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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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Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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 5.4.3 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 www.iso.org/members.html.

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

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 — 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.

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

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

Note 2 to entry: 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 1 to entry: 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 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.

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 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

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

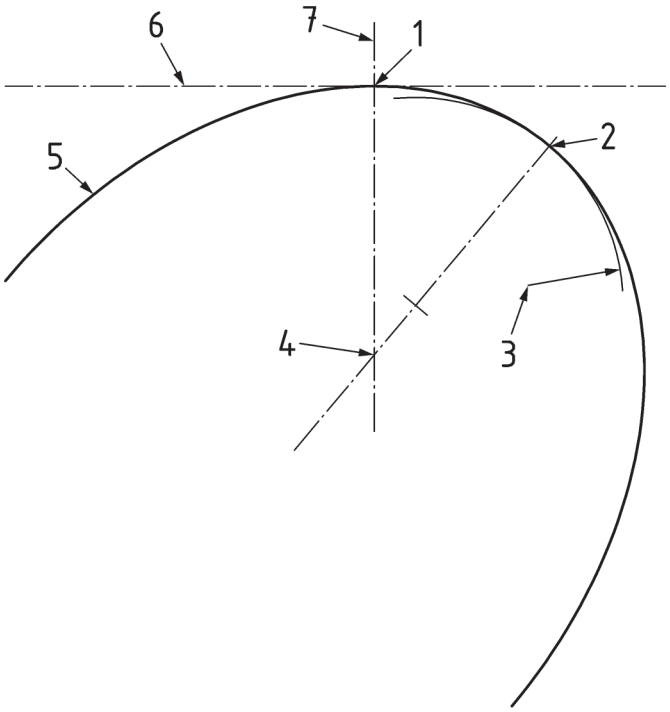
3.5.3
reflection-based corneal topographer
corneal topographer that measures the corneal surface using light reflected from the air/pre-corneal tear film interface

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
point of tangency of a plane perpendicular to the corneal topographer 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 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 Equation (1):

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

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 Equation (2):

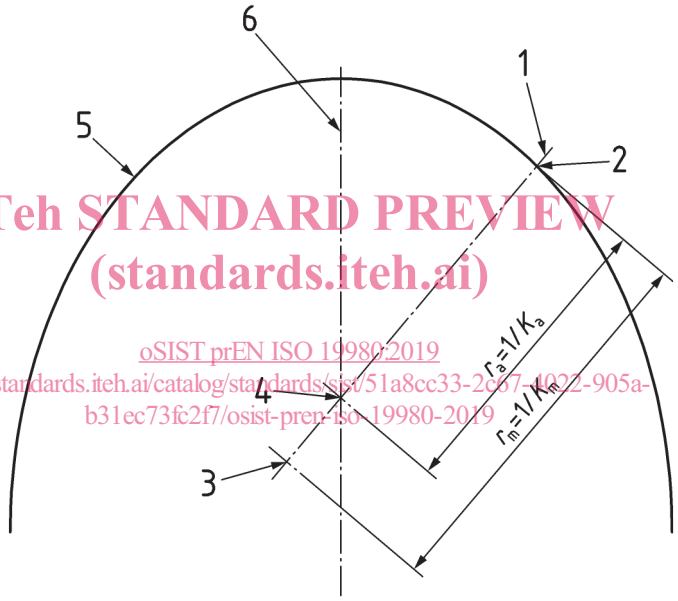
$$K_a = \frac{\int_0^{x_p} K_m(x)\,dx}{x_p} \tag{2}$$

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 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_a, axial radius of curvature, r_a, meridional curvature, K_m, and meridional radius of curvature, r_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.