for Ophthalmics –

Corneal Topography Systems – Standard Terminology, Requirements

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Approved American National Standard

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American National Standard
for Ophthalmics –

Corneal Topography Systems – Standard Terminology, Requirements

Secretariat
The Vision Council

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American National Standard

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Contents

Foreword (This foreword is not part of American National Standard ANSI Z80.23-2008 (R2013).

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 regarding 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 create this standard felt that at this time there is not sufficient consensus within the ophthalmic community to set performance requirements for these instruments beyond those for minimum area measured and measurement sample density. 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 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.

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

Suggestions for improvement of this standard will be welcome. They should be sent to the Vision Council, 225 Reinekers Lane, 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:

Organization Represented	*Name of Representative*
American Academy of Ophthalmology	Thomas C. White Gerhard Cibis (Alt.) Norman Lanphear (Alt.) Paul F. Vinger (Alt.)
American Academy of Optometry	David S. Loshin
American Ceramic Society	Lyle Rubin Herbert Hoover (Alt.)
American Glaucoma Society	Steven J. Gedde Douglas J. Rhee (Alt.)
American Optometric Association	William L. Brown William J. Benjamin (Alt.) Robert Rosenberg (Alt.) Jeffrey Weaver (Alt.)
American Society of Cataract and Refractive Surgery	Stephen Klyce Jack T. Holladay (Alt.) Stephen H. Johnson (Alt.)
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National Association of Optometrists & Opticians	Franklin D. Rozak Joe Dezenzo (Alt.)
Optical Laboratories Association	Daniel Torgersen Gregory S. Jacobs (Alt.) Susie Lesher (Alt.) Jonathan Schwartz (Alt.)
Optical Society of America	(Representation Vacant)
Opticians Association of America	Tom Hicks Catherine Langley (Alt.)
Prevent Blindness	Christine Bradley Jeff Todd (Alt.)
Sunglass Association of America	Kenneth L. Frederick Scott Macguffie (Alt.) Rick Van Arnam (Alt.)
US Leader to ISO TC 172/SC7	Charles E. Campbell
Vision Council of America	Jeff Endres Ken Wood (Alt.) Steve Drake (Alt.) Neil Roche (Alt.) Dick Whitney (Alt.)

The subcommittee on Ophthalmic Instruments, which developed this standard, had the following members:

William L. Brown, O. D., Ph.D, Chairman

Charles E. Campbell
Robert Landry
David Loshin
Robert Rosenberg
Thomas White

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 central anterior surfacecentral area. The measurements may be of the curvature of the anterior and/or posterior surfaces in local areas, three dimensional topographical measurements of the surface may be of curvature and/or elevation. The measurements may be used to derive more global parameters used to characterize the surfaces. or other more global parameters used to characterize the surface. Instruments classified as ophthalmometers or keratometers are not covered by this standard.

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1.2 Purpose

This standard defines certain terms that are peculiar to the characterization ofcharacterize 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 and tomographers.

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 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.

urements and physicochemical properties

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 Z80.20-1998, *Ophthalmics – Contact Lenses – Standard terminology, tolerances, meas-*[1)]

ANSI Z80.28- 2004,

Ophthalmic Instruments – Methods for reporting optical aberrations of eyes [1)]

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

[1)] For printed versions of all these standards, contact Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112-5704, (800) 854-7179.

For electronic copies of some standards, visit ANSI's Electronic Standards Store (ESS) at www.ansi.org.

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

ISO 15004:1998, *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 tomographer: An instrument or system that measures elevation of the corneal surfaces.

3.5.1 optical sectioning corneal to~~p~~mographer: An instrument ~~corneal topographer~~ that measures the corneal surface by analyzing multiple optical sections of that surface.

~~**3.5.4**~~**3.5.2** **luminous surface corneal to~~p~~mographer:** An ~~corneal topographer~~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.

3.5.3 interferometric corneal tomographer: An instrument that measures corneal surface elevations using interferometry, such as an optical coherence tomographer.

3.56

corneal topographer: An instrument or system that measures ~~features~~ curvatures of the corneal Surfaces using reflected images. ~~of living human eyes in a noninvasive manner~~.

~~A corneal topographer that uses a video camera system and video image processing to measure the corneal surface by analyzing 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:** A corneal topographer that measures the corneal surface by analyzing multiple optical sections of that surface.~~

3.5.12 grid-based corneal topographer: A corneal topographer that measures the corneal surface by analyzing the image(s) of a grid target reflected from the corneal surface(s).

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

~~**3.5.3 reflection-based corneal topographer:** A corneal topographer that measures the corneal surface using light reflected from the air – precorneal tear film interface.~~

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~~**3.5.4 luminous surface corneal topographer:** A corneal topographer 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 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.

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

3.8 curvature

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

3.8.1 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.

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

NOTE - Gaussian curvature has units of inverse millimeters squared.

3.8.3 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:

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

where

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

3.8.4 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.

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

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

3.9 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.

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

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

3.10.2 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.

3.10.3 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.

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

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

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

3.14 normal

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

3.14.2 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.

3.15 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:

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

or

$$\frac{z^2}{b^2} + \frac{x^2}{a^2} = 1$$ **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.

3.16 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.

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

3.17.1 axial radius of curvature (r_a): The distance from a surface point, P, to the axis along th e 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

φ(x) is the angle between the axis and the meridian normal at location x

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

3.18 surface

3.18.1 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.

3.18.2 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.

3.18.3 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.

3.18.4 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.

3.18.5 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 refer-

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ence 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.

3.18.6 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.

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

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

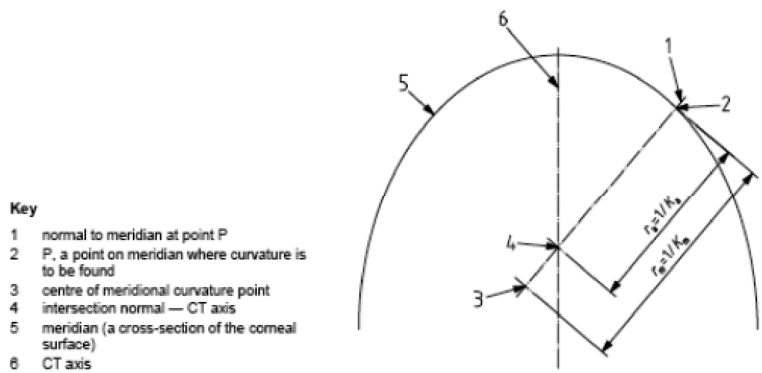
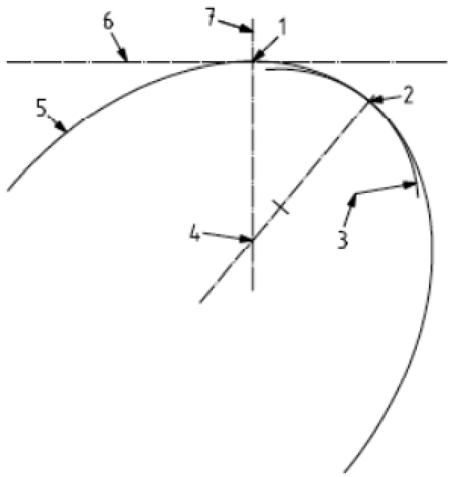


Figure 1 – Illustration of axial curvature, K_a, axial radius of curvature, r_a, meridional curvature, K_m, and meridional radius of curvature, r_m



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

Table1 – 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 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 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 is reported, it shall be repo rt-
ed 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 sufficie nt
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 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 systems collect data from a major 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. (IS THIS THE BEST WAY TO TEST THE REAL WORLD PERFORMANCE?)
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 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 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 except for systems that use reflections from the back surface of the cornea.

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

~~Specification of test surfaces~~

5.5 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 val-
ues will result from measurements by the corneal topography 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 microm-
eters.

NOTE – Specifications for various test surfaces that have been judged to be useful for the assessment of the performance of cornea topographers are given in Annex A.

5.2.5 Verification of test surfaces

Test surfaces used in accordance with 5.3 shall be verified to conform to their specification given in accordance with 5.2.4 within the limits specified in accordance with 5.2.4. Verification of elevation may be done either

a) by direct measure of the surface using profilimetry of precision at least twice that of the tolerance at a sample density at least that specified for the instrument by 4.2, or

b) by transference methods using a verified master surface and a measurement device of sufficient precision so that measurement differences of the master surface may be used to correct measured values of the tested surface.

Verification of curvature may be done either:

a) by mathematical calculation from verified elevation values, or

b) by direct physical measurement of curvature with a method of precision twice that of the specified tolerance limits.

5.2.6 Type testing using test surfaces

When the performance of a corneal topographer for the measurement of either curvature or elevation is assessed and reported, the following type testing shall be done.

Five test surfaces as defined in table 2 shall be type tested with every model of corneal topographer (CT) for which performance is to reported.

The CT may be marked as A or B according to the achieved tolerance level (see table 3) that is valid for the five test surfaces listed in table 2.

Surface (4) of table 2 shall be oriented for testing in the following two positions:

1) the axis of rotation of the surface parallel to the optical axis of the corneal topographer
2) the axis of rotation of the surface aligned tilted at 5 degrees from the optical axis of the corneal topographer in the 270 degree meridian.

	Surface	**Radius of Curvature + tolerance**	*e*	**Diameter**
1)	sphere	6.50 mm - 0.2 mm/+0.0 mm accuracy ± 1 µm		≥ 10 mm
2)	sphere	8.00 mm - 0.2 mm/+0.0 mm accuracy ± 1 µm		≥ 10 mm
3)	sphere	9.00 mm - 0.2 mm/+0.0 mm accuracy ± 1 µm		≥ 10 mm
4)	ellipsoid of revolution	radius of curvature: r_0 = 7.8 mm - 0.3 mm/+0.0 mm accuracy ± 1 µm	0.6 - 0.1	≥ 10 mm
5)	toric	r_1 = 8.0 mm ± 0.2 mm $r_2 > r_1$ $r_1 - r_2$ = 0.4 ± 0.07 mm accuracy ± 1 µm		≥ 10 mm
NOTE 1 Surface (1): Verification measurement is possible with a micrometer unit. NOTE 2 Surfaces (2) and (3): An ellipsoid and toric shape can be manufactured by contact lens company and measured with a 3D-coordinate measuring device.				

Table 2 – Test surfaces for type testing

Table 3 – Tolerance levels for test surface measurements

Tolerances if measurements are expressed in terms of curvature in keratometric diopters

Measuring accuracy	Type	Area		
		center diameter	middle diameter	outer diameter
Twice the standard deviation	A	0.27	0.16	0.16
Twice the standard deviation	B	0.52	0.37	0.37

Tolerances if measurements are expressed in terms of radius of curvature in millimeters

Measuring accuracy	Type	Area		
		center diameter	middle diameter	outer diameter
Twice the standard deviation	A	0.05	0.03	0.03
Twice the standard deviation	B	0.1	0.07	0.07

NOTE – Keratometric diopters are related to radius of curvature given in millimeters by: keratometric diopters = 337.5/radius of curvature.

5.3 Data collection

5.3.1 Test surfaces

Align the test surface to the instrument in the manner specified by the manufacturer of the system for measuring human eyes. Measure the surface and save the measured data. At each measured point, the data set consists of the value of the measured variable and the two-dimensional position of the measurement.

5.3.2 Human corneas

Align the instrument to the eye in the manner specified by the manufacturer of the system. Measure the corneal surface and save the measured data. At each measured point, the data set consists of the value of the measured variable and the two-dimensional position of the measurement.

Move the corneal topographer with respect to the eye and then recenter it. Take a second measurement and save the measured data.

5.4 Analysis of the data

The treatment of the corneal topographic data consists of a comparison between the measured values of two data sets. The structure of the data sets is slightly different for the analysis of accuracy and the analysis of repeatability, so they are given separately.

5.4.1 Structure of the accuracy data set

For the purpose of accuracy determination, one data set consists of the measured values and measurement locations from a measurement of a known test surface. The other data set consists of the known values of the test surface at the locations measured by the instrument and reported as part of the data set. The analysis of the paired sets of data is done in accordance with 5.4.3.

5.4.2 Structure of the repeatability data set

For the purpose of repeatability determination, a sample population of human corneas is chosen. Two measurements are taken on each cornea in the sample population, in close proximity in time, forming paired measurements. The ensemble of these paired measurements for the entire sample population comprise the data set. The measurement positions for a given cornea will generally not be identical and comparison is made between points that have the same nominal locations. The analysis of the paired sets of data is done in accordance with 5.4.3.

5.4.3 Analysis of the paired data sets

For each data set pair, a difference in measured values is taken. This gives rise to a data set of difference values, designated dD_{ijk}, for each measured point on the corneal surface. The indices i and j label the two data sets used. The index k labels the position of the individual points. The position is specified by two coordinate values that may be, for instance, the meridian θ and radial position x on which the point lies. The known values for the test surface are calculated from knowledge of its surface shape and the measured position.

The difference values, dD_{ijk}, are next grouped into subsets based on their position values. Each subset is associated with one of the measurement zones specified in table 4 and comprised of those data points whose positions are within that measurement zone.

Each subset of difference values is then treated as an ensemble. The mean values, M_{ij}, and standard deviations, SD_{ij}, are taken for an ensemble, where

$$dD_{ijk} = D_{ik} - D_{jk}$$

$$M_{ij} = \frac{1}{n}\sum_{k=1}^{n} w_k dD_{ijk}$$

$$SD_{ij} = \sqrt{\frac{\sum_{k=1}^{n}\left(w_k dD_{ijk} - M_{ij}\right)^2}{n-1}}$$

where

n k

i, j

is the number of measured points;

D_{ik}

are the indices specifying the two data sets;

M_{ij}

is the index specifying the point location;

is data value at point k, it can be a curvature value, a power value or an elevation value

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is the weighted ensemble difference mean for the data sets i and j;

SD_{ij} is the weighted standard deviation of the ensemble differences for the data sets i and j;

w_k is the area weighting value for position k as found using the method given in Annex C.

Table 4 – Analysis zones for accuracy and repeatability testing

Area
Central diameter =<3 mm
Middle 3 mm<diameter<= 6 mm
Outer diameter> 6 mm

5.4.3.1 Special considerations for the comparison of corneal elevation values

When corneal elevation data sets are to be compared in accordance with 5.4.2, a further step shall be included when processing the data. Since the cornea is a very highly curved surface, the elevation values in the periphery change quite rapidly with small changes in position. Thus, if there are small differences in the actual locations of nominally the same points in the two data sets, differences in the measured elevations values will be found even if the two surfaces are identical. Such small variations in measurement locations occur for all repeated measurements of the same eye. To remove this source of error, one of the two data sets to be compared is chosen as the *reference set*. Its location values are designated the reference locations. The other data set is designated the *interpolated set*. The data from this set is interpolated from its measured locations to the locations defined by the reference set. Following this interpolation step, the reference data set and the interpolated set are compared as indicated in 5.4.3.

It is also possible that the eye has moved with respect to the instrument coordinate system from the first to the second measurement. This introduces a different type of differencing error that is systematic in nature as all measurement locations are shifted a common amount between measurements. To remove this source of error the overall or common shift of the corneal surface from the first measurement to the second is found. One of the two data sets to be compared is then chosen as the *reference set*. Its location values are designated the reference locations. The other data set is designated the *interpolated set*. The data from this set is interpolated from its measured locations to these locations shifted by overall amount previously found. Following this interpolation step, the reference data set and the interpolated set are compared as indicated in 5.4.3.

Both types of location error shall be reduced using the method in Annex D, or equivalent, before the analysis of data using the method of 5.4.3 is performed.

5.4.4 Report of performance

The performance of a corneal topography system shall be described by reporting the following information:

5.4.4.1 Accuracy

a) specifications of test surface used

b) orientation of test surface with respect to the CT axis

c) mean difference for each zone in accordance with table 4

d) standard deviation of differences for each zone in accordance with table 4

5.4.4.2 Repeatability

a) number of eyes in the sample population

b) mean difference for the sample population for each zone in accordance with table 4

c) standard deviation of the differences for the sample population for each zone in accordance with table 4

6 Accompanying documents

The corneal topographer shall be accompanied by documents containing instructions for use together with maintenance procedures and their frequency of application. In particular, this information shall contain:

a) name and address of manufacturer

b) a list of accessories suitable for use with the corneal topographer

c) a reference to this American National Standard if the manufacturer claims compliance

d) any additional documents as specified in 6.8 of IEC 60601-1:2006

7 Marking

The corneal topographer shall be permanently marked with at least the following information:

a) name and address of manufacturer or supplier;

b) name and model of the corneal topographer

c) additional marking as required by IEC 60601-1:2006

Annex A
(informative)

Test surfaces for corneal topographers

A.1 General

This annex gives various test surfaces that have been judged to be useful for assessing the performance of corneal topographers. For each type of surface, a brief description is given along with its special applicability.

A.2 Spherical surfaces

Spherical surfaces are useful test objects for a variety of reasons. They have traditionally been used as test surfaces for keratometers and corneal topographers because they can be made and verified to extremely high precision. Their sphericity can be verified interferometrically and their absolute radius of curvature can be directly measured to submicron accuracy. They are useful for verifying the absolute scaling of a corneal topography system, for providing a standardized surface to measure system area coverage and for testing the sensitivity of a system to axial position (or defocus errors).

Spherical surfaces are easy to specify as they are defined by a single parameter, their radius of curvature. On the other hand, the lack of variables means that they cannot adequately assess all aspects of the performance of a corneal topography system and so must always be augmented by other more complex surfaces.

The three spherical surfaces specified in table 2 are chosen to be representative of the middle and the two extremes of the curvature of cornea found in the human population and hence the range expected for a corneal topography system.

A.3 Surfaces of revolution

Surfaces of revolution in which the generating arc is more complex than a circle are useful in that they can offer surfaces that present the corneal topography system with topographical situations more like those found in the human population than can spherical surfaces, yet they can be very precisely produced using high precision, numerically controlled lathes of the type used to manufacture contact lenses.

While these surfaces possess an axial symmetry that is seldom found in the human cornea, this symmetry can easily be broken in a controlled fashion by tipping the surface by a specified amount and in a specified direction from the CT axis of the instrument under test. As the surface can be completely described analytically with respect to its axis of symmetry, the values of either curvature or elevation can easily be found in the tipped coordinate system so that comparison can be directly made to measured values.

A.3.1 Ellipsoids of revolution

When the generating arc of a surface of revolution is an ellipse, an ellipsoid of revolution is the resulting surface. Such a surface is quite like many normal corneas and so is a useful surface to test the performance of a corneal topography system for this important case. In addition, such a surface has a continuous and exactly known rate of change of curvature with respect to position.

Hence, it is very useful to assess the ability of a corneal topography system to accurately map a surface with such behavior. When an ellipsoid of revolution is tipped, any axial symmetry that the system may have relied on to assist in the analysis of surfaces is broken and a fair test is given to the corneal topographer to measure a general, yet not too complex surface. Ellipsoids of revolution are not as easy to verify as are spheres, yet, because of the axial symmetry forced upon them by their method of generation, a limited number of meridians may be verified by profilimetry to ensure that the surface is indeed made as specified.

Ellipsoids of revolution are in the class of conics of revolution. They may be generated as either prolate or oblate surfaces. Both are useful test surfaces because while most human corneas are prolate surfaces, some corneas are found to be oblate.

Other members of this class are hyperboloids of revolution and parabolas of revolution. The hyperbola of revolution can be useful as a simulation of a keratoconic cornea in that such surfaces can be produced with a high apical curvature and with a proper choice of a conic constant, low curvature values in the periphery. When such a surface is presented to a corneal topographer in a tipped and rotated orientation, a situation simulating keratoconus is created with a surface whose surface parameters can be exactly calculated.

A.3.2 Higher order polynomial surfaces of revolution

Corneas that have undergone refractive surgery procedures are left with surface characteristics that cannot be adequately modeled by conics of revolution because they exhibit localized high variations in curvature in those areas known as transition zones. To test the ability of a corneal topographer to faithfully map such surfaces, surfaces of revolution with generating arcs consisting of higher order polynomial curves are useful. They can be manufactured using the same type of high-precision numerically controlled lathes used to generate the surfaces mentioned in 3.1. Because the generating arc is a polynomial function of order higher than 2, the second derivatives of the surface and hence the curvature is a continuous function of position that can be exactly calculated. The verification of such surfaces by profilimetry is no more complex a task than is that task of verifying a conic surface of revolution.

A.3.3 Multicurve composite surfaces with continuous first derivative

While higher order polynomial surfaces of revolution can be designed to test some of the special characteristics of refractive surgical cases, it is difficult to create annular bands with localized curvature quite different from surrounding areas using a single polynomial function for the entire generating arc. It is easier to create a surface of revolution comprised of sections of arc, with a smooth mathematical function, in which the sections are joined so that the first derivative of the composite generating arc is always a continuous function of position. Such surfaces do not exhibit continuous curvature at points where the sections of the arcs join.

If the sections of the composite generating arc are chosen to be circles, and the centers of some those circles lie on the axis of revolution, the resulting surface has associated areas that are spherical. This opens the possibility of verifying these areas interferometrically, a highly precise method that is not easily used for surfaces of revolution other than spheres.

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Annex B
(normative)

Standardized displays for corneal topographers

B.1 General

To facilitate the interpretation and comparison of corneal topographical results taken with different corneal topographer systems, this annex sets forth standardized displays that may be used by any corneal topographer. Specified are scale intervals, scale center value and color convention.
There is nothing in this standard to imply that displays using parameters different from these standardized ones may not be used by corneal topographers complying with this standard. However, if compliance with this standard is claimed, a corneal topographer shall make these displays available to the user and shall designate them as displays conforming to ANSI Z80.23.

B.2 Presentation

The following information shall be included in standardized maps;

- Step size (units)
- Color legend
- Map type
- Reference to ANSI Z80.23

B.3 Standardized scale and scale intervals

Standardized curvature maps shall use one of the three following corneal diopter intervals:

0.5 D
1.0 D
1.5 D

There shall be at least 21 but not more than 25 displayed intervals differentiated by color.
Central interval shall have a curvature value of 44 D.

Should the choice of dioptric interval and the measured curvature result in areas of the cornea where the value of curvature is greater than the highest interval or smaller than the lowest interval, those areas shall be displayed with the color assigned to highest interval or the lowest interval as appropriate.

Standardized elevation maps shall use one of the four following corneal elevation intervals:

2 microns
5 microns
10 microns
20 microns

There shall be at least 21, but not more than 25, displayed intervals differentiated by color. Central interval shall have an elevation value of 0.0 microns. However, if the reference surface is found by a best-fit technique, then the “elevation” values should represent the variation of the measured surface from the best-fit surface.

Should the choice of elevation interval and measured elevation result in areas of the cornea where the value of elevation is greater than the highest interval or smaller than the lowest interval, those areas shall be displayed with the color assigned to highest interval or the lowest interval as appropriate.

B.4 Standardized color scale

The fine and medium intervals standardized curvature maps shall use the color pallet given in table B.1.

Color pallet	Scale interval Keratometric diopters (D)	
	0.5	**1.0**
Red	49	54
Green	44	44
Blue	39	34

Table B.1 – Color pallet for the fine and medium intervals of standardized curvature maps

The hue shall be monotonically decreasing from green to red and shall be monotonically increasing from green to blue. (See clause 2 for Foley et al., 1990, for definition of hue.)

NOTE – It is recommended that the intermediate colors be chosen such that they are clearly discernable from their immediate neighbors for both the color monitor presentation and for printed presentation.

The expanded interval scale standardized curvature maps shall use the color pallet given in table B.2.

Table B.2 – Color pallet for the expanded interval scale of standardized curvature maps

Color name	sRGB			Hue, Brightness, Saturation (HBS)			Scale values: Keratometric diopters (D)
	R	G	B	H	B	S	
Pinkish white	255	238	248	325	7	100	67.5
Light pink	255	217	227	344	15	100	66
Light pink	255	197	207	350	23	100	64.5
Light pink	255	176	187	352	31	100	63
Pink	255	158	168	354	38	100	61.5
Pink	255	138	148	355	46	100	60
Med pink	255	115	125	356	55	100	58.5
Med pink	255	95	105	356	63	100	57
Dark pink	255	71	80	357	72	100	55.5
Dark pink	255	40	50	357	84	100	54
Red	255	0	0	0	100	100	52.5
Dark orange	255	102	0	24	100	100	51
Medium orange	252	153	0	36	100	100	49.5
Yellow gold	252	188	0	45	100	99	48
Yellow	255	255	0	60	80	100	46.5
Light green	162	250	59	88	76	98	45
Medium green	80	230	51	110	78	90	43.5
Dark green	51	204	51	120	75	80	42
Cyan green	32	176	72	137	82	69	40.5
Cyan blue	0	153	102	160	100	60	39
Blue	0	106	157	199	100	62	37.5
Medium blue	0	51	204	255	100	80	36
Dark blue	0	0	204	240	100	80	34.5
Dark blue	0	0	153	240	100	60	33
Dark blue	0	0	112	240	100	44	31.5
Dark blue	0	0	80	240	100	31	30

NOTE – These sRGB values were specifically chosen for an HDTV monitor with a gamma value of 2.2 and a color temperature of 6500 K. For other displays, slightly different settings may be needed to achieve the same HBS values.

Standardized elevation maps shall use the following color pallet:

Scale interval (microns)	2	5	10	20
Red	20	50	100	200
Green	0	0	0	0
Blue	−20	−50	−100	−200

The hue shall be monotonically decreasing from green to red and shall be monotonically increasing from green to blue. (See clause 2 for Foley et al., 1990, for definition of hue.)

Annex C
(normative)

Calculation of area weighting values

C.1 General

Area weighting of the data is used to ensure that the specific sampling distribution is equivalent to a uniform sampling distribution. If the data is collected over a square grid positional distribution, the area weighting values shall all be set equal to 1.0.

C.2 Area weighting values for polar coordinate distributions (Placido ring systems)

The area weighting value for each data point within a subset, w_k, shall be calculated as follows:

$$w_k = \frac{n r_k}{\sum_{k=1}^{n} r_k}$$

where

k is an index specifying measurement in the subset

n is the number of measurements in the subset area

r_k is the radial position of measurement k

C.3 Derivation of area weighting factor for polar coordinate distributions

To give measured values a weighting based on their area, a ratio is formed between the area associated with the measurement, ΔA_k, and the average area of measurement in the subset of measurements under consideration, $<\Delta A_k>$. Figure C.1 shows the geometry of the area associated with a measurement taken at radial position value r_k on a given meridian. It is assumed that the angle between meridians is constant so that the angle between the dotted meridians ($\Delta\theta$) associated with point k is the same for all measured points. These meridians form two of the boundaries of the area, ΔA_k. The other two boundaries are approximated by the radial positions midway between the mean radial positions, $<r_1>$ and $<r_3>$, for the rings on either side of the measured point. The distance between these two boundaries, Δr, is the value;

$$\Delta r = \frac{r_3 - r_1}{2}$$

It is assumed that this value is essentially constant throughout the subset area.

The distance between the other two boundaries is given by the value $r_k \Delta\theta$. So the value of ΔA_k is given by:

$$\Delta A_k = r_k \Delta\theta \Delta r$$

Since the value $\Delta\theta\Delta r$ is taken to be a constant over the subset area, the mean value of an are

a
associated with a measured point, $<\Delta A_k>$, is given by:

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$$\overline{\Delta A} = \frac{\sum_{k=1}^{n} \Delta A_k}{n} = \frac{\sum_{k=1}^{n} r_k \Delta\theta\Delta r}{n} = \Delta\theta\Delta r \frac{\sum_{k=1}^{n} r_k}{n}$$

Therefore the ratios between the area associated with measurement k and the average area for the subset area, w_k, is:

$$w_k = \frac{\Delta A_k}{\Delta A_k} = \frac{r_k \Delta\theta\Delta r}{\left(\sum_{k=1}^{n} r_k \Delta\theta\Delta r\right) / n} = \frac{n r_k}{\sum_{k=1}^{n} r_k}$$

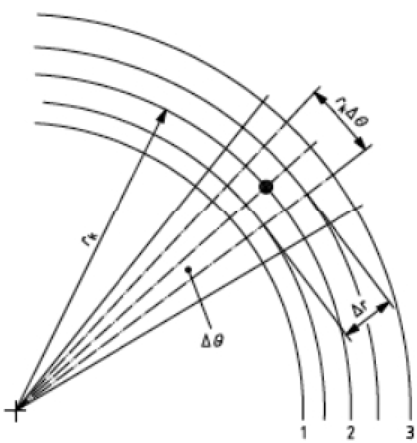

Figure C.1 - Geometry used to find area weighting factors for polar coordinate distribution s

Annex D
(normative)

Pre-processing of axial elevation data prior to analysis of paired data sets

D.1 Correction for de-centration

The first step in the correction for de-centration of a surface under measurement by the corneal topographer is to find amount of lateral translation of surface from the first measurement to the second. The major curvature component of the cornea is a spherical surface. When two spherical surfaces are de-centered with respect to one another and their elevation differences then taken, the difference takes the form of a tilted or prismatic surface. The amount of tilt is linearly proportional to the amount of de-centration, so once the tilt is found, the amount of de-centration may be found from it if the curvature of the surface is known.

These considerations allow the de-centration x and y values to be found as follows.

The difference of the axial elevation values of the two measurements is formed at each measured location. The difference values thus found are de-composed to obtain a set of Zernike polynomial coefficients to order 1 in accordance with ANSI Z80.28-2004. Axial elevation values of one of the measurements are de-composed to obtain a set of Zernike polynomial coefficients to order 2 in accordance with ANSI Z80.28-2004. The c_1^1 and c_1^{-1} coefficients from the difference values are combined with the c_2^0 coefficient from the surface and half the aperture diameter used in the Zernike de-composition, a, to find the horizontal, dx, and vertical dy de-centration values using the formulas:

$$dx = \frac{-a\, c_1^1}{2\sqrt{3}\, c_2^0} \quad \text{(D.1)}$$

$$dy = \frac{-a\, c_1^{-1}}{2\sqrt{3}\, c_2^0} \quad \text{(D.2)}$$

The elevation values from the surface measurement used to find c_2^0 are interpolated to new coordinate locations

$$x' = x - dx$$

$$y' = y - dy$$

When the coordinate system used is not a Cartesian system, such as polar coordinate system commonly used in Placido disk corneal topography system, the coordinates must be converted from polar to Cartesian form before the above procedure is applied.

D.2 Correction for different position grid locations

When the location grids of the paired measurements are not the same, as is commonly found in data from paired measurements using Placido disk systems, an apparent difference in elevation will be found due to the mismatch in sample location, especially in the periphery of the cornea, even when measurement error does not exist. Since Placido disk systems typically have fixed meridians, the difference in sample locations will typically only occur in the radial dimension.

This shall be corrected for each meridian either by (1) choosing the radial location values from one measurement on the meridian and interpolating the elevation data for the other measurement to the chosen radial locations, or (2) by forming the average radial locations for the meridian using the locations from both measurements and then interpolating both sets of radial values for that meridian to the average radial locations.