
**Optics and optical instruments — Medical
endoscopes and certain accessories —**

Part 4:

Determination of maximum width of insertion
portion

iTeh STANDARD PREVIEW

*Optique et instruments d'optique — Endoscopes médicaux et certains de
leurs accessoires —*

Partie 4: Détermination de la largeur maximale de la partie insérée

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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.

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 8600-4 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 4:

Determination of maximum width of insertion portion

1 Scope

This part of ISO 8600 specifies a method of measurement of the maximum width of the insertion portion of medical endoscopes and certain endoscopic accessories, using either millimetre indication or French size indication.

2 Test conditions

The test conditions shall be as follows:

- a) Temperature: from 15 °C to 35 °C;
 - b) Relative humidity: from 45% to 75%;
 - c) Atmospheric pressure: from 86 kPa to 106 kPa.
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3 Accuracy of measuring instruments

Measuring instruments with a minimum accuracy of 0,05 mm shall be used (e.g. 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. tape measure or similar tool).

4 Measurement procedure

4.1 Millimetre indication

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 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.

Flexible endoscopes shall be measured with the insertion portion straight.

To obtain the millimetre indication:

- a) Measure the maximum diameter of a circumscribed circle.
- 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 b)].
- c) The unit of measurement shall be millimetres.

4.2 French size indication

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 longest 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.

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*, utilizing the following formula:

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

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

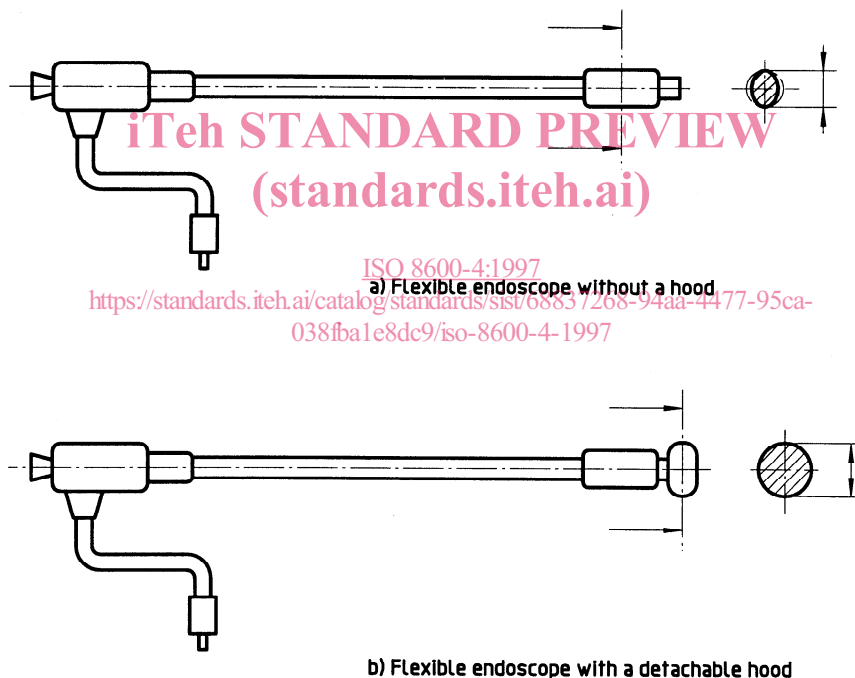


Figure 1 — Examples of measurement of maximum width of insertion portion

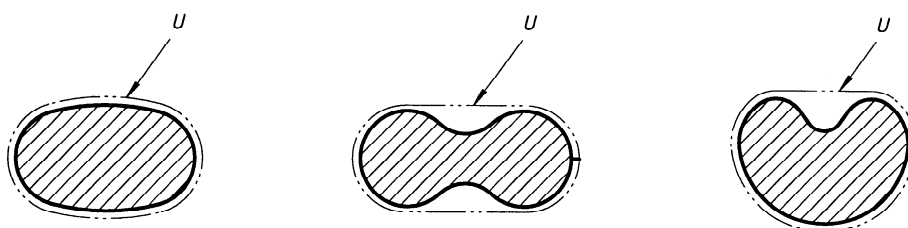


Figure 2 — Examples of non-circular insertion portion sections

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