SLOVENSKI STANDARD
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Oļesna optika ï Topografi roģenice (ISO 19980:2005)

Ophthalmic instruments - Corneal topographers (ISO 19980:2005)

Ophthalmische Instrumente - Hornhauttopographen (ISO 19980:2005)

Instruments ophtalmiques - Topographes de la cornée (ISO 19980:2005)

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11.040.70 Oftalmološka oprema Ophthalmic equipment

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Ophthalmic instruments - Corneal topographers (ISO 19980:2005)

Instruments ophtalmiques - Topographes de la cornée (ISO 19980:2005)

Ophthalmische Instrumente - Hornhauttopographen (ISO 19980:2005)

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Foreword

This document (EN ISO 19980:2005) 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of an identical text or by endorsement, at the latest by February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

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

Endorsement notice

The text of ISO 19980:2005 has been approved by CEN as EN ISO 19980:2005 without any modifications.

INTERNATIONAL STANDARD

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Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

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Foreword

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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*.

Ophthalmic instruments — Corneal topographers

1 Scope

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.

This International Standard defines certain terms that are specific to the characterization of the corneal shape so that they may be standardized throughout the field of vision care and have common meaning for all those who have occasion to participate in this area.

This International Standard specifies minimum requirements for instruments and systems that fall into the class of corneal topographers. It specifies tests and procedures that will verify that a system or instrument complies with the standard and so qualifies as a corneal topographer in the meaning of this International Standard. It specifies certain tests and procedures that will allow the verification of capabilities of systems that are beyond the minimum required for corneal topographers.

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 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

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
eccentricity e (3.9) of the conic section which 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 corneal surface and a plane which contains the corneal topographer (CT) axis

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

NOTE 2 The value of θ, for a full meridian, takes values 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 takes values from 0° to 360°.

3.4
corneal shape factor
E
value which specifies the asphericity and type (prolate or oblate) of conic section which 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 that of the square of the eccentricity and so must always be positive definite, the sign of E is a convention to signify if 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
instrument or system which measures the shape of corneal surface in a non-contact manner

NOTE A corneal topographer which 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 which measures the corneal surface by analysing multiple optical sections of that surface

3.5.2
Placido ring corneal topographer
corneal topographer which 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 which measures the corneal surface using light reflected from the air – pre-corneal tear film interface

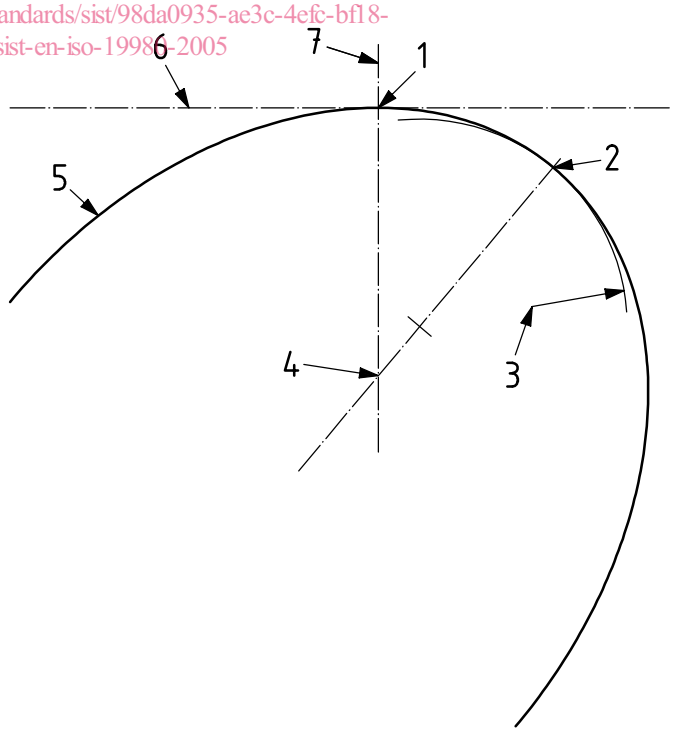
3.5.4
luminous surface corneal topographer
corneal topographer which measures the corneal surface using light back scattered from a target projected onto the pre-corneal tear film or the corneal anterior tissue surface

NOTE Back scattering is usually introduced in these optically clear substances by the addition of a fluorescent material into the pre-corneal tear film. A target may include a slit or scanning slit of light or another projecting pattern of light. Other methods are possible.

3.6
corneal topographer axis
CT axis
line parallel to the optical axis of the instrument and often coincident with it, which serves as one of the coordinate axes used to describe and define the corneal shape

3.7
corneal vertex
point of tangency of a plane perpendicular to the CT axis with the corneal surface

See Figure 1.



Key

1 corneal vertex
2 apex
3 radius of curvature at the apex
4 centre of meridional curvature point
5 cross-section of the corneal surface
6 plane perpendicular to the CT axis
7 CT axis

Figure 1 — Illustration of the corneal vertex and the apex

3.8 Curvature

NOTE For the purposes of this document, the unit of curvature is mm^{-1}.

3.8.1 Axial curvature

3.8.1.1
axial curvature
sagittal curvature
K_a
⟨calculated using the axial radius of curvature⟩ reciprocal of the distance from a point on a surface to the CT axis along the corneal meridian normal at the point (see Figure 2) and given by the equation:

$$K_a = \frac{1}{r_a} \tag{1}$$

where r_a is the axial radius of curvature

3.8.1.2
axial curvature
K_a
⟨calculated using the meridional curvature⟩ average of the value of the tangential curvature from the corneal vertex to the meridional point and given by the equation:

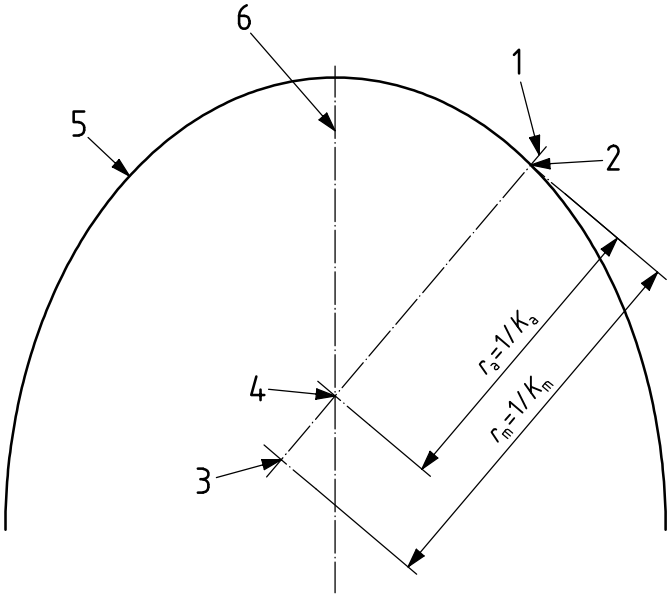
$$K_a = \frac{\int_0^{x_p} K_m(x)\,dx}{x_p} \tag{2}$$

where

x is the radial position variable on the meridian;

x_p is the radial position at which K_a is evaluated;

K_m is the meridional curvature



Key

1 normal to meridian at point P
2 P, a point on meridian where curvature is to be found
3 centre of meridional curvature point
4 intersection normal — CT axis
5 meridian (a cross-section of the corneal surface)
6 CT axis

Figure 2 — Illustration of axial curvature K_a, axial radius of curvature r_a, meridional curvature K_m, and meridional radius of curvature r_m