pressure developed by any jet-injector depends on the characteristics of the bronchoscope with which it is used or tested. Users should be aware that ventilation pressure can be greatly increased by insertion of any obstruction, e.g. an aspirator or forceps, into the lumen of the rigid bronchoscope.

4.5 Side apertures

4.5.1 Side apertures, if provided, shall be located on the rigid bronchoscope no closer than 5 % of the working length from the distal tip.

4.5.2 The minimum total area of the side apertures shall not be less than the cross-sectional area of the minimum instrument channel width.

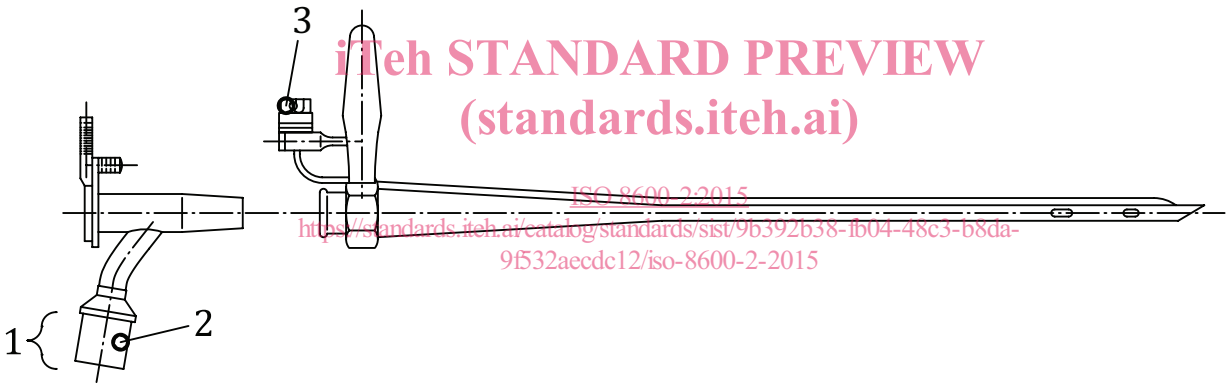
4.5.3 The side apertures shall have a smooth rounded finish.



Key

1 connector for respiration and jet ventilation
2 15 mm male conical connector
3 end-cap closed

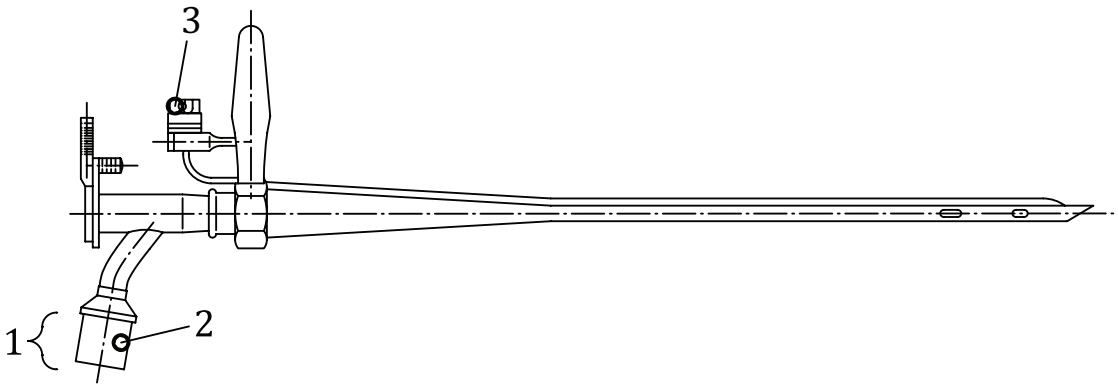
Figure 1 — Rigid ventilation bronchoscope with integrated ventilation connector



Key

1 connector for respiration and jet ventilation
2 15 mm male conical connector
3 fibre optic light guide

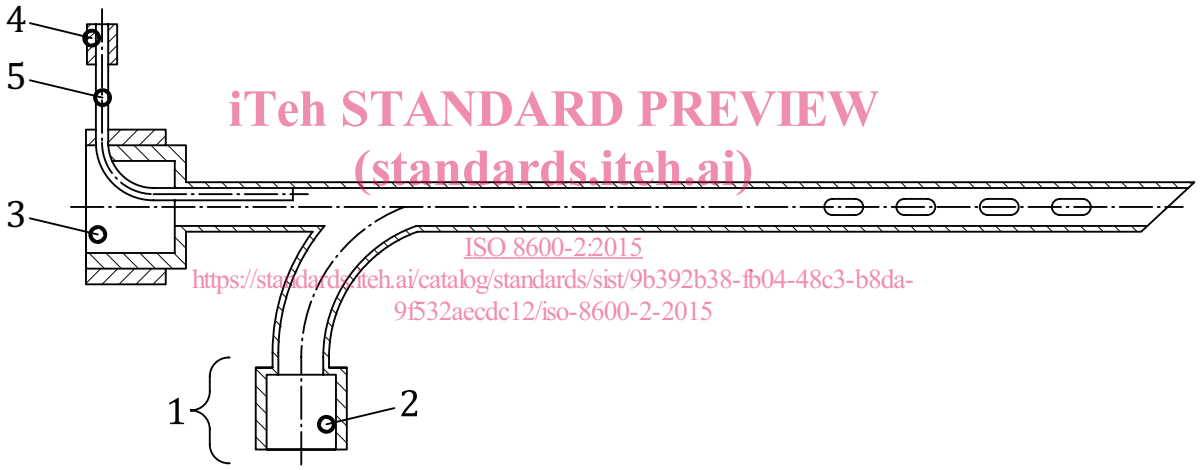
Figure 2 — Rigid ventilation bronchoscope with detachable ventilation connector — Detached



Key

1 connector for respiration and jet ventilation
2 15 mm male conical connector
3 fibre optic light guide

Figure 3 — Rigid ventilation bronchoscope with detachable ventilation connector — Assembled



Key

1 connector for respiration and jet ventilation
2 15 mm male conical connector
3 open end
4 connector for jet-ventilation tubing
5 jet-injector

Figure 4 — Rigid bronchoscopes — Jet ventilation tubing