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BSI Standards Publication

Ophthalmic instruments — Corneal topographers

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National foreword

This British Standard is the UK implementation of EN ISO 19980:2021. It is identical to ISO 19980:2021. It supersedes BS EN ISO 19980:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/6, Ophthalmic instruments.

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European foreword

This document (EN ISO 19980:2021) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

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Endorsement notice

The text of ISO 19980:2021 has been approved by CEN as EN ISO 19980:2021 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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
θ
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 θ, that the plane creating it makes to the horizontal (see ISO 8429).

Note 2 to entry: The value of θ, 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):

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

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):

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

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):

$$\frac{z^2}{b^2} \pm \frac{x^2}{a^2} = 1 \tag{3}$$

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

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

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

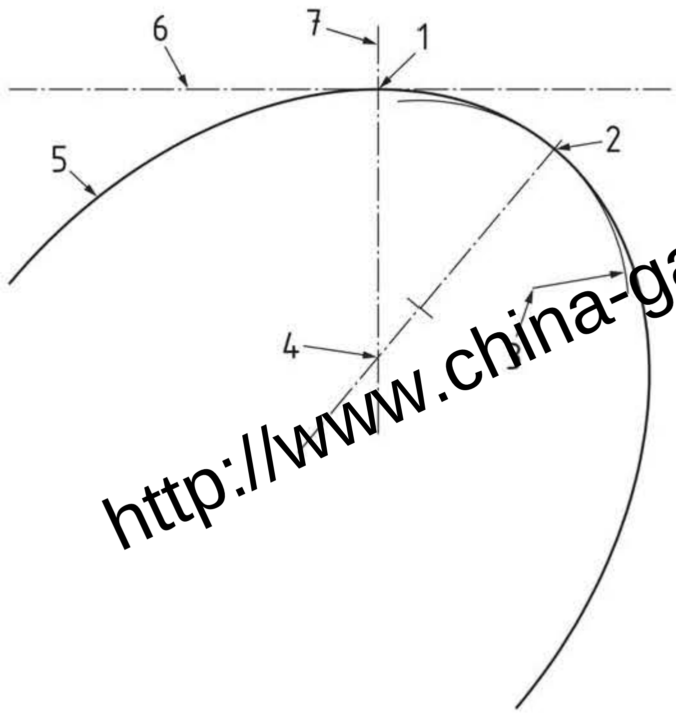
3.5.4
luminous surface corneal topographer
corneal topographer (3.5) that measures the corneal surface using light back-scattered from a target projected onto the pre-corneal tear film or the corneal anterior tissue surface

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):

$$K_a = \frac{1}{r_a} \tag{5}$$

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):

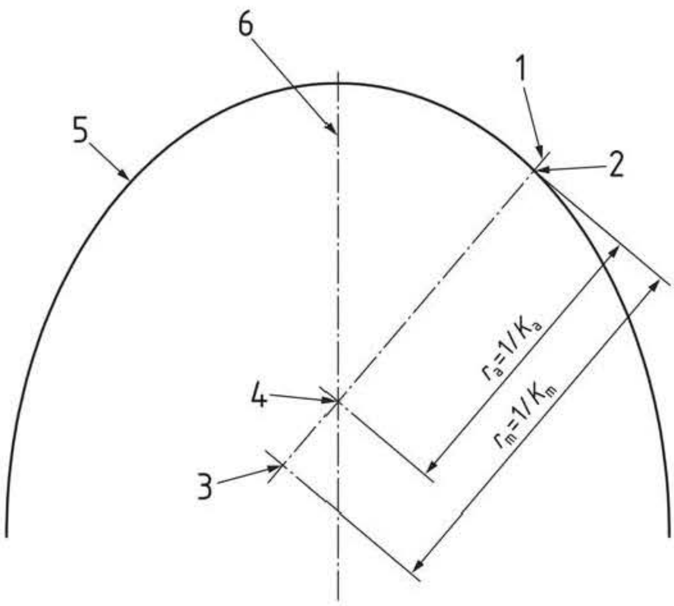
$$K_a = \frac{\int_0^{x_p} K_m(x)\,\mathrm{d}x}{x_p} \qquad (6)$$

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):

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

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

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
corneal power
refracting power of the cornea based on the radius of curvature of the front surface

Note 1 to entry: Corneal power is expressed in *keratometric dioptres* (3.12).

3.12
keratometric dioptres
unit of corneal power based on the radius of curvature of the front surface and the keratometric constant, 337,5, using Formula (8):

$$\text{keratometric dioptres} = 337{,}5/\text{radius of curvature} \tag{8}$$

Note 1 to entry: The radius of curvature is expressed in millimetres.

3.13
surface normal
line passing through a surface point of the surface perpendicular to the plane tangent to the surface at that point

3.14
ellipsoid of revolution
surface of revolution that results when the generating arc is non-circular

3.15
radius of curvature
reciprocal of the curvature

Note 1 to entry: The radius of curvature is expressed in millimetres.

3.15.1
axial radius of curvature
sagittal radius of curvature
r_a
distance from a surface point, P, to the axis along the normal to corneal meridian at that point, and defined by Formula (9):

$$r_a = \frac{x}{\sin \varphi(x)} \tag{9}$$

where

x	is the perpendicular distance from the axis to the meridian point, in millimetres;
$\varphi(x)$	is the angle between the axis and the meridian normal at point x.

Note 1 to entry: See Figure 2.

3.15.2
meridional radius of curvature
tangential radius of curvature
r_m
distance from a surface point, P, and the centre of the meridional curvature point, and defined by Formula (10):

$$r_m = \frac{1}{K_m} \tag{10}$$

Note 1 to entry: See Figure 2.

3.16 Surface

3.16.1
aspheric surface
non-spherical surface
surface with at least one principal meridian that is non-circular in cross-section, i.e., $e \neq 0$

3.16.2
atoric surface
surface having mutually perpendicular principal meridians of unequal curvature where at least one principal meridian is non-circular in cross-section

Note 1 to entry: Atoric surfaces are symmetrical with respect to both principal meridians.

3.16.3
oblate surface
surface whose curvature increases as the location on the surface moves from a central position to a peripheral position in all meridians

3.16.4
prolate surface
surface whose curvature decreases as the location on the surface moves from a central position to a peripheral position in all meridians

3.16.5
reference surface
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, and for which, in addition to the mathematical description, the positional relationship to the corneal surface is specified

Note 1 to entry: For instance, a reference surface might be described as a sphere that is the best least-squares fit to the measured corneal surface. Similarly, a plane could serve as a reference surface.

3.16.6
toric surface
surface for which the principal curvatures are unequal and for which principal meridians are circular sections

Note 1 to entry: Such surfaces are said to exhibit central astigmatism.

3.17
toricity
difference in principal curvatures at a specified point or local area on a surface

4 Requirements

4.1 Area measured

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

4.2 Measurement sample density

Within the area defined 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 CT 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 CT shall present the results according to the colour palette presented in Annex B.

5 Test methods and test devices

5.1 Tests

5.1.1 Accuracy test

An accuracy test shall be conducted by measuring a test surface specified in 5.2 using the method specified in 5.3 and analysing the measured data using the method specified in 5.4.

NOTE An accuracy test checks the ability of a corneal topography system to measure the absolute surface curvature of a known surface at known locations.

5.1.2 Repeatability test

A repeatability test shall be conducted in order to determine the topographer's performance in relation to human interface factors such as eye movements, accuracy and speed of alignment of the instrument on the eye and the time taken to complete a measurement.

This test shall be conducted *in vivo* on human eyes. See Annex D.

5.2 Test surfaces

5.2.1 Reflection-based and Placido ring corneal topographers

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 avoid unwanted reflections.

5.2.2 Luminous surface corneal topographer

The test surfaces shall be constructed of optical-grade plastic such as polymethylmethacrylate, impregnated with fluorescent molecules. The surfaces shall be optically smooth. Unwanted reflections shall be eliminated.

5.2.3 Optical-sectioning corneal topographer

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

Test surfaces used to establish measurement repeatability may be constructed as meniscus shells.

5.2.4 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 essential since, when in use, as required in 5.3 and 5.4, the position coordinates needed to find the parameter values will result from measurements made by the corneal topographer under test and can therefore take any value within the range of the instrument.

Specification of the test surface shall include tolerance limits on curvature, expressed as a tolerance on the radius of curvature given in millimetres, and tolerance limits on elevation given in micrometres.

NOTE Specifications for various test surfaces that have been judged to be useful for assessing the performance of CTs are given in Annex A.

5.2.5 Verification of test surfaces

Conformity to the specifications of 5.2.4 for test surfaces used in accordance with 5.3 shall be verified within the limits specified in 5.2.4. Verification of elevation may be done either:

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

b) by transference methods using a verified master surface and a measurement device of sufficient precision 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:

— by mathematical calculation from verified elevation values, or

— by direct physical measurement of the curvature using a method that has a precision of twice the specified tolerance limits.

5.2.6 Type testing of surfaces

Three sphere test surfaces (1, 2, 3) as defined in Table 2 shall be type-tested with every CT. The test ellipsoid surface (4) and the test surface with specific toricity (5) should be type-tested.

The CT should be marked A or B according to the achieved tolerance level (see Table 3) valid for the three sphere test surfaces mentioned in Table 2.

Table 2 — Test surfaces for type testing

	Surface	Radius of curvature	Eccentricity e	Diameter
1)	sphere	$6,50^{+0,0}_{-0,2}$ mm		≥ 10 mm
2)	sphere	$\left(8,00^{+0,0}_{-0,2}\right)$ mm		≥ 10 mm

NOTE 1 For all test surfaces, surface profile tolerance is ±1 µm.

NOTE 2 According to 1), 2) and 3): control measurement possible with a micrometer unit.

NOTE 3 According to 4) and 5): an ellipsoid surface and toric surface can be manufactured by a contact lens company and measured with a 3D-coordinate measuring device.

	Surface	Radius of curvature	Eccentricity e	Diameter
3)	sphere	$\left(9{,}50^{+0{,}0}_{-0{,}2}\right)$ mm		≥ 10 mm
4)	ellipsoid of revolution	$r_0 = \left(7{,}80^{+0{,}0}_{-0{,}3}\right)$ mm	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		≥ 10 mm
NOTE 1 For all test surfaces, surface profile tolerance is ±1 µm.				
NOTE 2 According to 1), 2) and 3): control measurement possible with a micrometer unit.				
NOTE 3 According to 4) and 5): an ellipsoid surface and toric surface can be manufactured by a contact lens company and measured with a 3D-coordinate measuring device.				

Table 3 — Tolerance level for test surfaces

Tolerances, if measurements are expressed in terms of radius of curvature, in millimetres		
Measuring accuracy	**Type**	
Twice the standard deviation	A	0,05
Twice the standard deviation	B	0,1
Tolerances, if measurements are expressed in terms of curvature, in keratometric dioptres		
Measuring accuracy	**Type**	
Twice the standard deviation	A	0,27
Twice the standard deviation	B	0,52

The analysis zone for accuracy and repeatability testing shall be tested within a zone area of 1 mm ≤ diameter ≤ 6 mm.

5.3 Data collection — 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.

5.4 Analysis of the data

5.4.1 General

The treatment of the corneal topographic data consists of a comparison between the measured values of two data sets. The measured values can be any of the following:

— axial curvature (calculated using either axial radius of curvature or meridional curvature);

— Gaussian curvature;

— meridional curvature;

— normal curvature;

— mean curvature;

— principal curvature;

— corneal power;

— axial elevation;

— normal elevation;

— reference normal elevation.

The structure of the data sets is slightly different for the analysis of accuracy and the analysis of repeatability, so they will be given separately. (see Annex D).

5.4.2 Structure of the accuracy data set

Data values are collected using the method specified in 5.3.1. For the purpose of accuracy determination, one data set consists of the measured values and measurement locations from the measurement of a known test surface, a reference 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.

5.4.3 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 ΔD_{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 which may be, for instance, the corneal 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.

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

$$s_{ij} = \sqrt{\frac{\sum_{k=1}^{n} w_k \left(\Delta D_{ijk} - M_{ij}\right)^2}{n-1}} \tag{11}$$

$$\Delta D_{ijk} = w_k \left(D_{ik} - D_{jk}\right) \tag{12}$$

$$M_{ij} = \frac{1}{n}\sum_{k=1}^{n} w_k \Delta D_{ijk} \tag{13}$$

where

n is the number of measured points;

i, j are the indices specifying the two data sets;

k is the index specifying the point location;

D_{ik}, D_{jk} are the data values at point k for each data set, i and j, respectively;

M_{ij} is the ensemble difference mean for the data sets i and j;

s_{ij} is the 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.

5.4.4 Report of accuracy performance

The accuracy performance of a corneal topographer shall be described by reporting the following information:

a) specifications of test surface used;

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

c) mean difference according to Formula (13);

d) twice the standard deviation of differences according to Table 3.

6 Accompanying documents

The CT 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) name, model and type (A or B according to Table 3) of the CT;

c) a list of accessories suitable for use with the CT;

d) a reference to this document, i.e. ISO 19980:2021, if the manufacturer claims conformity;

e) any additional documents as specified in IEC 60601-1:2005 + A1:2012 + A2:2020, 7.9.

7 Marking

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

a) name and address of manufacturer or supplier;

b) name, model of the CT;

c) additional marking as required by IEC 60601-1.

Annex A
(informative)

Test surfaces for corneal topographers (CTs)

A.1 General

This annex gives various test surfaces that have been judged to be useful for assessing the performance of CTs. The goal of assessing the performance of a CT with various test surfaces is to ensure that the CT is capable of measuring with accuracy and repeatability, within the defined range of the instrument, human eyes that can have different corneal eccentricities and corneal shape factors.

For each type of surface, a brief description is given along with its special application.

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 CTs 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 on which to measure the 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 should always be augmented by other more complex surfaces.

The three sphere surfaces 1), 2) and 3) specified in Table 2 are chosen to be representative of the middle and of the two extremes of the curvature of the cornea found in the human population and hence the range expected for a corneal topography system.

A.3 Surfaces of revolution

A.3.1 General

Surfaces of revolution in which the generating arc is more complex than a circle are useful in order to imitate the human cornea. Such surfaces are referred to as aspheric and atoric surfaces. Compared to spherical surfaces they offer surfaces which present the corneal topography system with topographical situations more like those found in the human population. 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 which 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.3.2 Ellipsoids of revolution

When the generating arc of a surface of revolution is an ellipse, an ellipsoid of revolution is the resulting surface. This type of surface is quite like many normal corneas and is therefore a useful surface to test, for example the corneal apex, hence the performance of a corneal topography system for this important case. In addition, the rate of curvature change of this type of surface with respect to position is continuous and is precisely known.

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

Ellipsoids of revolution belong to the same class as conics of revolution. They may be generated as either prolate or oblate surfaces. Both are useful test surfaces because, whilst 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 conic constant, low curvature values in the periphery. When such a surface is presented to a CT in a tipped and rotated orientation, a situation simulating a keratoconus is created with a surface whose surface parameters can be calculated exactly.

A.3.3 Higher-order polynomial surfaces of revolution

Corneas which have undergone refractive surgery procedures are left with surface characteristics which cannot be adequately modelled 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 CT 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 mentioned in A.3.1. Because the generating arc is a polynomial function of order higher than two, the second derivatives of the surface, and hence the curvature, is a continuous function of position which can be calculated exactly. The verification of such surfaces by profilometry is no more complex a task than is that task of verifying a conic surface of revolution.

Annex B
(informative)

Standardized displays for corneal topographers (CTs)

B.1 General

To facilitate the interpretation and comparison of corneal topographical results taken with different CT systems, this annex sets forth standardized displays which may be used by any CT. Specified are scale intervals, scale centre value and colour convention.

CTs for which compliance with this document is claimed shall make these displays available to the user and shall designate them as standardized displays. CTs complying with this document may additionally provide displays using parameters different from these standardized ones.

B.2 Presentation

The following information shall be included in standardized maps:

— step size (units);

— colour legend;

— map type.

B.3 Standardized scale and scale intervals

Standardized curvature maps shall use one of the following corneal intervals, expressed in dioptres (D):

— 0,1 mm (0,5 D);

— 0,2 mm (1,0 D);

— 0,25 mm (1,5 D).

Should the choice of curvature interval found 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 colour assigned to highest interval or the lowest interval, as appropriate.

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

— 2 µm;

— 5 µm;

— 10 µm;

— 20 µm.

Should the choice of elevation interval and elevation found 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 colour assigned to highest interval or the lowest interval, as appropriate.

B.4 Standardized colour scale

For the fine and medium intervals, standardized curvature maps shall use the colour palette given in Table B.1.

Table B.1 — Colour palette for the fine and medium intervals of standardized curvature maps

Colour palette	Scale interval mm	
	0,1	0,2
Red	7,0	6,0
Green	8,0	8,0
Blue	9,0	10,0
Colour palette	**Scale interval** D	
	0,5	1,0
Red	49	54
Green	44	44
Blue	39	34

The hue shall change monotonically from green to red and shall change monotonically from green to blue.

For the expanded interval scale, standardized curvature maps shall use the colour palettes given in Table B.2.

Table B.2 — Colour palette for the expanded interval scale of standardized curvature maps

Colour name	sRGB[a]			Hue, brightness, saturation (HBS)			Scale values: keratometric dioptres
	R	G	B	H	B	S	D
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		352	31	100	63
Pink	255	158	168	354	38	100	61,5
Pink	255	138	148	355	46	100	60
Medium pink	255	115	125	356	55	100	58,5
Medium 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

NOTE These sRGB values were specifically chosen for an HDTV monitor with a gamma value of 2,2 and a colour temperature of 6 500 K. For other displays, slightly different settings may be needed to achieve the same HBS values.

[a] sRGB is the standard RGB colour space specified in IEC 61966-2-1. The letters RGB stand for red-green-blue.

Colour name	sRGB[a]			Hue, brightness, saturation (HBS)			Scale values: keratometric dioptres
	R	G	B	H	B	S	D
Medium green	80	230	51	110	78	90	43,5
Dark green	51	204	51		75	80	42
Cyan green	32	176	72		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 colour temperature of 6 500 K. For other displays, slightly different settings may be needed to achieve the same HBS values.

[a] sRGB is the standard RGB colour space specified in IEC 61966-2-1. The letters RGB stand for red-green-blue.

For the expanded scale, the hue shall change monotonically from 100 % green to 100 % red and shall change monotonically from 100 % green to 100 % blue. From 100 % red, the colour intensity shall increase monotonically to white. From 100 % blue, the colour intensity shall decrease monotonically to 20 %. Note that the intensity for 100 % blue or 100 % red is 50 %, black being 0 % intensity and white being 100 % intensity.

Standardized elevation maps shall use the colour palette given in Table B.3.

Table B.3 — Colour palette for standardized elevation maps

Colour palette	Scale interval μm			
	2	5	10	20
Red	20	50	100	200
Green	0	0	0	0
Blue	−20	−50	−100	−200

The hue shall change monotonically from green to red and shall change monotonically from green to blue.

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 are 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 area, w_k, shall be calculated as given in Formula (C.1):

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

where

k is an index specifying measurement in the subset area;

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 given in Formula (C.2):

$$\Delta r = \frac{<r_3> - <r_1>}{2} \tag{C.2}$$

This value is assumed to be 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 in Formula (C.3):

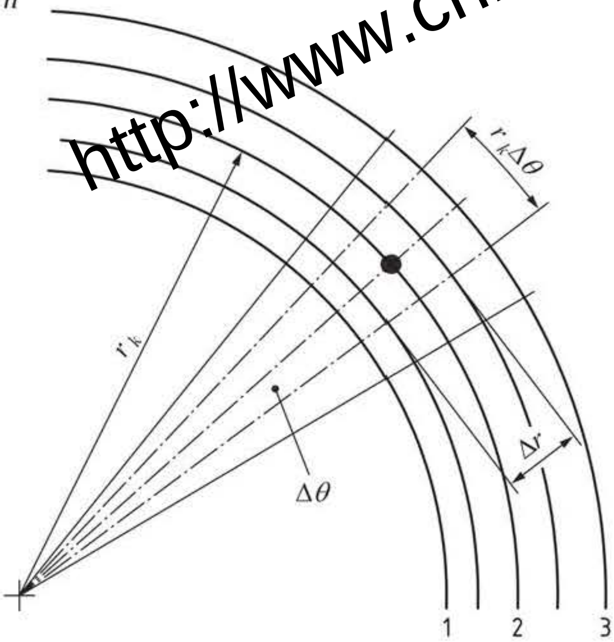
$$\Delta A_k = r_k \Delta\theta \Delta r \tag{C.3}$$

Since the value $\Delta\theta\Delta r$ is taken to be a constant over the subset area, the mean value of an area associated with a measured point, $<\Delta A_k>$, is given in Formula (C.4):

$$<\Delta A_k> = \frac{\sum_{k=1}^{n} \Delta A_k}{n} = \frac{\sum_{k=1}^{n} r_k \Delta\theta \Delta r}{n} = \Delta\theta r \frac{\sum_{k=1}^{n} r_k}{n} \quad \text{(C.4)}$$

Therefore the ratios between the area associated with measurement k, ΔA_k, and the average area, $<\Delta A_k>$, for the subset area, w_k, is given in Formula (C.5):

$$w_k = \frac{\Delta A_k}{<\Delta A_k>} = \frac{r_k \Delta\theta \Delta r}{\Delta\theta \Delta r \frac{\sum_{k=1}^{n} r_k}{n}} = \frac{n r_k}{\sum_{k=1}^{n} r_k} \quad \text{(C.5)}$$



Key

r_k radial position of measurement k;

$\Delta\theta$ change in corneal median;

Δr change in radial position.

Figure C.1 — Geometry used to find area-weighting factors for polar coordinate distributions

Annex D
(normative)

Test methods for measuring human corneas

D.1 Repeatability test

A repeatability test as defined in 5.1.2 shall be conducted by measuring human corneas, as specified in 5.3, on a minimum sample size of 20 subjects, with measurements being repeated on each subject. The measured values shall be analysed using the method specified in 5.4.

D.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 CT with respect to the eye and then re-centre it. Take a second measurement and save the measured data.

D.3 Structure of the repeatability data set

For the purpose of repeatability determination, a minimum sample size of 20 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 comprises the data set. The measurement positions for a given cornea, determined by the location of the corneal vertex, 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.

D.4 Report of repeatability performance

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

a) number of measured eyes in the sample population;

b) mean difference for the sample population;

c) twice the standard deviation of the differences for the sample population.

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[3] ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

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