International Standard

ISO 8600-1

Fifth edition

Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie —

Partie 1: Exigences générales

PROOF/ÉPREUVE

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Contents

Page

Foreword

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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 document 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 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.

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

This fifth edition cancels and replaces the fourth edition (ISO 8600-1:2015), which has been technically revised.

The main changes are as follows:

— update of the definition and the corresponding Figure 1 for the term “field of view”.

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 1: General requirements

1 Scope

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

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 8600-3, *Endoscopes — Medical endoscopes and endotherapy devices — Part 3: Determination of field of view and direction of view of endoscopes with optics*

ISO 8600-4, *Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60601-2–18, *Medical electric equipment — Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology 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/

3.1
French
Fr
measure of the size of certain circular or non-circular cross-section endoscopes defined as

$$Fr = 3u/\pi$$

where u is the perimeter of the cross-section, expressed in millimetres

3.2
distal
any location of that portion of an endoscope or endotherapy device which is farther from the user than some referenced point

3.3
proximal
any location of that portion of an endoscope or endotherapy device which is closer to the user than some referenced point

3.4
instrument channel
portion of an endoscope or endotherapy device through which an endoscope or an endotherapy device is intended to pass

Note 1 to entry: See also ISO 8600-6.

3.5
insertion portion
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* (3.4) of an endoscope or endotherapy device

Note 1 to entry: See also ISO 8600-6.

3.6
maximum insertion portion width
maximum external width of an endoscope or endotherapy device throughout the length of the *insertion portion* (3.5) to be inserted

Note 1 to entry: The maximum width of any expandable or transformable portion of the insertion portion is not considered as a maximum insertion portion width, such as balloons, controllable parts, jaws and the like having variable insertion portion widths.

3.7
minimum instrument channel width
minimum internal width of an *instrument channel* (3.4)

3.8
working length
length of the *insertion portion* (3.5) stated in the instruction manual

3.9
field of view
view of an endoscope with optics as stated by the manufacturer or distributor

Note 1 to entry: The field of view is not appropriate when the endoscope is intended to be in contact with the object.

Note 2 to entry: For non-circular images, the field of view may be the largest visible circle. (If the endoscope rotates, the definition doesn't change because of vertical and horizontal symmetry.)

Note 3 to entry: See Figure 1.