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STANDARD

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Third edition
2014-07-01

**Ophthalmic instruments —
Ophthalmometers**

Instruments ophtalmiques — Ophtalmomètres

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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. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 10343:2009), which has been technically revised.

[ISO 10343:2014](https://standards.iteh.ai/standards/iso-10343-2014)

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Ophthalmic instruments — Ophthalmometers

1 Scope

This International Standard, together with ISO 15004-1, specifies requirements and test methods for continuously or digitally indicating ophthalmometers. Certain types of ophthalmometer have sufficient resolution and range (see [Table 2](#)) to adequately measure the radii of curvature of contact lenses complying with ISO 18369-3:2006, 4.1.3, and [Clause 5](#). It is assumed that the local corneal front surface and both contact lens surfaces are spherical or toroidal.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8429, *Optics and optical instruments — Ophthalmology — Graduated dial scale*

ISO 15004-1:2006, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1, *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 ophthalmometer

instrument designed to measure and indicate the radii of curvature and principal meridians of the human cornea's central area and of contact lenses

3.2 distance-dependent ophthalmometer

ophthalmometer in which the result of measurement is influenced by the distance between the instrument and the surface to be measured

3.3 toroidal surface

surface having two orthogonal, circular "principal meridians", one maximum and one minimum, and generated by a circular arc rotating about an axis which is in the same plane as the arc but which does not pass through its centre of curvature

3.4 principal curvature direction

direction in which the radius of curvature of the reflecting surface to be measured is at its minimum or maximum

3.5

keratometric constant

conversion value equal to 337,5 used to convert corneal curvature from inverse millimetres (mm⁻¹) to keratometric dioptries

[SOURCE: ISO 19980:2012, 3.11]

3.6

keratometric dioptries

KD

value of curvature, expressed in inverse millimetres (mm⁻¹), multiplied by the keratometric constant 337,5

[SOURCE: ISO 19980:2012, 3.12]

4 Requirements

4.1 General

The ophthalmometer shall conform to the requirements specified in ISO 15004-1.

4.2 Radius of curvature measurements

The ophthalmometer shall conform to requirements given in [Table 1](#) or [Table 2](#). Conformity shall be verified as described in [5.2](#). If the instrument conforms to the requirement of [Table 1](#) it is a “Type B” ophthalmometer. If the instrument conforms to the requirements of [Table 2](#) it is a “Type A” ophthalmometer. Type A and Type B ophthalmometers have sufficient resolution and range to adequately measure human corneas. Type A ophthalmometers have sufficient resolution and range (see [Table 2](#)) to adequately measure the radii of curvature of contact lenses complying with ISO 18369-3:2006, 4.1.3, and [Clause 5](#). It is assumed that the local corneal front surface and both contact lens surfaces are spherical or toroidal.

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<https://standards.iso.org/iso-10343-2014> **Table 1 — Requirements for measurement of radius of curvature and curvature for Type B ophthalmometers (applicable to human corneas only)**

Criterion		Requirement
Measuring range		6,5 mm to 9,4 mm (52,0 KD to 36,0 KD)
Indications given in terms of radii of curvature	continuously indicating instruments	scale interval of 0,1 mm (0,25 KD)
	digitally indicating instruments	increment 0,02 mm (0,125 KD)
Measurement accuracy (twice the standard deviation, i.e. 2σ)		±0,05 mm