ANSI Z80.23-2018

American National Standard

for Ophthalmics –

Corneal Topography and Tomography Systems – Standard Terminology, Requirements

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Approved American National Standard

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Contents

Page

Tables

Figures

Annexes

Foreword (This foreword is not part of American National Standard ANSI Z80.23-2018.)

This American National Standard continues to address the expressed needs of those members of the ophthalmic community who use corneal topography in clinical settings, those who manufacture corneal topographers and those who teach others in the use of the information collected by corneal topographers. In particular, there continues to be a need for standardization of the terms and definitions used in the field, for standardization of the methods used for characterizing the performance of these instruments and for standardization of displays of corneal topographical information. The experts who worked together to initially create this standard felt that, at the time, there was not sufficient consensus within the ophthalmic community to set performance requirements for these instruments beyond those for minimum area measured and measurement sample density. Later, in working with international experts in the field, it was decided that instruments should be tested on a selected set of test surfaces to ensure that the calibration to set their scale factors had been done correctly. The standard continues to address standardization of the methods for testing these instruments, for assessing their performance, and for reporting the results thus obtained.

The number and type of test surfaces to be used has been changed to include only test surfaces for which the results can be verified. When these surfaces are tilted or rotated the expected surface measurements are easy to predict. These surfaces were considered to be adequate as minimum verification surfaces for corneal topographers; if a corneal topography system can measure these surfaces well, it will be a clinically useful instrument. The method for standardization of color maps has been changed in an effort to improve the user's ability to discern just-noticeable differences in corneal topography. The user always has the option of using a scale with less resolution but with greater range, as long as the scale recommended in this document is available to be used.

This standard contains four annexes. Annex A is informative and is not considered part of this standard. Annexes B through D are normative and are considered part of this standard.

This standard was created by a special working group created by the Z80 Subcommittee on Ophthalmic Instruments and included experts in the field of corneal topography from the clinical, manufacturing and academic areas of the ophthalmic community. Suggestions for improvement of this standard will be welcome. They should be sent to the Vision Council, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmics, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z80 Committee had the following members:

Carl Tubbs, M.D., Chairman
Neal Roche, Vice-Chairman
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
Advanced Medical Technology Association	Michael Pfleger
American Academy of Ophthalmology	Carl Tubbs
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Sunglass Association of America	Tibor Gross
The Vision Council	Michael Vitale
ISO TC 172/SC7	Michael Vitale

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Ralph Stone

The members of the subcommittee on Ophthalmic Instruments who contributed to this standard are:

Charles E. Campbell, Chair
William L. Brown, O.D., Ph.D,
Karl Citek, O.D. Ph.D.
Bruce Drum, Ph.D.
Stephen Farrer
Stephen Kylce, Ph.D.
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David Sliney, Ph.D.
Robert Rosenberg, O.D.

American National Standard
for Ophthalmics –

Corneal Topography and Tomography Systems – Standard Terminology, Requirements

1 Scope and purpose

1.1 Scope

This American National Standard applies to instruments, systems and methods that are intended to measure the shape of the cornea of the human eye over a majority of its area. The measurements of the anterior and/or posterior surface in local areas may be of curvature and/or three dimensional topographical measurements of the surface. The measurements may be used to derive more global parameters used to characterize the surfaces. Instruments classified as ophthalmometers or keratometers are not covered by this standard.

1.2 Purpose

This standard defines certain terms that are peculiar 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 standard sets forth minimum requirements for instruments and systems that fall into the class of corneal topographers.

This standard sets forth tests and verification procedures that will verify that a system or instrument complies with the standard and so qualifies as a corneal topographer or corneal tomographer in the meaning of this standard.

This standard sets forth certain tests and verification procedures that will allow the verification of capabilities of systems that are beyond the minimum required for corneal topographers or corneal tomographers.

2 Normative references

The following standard contains provisions that, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

ANSI Z80.20-2004, *Ophthalmics – Contact Lenses – Standard terminology, tolerances, measurements and physicochemical properties*[1)]

ANSI Z80.28-2017, *Ophthalmic Instruments – Methods for reporting optical aberrations of eyes*[1)]

ISO 8429:1986, *Optics and optical instruments – Ophthalmology – Gradual dial scale*[1)]

[1)] For electronic copies of some standards, visit ANSI's Electronic Standards Store (ESS) at www.ansi.org. For printed versions of all these standards, contact Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112-5704, (800) 854-7179.

ISO 10110-12:1997, *Optics and optical instruments – Preparation of drawings for optical elements and systems – Part 12: Aspheric surfaces*[1)]

ISO 15004-1:2006, *Optics and Optical Instruments – Ophthalmic instruments – Fundamental requirements and test methods*[1)]

IEC 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for safety*[1)]

Foley JD, van Dam A, Finer SK, et al. *Fundamentals of Interactive Computer Graphics*. Addison-Wesley, Reading, MA, 1990

3 Terminology

3.1 corneal apex: The location on the corneal surface, of a normal cornea, where the mean of the local principal curvatures is greatest.

3.2 corneal eccentricity (*e*): The eccentricity (*e*) of the ellipse that best fits the corneal meridian of interest (see 3.9). 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): The curve created by the intersection of corneal surface and a plane that contains the CT axis. A meridian is identified by the angle, θ, that the plane creating it makes to the horizontal as described by ISO 8429. The value of θ, for a full meridian, takes values from 0 to 180 degrees.

3.3.1 corneal semi-meridian: The portion of a full meridian extending from the CT axis toward the periphery in one direction. The value of θ for a semi-meridian takes values from 0 to 360 degrees.

3.4 corneal shape factor (*E*): A value that specifies the asphericity and type (prolate or oblate) of conic section that best fits a corneal meridian. Unless otherwise specified, it refers to the meridian with least curvature (flattest meridian) (see Table 1 and Annex A).

$$E = 1 - p$$

NOTE - The negative of *E* is defined by ISO 10110-12, Part 12: Aspheric surfaces, as the conic constant designated by symbol K. The negative of *E* has also been called asphericity and given the symbol Q.

3.5 corneal topographer: An instrument or system that measures features of the corneal surface of living human eyes in a noninvasive manner by using reflected images from the precorneal tear film.

Such an instrument is also referred to as a *videokeratographer*.

3.5.1 Placido ring corneal topographer: A corneal topographer that measures the corneal surface by analyzing the image reflected from the precorneal tear film of a Placido ring target.

3.5.2 grid-based corneal topographer: A corneal topographer that measure the corneal surface by analyzing the image(s) of a grid target reflected from the precorneal tear film.

NOTE - Such a grid could be a grid of illuminated points, a grid of illuminated, intersecting lines or a tiling pattern of small illuminated surfaces that are reflected from the precorneal tear film.

3.6 corneal tomographer: An instrument or system that measures the features of the anterior corneal surface and, for some instruments, of the posterior corneal surface of living human eyes in a noninvasive manner by measuring the height of the surface(s) at measured locations.

3.6.1 optical sectioning corneal tomographer: An instrument that measures the corneal surfaces by analyzing multiple optical sections of the cornea

3.6.2 luminous surface corneal tomographer: An instrument that measures the corneal surface using light back scattered from a target projected onto the precorneal tear film or the corneal anterior tissue surface. Back scattering is usually introduced in these optically clear substances by the addition of a fluorescent material into the precorneal tear film.

3.6.3 interferometric corneal tomographer: An instrument that measures the height of the corneal surface(s) at measured locations by using interferometry, such as an optical coherence tomographer.

3.7 corneal topographer axis (CT axis): A line parallel to the instrument optical axis and often coincident with it, that serves as one of the coordinate axes used to describe and define the corneal shape.

3.8 corneal vertex: The point of tangency of a plane perpendicular to the CT axis with the corneal surface (see figure 2).

3.9 curvature

NOTE - For the purposes of this standard, the units of curvature are mm^{-1}.

3.9.1 axial curvature (*K_a*): The reciprocal of the distance from a surface point to the CT axis along the corneal meridian normal at the point (see figure 1). K_a is defined by the equation:

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

K_a is also, and equivalently, defined as the average of the value of the meridional curvature from the corneal vertex to the meridional point and given by the equation:

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

where

x is the radial position variable on the meridian

x_p is the radial position at which K_a is evaluated.

3.9.2 Gaussian curvature: The product of the two principal normal curvature values at a surface location.

NOTE - Gaussian curvature has units of inverse millimeters squared.

3.9.3 meridional curvature (*K_m*): Local surface curvature measured in the meridional plane. Meridional curvature is in general a non-normal or oblique curvature. It is the curvature of the corneal meridian at a surface point. K_m is also defined by the equation:

$$K_{\mathrm{m}} = \frac{\partial^2 M(x)/\partial x^2}{\left(1+\left(\partial M(x)/\partial x\right)^2\right)^{3/2}}$$

where

$M(x)$ is a function giving the elevation of the meridian at any perpendicular distance, *x*, from the CT axis (see figure 1).

3.9.4 normal curvature: The curvature at a surface location of the curve created by the intersection of the surface with any plane containing the local surface normal.

3.9.4.1 mean curvature: The arithmetic average of the principal curvatures at a surface location.

3.9.4.2 principal curvature: The maximum or minimum normal curvature at a surface location.

3.10 eccentricity (*e*): A 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 (see table 1). Eccentricity ranges from zero to positive infinity for the group of conic sections:

Circle (e=0); ellipse($0<e<1$); parabola (e=1); and hyperbola ($e>1$).

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.

3.11 elevation: The distance between the corneal surface and a defined reference surface, measured in a defined direction from a specified position.

3.11.1 axial elevation: The elevation as measured from a selected point on the corneal surface in a direction parallel to the CT axis.

3.11.2 normal elevation: The elevation as measured from a selected point on the corneal surface in a direction along the normal to the corneal surface at the point.

3.11.3 reference normal elevation: The elevation as measured from a selected point on the corneal surface in a direction along the normal to the reference surface.

3.12 keratometric constant: The value 337.5 used to convert corneal curvature from inverse millimeters (mm^{-1}) to keratometric diopters.

3.13 keratometric diopters: Curvature, in inverse millimeters (mm^{-1}), multiplied by the keratometric constant, 337.5.

3.14 meridional plane: The plane that includes the surface point and the chosen axis.

3.15 normal

3.15.1 surface normal: A line passing through a surface location perpendicular to the plane tangent to the surface at that location.

3.15.2 meridian normal: A line passing through a surface location, perpendicular to the tangent to the meridian curve at the location and lying in the plane creating the meridian.

3.16 conic parameter (*p*): A number that specifies a conic section such as an ellipse, a hyperbola or a parabola. (See table 1.) With a conic section given in the form:

$$\frac{z^2}{b^2}+\frac{x^2}{a^2}=1 \qquad \textbf{an ellipse}$$

or

$$\frac{z^2}{b^2}-\frac{x^2}{a^2}=1 \qquad \textbf{a hyperbola}$$

the conic parameter is defined by:

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

$$E=1-p$$

where

a and b are constants
+ indicates an ellipse
- indicates a hyperbola

The conic parameter of a parabola is zero.

3.17 placido ring target: A target used in corneal topographers consisting of multiple concentric rings. Each individual ring lies in a plane; however, the rings are not in general coplanar.

3.18 radius of curvature: The inverse of the curvature. The units of radius of curvature, for the purpose of this standard, are millimeters.

3.18.1 axial radius of curvature (r_a): The distance from a surface point, P, to the axis along the corneal meridian normal at the point (see figure 1). r_a is also defined by the equation:

$$r_a=\frac{x}{\sin\Phi(x)}$$

where

x is the perpendicular distance from the axis to the meridian location millimeters

$\phi(x)$ is the angle between the axis and the meridian normal at location *x*

3.18.2 meridional radius of curvature (r_m): $r_m = 1/K_m$ (see figure 1).

3.19 surface

3.19.1 aspheric surface: A nonspherical surface. For corneal topography, a surface with at least one principal meridian that is a noncircular section. For ophthalmic lenses, an axisymmetrical surface.

3.19.2 atoric surface: A surface having mutually perpendicular principal meridians of unequal curvature where at least one principal meridian is a noncircular section. These surfaces are symmetrical with respect to both principal meridians.

3.19.3 oblate surface: A surface whose curvature increases as the location on the surface moves from a central position to a peripheral position in all meridians.

3.19.4 prolate surface: A surface whose curvature decreases as the location on the surface moves from a central position to a peripheral position in all meridians.

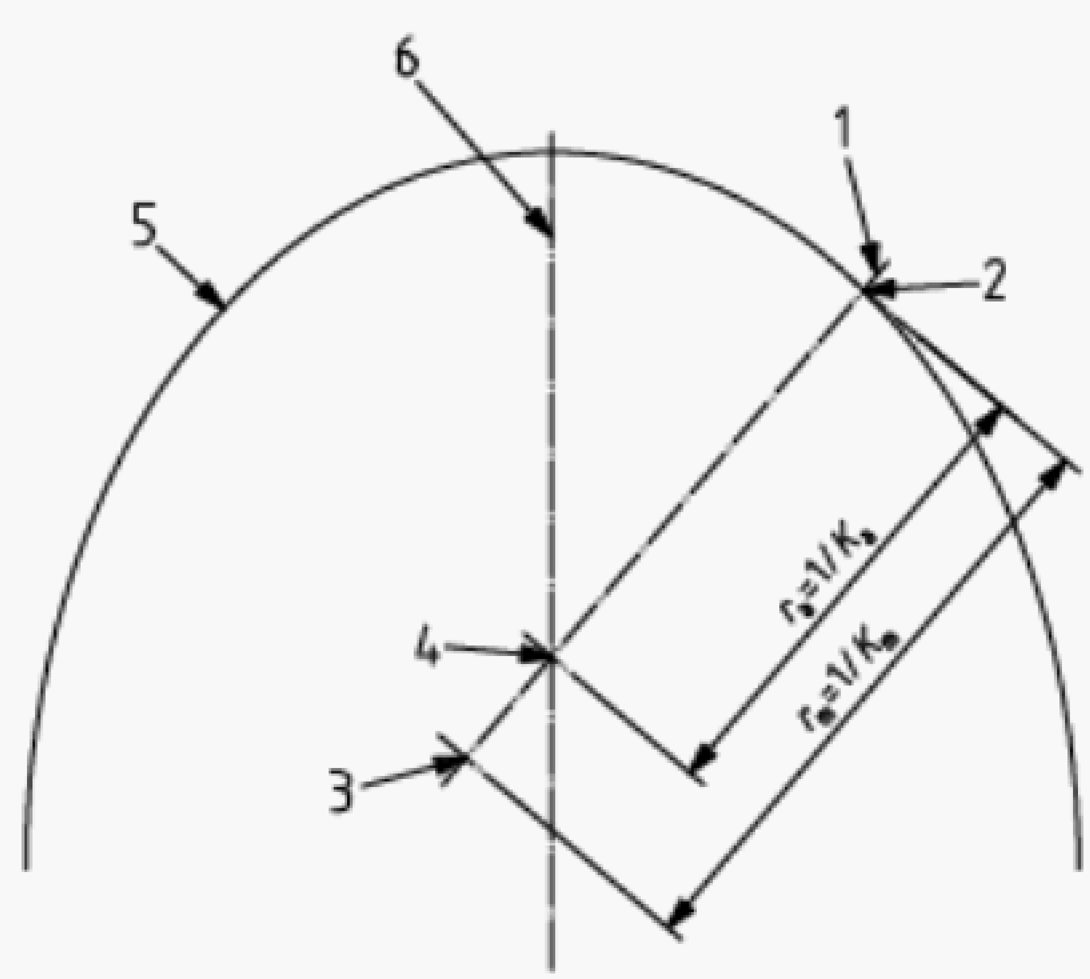
3.19.5 reference surface: A surface that can be described in an exact, preferably mathematical fashion, used as a reference from which distance measurements are made to the measured corneal surface. In addition to its mathematical description, the positional relationship of the reference surface to the corneal surface shall be specified. For instance, a reference surface might be described as the sphere that is the best least squares fit to the measured corneal surface. Likewise, a plane could serve as a reference surface.

3.19.6 toric surface: A surface for which the principal curvatures are unequal and for which principle meridians are circular sections. Such surfaces are said to exhibit central astigmatism.

3.20 surface height: The distance measured from a surface location to a reference plane perpendicular to the CT axis. Often this reference plane is chosen to be the plane tangent to the corneal vertex (see figure 2)

3.21 toricity: The difference in principal curvatures at a specified point or local area on a surface.

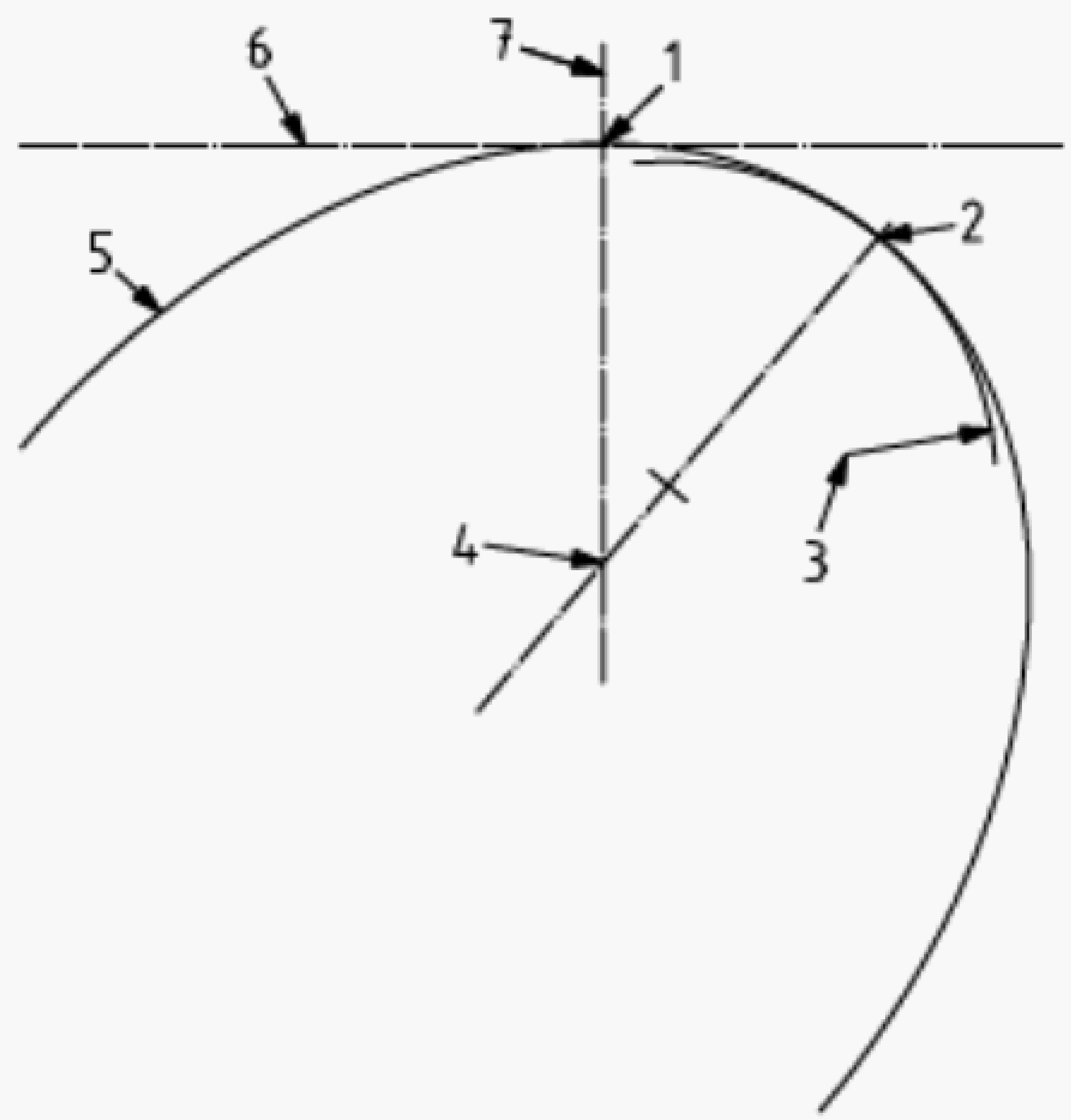
3.22 transverse plane: The plane perpendicular to the meridional plane that includes the normal to the surface point.



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 1 – Illustration of axial curvature, K_a, axial radius of curvature, r_a, meridional curvature, K_m, and meridional radius of curvature, r_m



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 2 – Illustration of the corneal vertex and the apex

Table 1 – Conic section descriptors

Conic Section	Conic Parameter, *p*	Corneal Shape Factor, *E*	Eccentricity, *e*
hyperbola	$p < 0$	$E > 1$	$e > 1$
parabola	0.0	1.0	1.0
prolate ellipse	$1 > p > 0$	$0 < E < 1$	*$0 < e < 1$
sphere	1.0	0.0	0.0
oblate ellipse	$p > 1$	$E < 0$	*$0 < e < 1$

* The eccentricity (*e*) does not distinguish between prolate and oblate orientations of an ellipse (see 3.9 and Annex A).

4 Requirements

Corneal topographers and corneal tomographers complying with this standard shall meet the requirements of 4.1 and 4.2.

4.1 Area measured

When measuring an 8-mm spherical surface (i.e., 8-mm radius of curvature), a corneal topographer or tomographer shall directly measure locations on the surface whose radial distance from the corneal vertex is at least 3.75 mm. If the maximum area covered by a corneal topographer or tomographer is reported, it shall be reported as the maximum radial distance from the corneal vertex sampled on this 8-mm 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

When the performance of a corneal topographer or tomographer for the measurement of either curvature or elevation is assessed and 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 done in accordance with 5.4.

5 Test methods and test devices

Corneal measurements made with corneal topography and corneal tomography systems collect data from a large portion of the corneal surface and consist of thousands of individual measurements. Each measurement is associated with a surface location and, when repeated measurements are made, some alignment variability will always exist. This is especially true for human corneas as opposed to test surfaces. While this does not affect the overall validity of measurements, it does mean that the same identical points are not measured from one measurement to the next. Therefore, it is best to use a method of analysis that will not overly penalize local, random error but will give an overall measure of system performance. It is possible and practical to align the system as identically as possible between repeated measurements and then treat the entire measurement (or specified parts of it) as an ensemble and find measures of mean error and standard deviation for the ensemble. Such measures will be used herein to assess corneal topography system performance.

5.1 Types of test

5.1.1 Accuracy

An accuracy test shall be conducted by measuring a test surface specified in 5.2 using the method specified in 5.3.1 and analyzing the measured data using the method specified in 5.4. An accuracy test tests the ability of a corneal topography or tomography system to measure the elevation and curvature of a test surface at known locations.

5.1.2 Repeatability

A repeatability test shall be conducted by measuring human corneas as specified by 5.3.2 and analyzing the measured values using the method specified in 5.4. A repeatability test assesses

the ability of corneal topography or tomography system to report the same measured values at similar locations for a human cornea when these measurements are taken close together in time.

5.2 Test surfaces

5.2.1 Reflection-based systems

The test surfaces shall be constructed of glass or of optical grade plastic, such as polymethyl-methacrylate. The surfaces shall be optically smooth. The back of the surfaces shall be blackened to remove unwanted reflections.

5.2.2 Luminous surface systems

The test surfaces shall be constructed of optical grade plastic, such as polymethylmethacrylate, impregnated with fluorescent molecules. The surfaces shall be optically smooth. The back of the surfaces shall be blackened to remove unwanted reflections.

5.2.3 Optical sectioning systems

The test surfaces shall be constructed of glass or of optical grade plastic, such as polymethyl-methacrylate. If desired, the bulk material of which the surface is formed may be altered to produce a limited amount of bulk optical scattering to assist in the measurement process. The surfaces shall be optically smooth.

NOTE 1 – The back of the surfaces should not be blackened to remove unwanted reflections.

NOTE 2 – If necessary, test surfaces for use in establishing the repeatability of measurements may be constructed as meniscus shells.

5.2.4 Interference-based systems

The test surfaces shall be meniscus shells with optically smooth surfaces made of optical-grade plastic, such as polymethylmethacrylate, with central thickness similar to that of human corneas.

For interference-based systems that claim to measure the posterior corneal surface and the local thickness of the cornea, meniscus shells with radii of curvature 0.82, the radii of curvature given in table 2, and central thickness similar to human corneas shall be used.

5.2.5 Specification of test surfaces

The curvature and elevation values of a test surface shall be given in the form of continuous mathematical expressions along with the specification of the appropriate coordinate system for these expressions. This ensures that the values for curvature or elevation can be obtained for any given position on the surface and that this can be done if there is a specified translation or rotation of the given coordinate system. This requirement is necessary as in use, in accordance with the requirements of 5.3.1 and 5.4, the position coordinates needed to find the parameter values will result from measurements by the corneal topography or tomography system under test and so can take any value within the range of the instrument.

The specification of test surface shall include tolerance limits on curvature, expressed as a tolerance on radius of curvature given in millimeters and tolerance limits on elevation given in micrometers.

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The specification of test surface shall include tolerance limits on curvature, expressed as a tolerance on radius of curvature given in millimeters and tolerance limits on elevation given in micrometers.

the ability of corneal topography or tomography system to report the same measured values at similar locations for a human cornea when these measurements are taken close together in time.

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5.2.1 Reflection-based systems

The test surfaces shall be constructed of glass or of optical grade plastic, such as polymethylmethacrylate. The surfaces shall be optically smooth. The back of the surfaces shall be blackened to remove unwanted reflections.

5.2.2 Luminous surface systems

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For interference-based systems that claim to measure the posterior corneal surface and the local thickness of the cornea, meniscus shells with radii of curvature 0.82, the radii of curvature given in table 2, and central thickness similar to human corneas shall be used.

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