

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 1553 : 2005

(JMOIA/JSA)

**Optics and optical instruments —
Medical endoscopes and endotherapy
devices**

ICS 11.040.55

Reference number : JIS T 1553 : 2005 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Medical-optical equipment Industrial Association (JMOIA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently JIS T 1553 : 1984 is replaced with this Standard.

This Standard has been made based on ISO 8600-1 : 1997 *Optics and optical instruments—Medical endoscopes and endoscopic accessories—Part 1 : General requirements*, 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* and ISO 8600-4 : 1997 *Optics and optical instruments—Medical endoscopes and certain accessories—Part 4 : Determination of maximum width of insertion portion* for the purposes of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

Date of Establishment: 1984-11-15

Date of Revision: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 1553 : 2005, First English edition published in 2005-08

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Printed in Japan

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	1
3 Definitions	2
4 Requirements.....	4
4.1 Surface and edges	4
4.2 Maximum insertion portion width.....	4
4.3 Minimum instrument channel width	4
4.4 Field of view	4
4.5 Direction of view	4
4.6 Safety	4
4.7 Biological compatibility	4
4.8 Environmental requirements	4
5 Testing.....	4
5.1 Surface and edges	4
5.2 Maximum insertion portion width.....	5
5.3 Minimum instrument channel width	5
5.4 Field of view	5
5.5 Direction of view	5
6 Marking	5
6.1 Minimum marking.....	5
6.2 Marking legibility	5
6.3 Marking exceptions	5
7 Instruction manual.....	5
8 Packaging	7
Annex 1 (normative) Determination of field of view and direction of view of endoscopes with optics	8
Annex 2 (normative) Determination of maximum width of insertion portion.....	12
Annex 3 (informative) Comparison table between JIS and corresponding International Standards.....	15

Optics and optical instruments— Medical endoscopes and endotherapy devices

Introduction This Japanese Industrial Standard has been prepared based on the first edition of **ISO 8600-1** *Optics and optical instruments—Medical endoscopes and endoscopic accessories—Part 1: General requirements*, **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* and **ISO 8600-4** *Optics and optical instruments—Medical endoscopes and certain accessories—Part 4: Determination of maximum width of insertion portion* published in 1997 with some modifications of the technical contents.

The portions underlined with dots are the matters not stated in or modified from the original International Standard. A list of modifications with the explanations is given in annex 3 (informative).

1 Scope This Standard gives definitions of terms and requirements for endoscopes and endotherapy devices used in the practice of medicine.

Remarks : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

ISO 8600-1 : 1997 *Optics and optical instruments—Medical endoscopes and endoscopic accessories—Part 1 : General requirements* (MOD)

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* (MOD)

ISO 8600-4 : 1997 *Optics and optical instruments—Medical endoscopes and certain accessories—Part 4 : Determination of maximum width of insertion portion* (MOD)

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0993-1 *Biological evaluation of medical devices—Part 1 : Evaluation and testing*

Remarks : **ISO 10993-1** *Biological evaluation of medical devices—Part 1: Evaluation and testing* is identical with the said standard.

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 8600-3/Amd.1 *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 3: Determination of field of view and direction of view of endoscopes with optics* AMENDMENT 1.

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

IEC 60601-2-18 *Medical electrical equipment — Part 2: Particular requirements for the safety of endoscopic equipment*

3 Definitions For the purposes of this Standard, 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).

3.2 endotherapy device 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 : 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.

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

Remarks : The rigid endoscope for urinary organs satisfies the fundamental functions if used in combination with a telescope, sheath and working elements, etc. Therefore, these sheath and working elements are part of the endoscope.

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

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 : the perimeter of the cross-section (mm)

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

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

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

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

3.10 maximum insertion portion width maximum external width of an endoscope or endotherapy device at insertion 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.

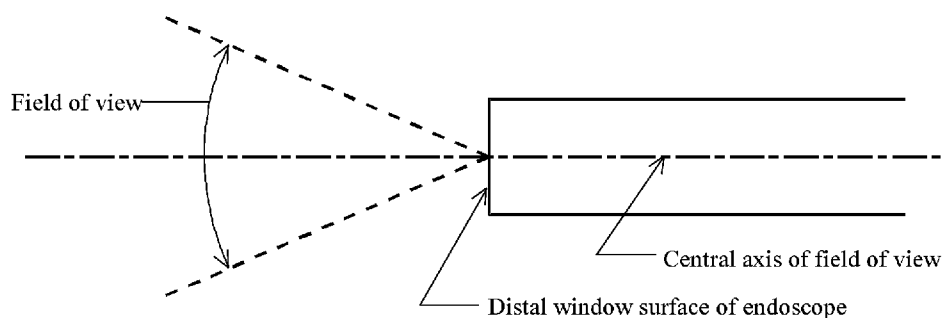


Figure 1 Field of view

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)

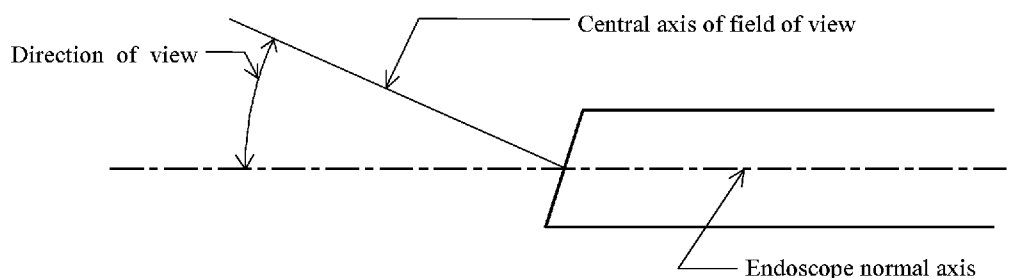


Figure 2 Direction of view

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

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

4.1 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 endoscopes and endotherapy devices 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 [see clause 7 d) 3)].

4.3 Minimum instrument channel width As for endoscopes and endotherapy devices with channel, the minimum instrument channel width shall not be smaller than that stated in the instruction manual. [see clause 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 instruction manual 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 instruction manual shall not be greater than 10°.

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

4.7 Biological compatibility Materials used for the outer surface of the insertion portion shall be evaluated for biological compatibility in accordance with JIS T 0993-1.

4.8 Environmental requirements The endoscopes and endotherapy devices shall meet the requirements of IEC 60601-2-18.

5 Testing All tests described in this Standard 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 annex 2.

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 annex 1.

5.5 Direction of view The direction of view of an endoscope with optics shall be determined in accordance with annex 1.

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 endoscope and endotherapy device and its manufacture;
- 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 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 and encircled number;
- c) wherever reasonable and practicable, the endoscopes and endotherapy devices and detachable components or detachable semiassembled components shall be identified in terms of lot numbers or serial numbers, etc.

6.2 Marking legibility The marking shall remain legible when the endoscopes and endotherapy devices are used, cleaned, disinfected, sterilized and stored in accordance with the instruction manual.

6.3 Marking exceptions When marking on the endoscopes and endotherapy devices, 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 user shall be provided with an instruction manual containing at least the following information:

- a) a statement of the intended uses of the endoscopes and endotherapy devices;
- b) instructions on the functions and proper use of the endoscopes and endotherapy devices;
- c) an annotated illustration of the endoscopes and endotherapy devices as appropriate to permit the user to identify pertinent parts and characteristics of the endoscopes and endotherapy devices which are referenced in the instruction manual, and are