Tell Services October 1975 **Ophthalmic instruments - Ophthalmometers (ISO** 10343:2014)



### EESTI STANDARDI EESSÕNA

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·	Date of Availability of the European standard is 02.07.2014.
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## **EUROPEAN STANDARD**

### **EN ISO 10343**

# NORME EUROPÉENNE

**EUROPÄISCHE NORM** 

July 2014

ICS 11.040.70

Supersedes EN ISO 10343:2009

### **English Version**

### Ophthalmic instruments - Ophthalmometers (ISO 10343:2014)

Instruments ophtalmiques - Ophtalmomètres (ISO 10343:2014)

Ophthalmische Instrumente - Ophthalmometer (ISO 10343:2014)

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION 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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.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.

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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.

### 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 (designated as code 1 in Table 1) are capable of measuring radii of curvature of contact lenses as described in ISO 18369-3:2006, 4.1. 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 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 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

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