
**Endoscopes — Medical endoscopes and
endotherapy devices —**

Part 7:

**Basic requirements for medical
endoscopes of water-resistant type**

*Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie —
Partie 7: Exigences de base pour les endoscopes médicaux
résistants à l'eau*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 8600-7 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

ISO 8600 consists of the following parts, under the general title *Endoscopes — Medical endoscopes and endotherapy devices*¹⁾:

- 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*

1) This title will be used uniformly after the systematic review of all parts of ISO 8600. At present, Parts 1, 5 and 6 have the title *Optics and photonics — Medical endoscopes and endotherapy devices*, Parts 2 and 3 have the title *Optics and optical instruments — Medical endoscopes and endoscopic accessories* and Part 4 has the title *Optics and optical instruments — Medical endoscopes and certain accessories*.

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Endoscopes — Medical endoscopes and endotherapy devices —

Part 7:

Basic requirements for medical endoscopes of water-resistant type

1 Scope

This part of ISO 8600 specifies requirements for medical endoscopes, either flexible or rigid with a bending section, of water-resistant type.

2 Requirement

Endoscopes of water-resistant type shall demonstrate resistance to air leakage when a positive pressure of at least 20 kPa is applied to the inside of the endoscope enclosure.

3 Testing

The endoscope of water-resistant type shall be completely submerged in water and a positive pressure applied to the inside of the endoscope enclosure as specified in Clause 4.

While the endoscope is submerged in water for no less than 1 min, with a positive pressure applied to the inside of the endoscope enclosure, a steady stream of air bubbles from a single part of the endoscope enclosure or channel opening shall not be seen with the naked eye. Those air bubbles attached by surface tension to the external surface of the endoscope, or air trapped in an internal channel when the endoscope is submerged in water, should be disregarded.

Endoscopes to be tested shall be placed in the water in an appropriate configuration such that any leaked air accumulating inside a channel tube could not be trapped in a bowed section of the channel tube and thereby escape detection. Depending on the diameter and length of the channel tube, it may be necessary to increase the pressurization time beyond 1 min in order to observe leaked air accumulating within a channel tube.

When an endoscope has electric connecting points on its surface, as in the case of video endoscopes and ultrasonic endoscopes, those parts unable to ensure water-resistance alone may be tested by taking measures such as mounting water-resistant caps.

4 Test conditions

The test conditions shall be as follows:

- a) Temperature: any temperature between 10 °C and 40 °C;
- b) Pressure difference: not less than 20 kPa;
- c) Immersion depth: any depth that allows complete immersion of the endoscope;
- d) Pressure time: not less than 1 min.

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