

**Ophthalmic instruments - Refractor heads (ISO  
10341:2012)**

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English Version

## Ophthalmic instruments - Refractor heads (ISO 10341:2012)

Instruments ophtalmiques - Têtes de réfracteurs (ISO 10341:2012)

Ophthalmische Instrumente - Phoropter (ISO 10341:2012)

This European Standard was approved by CEN on 14 January 2013.

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## Foreword

This document (EN ISO 10341:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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 10341:2009.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 10341:2012 has been approved by CEN as a EN ISO 10341:2012 without any modification.

# Ophthalmic instruments — Refractor heads

## 1 Scope

This International Standard specifies requirements and test methods for refractor heads used for the determination of refractive errors and binocular functions of the human eye.

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 7944, *Optics and optical instruments — Reference wavelengths*

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

ISO 13666, *Ophthalmic optics — Spectacle lenses — Vocabulary*

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 terms and definitions given in ISO 13666 and the following apply.

### 3.1

#### **refractor head**

instrument providing a means of positioning spherical and cylindrical lenses, prisms and other optical devices in front of a subject's eyes for the purpose of determining refractive error and binocular functions

### 3.2

#### **reference plane**

plane at which the readings and the power tolerances of the refractor head apply

### 3.3

#### **reference distance**

distance between the reference plane of the refractor head and the corneal vertex

## 4 Requirements

### 4.1 General

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

### 4.2 Measuring ranges

The requirements specified in Table 1 for refractor heads shall apply.