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Endoscopes — Medical endoscopes and endotherapy devices —

Part 4: Determination of maximum width of insertion portion

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie — Partie 4: Détermination de la largeur maximale de la partie insérée

Reference number
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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.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This third edition cancels and replaces the second edition (ISO 8600-4:2014), which has been technically revised.

The main change is as follows:

— 5.2, Capsule endoscope, was added.

A list of all parts in the ISO 8600 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Endoscopes — Medical endoscopes and endotherapy devices —

Part 4: Determination of maximum width of insertion portion

1 Scope

This document specifies a method of measurement of the maximum insertion portion width of medical endoscopes and certain endoscopic accessories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 8600-1, *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*

ISO 8600-6, *Endoscopes — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-1, ISO 8600-6 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Test conditions

4.1 Test environments

The test environment conditions shall be as follows:

— temperature from 15 °C to 35 °C.

NOTE Relative humidity and atmospheric pressure is not defined because measurement devices made of metal or plastic are not affected by them.

4.2 Accuracy of measuring instruments

Measuring instruments with a minimum accuracy of 0,05 mm shall be used (e.g. by a vernier caliper).

For measurement of the peripheral length, in French size, measuring instruments with a minimum accuracy of 0,5 mm shall be used (e.g. by a tape measure or a similar tool).

5 Method of measurement

5.1 Flexible and rigid endoscope

5.1.1 General

For measurement of the millimetre indication, the maximum diameter of a circumscribed circle perpendicular to the nominal axis of the insertion portion shall be measured. See Figure 1 a) and Figure 1 b). This maximum diameter is defined as the largest diameter measured in all sections perpendicular to the nominal axis along the length of the insertion portion.

For measurement of the French size indication, the maximum peripheral length of a section perpendicular to the nominal axis of the insertion portion shall be measured. The maximum peripheral length is defined as the largest peripheral length measured in all sections perpendicular to the nominal axis along the length of the insertion portion.

Flexible endoscopes shall be measured with the insertion portion straight.

5.1.2 Diameter indication, *d*

To obtain the diameter of an endoscope:

a) measure the maximum diameter of a circumscribed circle, in millimetres;

b) if an endoscope utilizes a detachable hood, measure the maximum diameter of the endoscope both with and without the detachable hood. See Figure 1 a) and Figure 1 b);

c) the unit of measurement shall be millimetres.

5.1.3 French size indication, *Fr*

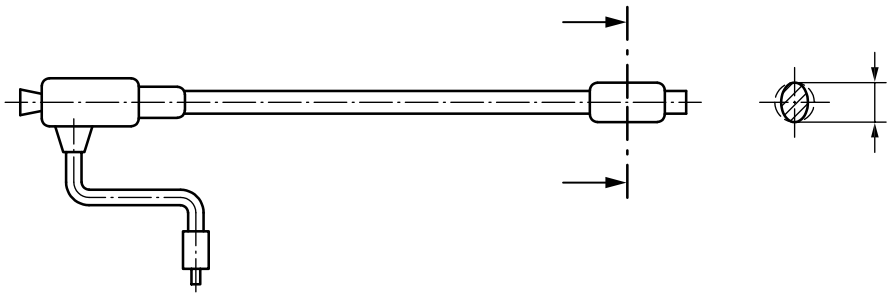
To obtain the French size indication:

a) if the section of the insertion portion is circular, the French size is calculated by multiplying the measured diameter by three;

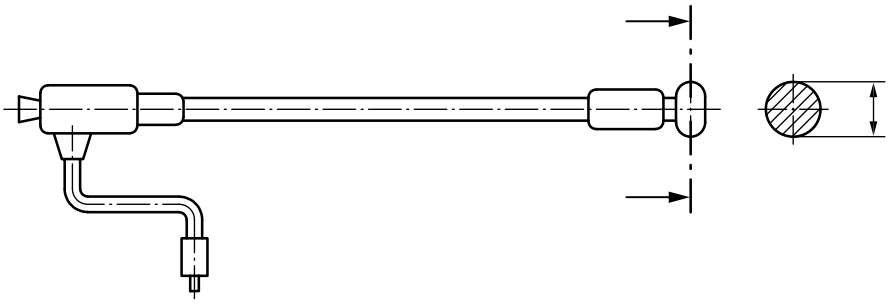
b) if the section of the insertion portion is noncircular (see Figure 2) measure the minimum length, *u* of the circumscribed curve and calculate the French size, *Fr*, by Formula (1):

$$Fr = \frac{3u}{\pi} \tag{1}$$

where *u* is the minimum length of the circumscribed curve, in millimetres.

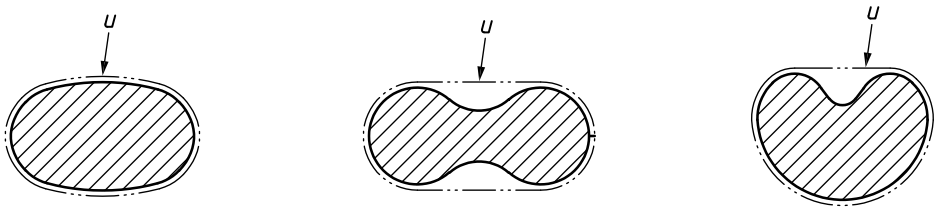


a) Without detachable hood



b) With hood

Figure 1 — Examples of measurement of maximum diameter of a flexible endoscope



Key

u is the minimum length of the circumscribed curve, in millimetres

Figure 2 — Examples of non-circular insertion portion sections

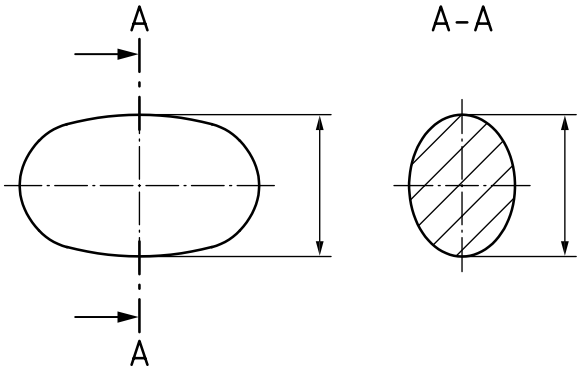
5.2 Capsule endoscope

For measurement of the millimetre indication, the maximum diameter of a circumscribed circle perpendicular to the nominal axis of the longer direction of the capsule endoscope shall be measured. See Figure 3. This maximum diameter is defined as the largest diameter measured in all sections perpendicular to the nominal axis along the longer direction of the capsule endoscope.

To obtain the millimetre indication:

a) measure the maximum diameter of a circumscribed circle;

b) the unit of measurement shall be the millimetres.



a) b)

Figure 3 — Example of measurement of the maximum diameter of longer direction of a capsule endoscope