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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 10940**

August 2009

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English Version

## Ophthalmic instruments - Fundus cameras (ISO 10940:2009)

Instruments ophtalmiques - Appareils photographiques du  
fond de l'oeil (ISO 10940:2009)

Ophthalmische Instrumente - Funduskameras (ISO  
10940:2009)

This European Standard was approved by CEN on 31 July 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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**Contents**

Page

Foreword.....3

**iTeh STANDARD PREVIEW  
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[SIST EN ISO 10940:2009](https://standards.iteh.ai/catalog/standards/sist/5c441e5f-2d7c-42bb-b922-5d5014b7a7c9/sist-en-iso-10940-2009)

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## Foreword

This document (EN ISO 10940:2009) 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of an identical text or by endorsement, at the latest by February 2010, and conflicting national standards shall be withdrawn at the latest by February 2010.

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 10940:1998.

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

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The text of ISO 10940:2009 has been approved by CEN as a EN ISO 10940:2009 without any modification.

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# INTERNATIONAL STANDARD

**ISO  
10940**

Second edition  
2009-08-01

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## Ophthalmic instruments — Fundus cameras

*Instruments ophtalmiques — Appareils photographiques du fond de  
l'œil*

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## Contents

Page

Foreword.....	iv
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 Requirements .....</b>	<b>2</b>
4.1 General.....	2
4.2 Optical properties .....	2
4.3 Construction and function.....	3
4.4 Optical radiation hazard with fundus cameras.....	3
<b>5 Test methods for checking the optical properties .....</b>	<b>4</b>
5.1 General.....	4
5.2 Test target arrangement.....	4
5.3 Checking the resolving power of the fundus camera optics .....	5
5.4 Checking the angular field of view.....	5
5.5 Checking the magnification of the image.....	5
5.6 Checking the pixel pitch of a sensor on the fundus .....	6
<b>6 Accompanying documents.....</b>	<b>6</b>
<b>7 Marking .....</b>	<b>6</b>
<b>Annex A (normative) Guidance for the measurement and calculation of the light hazard related values .....</b>	<b>7</b>
<b>Annex B (informative) Guidance for safe use of the fundus camera .....</b>	<b>12</b>

## ISO 10940:2009(E)

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10940 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 10940:1998) which has been technically revised.

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# Ophthalmic instruments — Fundus cameras

## 1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2, specifies requirements and test methods for fundus cameras operating for observing, photographing or recording electronic images of the fundus of the human eye in order to provide the image information for diagnosis. This International Standard is not applicable to the following instruments:

- those that contact the eye during the examination;
- those using scanning laser sources.

This International Standard takes precedence over ISO 15004-1 and ISO 15004-2, 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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

ISO 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005, *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

#### **resolving power of the fundus camera optics on the fundus**

minimum separation allowing recognition of two adjacent lines on the fundus, expressed as number of line pairs per millimetre (lp/mm)

### 3.2

#### **angular field of view**

#### **FOV**

maximum image size displayed on the image plane, expressed as the angle subtended at the exit pupil of the eye by the maximum dimension  $2r$

See Figure 1.