

# SLOVENSKI STANDARD oSIST prEN ISO 19980:2019

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Oftalmični instrumenti - Topografi roženice (ISO/DIS 19980:2019)

Ophthalmic instruments - Corneal topographers (ISO/DIS 19980:2019)

Ophthalmische Instrumente - Hornhauttopographen (ISO/DIS 19980:2019)

Instruments ophtalmiques - Topographes de la cornée (ISO/DIS 19980:2019)

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ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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# Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

ICS: 11.040.70

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Contents				
Forewo	ord	iv		
1	Scope	1		
2	Normative references	1		
3	Terms and definitions			
	Requirements			
	4.1 Area measured			
	4.2 Measurement sample density			
	4.3 Measurement and report of performance			
	4.4 Colour presentation of results			
5	Test methods and test devices			
	5.1 Tests	10		
	5.1.1 Accuracy test			
	5.1.2 Repeatability test			
	5.2 Test surfaces			
	5.2.1 Reflection-based systems			
	5.2.2 Luminous surface systems 5.2.3 Optical-sectioning systems			
	5.2.4 Specification of test surfaces			
	<ul><li>5.2.5 Verification of test surfaces</li><li>5.2.6 Type testing of surfaces R.D. P.R.E. V. IE. V.</li></ul>	11		
	5.3 Data collection — Test surfaces	12		
	<ul> <li>5.3 Data collection — Test surfaces</li> <li>5.4 Analysis of the dataStandards.iteh.ai)</li> </ul>			
	5.4.1 General			
	5.4.2 Structure of the accuracy data set 2019			
	5.4.3 http:// Analysis.of.the.paired.data.sets/51a8cc33-2c67-4022-905a			
	5.4.4 Report of accuracy performance 19980-2019			
	Accompanying documents			
7	Marking	13		
Annex	A (informative) Test surfaces for corneal topographers (CTs)	14		
Annex B (informative) Standardized displays for corneal topographers (CTs)				
Annex C (normative) Calculation of area-weighting values				
Annex	D (normative) Test methods for measuring human corneas	21		
Bibliog	graphy	22		

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*. oSIST prEN ISO 19980:2019

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This third edition cancels and replaces the second edition (ISO 19980:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

- a) Normative reference updated;
- b) 5.2.6 regarding requirements for test surfaces and requirement for testing of accuracy changed;
- c) in <u>5.4.3</u> equations for data analysis updated;
- d) table 4 deleted;
- e) document editorially revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

# Ophthalmic instruments — Corneal topographers

## 1 Scope

This document 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 document and thus qualifies as a CT according to this document. It also specifies tests and procedures that allow the verification of capabilities of systems that are beyond the minimum requirements for CTs.

This document 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 document 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.

This document is not applicable to ophthalmic instruments classified as ophthalmometers.

# 2 Normative references TANDARD PREVIEW

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, + A1:2012, Medical electrical equipment 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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <a href="http://www.iso.org/obp">http://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 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 1 to entry: If the meridian is not specified, the corneal eccentricity is that of the flattest corneal meridian (see  $\underline{\text{Table 1}}$  and  $\underline{\text{Annex A}}$ ).

#### 3.3

#### corneal meridian

A

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

Note 1 to entry: A meridian is identified by the angle  $\theta$ , that the plane creating it makes to the horizontal (see ISO 8429).

Note 2 to entry: The value of  $\theta$ , for a full meridian, ranges from 0  $^{\circ}$  to 180  $^{\circ}$ .

#### 3.3.1

#### corneal semi-meridian

portion of a full meridian extending from the CT axis toward the periphery in one direction

Note 1 to entry: The value of  $\theta$  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 to entry: Unless otherwise specified, it refers to the meridian with least curvature (flattest meridian). See Table 1 and Annex A.

Note 2 to entry: 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 to entry: 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.

https://standards.iteh.ai/catalog/standards/sist/51a8cc33-2c67-4022-905a-**Table 1**3 Tec **Conic section descriptors**)

Conic section	Value of p a	Value of E	Value of e
Hyperbola	<i>p</i> < 0	<i>E</i> > 1	e > 1
Parabola	0,0	1,0	1,0
Prolate ellipse	1 > p > 0	0 < E < 1	0 < e < 1b
Sphere	1,0	0,0	0,0
Oblate ellipse	<i>p</i> > 1	<i>E</i> < 0	0 < e < 1 <sup>b</sup>

a See <u>3.15</u>.

#### 3.5

#### corneal topographer

CT

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

Note 1 to entry: 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

The eccentricity, e, does not distinguish between prolate and oblate orientations of an ellipse (see  $\underline{3.9}$  and  $\underline{\text{Annex A}}$ ).

#### 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

#### 3.5.4

#### luminous surface corneal topographer

corneal topographer that 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 1 to entry: 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, that serves as one of the coordinate axes used to describe and define the corneal shape

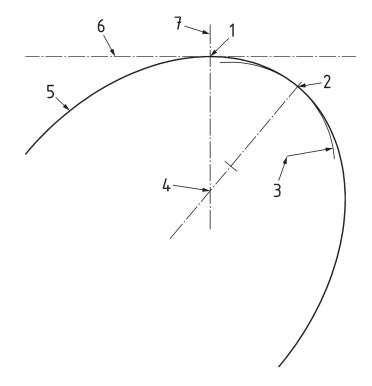
# 3.7 corneal vertex

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point of tangency of a plane perpendicular to the corneal topographer axis with the corneal surface See <u>Figure 1</u>.

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Key

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1 corneal vertex2 apex

- (standards.iteh.ai)
- 3 radius of curvature at the apex
- 4 centre of meridional curvature point <u>oSIST prEN ISO 19980:2019</u>
- 5 cross-section of the cornean surfaceards.itch.ai/catalog/standards/sist/51a8cc33-2c67-4022-905a-
- 6 plane perpendicular to the CT axis b31ec73fc2f7/osist-pren-iso-19980-2019
- 7 CT axis

Figure 1 — Illustration of the corneal vertex and the apex

### 3.8 Curvature

Note 1 to entry For the purposes of this document, the unit of curvature is reciprocal millimetre.

#### 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 corneal topographer axis along the corneal meridian normal at the point and given by <a href="Equation (1)">Equation (1)</a>:

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

where  $r_a$  is the axial radius of curvature

SEE: Figure 2.

#### 3.8.1.2

## axial curvature

 $K_{a}$ 

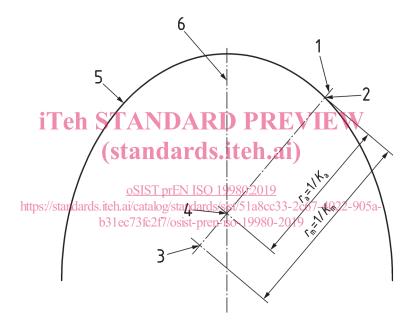
<calculated using the meridional curvature> average of the value of the tangential curvature from the
corneal vertex to the meridional point and given by <u>Equation (2)</u>:

$$K_{a} = \frac{\int_{0}^{x_{p}} K_{m}(x) dx}{x_{p}} \tag{2}$$

where

- *x* is the radial position variable on the meridian;
- $x_{\rm p}$  is the radial position at which  $K_{\rm a}$  is evaluated;

 $K_{\rm m}$  is the meridional curvature.



#### Key

- 1 normal to meridian at point P
- 2 P, a point on the 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,  $K_{\rm a}$ , axial radius of curvature,  $r_{\rm a}$ , meridional curvature,  $K_{\rm m}$ , and meridional radius of curvature,  $r_{\rm m}$ 

#### 3.8.2

#### Gaussian curvature

product of the two principal normal curvature values at a surface location

Note 1 to entry: Gaussian curvature is expressed in reciprocal square millimetres.