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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This first edition of ISO 8612 cancels and replaces ISO/TR 8612:1997, which has been technically revised.

Annexes A and B form a normative part of this International Standard.

Ophthalmic instruments — Tonometers

1 Scope

This International Standard, together with ISO 15004, 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 the ISO 15004, if differences exist.

NOTE 1 The true intraocular pressure is seldom directly measured since it would require invasion of the eye. Since the true IOP cannot be known, the instrument (annex A) and method (annex B) for determining a reference IOP are instead specified.

NOTE 2 Clinical tonometers may employ different parameters or correlates in the indirect assessment of measured IOP. The manufacturer states the exact design parameters of the specific tonometer, and then, on the basis of design compliance testing as specified in 4.2, demonstrates that the specific design performs acceptably compared to the reference method. This process is referred to as certification.

The manufacturer also demonstrates, by methods specified in 4.3, that individual manufactured instruments perform the same (within defined limits) as the test tonometer. This process is referred to as verification.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 15004, *Ophthalmic instruments — Fundamental requirements and test methods.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Terms and definitions

For the purposes of this International Standard, 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 = 1,333 hPa.

3.2
reference IOP
IOP that is measured with a reference tonometer, as specified in annex A, in accordance with the procedures given in annex B

