INTERNATIONAL STANDARD

ISO 8600-1

Fourth edition
2015-10-15

Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie —

Partie 1: Exigences générales

Reference number
ISO 8600-1:2015(E)

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Foreword

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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).

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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.

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* (3.1) for examination, diagnosis, or therapy

Note 1 to entry: Endotherapy devices include the instrument to create the body opening and through which an *endoscope* (3.1) 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* (3.1), 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 (3.1) or *endotherapy device* (3.2) whose insertion portion is intended to be unyielding to natural or surgically created body cavities or *instrument channels* (3.8)

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

3.4
flexible endoscope (endotherapy device)
endoscope (3.1) or *endotherapy device* (3.2) whose insertion portion is intended to conform to natural or surgically created body cavities or *instrument channels* (3.8)

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* (3.1) or *endotherapy device* (3.2) 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* (3.1) or *endotherapy device* (3.2) 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* (3.1) or *endotherapy device* (3.2) 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
portion of an *endoscope* (3.1) or *endotherapy device* (3.2) 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* (3.8) of an *endoscope* (3.1) or endotherapy device

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

3.10
maximum insertion portion width
maximum external width of an *endoscope* (3.1) or *endotherapy device* (3.2) throughout the length of the *insertion portion* (3.9) 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* (3.8)

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

3.12
working length
length of the *insertion portion* (3.9) stated in the instruction manual

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

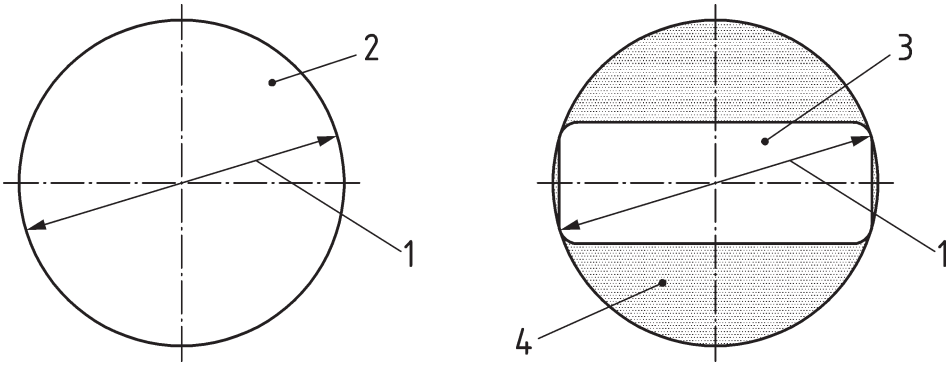
3.13
field of view
view of an *endoscope* (3.1) with optics as stated by the manufacturer or distributor

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.



Key

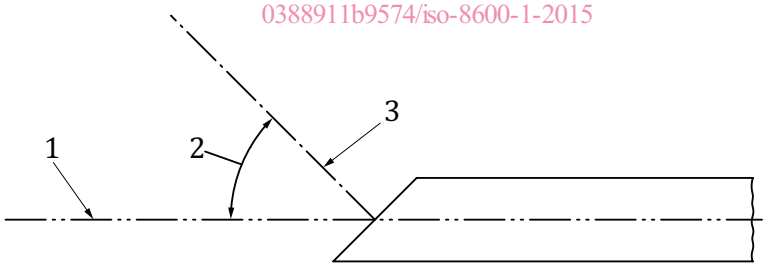
1 field of view
2 visible area of a circular image
3 visible area of a non-circular image
4 non-visible area of a non-circular image

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* (3.1), expressed as the angle (in degrees) between the normal axis of the endoscope (0°) and the central axis of the *field of view* (3.13)

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

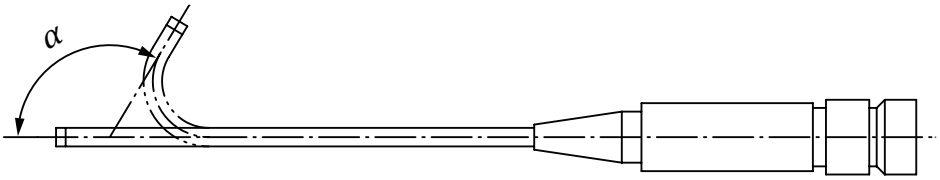
3.15
controllable portion
part of the *insertion portion* (3.9) of an *endoscope* (3.1) or *endotherapy device* (3.2) whose motion is intended to be remotely controlled by the user

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* (3.1) or *endotherapy devices* (3.2)

3.17
angle of deflection
α
angle between the centre line of the straightened *insertion portion* (3.9) and the centre line of the deflected *distal* (3.6) 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 Clause 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 Clause 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°.