INTERNATIONAL STANDARD

ISO 8600-1

Second edition
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Optics and photonics — Medical endoscopes and endotherapy devices —

Part 1: General requirements

Optique et photonique — Endoscopes médicaux et dispositifs d'endothérapie —

Partie 1: Exigences générales

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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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 second edition cancels and replaces the first edition (ISO 8600-1:1997) which has been technically revised.

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

Optics and photonics — Medical endoscopes and endotherapy devices —

Part 1: General requirements

1 Scope

This part of ISO 8600 defines terms and gives 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, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 4: Determination of maximum width of insertion portion*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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

IEC 60601-2-18, *Medical electrical equipment — Part 2: Particular requirements for the safety 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 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).

[ISO 8600-6:2005]

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 Endotherapy devices include the instrument through which an endoscope or endotherapy device is inserted, such as a guide tube, trocar tube or sliding tube, etc. 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.

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

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

$$F_r = 3u/\pi$$

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

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

3.9
insertion portion
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

[ISO 8600-6:2005]

3.10
maximum insertion portion width
maximum external width of an endoscope or endotherapy device throughout the length of the insertion portion

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

3.12
working length
maximum length of the insertion portion

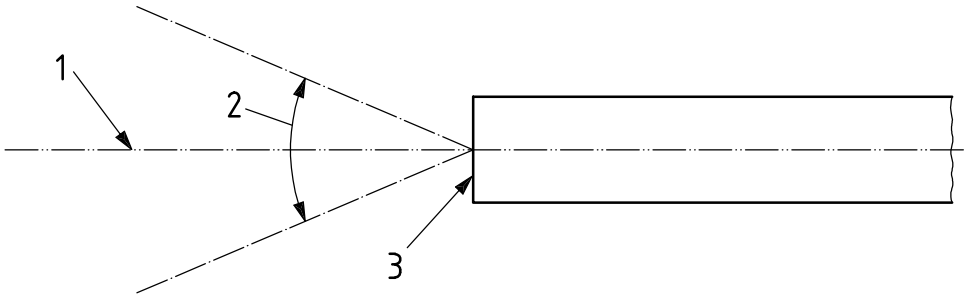
[ISO 8600-6:2005]

3.13
field of view
size of the object field viewed through an optical endoscope, expressed as the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the endoscope

See Figure 1.

NOTE The field of view is not appropriate when the endoscope is intended to be in contact with the object.

[ISO 8600-6:2005]

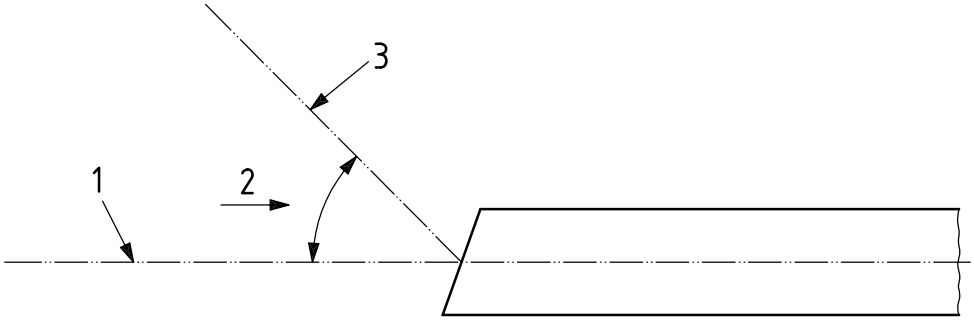


Key
1 central axis of field of view
2 field of view
3 distal window surface of endoscope

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

See Figure 2.



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

Figure 2 — Direction of view

[ISO 8600-6:2005]

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

[ISO 8600-6:2005]

4 Requirements

4.1 General

Design and construction of endoscopes and endotherapy devices shall comply with the requirements specified in 4.2 to 4.9, considering the present state of the art.

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 instruments 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 provided by the manufacturer [see 7 d) 3)].

4.4 Minimum instrument channel width

The minimum instrument channel width shall not be smaller than that stated in the instruction manual provided by the manufacturer [see 7 d) 8)].

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 nominal value stated by the manufacturer shall not be greater than 15 %. In catalogues, manuals, etc., the declaration of the field of view is not imperative.

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 nominal value stated by the manufacturer shall not be greater than 10°.

4.7 Safety

Endoscopes and endotherapy devices shall conform to IEC 60601-2-18.

4.8 Biological compatibility

Materials used for the outer surface of the insertion portion shall be evaluated for biological compatibility in accordance with ISO 10993-1.

4.9 Connectors

The manufacturer of endoscopes and endotherapy devices shall carry out a risk management procedure in accordance with ISO 14971 to consider the probability of misconnection of medical devices intended for connection to endoscopes or endotherapy devices to non-endoscopic patient connections (e.g. intravenous applications).

The purpose of the risk management procedure is to assess both the physical possibility of a misconnection of such medical devices to non-endoscopic patient connections, particularly to Luer connectors in accordance with ISO 594-1 and ISO 594-2, and the probability of occurrence of such a misconnection, together with the potential severity of harm for the patient. Where relevant standards exist for connectors that match the intended use of the endoscope, endotherapy device or medical device intended for connection to endoscopes or endotherapy devices, these should be used unless contra-indicated by the risk management procedure.

Guidelines on the application of risk management to endoscopic system connectors are given in Annex A for information.

5 Testing

5.1 General

All tests described in this document are type tests.

5.2 Surface and edges

The compliance of an instrument with the requirements of 4.2 shall be judged visually and subjectively, without magnifying aids and with sufficient illumination.