INTERNATIONAL STANDARD

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First edition

Endoscopes — Medical endoscopes and endotherapy devices —

Part 8: Particular requirements for capsule endoscopes

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie — Partie 8: Exigences particulières pour les endoscopes à capsule

PROOF/ÉPREUVE

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC172, *Optics and photonics*, Subcommittee SC 5,*Microscopes and endoscopes*.

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

Endoscopes — Medical endoscopes and endotherapy devices —

Part 8: Particular requirements for capsule endoscopes

1 Scope

This document applies to capsule endoscopes used for clinical practice. The document defines relevant terms and gives requirements for them.

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 8600-1:2015, *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*

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

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-1, ISO 8600-6 and the following 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 http://www.electropedia.org/

3.1
maximum diameter
maximum diameter at all cross sectional surfaces which is perpendicular to the longer axis of capsule-shaped body

Note 1 to entry: Note to entry 1: The maximum diameter is measured in millimetres.

3.2
maximum length
maximum length at the longer axis of capsule-shaped body

Note 1 to entry: Note to entry 1: The maximum length is measured in millimetres.

3.3
recording time
time in which observation images can be recorded under the environments stated in the instruction manual

4 Requirements

4.1 General

The requirements given in ISO 8600-1:2015, Clause 4 apply where applicable.

4.2 Requirements specific for capsule endoscopes

4.2.1 Maximum diameter

The maximum diameter shall not be larger than that stated in the instruction manual.

4.2.2 Maximum length

The maximum length shall not be larger than that stated in the instruction manual.

4.2.3 EMC/EMI

Capsule endoscopes shall conform to IEC 60601-1-2.

5 Testing

5.1 General

For testing, the requirements in ISO 8600-1:2015, Clause 5 apply where applicable.

5.2 Testing specific for capsule endoscopes

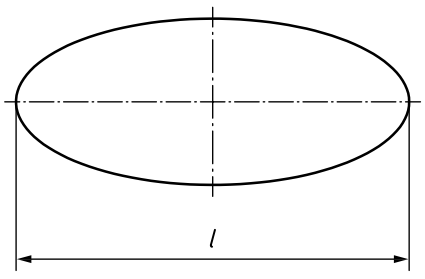
5.2.1 Maximum diameter

The requirements of ISO 8600-4 apply.

5.2.2 Maximum length

The requirements of ISO 8600-4 apply.

For measurement of the maximum length, the maximum length of the longer direction of the capsule endoscope shall be measured (see Figure 1). This maximum length is defined as the longest length measured along the longer direction of the capsule endoscope. The unit of measurement shall be millimetre.



Key

l maximum length

Figure 1 — Example of measurement of the maximum length of longer direction of a capsule endoscope

6 Marking

6.1 General

The requirements given in ISO 8600-1:2015, Clause 6 apply, where applicable.

6.2 Minimum marking specific for capsule endoscopes

Each individual capsule endoscope shall have at least the following minimum marking:

a) model number and/or other mark sufficient to identify the capsule endoscope and its manufacturer;

b) maximum diameter and maximum length, measured in millimetres;

c) field of view and/or direction of view, where such identification is necessary for the intended use of the capsule endoscope;

d) lot numbers or serial numbers, if applicable;

e) expiration date for use.

7 Instruction manual

7.1 General

The requirements given in ISO 8600-1:2015, Clause 7 apply where applicable.

7.2 Information specific for capsule endoscopes

The instruction manual for capsule endoscopes shall contain the following information:

a) The technology for data transfer (e.g. radio transmission, body communication) between the capsule endoscope and receiving unit;

b) Modulation method and transmitting and receiving frequency characteristic of capsule endoscopes and receiving units when applicable;

c) recording time;

d) storage environment (temperature and humidity);

e) type and rated watt-hours of batteries.

8 Packaging

The requirements given in ISO 8600-1:2015, Clause 8 apply.

Bibliography

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

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

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