INTERNATIONAL STANDARD

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Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

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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.

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

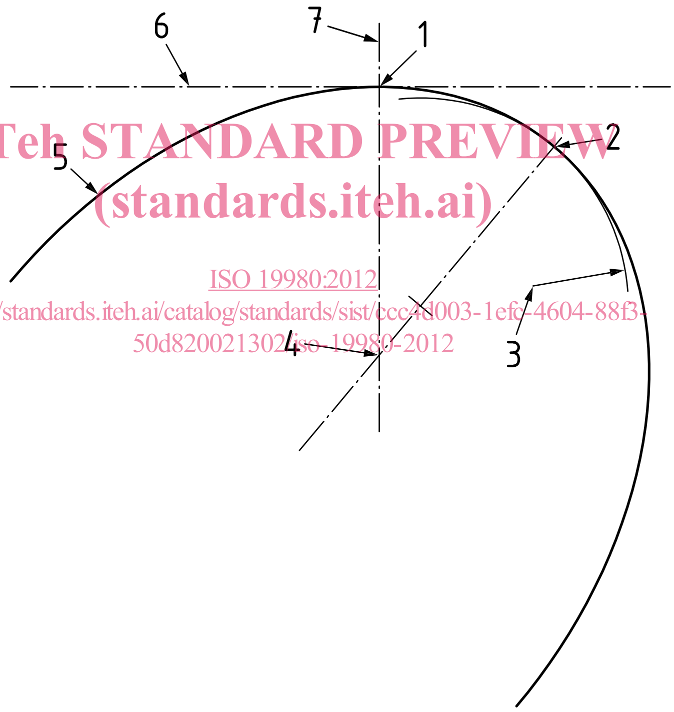
3.5.4
luminous surface corneal topographer
corneal topographer that measures the corneal surface using light back-scattered from a target projected onto the pre-corneal tear film or the corneal anterior tissue surface

NOTE 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 For the purposes of this International Standard, 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):

$$K_a = \frac{1}{r_a} \qquad (1)$$

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):

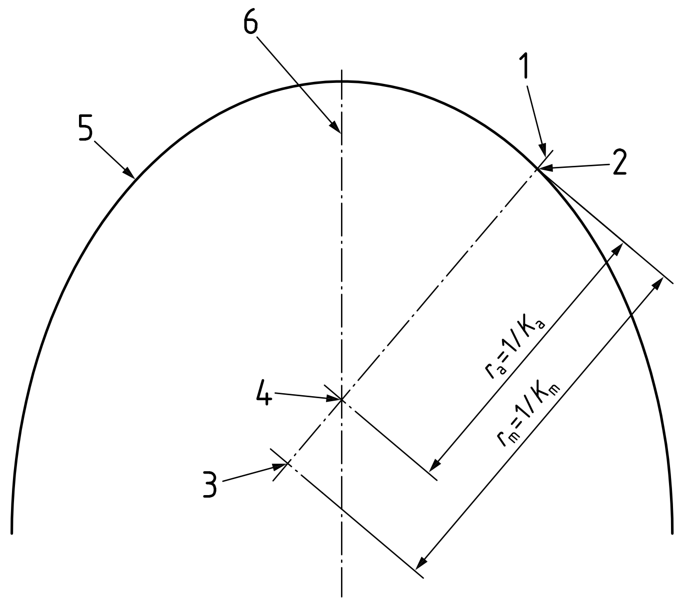
$$K_a = \frac{\int_0^{x_p} K_m(x)\,dx}{x_p} \qquad (2)$$

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 Gaussian curvature is expressed in reciprocal square millimetres.

3.8.3
meridional curvature
tangential curvature
K_m
local surface curvature measured in the meridional plane and defined by Equation (3):

$$K_m = \frac{\partial^2 M(x) / \partial x^2}{\left\{1 + \left[\partial M(x) / \partial x\right]^2\right\}^{3/2}} \tag{3}$$

where $M(x)$ is a function giving the elevation of the meridian at any perpendicular distance, x, from the corneal topographer axis

NOTE Meridional curvature is in general not a normal curvature. It is the curvature of the corneal meridian at a point on a surface.

See Figure 2.

3.8.4
normal curvature
curvature at a point on the surface of the curve created by the intersection of the surface with any plane containing the normal to the surface at that point

3.8.4.1
mean curvature
arithmetic average of the principal curvatures at a point on the surface

3.8.4.2
principal curvature
maximum or minimum curvature at a point on the surface

3.9
eccentricity
e
value descriptive of a conic section and the rate of curvature change away from the apex of the curve, i.e. how quickly the curvature flattens or steepens away from the apex of the surface

NOTE Eccentricity ranges from zero to positive infinity for the group of conic sections:

— circle ($e = 0$);

— ellipse ($0 < e < 1$);

— parabola ($e = 1$);

— hyperbola ($e > 1$)

$$E = e^2 \tag{4}$$

In order to signify use of an oblate curve of the ellipse, e is sometimes given a negative sign that is not used in computations. Otherwise, use of the prolate curve of the ellipse is assumed.

3.10
elevation
distance between a corneal surface and a defined reference surface, measured in a defined direction from a specified position

3.10.1
axial elevation
elevation as measured from a selected point on the corneal surface in a direction parallel to the corneal topographer axis

3.10.2
normal elevation
elevation as measured from a selected point on the corneal surface in a direction along the normal to the corneal surface at that point

3.10.3
reference normal elevation
elevation as measured from a selected point on the corneal surface in a direction along the normal to the reference surface

3.11
keratometric constant
conversion value equal to 337,5 used to convert corneal curvature from reciprocal millimetres (mm^{-1}) to keratometric dioptres

3.12
keratometric dioptres
value of curvature, expressed in reciprocal millimetres (mm^{-1}), multiplied by the keratometric constant, 337,5

3.13
meridional plane
plane that includes the surface point and the chosen axis

3.14 Normal

3.14.1
surface normal
line passing through a surface point of the surface perpendicular to the plane tangent to the surface at that point

3.14.2
meridional normal
line passing through a surface point of the surface, perpendicular to the tangent to the meridional curve at that point and lying in the plane creating the meridian

3.15
***p*-value**
number that specifies a conic section such as an ellipse, a hyperbola or a parabola, with the conic section given in Equation (5):

$$\frac{z^2}{b^2} \pm \frac{x^2}{a^2} = 1 \tag{5}$$

and the p-value defined by Equation (6):

$$p = \pm \frac{a^2}{b^2} \tag{6}$$

$$E = 1 - p \tag{7}$$

where

a and b are constants;

$+$ indicates an ellipse;

$-$ indicates a hyperbola

See Table 1.

3.16
Placido ring target
target consisting of multiple concentric rings, where each individual ring lies in a plane but the rings are not, in general, coplanar

3.17
radius of curvature
reciprocal of the curvature

NOTE For the purpose of this International Standard, the radius of curvature is expressed in millimetres.

3.17.1
axial radius of curvature
sagittal radius of curvature
r_a
distance from a surface point, P, to the axis along the normal to corneal meridian at that point, and defined by Equation (8):

$$r_a = \frac{x}{\sin \phi(x)} \tag{8}$$