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Ophthalmic instruments — Tonometers

Instruments ophtalmiques — Tonomètres

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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 8612 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 8612:2001), which has been technically revised.

Ophthalmic instruments — Tonometers

1 Scope

This International Standard, together with ISO 15004-1, specifies minimum requirements and the design compliance procedure for tonometers intended for routine clinical use in the estimation of intraocular pressure (IOP).

This International Standard takes precedence over ISO 15004-1, if differences exist.

NOTE The true intraocular pressure is seldom directly measured since it would require invasion of the eye. Since the true IOP cannot be clinically measured, alternative methods are specified for determining a reference IOP (Annex A and Annex B).

2 Normative references

The following referenced documents are indispensable for the application 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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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

3.1
intraocular pressure
IOP
pressure within the eye

NOTE It is expressed in millimetres of mercury (mmHg), where 1 mmHg = 0,133 3 kPa.

3.2
reference tonometer
tonometer as described in Annex A

3.3
test tonometer
verified tonometer used in design compliance testing

3.4
reference IOP
IOP that is measured with a reference tonometer, as specified in Annex A, in accordance with the procedures given in Annex B

