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# Ophthalmic instruments — Corneal topographers

*Instruments ophtalmiques — Topographes de la cornée*



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# Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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 references were updated;

b) 5.2.6 regarding requirements for test surfaces and requirement for testing of accuracy was changed;

c) in 5.4.3, formulae for data analysis have been updated;

d) Table 4 was 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 + A2:2020, *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 https://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

Note 1 to entry: See Figure 1.

**3.2**
**corneal eccentricity**
$e_c$
eccentricity, $e$, of the conic section that best fits the *corneal meridian* (3.3) 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**
$\theta$
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° to 180°.

**3.4**
**corneal shape factor**
$E$
value that specifies the type of conic section that best fits a *corneal meridian* (3.3), given by Formula (1):

$$E = 1 - p \quad (1)$$

where

$p$ is the value that specifies a conic section such as a circle, ellipse, hyperbola, or parabola

value $p$ is given by Formula (2):

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



where

$a$ and $b$ are the semi-diameters of the axes of the conic section;

+ indicates a circle or ellipse;

− indicates a hyperbola



a conic section is specified by Formula (3):

$$\frac{z^2}{b^2} \pm \frac{x^2}{a^2} = 1 \quad (3)$$

value $E$ also is the square of the *eccentricity* (3.9) of the conic section, given by Formula (4):

$$E = e^2 \quad (4)$$

Note 1 to entry: Unless otherwise specified, $E$ 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 is always 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 $Q$.

Note 4 to entry:

Note 5 to entry:

**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 | $0 < p < 1$ | $1 > E > 0$ | $1 > e > 0$[b] |
| Circle | 1,0 | 0,0 | 0,0 |
| Oblate ellipse | $p > 1$ | $E < 0$ | $0 < e < 1$[b] |

[a] See 3.4.

[b] 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* (3.5) that measures the corneal surface by analysing multiple optical sections of that surface



**3.5.2**
**Placido ring corneal topographer**
*corneal topographer* (3.5) 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* (3.5) that measures the corneal surface using light reflected from the air/pre-corneal tear film interface

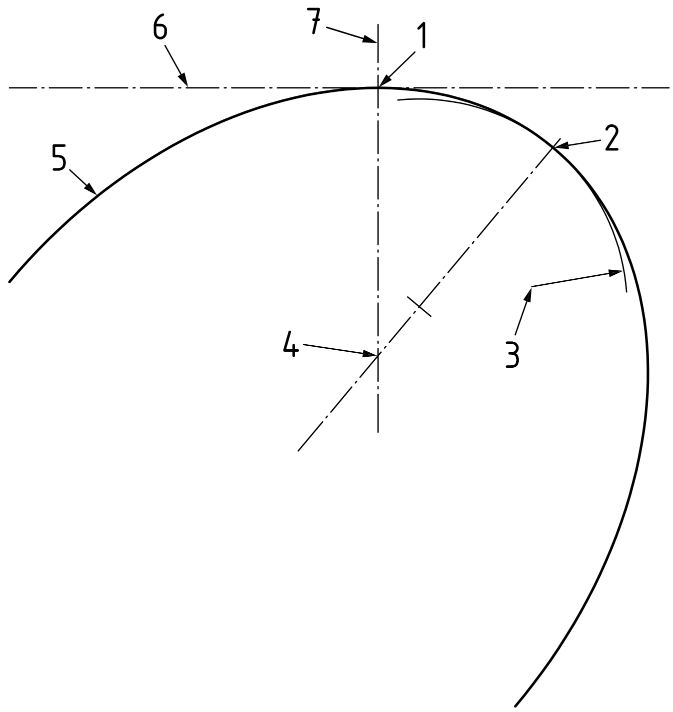
**3.5.4**
**luminous surface corneal topographer**
*corneal topographer* (3.5) that measures the corneal surface using light back-scattered from a target projected onto the pre-corneal tear film or the corneal anterior tissue surface

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* (3.6) with the corneal surface

Note 1 to entry: See Figure 1.




**Key**

1 corneal vertex
2 corneal apex
3 radius of curvature at the corneal 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 corneal apex**

## 3.8 Curvature

### 3.8.1 Axial curvature

Note 1 to entry Axial curvature is expressed in reciprocal millimetres.

**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* (3.6) along the *corneal meridian* (3.3) normal at the point and given by Formula (5):

$$K_a = \frac{1}{r_a} \quad (5)$$

where $r_a$ is the axial radius of curvature

Note 1 to entry: 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 Formula (6):

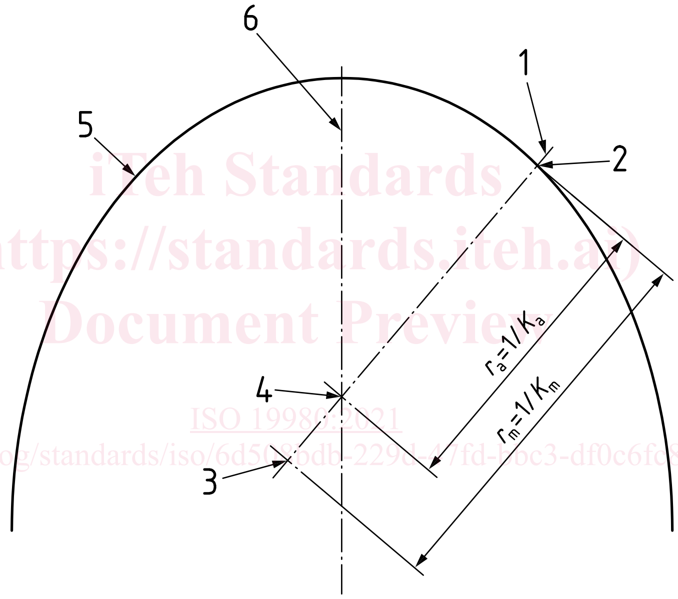
$$K_a = \frac{\int_0^{x_p} K_m(x)\,\mathrm{d}x}{x_p} \tag{6}$$

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.

**3.8.3**
**meridional curvature**
**tangential curvature**
$K_m$
local surface curvature measured in the meridional plane and defined by Formula (7):

$$K_m = \frac{\partial^2 M(x)/\partial x^2}{\left\{1+[\partial M(x)/\partial x]^2\right\}^{3/2}} \quad (7)$$

where $M(x)$ is a function giving the elevation of the meridian at any perpendicular distance, $x$, from the *corneal topographer axis* (3.6)

Note 1 to entry: The meridional plane includes the surface point and the chosen axis. The meridional normal is a line passing through the surface point perpendicular to the tangent to the meridional curve at that point and lying in the meridional plane.

Note 2 to entry: Meridional curvature is in general not a normal curvature. It is the curvature of the corneal meridian at a point on a surface.

Note 3 to entry: 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 1 to entry: Eccentricity ranges from zero to positive infinity for the group of conic sections. In order to signify use of an oblate ellipse, $e$ is sometimes given a negative sign that is not used in computations. Otherwise, use of the prolate ellipse is assumed. See Table 1.

**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* (3.6)

**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