BRITISH STANDARD

BS ISO
8600-1:2005

Optics and photonics — Medical endoscopes and endotherapy devices —

Part 1: General requirements

ICS 11.040.55

BSI
British Standards

National foreword

This British Standard reproduces verbatim ISO 8600-1:2005 and implements it as the UK national standard. It supersedes BS ISO 8600-1:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/33, Microscopes, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

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Summary of pages

This document comprises a front cover, an inside front cover, the ISO title page, pages ii and iii, a blank page, pages 1 to 10, an inside back cover and a back cover.

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INTERNATIONAL STANDARD

ISO 8600-1

Second edition
2005-05-01

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
ISO 8600-1:2005(E)

Foreword

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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*

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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

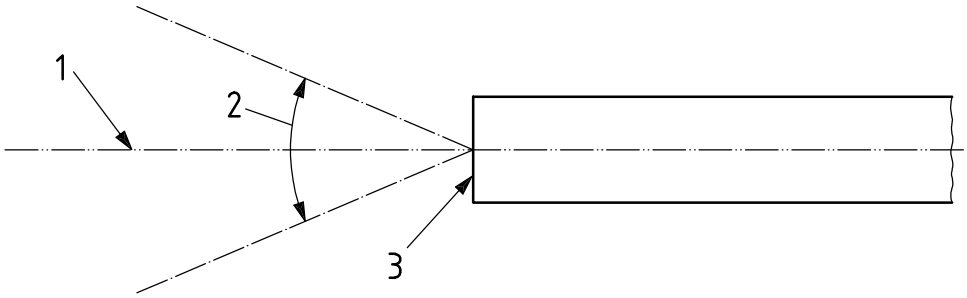
[ISO 8600-6:2005]

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]

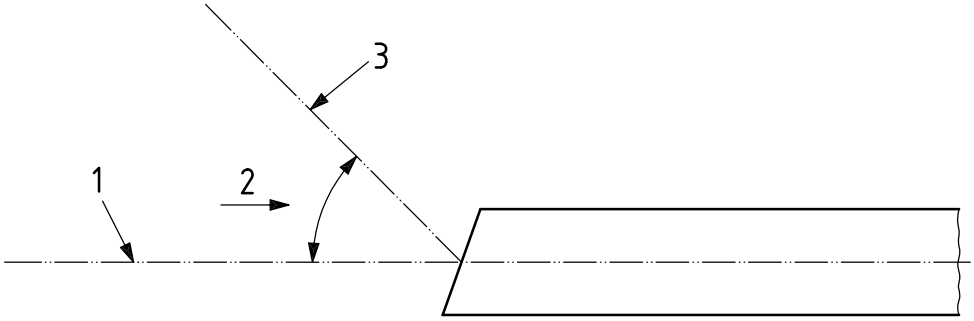


Key
1 central axis of field of view
2 field of view
3 distal window surface of endoscope

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.

5.3 Maximum insertion portion width

The maximum insertion portion width shall be determined in accordance with ISO 8600-4.

5.4 Minimum instrument channel width

For the determination of minimum instrument channel width, the measuring instrument shall have an accuracy of greater than 0,01 mm.

5.5 Field of view

The field of view of an endoscope with optics shall be determined in accordance with ISO 8600-3.

5.6 Direction of view

The direction of view of an endoscope with optics shall be determined in accordance with ISO 8600-3.

6 Marking

6.1 Minimum marking

Each individual endoscope and endotherapy device shall have the following minimum marking:

a) catalogue number and/or other mark sufficient to identify the instrument and its manufacturer;

b) maximum insertion portion width, minimum instrument channel width, working length, field of view and/or direction of view where such identification is necessary for the intended use of the endoscope or endotherapy device. The insertion portion width and instrument channel width units shall be expressed in millimetres. The insertion portion width and instrument channel width can also be marked in French size (3.5), shown by either F_r or an encircled number;

c) wherever reasonable and practicable, the instruments and detachable components or detachable semi-assembled components shall be identified in terms of lot numbers or serial numbers, etc.

6.2 Marking legibility

The marking shall remain legible when the instruments are used, cleaned, disinfected, sterilized and stored in accordance with the manufacturer's instruction manual.

6.3 Marking exceptions

When marking on the instruments, detachable components and detachable semi-assembled components is impossible to achieve due to size or configuration, the required marking shall be part of the packaging or part of the accompanying instruction manual.

7 Instruction manual

The manufacturer of the endoscopes or endotherapy devices shall provide the user with an instruction manual containing at least the following information:

a) a statement of the intended uses of the instrument;

b) instructions on the functions and proper use of the instrument;

c) annotated illustration of the instrument as appropriate to permit the user to identify pertinent parts and characteristics of the instrument which are referenced in the instruction manual, and are consistent with Clause 3;

d) identification and specifications of the instrument, including the following:

   1) manufacturer's or distributor's name and address;

   2) instrument catalogue number and name;

   3) maximum insertion portion width and working length;

   4) direction of view;

   5) remote controls and associated controllable portion positions available to the user;

   6) identification of any user-replaceable parts and instructions for their replacement;

   7) identification of where the user can obtain authorized service on the instrument;

   8) minimum instrument channel width of each instrument; the following precaution shall be given in the instruction manual, if necessary: “There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination”;

e) instructions as required for assembling the instrument for its intended uses, and for the disassembling of the instrument and reassembling after cleaning, disinfection and/or sterilization processes;

f) precautions and instructions applicable for the intended uses of the instrument, including those related to electrical, electronic, electro-optical, electro-medical, or electro-acoustical apparatus intended to be used with the instrument and in conformance with IEC 60601-2-18:

   1) any available and unavailable liquids intended to be used with the endoscope, e.g. contrast medium, sclerosis therapy medium, lubricant and anaesthetic, as well as any warnings concerning the usage of liquids not mentioned here;

   2) precautions for use in flammable atmospheres;

g) inspection instructions to provide reasonable assurance that the instrument is in working order;

h) instructions for the cleaning of reusable instruments and identification of any specific cleaning tools or equipment;

i) instructions for the specific disinfection and sterilization environments which the equipment can survive;

j) recommended procedures for the storage of the instrument prior to use and, for reusable instruments, between use.

8 Packaging

The manufacturer should package the instrument so as to protect the instrument from the adverse effects of storing and shipping environments.

Annex A
(informative)

Guidelines on the application of risk management to endoscopic system connectors

A.1 As stated in 4.9, 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, 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.

This annex provides guidance for manufacturers of endoscopes, endotherapy devices and medical devices intended for connection to endoscopes and endotherapy devices in assessing the level of risk associated with connectors in endoscopy systems related to their intended use, where specific connectors in accordance with relevant standards do not exist.

A.2 As outlined in ISO 14971:2000, Annex E, risk estimation for medical devices should be accomplished by combining two components:

— the probability of occurrence of harm, i.e. how often the harm may occur;

— the consequences of that harm, i.e. how severe it might be.

Where possible, the estimation of probability of occurrence should be based on quantitative data, but if there is no such data, then a qualitative approach should be taken, commonly involving the prediction of probability using analytical or simulation techniques, and/or the use of expert judgement.

The severity of harm will generally be easier to quantify, perhaps distinguishing between only three or four levels.

The acceptability of risk is generally recognized to fall into three regions:

a) broadly acceptable;

b) as low as reasonably possible (ALARP); and

c) intolerable.

A.3 When considering endoscopy system connectors, the manufacturer's risk analysis should include consideration of “probability” and “severity” of at least the following factors:

a) cross-connection within the endoscopy system;

b) misconnection to unrelated patient connections;

c) misconnection to unrelated medical equipment;

d) security of connection under normal and single-fault conditions;

e) intended use of connector (e.g. dedicated or multi-use);

f) reprocessing of reusable connectors.

In making an assessment of the probability of such possible events, consideration should also be given to other factors of use, including:

— intended or anticipated location of use (e.g. use in an intensive care facility, where a number of patient connections are probable, may present higher risks of misconnection than use in an endoscopy suite);

— whether it is normal for patient connections to be covered/hidden from immediate view for the intended procedure;

— the proximity of the endoscopy system connections to other probable patient connections;

— whether use of the connector is intended to take place inside or outside the patient environment;

— whether patient connections made during the endoscopy procedure remain in place after the procedure;

— whether it is possible/impossible for the connector to reach the patient in normal use/single fault condition;

— the normal level of supervision/staffing associated with the procedure.

For reusable devices, the risks of changing from the *status quo* should also be assessed, including any transitional provisions that may be necessary should equipment with “new” connectors be expected to be used safely in combination with equipment having “old” connectors.

Where, following application of risk management in accordance with ISO 14971, a manufacturer decides to use a Luer connector in accordance with ISO 594-1 and ISO 594-2, then it is advisable to record a full justification for this decision in the risk management file, as misconnection of endoscope supply lines (e.g. insufflating gas, suction, irrigation fluid) and substances delivered via syringes (e.g. air, water, contrast media, topical anaesthetic, sclerosant, mucosa staining fluid, etc.) may prove fatal if misconnected to particular non-endoscopic patient ports (such as high pressure gas insufflation to the vascular system).

Bibliography

[1] ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

[2] ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

[3] ISO 8600-6:2005, *Optics and photonics — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*

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