

This standard supersedes the Swedish Standard SS-EN ISO 10342, edition 1.
EN ISO 10342

Ophthalmic instruments - Eye refractometers (ISO 10342:2003)

This European Standard was approved by CEN on 5 May 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Ref. No. EN ISO 10342:2003 E
Foreword

This document (EN ISO 10342:2003) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

This document supersedes EN ISO 10342:1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10342:2003 has been approved by CEN as EN ISO 10342:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).
Ophthalmic instruments — Eye refractometers

1 Scope

This International Standard, together with ISO 15004, specifies requirements and test methods for eye refractometers using an objective measuring principle.

This International Standard takes precedence over ISO 15004, 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 7944:1998, Optics and optical instruments — Reference wavelengths
ISO 8429:1986, Optics and optical instruments — Ophthalmology — Graduated dial scale
ISO 13666:1998, Ophthalmic optics — Spectacle lenses — Vocabulary
ISO 15004:1997, 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 terms and definitions given in ISO 13666 as well as the following apply.

3.1 eye refractometer
instrument with continuous or digital readout used for measuring the refractive errors of the eye

3.2 tolerance
difference between mean measured value and nominal value

4 Requirements

4.1 General

The eye refractometer shall conform to the general requirements specified in ISO 15004.
4.2 Optical requirements

The eye refractometer shall conform to the requirements given in Table 1 or Table 2.

The dioptric powers indicated in the requirements shall be referenced to the specific wavelengths used, $\lambda = 546.07$ nm or $\lambda = 587.56$ nm as required in ISO 7944.

The indication of the readings of cylinder power shall be possible in plus or minus cylinder convention.

<table>
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4.3 Measuring range

The eye refractometer shall have a minimum measuring range for vertex power of $-15$ D to $+15$ D.

Eye refractometers that indicate cylindrical power shall have a minimum measuring range for cylinder power of 0 D to 6 D.

The eye refractometer shall have an axis direction range of 0° to 180°.

4.4 Eyepiece (if applicable)

The dioptric adjustment range of the operator's eyepiece shall be a minimum of $-4$ D to $+4$ D.