INTERNATIONAL STANDARD

ISO 8600-4

Third edition
2023-01

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
ISO 8600-4:2023(E)

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Published in Switzerland

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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).