INTERNATIONAL STANDARD

ISO 8600-1

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Optics and optical instruments — Medical endoscopes and endoscopic accessories —

Part 1:
General requirements

Optique et instruments d'optique — Endoscopes médicaux et accessoires d'endoscopie —

Partie 1: Prescriptions générales

Reference number
ISO 8600-1:1997(E)

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.

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.

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

ISO 8600 consists of the following parts, under the general title *Optics and optical instruments — Medical endoscopes and endoscopic accessories*:

— *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*

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Optics and optical instruments – Medical endoscopes and endoscopic accessories – Part 1: General requirements

1 Scope

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8600. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8600 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8600-3:1997, *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 8600-4:1997, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 4: Determination of maximum width of insertion portion.*

ISO 9022-2:1994, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat, humidity.*

ISO 9022-3:1994, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress.*

ISO 9022-13:1994, *Optics and optical instruments — Environmental test methods — Part 13: Combined shock, bump or free fall, dry heat or cold.*

ISO 10109-6:1994, *Optics and optical instruments — Environmental requirements — Part 6: Test requirements for medical optical devices.*

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

IEC 601-2-18:1996, *Medical electric equipment — Part 2: Particular requirements for the safety of endoscopic equipment.*

3 Definitions

For the purposes of this part of ISO 8600, the following 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).

1) To be published. (Revision of ISO 10993-1:1992)

3.2 endoscopic accessory: Medical instrument inserted into a natural or surgically created body opening through which an endoscope is inserted; or a medical instrument inserted through or with an endoscope for examination, diagnosis or therapy.

NOTE — Endoscopic accessories include the instrument through which an endoscope or endoscopic accessory is inserted, such as a guide tube, trocar tube or sliding tube, etc. Endoscopic accessories include the accessories to be inserted through the openings other than the opening for an endoscope to ensure the safety of the accessories for the intended use under the endoscopic view.

3.3 rigid endoscope (endoscopic accessory): Endoscope (endoscopic accessory) whose insertion portion is intended to be unyielding to natural or surgically created body cavities or instrument channels.

3.4 flexible endoscope (endoscopic accessory): Endoscope (endoscopic accessory) whose insertion portion is intended to conform to natural or surgically created body cavities or instrument channels.

3.5 French (Charrière) *Fr*: A measure of the size of certain circular or non-circular cross-section endoscopes, defined as:

$$Fr = 3\frac{u}{\pi}$$

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

3.6 distal (adj.): Any location of that portion of an endoscope or endoscopic accessory which is farther from the user than some referenced point.

3.7 proximal (adj.): Any location of that portion of an endoscope or endoscopic accessory which is closer to the user than some referenced point.

3.8 instrument channel: Portion of an endoscope or endoscopic accessory through which an endoscope or an endoscopic accessory is intended to pass.

3.9 insertion portion: That portion of an endoscope or endoscopic accessory 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 endoscopic accessory.

3.10 maximum insertion portion width: Maximum external width of an endoscope or endoscopic accessory throughout the length of the insertion portion.

3.11 minimum instrument channel width: Minimum internal width of an instrument channel.

3.12 working length: Maximum length of the insertion portion.

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.

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).

3.15 controllable portion: That part of the insertion portion of an endoscope or endoscopic accessory whose motion is intended to be remotely controlled by the user.

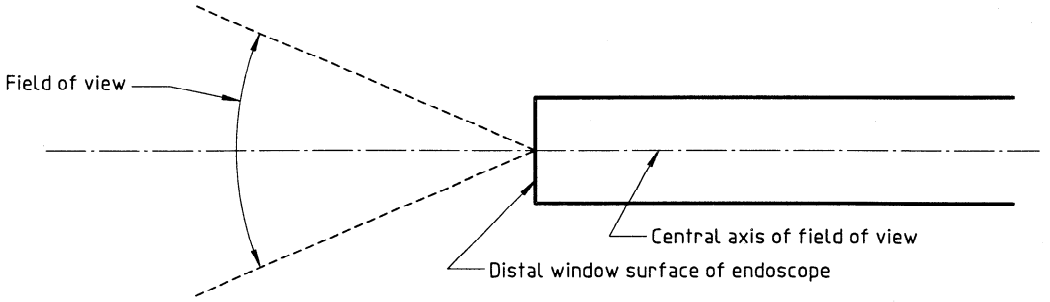


Figure 1 – Field of view

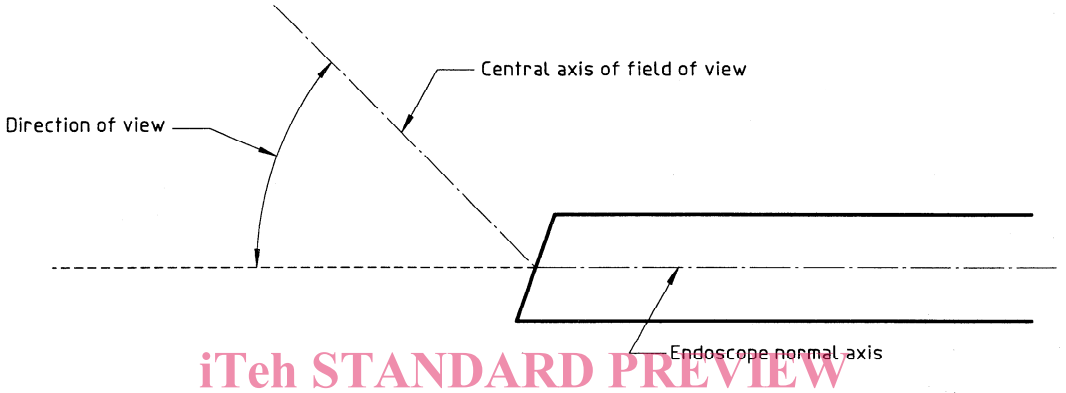


Figure 2 – Direction of view

4 Requirements

Design and construction of endoscopes and endoscopic accessories shall comply with the following requirements, considering the present state of the art.

4.1 Surface and edges

Endoscopes and endoscopic accessories 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.

4.2 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)].

4.3 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)].

4.4 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.

4.5 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°.

4.6 Safety

Endoscopes and endoscopic accessories shall conform to IEC 601-2-18.

4.7 Biological compatibility

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

4.8 Environmental requirements

4.8.1 Type or sample testing of an instrument in its normal transport and/or storage container as provided by the manufacturer (state of operation 0)

Endoscopes and endoscopic accessories shall continue to function as specified in the instruction manual (see clause 7) after being tested in accordance with the environmental requirements given in table 1. Each test shall be performed with at least two new instruments.

Table 1 — Environmental requirements for endoscopes and endoscopic accessories

Environmental requirement ISO 10109 - 05 - 03 - T	Part of ISO 9022
Environmental test ISO 9022	
10 - 08 - 0 11 - 05 - 0 16 - 01 - 0	2
30 - 03 - 0 31 - 01 - 0 36 - 01 - 0	3
66 - 14 - 0	13

4.8.2 Type or sample testing of an instrument in normal operating condition (state of operation 2)

The instruments shall meet the requirements of IEC 601-2-18.

5 Testing

All tests described in this part of ISO 8600 are type tests.

5.1 Surface and edges

The compliance of an instrument with the requirements of 4.1 shall be judged visually and subjectively, without magnifying aids and with sufficient illumination.

5.2 Maximum insertion portion width

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

5.3 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.

5.4 Field of view

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

5.5 Direction of view

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

5.6 Environmental tests

The tests for meeting the required environmental conditions in accordance with 4.8 are defined in ISO 10109-6, ISO 9022-2, ISO 9022-3 and ISO 9022-13, to which the user is referred. For better understanding, the following gives a short description of the tests.

5.6.1 Environmental test ISO 9022-10-08-0, "Cold": Expose the instrument to be tested for 16 h in a test chamber with a temperature of – (40 ± 3) °C.

5.6.2 Environmental test ISO 9022-11-05-0, "Dry heat": Expose the instrument to be tested for 6 h in a test chamber with a temperature of (70 ± 2) °C and less than 40 % relative humidity.

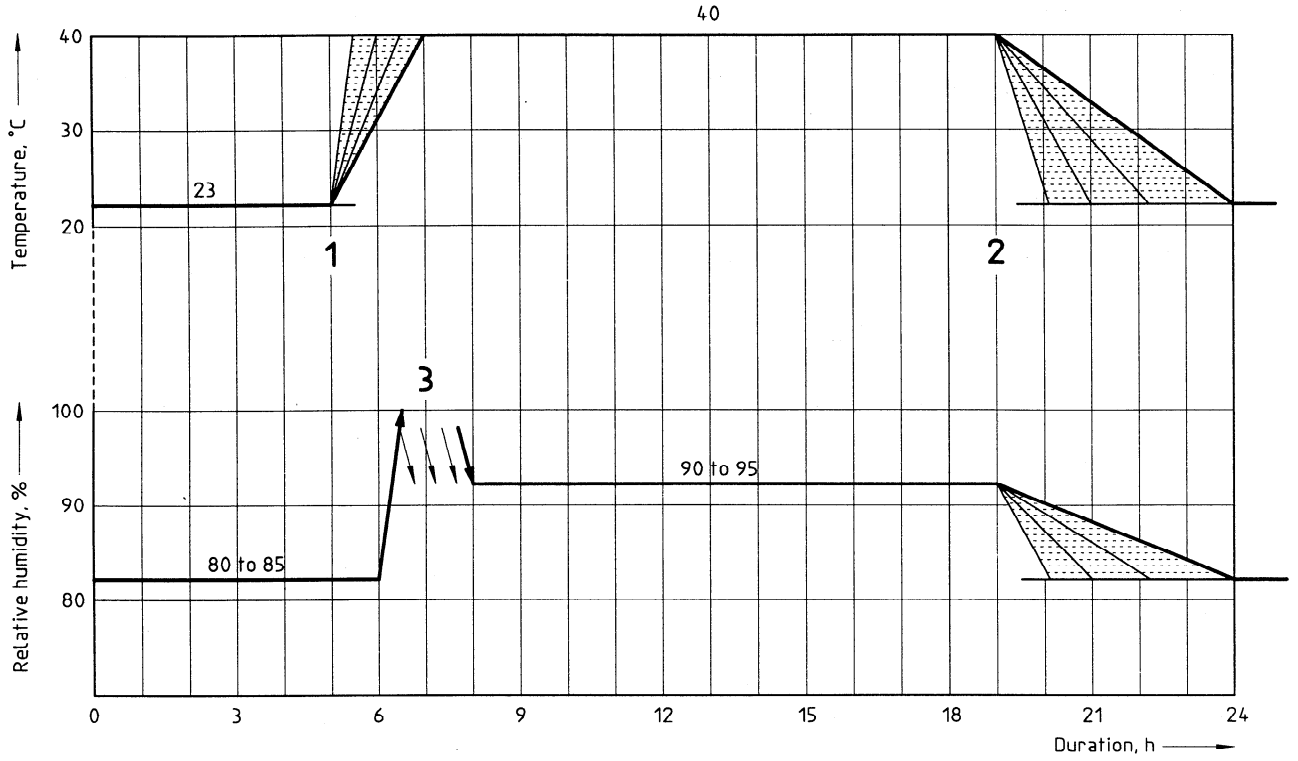
5.6.3 Environmental test ISO 9022-16-01-0, "Damp heat, cyclic": Expose the instrument to be tested for 5 cycles (24 h each) in a test chamber with a conditioning cycle according to figure 3.

5.6.4 Environmental test ISO 9022-30-03-0, "Shock": A half-sine shock pulse of 6 ms duration of nominal shock and 30 g (294 $m \cdot s^{-2}$) acceleration amplitude shall be applied to the instrument. The instrument shall be subjected to three shocks in each direction along each axis.

5.6.5 Environmental test ISO 9022-31-01-0, "Bump": (1 000 ± 10) shocks of 6 ms duration of nominal shock and 10 g (98 $m \cdot s^{-2}$) acceleration amplitude shall be applied to the instrument. The instrument shall be subjected to the shocks in each direction along each axis.

5.6.6 Environmental test ISO 9022-36-01-0, "Sinusoidal vibration, using sweep frequencies": The instrument shall be vibrated for two cycles on each axis from 10 Hz to 500 Hz. The sweep rate for the two frequency cycles shall be 1 octave per minute. The acceleration shall be 0,5 g (4,9 $m \cdot s^{-2}$) with a displacement of 0,035 mm.

5.6.7 Environmental test ISO 9022-66-14-0, "Combined shock, cold": A half-sine shock pulse of 11 ms duration of nominal shock and 15 g (147 $m \cdot s^{-2}$) acceleration amplitude shall be applied to the instrument. The instrument shall be subjected to three shocks in each direction along each axis. The test chamber temperature shall be – (35 ± 3) °C.



1 Change to (40 ± 2) °C temperature and (90 to 95) % relative humidity

2 Change to (23 ± 2) °C temperature and (80 to 85) % relative humidity

3 Bedewing

Figure 3 – Cycling curve for conditioning in accordance with 5.6.3

6 Marking

6.1 Minimum marking

Each individual endoscope and endoscopic accessory 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 endoscopic accessory. The insertion portion width and instrument channel width units shall be in millimetres. The insertion portion width and instrument channel width can also be marked in French size as defined in 3.5, shown by either *Fr* 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 semiassembled 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 endoscopic accessories 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) an 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 of this part of ISO 8600.

d) the 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 601-2-18.

   1) Any available and not available liquids intended to be used with the endoscope, e.g. contrast medium, sclerosis therapy medium, lubricant and anaesthetic, and 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 uses.