SLOVENSKI STANDARD
SIST EN ISO 19980:2012

01-september-2012

Nadomešča:
SIST EN ISO 19980:2005

Oftalmični instrumenti - Topografi roženice (ISO 19980:2012)

Ophthalmic instruments - Corneal topographers (ISO 19980:2012)

Ophthalmische Instrumente - Hornhauttopographen (ISO 19980:2012)

Instruments ophtalmiques - Topographes de la cornée (ISO 19980:2012)

Ta slovenski standard je istoveten z: EN ISO 19980:2012

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 19980:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19980

April 2012

ICS 11.040.70

Supersedes EN ISO 19980:2005

English Version

Ophthalmic instruments - Corneal topographers (ISO 19980:2012)

Instruments ophtalmiques - Topographes de la cornée (ISO 19980:2012)

Ophthalmische Instrumente - Hornhauttopographen (ISO 19980:2012)

This European Standard was approved by CEN on 31 March 2012.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN ISO 19980:2012) 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 October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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 19980:2005.

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, Croatia, 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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19980:2012 has been approved by CEN as a EN ISO 19980:2012 without any modification.

INTERNATIONAL STANDARD

ISO 19980

Second edition
2012-04-01

Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

Reference number
ISO 19980:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 19980 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 19980:2005), which has been technically revised.

This corrected version of ISO 19980:2012 incorporates the following corrections:

Equations (7) and (8), which were missing, have been added.

Ophthalmic instruments — Corneal topographers

1 Scope

This International Standard specifies minimum requirements for instruments and systems that fall into the class of corneal topographers (CTs). It also specifies tests and procedures to verify that a system or instrument complies with this International Standard and thus qualifies as a CT according to this International Standard. It also specifies tests and procedures that allow the verification of capabilities of systems that are beyond the minimum requirements for CTs.

This International Standard defines terms that are specific to the characterization of the corneal shape so that they may be standardized throughout the field of vision care.

This International Standard is applicable to instruments, systems and methods that are intended to measure the surface shape of the cornea of the human eye.

NOTE The measurements can be of the curvature of the surface in local areas, three-dimensional topographical measurements of the surface or other more global parameters used to characterize the surface.

It is not applicable to ophthalmic instruments classified as ophthalmometers.

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.

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
corneal apex
location on the corneal surface where the mean of the local principal curvature is greatest

3.2
corneal eccentricity
e_c
eccentricity, e, of the conic section that best fits the corneal meridian of interest

NOTE If the meridian is not specified, the corneal eccentricity is that of the flattest corneal meridian (see Table 1 and Annex A).

3.3
corneal meridian
θ
curve created by the intersection of the corneal surface and a plane that contains the corneal topographer axis

NOTE 1 A meridian is identified by the angle θ, that the plane creating it makes to the horizontal (see ISO 8429).

NOTE 2 The value of θ, for a full meridian, ranges from 0° to 180° .

3.3.1
corneal semi-meridian
portion of a full meridian extending from the CT axis toward the periphery in one direction

NOTE The value of θ for a semi-meridian ranges from 0° to 360° .

3.4
corneal shape factor
E
value that specifies the asphericity and type (prolate or oblate) of the conic section that best fits a corneal meridian

NOTE 1 Unless otherwise specified, it refers to the meridian with least curvature (flattest meridian). See Table 1 and Annex A.

NOTE 2 Although the magnitude of E is equal to the square of the eccentricity and so must always be positive, the sign of E is a convention to signify whether an ellipse takes a prolate or oblate orientation.

NOTE 3 The negative value of E is defined by ISO 10110-12 as the conic constant designated by the symbol K. The negative value of E has also been called asphericity and given the symbol Q.

Table 1 — Conic section descriptors

Conic section	Value of p[a]	Value of E	Value of e
Hyperbola	$p < 0$	$E > 1$	$e > 1$
Parabola	0,0	1,0	1,0
Prolate ellipse	$1 > p > 0$	$0 < E < 1$	$0 < e < 1$[b]
Sphere	1,0	0,0	0,0
Oblate ellipse	$p > 1$	$E < 0$	$0 < e < 1$[b]

[a] See 3.15.

[b] The eccentricity, e, does not distinguish between prolate and oblate orientations of an ellipse (see 3.9 and Annex A).

3.5
corneal topographer
CT
instrument or system that measures the shape of corneal surface in a non-contact manner

NOTE A corneal topographer that uses a video camera system and video image processing to measure the corneal surface by analysing the reflected image created by the corneal surface of a luminous target is also referred to as a videokeratograph.

3.5.1
optical-sectioning corneal topographer
corneal topographer that measures the corneal surface by analysing multiple optical sections of that surface

3.5.2
Placido ring corneal topographer
corneal topographer that measures the corneal surface by analysing the reflected image of a Placido ring target created by the corneal surface

3.5.3
reflection-based corneal topographer
corneal topographer that measures the corneal surface using light reflected from the air/pre-corneal tear film interface