
**Optics and optical instruments — Medical
endoscopes and endoscopic
accessories —**

Part 2:
**Particular requirements for rigid
bronchoscopes**

*Optique et instruments d'optique — Endoscopes médicaux et accessoires
endoscopiques —*

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 part of ISO 8600 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8600-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 5, *Microscopes and endoscopes*, in close collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

ISO 8600 consists of the following parts, under the general title *Optics and optical instruments — 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*

Annex A of this part of ISO 8600 is for information only.

Introduction

Rigid bronchoscopes need to serve three simultaneous functions during endoscopic procedures:

- 1) as an endoscope with distal illumination to allow visualization of the larynx, trachea and bronchi, and views into the bronchial trees;
- 2) as a sheath for a flexible or rigid endoscope, aspirator (suction channel), biopsy forceps, scissors, etc.;
- 3) as a gas passage (airway) for the terminal part of an anaesthesia ventilation system or the upper respiratory tract.

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

Ideally, all rigid bronchoscopes should 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 a 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.

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Optics and optical instruments — Medical endoscopes and endoscopic accessories —

Part 2:

Particular requirements for rigid bronchoscopes

1 Scope

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8600. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8600 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 8600-1:1997, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 1: General requirements*

3 Terms and definitions

For the purposes of this part of ISO 8600, 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 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.