
**Endoscopes — Medical endoscopes
and endotherapy devices —**

**Part 1:
General requirements**

*Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie —
Partie 1: Exigences générales*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	5
4.1 General	5
4.2 Surface and edges	5
4.3 Maximum insertion portion width	5
4.4 Minimum instrument channel width	5
4.5 Field of view	5
4.6 Direction of view	5
4.7 Safety	6
4.8 Biological compatibility	6
4.9 Fittings/connectors for liquid or gaseous media	6
4.10 Deflection control system for the controllable portion	6
4.10.1 General	6
4.10.2 Deflection up and down	6
4.10.3 Deflection right and left	6
4.10.4 Arrangement of the hand wheels	6
4.10.5 Maximum angle of deflection	7
5 Testing	7
5.1 General	7
5.2 Surface and edges	7
5.3 Maximum insertion portion width	7
5.4 Minimum instrument channel width	8
5.5 Field of view	8
5.6 Direction of view	8
6 Marking	8
6.1 Minimum marking	8
6.2 Marking legibility	9
6.3 Marking exceptions	9
7 Instruction manual	9
8 Packaging	10
Annex A (informative) Guidelines on the application of risk management to endoscopic system connector	11
Bibliography	13

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 fourth edition cancels and replaces the third edition (ISO 8600-1:2013), of which it constitutes a minor revision in order to update the definition and the corresponding Figure 1 for the term "field of view".

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

- *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*

Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

1 Scope

This part of ISO 8600 gives definitions of terms and requirements for endoscopes and endotherapy devices used in the practice of medicine.

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 8600-3, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 3: Determination of field of view and direction of view of endoscopes with optics*

ISO 8600-4, *Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60601-2-18, *Medical electric equipment — Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 endoscope

medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis, or therapy

Note 1 to entry: Endoscopes may be of rigid or flexible type; all types may have different image pick-up systems (e.g. via lenses or ultrasonic sensors) and different image-transmitting systems (e.g. optical, via lenses, or fibre bundles, or electrical).

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