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BSI Standards Publication

Ophthalmic instruments — Ophthalmometers (ISO 10343:2014)

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/172/6, Ophthalmic instruments.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Ophthalmic instruments - Ophthalmometers (ISO 10343:2014)

Instruments ophtalmiques - Ophthalmomètres (ISO
10343:2014)

Ophthalmische Instrumente - Ophthalmometer (ISO
10343:2014)

This European Standard was approved by CEN on 24 April 2014.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 10343:2014) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10343:2009.

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Endorsement notice

The text of ISO 10343:2014 has been approved by CEN as EN ISO 10343:2014 without any modification.

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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

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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.

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