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Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

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Contents

Page

Foreword

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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

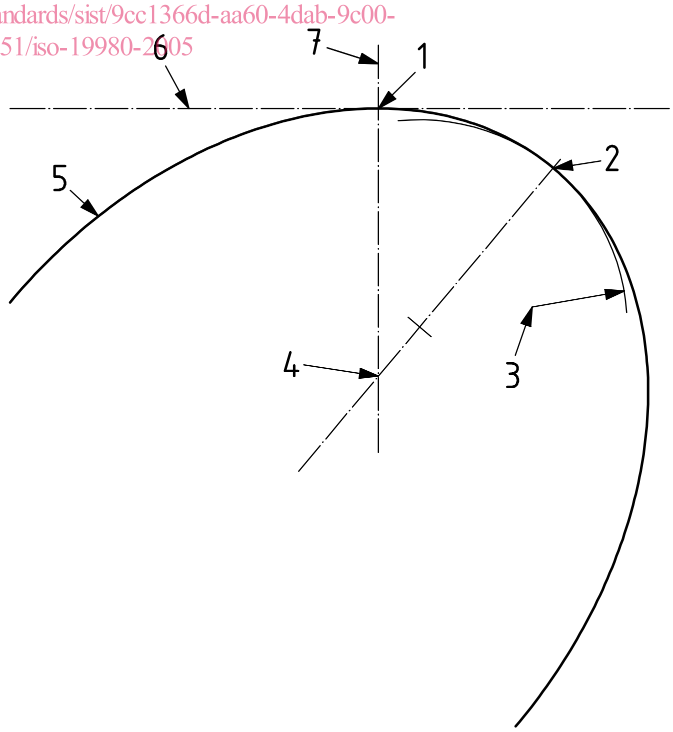
3.5.4
luminous surface corneal topographer
corneal topographer which measures the corneal surface using light back scattered from a target projected onto the pre-corneal tear film or the corneal anterior tissue surface

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:

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

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:

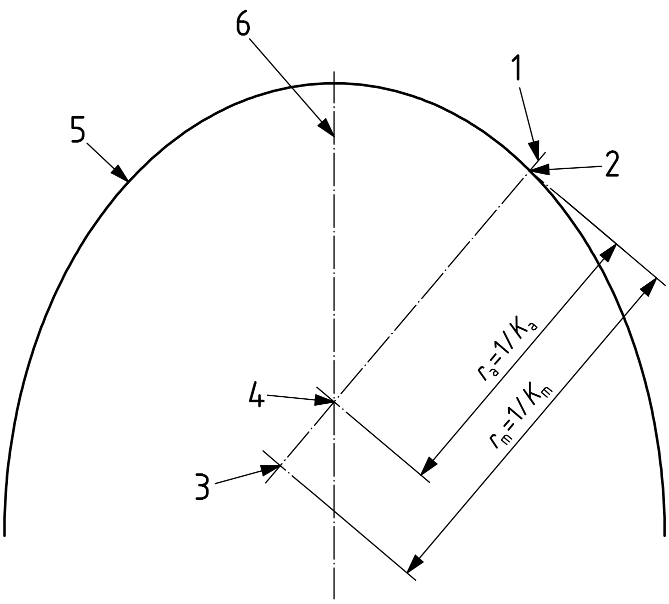
$$K_a = \frac{\int_0^{x_p} K_m(x)\,dx}{x_p} \quad (2)$$

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

3.8.2
Gaussian curvature
product of the two principal normal curvature values at a surface location

NOTE Gaussian curvature has units of reciprocal millimetres squared.

3.8.3
meridional curvature
tangential curvature
K_m
local surface curvature measured in the meridional plane and defined by the equation:

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

where $M(x)$ is a function giving the elevation of the meridian at any perpendicular distance, x, from the CT axis (see Figure 2)

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

3.8.4
normal curvature
curvature at a point of 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 CT 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 the 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 inverse millimetres (mm^{-1}) to keratometric dioptres

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

3.13
meridional plane
plane which 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 (see Table 1), with the conic section given in the form:

$$\frac{z^2}{b^2} \pm \frac{x^2}{a^2} = 1 \qquad (5)$$

and the p-value defined by:

$$p = \pm \frac{a^2}{b^2} \qquad (6)$$

$$E = 1 - p \qquad (7)$$

where

a and b are constants;

$+$ indicates an ellipse;

$-$ indicates a hyperbola

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 The units of radius of curvature, for the purpose of this document, are 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 (see Figure 2), and defined by the equation:

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

where

x is the perpendicular distance from the axis to the meridian point in millimetres;

$\phi(x)$ is the angle between the axis and the meridian normal at point x.

3.17.2
meridional radius of curvature
tangential radius of curvature
r_m

$$r_m = \frac{1}{K_m} \quad (9)$$

See Figure 2.

3.18 Surface

3.18.1
aspheric surface
non-spherical surface
surface with at least one principal meridian that is non-circular in cross-section

3.18.2
atoric surface
surface having mutually perpendicular principal meridians of unequal curvature where at least one principal meridian is non-circular in cross-section

NOTE Atoric surfaces are symmetrical with respect to both principal meridians.

3.18.3
oblate surface
surface whose curvature increases as the location on the surface moves from a central position to a peripheral position in all meridians

3.18.4
prolate surface
surface whose curvature decreases as the location on the surface moves from a central position to a peripheral position in all meridians

3.18.5
reference surface
surface, which can be described in an exact, preferably mathematical fashion, used as a reference from which distance measurements are made to the measured corneal surface, and for which, in addition to the mathematical description, the positional relationship to the corneal surface is specified

NOTE For instance, a reference surface might be described as a sphere which is the best least squares fit to the measured corneal surface. Similarly, a plane could serve as a reference surface.

3.18.6
toric surface
surface for which the principal curvatures are unequal and for which principal meridians are circular sections

NOTE Such surfaces are said to exhibit central astigmatism.

3.19
toricity
difference in principal curvatures at a specified point or local area on a surface

3.20
transverse plane
plane perpendicular to the meridional plane which includes the normal to the surface point

4 Requirements

4.1 Area measured

When measuring a spherical surface with a radius of curvature of 8 mm, a corneal topographer shall directly measure locations on the surface whose radial perpendicular distance from the corneal topographer axis is at least 3,75 mm. If the maximum area covered by a corneal topographer is claimed, it shall be reported as the maximum radial perpendicular distance from the corneal topographer axis sampled on this 8 mm radius spherical surface.

4.2 Measurement sample density

Within the area bounded by the requirement of 4.1 the surface shall be directly sampled in sufficient locations so that any surface location within the area has a sample taken within 0,5 mm of it.

4.3 Measurement and report of performance

If the performance of a corneal topographer for the measurement of either curvature or elevation is claimed or reported, the testing shall be done in accordance with 5.1, 5.2 and 5.3 and the analysis and reporting of results shall be performed in accordance with 5.4.

4.4 Colour presentation of results

The corneal topographer shall present the results according to the colour presentation definition described in Annex B.