INTERNATIONAL STANDARD

ISO 8600-1

Third edition
2013-03-01

Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie —

Partie 1: Exigences générales

Reference number
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Contents

Page

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8600-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This third edition cancels and replaces the second edition (ISO 8600-1:2005), which has been technically revised.

ISO 8600 consists of the following parts, under the general title *Endoscopes — Medical endoscopes and endotherapy devices*[1)]:

— *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*

1) This title will be used uniformly after the systematic review of all parts of ISO 8600. At present Parts 1, 5 and 6 have the title *Optics and photonics — Medical endoscopes and endotherapy devices*; Parts 2 and 3 have the title *Optics and optical instruments — Medical endoscopes and endoscopic accessories*; Part 4 has the title *Optics and optical instruments — Medical endoscopes and certain accessories*.

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 referenced documents are indispensable for the application of this document. 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 certain accessories — 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 14971:2007, *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.

3.2
endotherapy device
medical device intended to be inserted into a natural or surgically created body opening during endoscopic procedures, whether through the same or a different orifice from the endoscope for examination, diagnosis or therapy

Note 1 to entry: Endotherapy devices include the instrument to create the body opening and through which an endoscope or endotherapy device is inserted, such as a guide tube, trocar pin, trocar sleeve or sliding tube. Endotherapy devices include the devices to be inserted through the openings other than the opening for an endoscope, to ensure the safety of the devices for the intended use under the endoscopic view.

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

3.3
rigid endoscope (endotherapy device)
endoscope (endotherapy device) whose insertion portion is intended to be unyielding to natural or surgically created body cavities or instrument channels

Note 1 to entry: See also ISO 8600-6.

3.4
flexible endoscope (endotherapy device)
endoscope (endotherapy device) whose insertion portion is intended to conform to natural or surgically created body cavities or instrument channels

Note 1 to entry: See also ISO 8600-6.

3.5
French
Charrière
Fr
measure of the size of certain circular or non-circular cross-section endoscopes defined as

$$Fr = 3u / \pi$$

where u is the perimeter of the cross-section, expressed in millimetres

Note 1 to entry: See also ISO 8600-6.

3.6
distal
any location of that portion of an endoscope or endotherapy device which is farther from the user than some referenced point

Note 1 to entry: See also ISO 8600-6.

3.7
proximal
any location of that portion of an endoscope or endotherapy device which is closer to the user than some referenced point

Note 1 to entry: See also ISO 8600-6.

3.8
instrument channel
portion of an endoscope or endotherapy device through which an endoscope or an endotherapy device is intended to pass

Note 1 to entry: See also ISO 8600-6.

3.9
insertion portion
insertion tube
that portion of an endoscope or endotherapy device which is intended to be inserted into a natural or surgically created body opening or which is intended to be inserted into the instrument channel of an endoscope or endotherapy device

Note 1 to entry: See also ISO 8600-6.

3.10
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.

3.11
minimum instrument channel width
minimum internal width of an instrument channel

Note 1 to entry: See also ISO 8600-6.

3.12
working length
length of the insertion portion stated in the instruction manual

Note 1 to entry: See also ISO 8600-6.

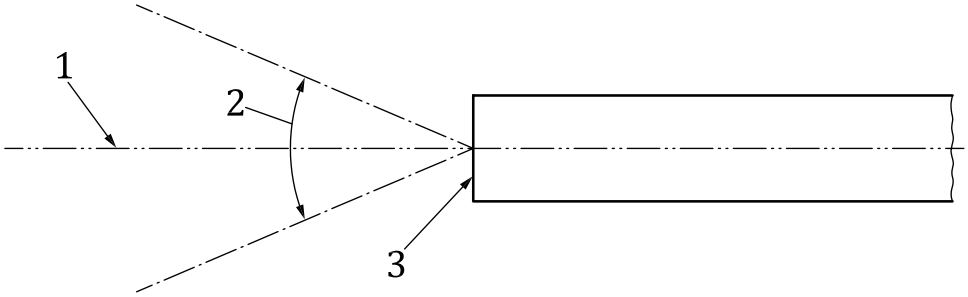
3.13
field of view
view of an endoscope with optics as stated by the manufacturer or distributor, expressed as the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the endoscope

Note 1 to entry: The field of view is not appropriate when the endoscope is intended to be in contact with the object.

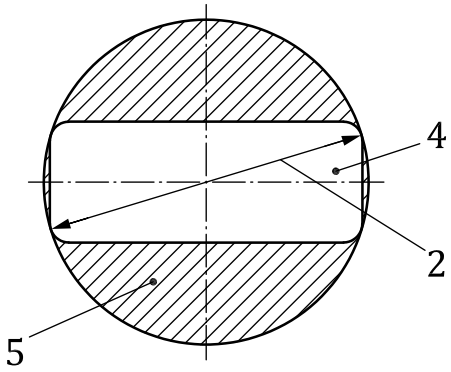
Note 2 to entry: For non-circular images, the field of view may be the largest visible circle.

Note 3 to entry: See Figure 1.

Note 4 to entry: See also ISO 8600-6.



a)



b)

Key

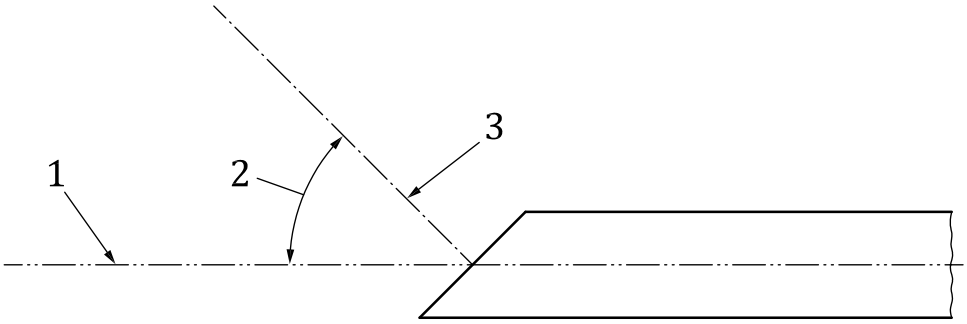
1 central axis of field of view
2 field of view
3 distal window surface of endoscope
4 visible area
5 non-visible area

Figure 1 — Field of view

3.14
direction of view
location of the centre of the object field relative to the normal axis of the endoscope, expressed as the angle (in degrees) between the normal axis of the endoscope (0°) and the central axis of the field of view

Note 1 to entry: See Figure 2.

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



Key

1 endoscope normal axis
2 direction of view
3 central axis of field of view

Figure 2 — Direction of view

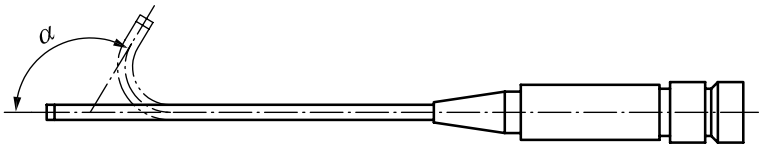
3.15
controllable portion
that part of the insertion portion of an endoscope or endotherapy device whose motion is intended to be remotely controlled by the user

Note 1 to entry: See also ISO 8600-6.

3.16
fitting/connector for liquid or gaseous media
port for input/injection or output/suction of liquid or gaseous media on endoscopes or endotherapy devices

3.17
angle of deflection
α
angle between the centre line of the straightened insertion portion and the centre line of the deflected distal tip when deflection control system is operated

Note 1 to entry: See Figure 3.



Key
α angle of deflection

Figure 3 — Angle of deflection

4 Requirements

4.1 General

Design and construction of endoscopes and endotherapy devices shall comply with the following requirements.

4.2 Surface and edges

Endoscopes and endotherapy devices shall be designed in such a way that their intended use will not lead to any unintentional injuries.

The surfaces of all endoscopes and endotherapy devices shall be free of pores, cracks and remainders of tooling agents.

4.3 Maximum insertion portion width

The maximum insertion portion width shall not be larger than that stated in the instruction manual [see 7 e) 3)].

4.4 Minimum instrument channel width

The minimum instrument channel width shall not be smaller than that stated in the instruction manual [see 7 e) 4)].

4.5 Field of view

If not otherwise specified by the manufacturer, the deviation of the field of view of an endoscope with optics from the value stated by the manufacturer or distributor shall not be greater than 15 %.

4.6 Direction of view

If not otherwise specified by the manufacturer, the deviation of the direction of view of a rigid endoscope with optics from the value stated in the instruction manual shall not be greater than 10°.