INTERNATIONAL STANDARD

ISO 8600-4

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This second edition cancels and replaces the first edition (ISO 8600-4:1997), of which it constitutes a minor revision.

ISO 8600 consists of the following parts, under the general title *Endoscopes — 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*

— *Part 7: Basic requirements for medical endoscopes of water-resistant type*

Endoscopes — Medical endoscopes and endotherapy devices —

Part 4: Determination of maximum width of insertion portion

1 Scope

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

2 Test conditions

2.1 Test environments

The test environment 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.

2.2 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).

3 Method of measurement

3.1 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 [refer to Figure 1a) and Figure 1b)]. 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.

3.2 Millimetre indication

To obtain 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 [refer to Figure 1a) and Figure 1b)];

c) the unit of measurement shall be millimetres.

3.3 French size indication

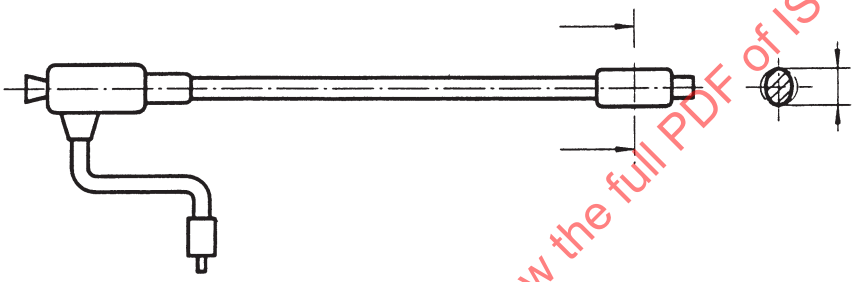
To obtain the French size indication:

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

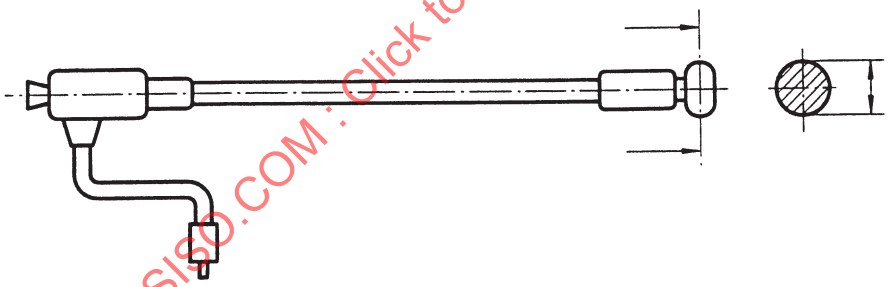
b) if the section of the insertion portion is noncircular (refer to Figure 2) measure the minimum length (U) of the circumscribed curve and calculate the French size, Fr, utilizing the following formula:

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

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

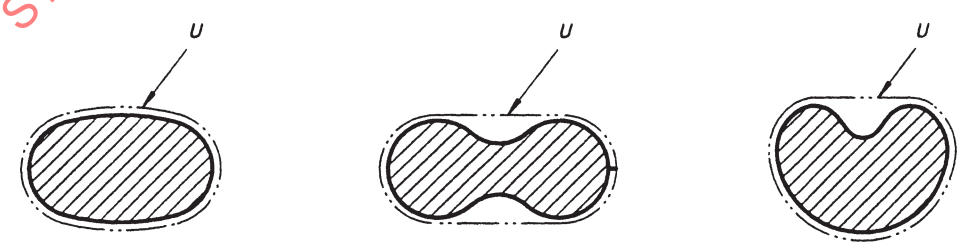


Figure 2 — Examples of non-circular insertion portion sections