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Standard

ISO 11979-2

**Ophthalmic implants — Intraocular
lenses —**

**Part 2:
Optical properties and test methods**

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 2: Propriétés optiques et méthodes d'essai*

**Third edition
2024-10**

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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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

This third edition cancels and replaces the second edition (ISO 11979-2:2014), which has been technically revised.

The main changes are as follows:

- A new category of simultaneous vision IOLs (SVIOL) is introduced for non-accommodating lenses that provide simultaneous vision at multiple distances. It includes multifocal IOLs (MIOL), extended depth of focus IOLs (EDF), and full visual range IOLs (FVR).
- Dioptric power, imaging quality, and characterization clauses and annexes were modified to include requirements for SVIOLs.
- Respective units of mm^{-1} and degree^{-1} were adopted for linear and angular spatial frequencies per ISO 9334.
- The resolution efficiency and associated annex have been removed from this document due to advancements in optical designs and the availability of modulation transfer function (MTF) imaging quality measurement methods.
- A new [Annex C](#) with associated requirements for all IOL categories has been added.
- Clarified description of UV cut-off wavelength.
- New references were added to the Bibliography.

A list of all parts in the ISO 11979 series can be found on the ISO website.

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.

Introduction

This document initially addressed monofocal IOLs and now includes the optical requirements and test methods for monofocal, toric, simultaneous vision, and accommodating IOLs. This document generally provides specific test methods and requirements connected to the optical function of intraocular lenses. In some cases, test methods do not have specified requirements, including:

- the spectral transmittance test that provides information related to UV transmission and potential exposure situations, e.g. when using laser light sources for diagnosis and treatment;
- optical characterization testing that informs potential optical design risks and guides potential clinical investigation design.

The specified dioptric power and imaging quality limits result from the analysis of extensive interlaboratory testing of the original spherical monofocal IOLs. Based on these studies, the respective dioptric power repeatability and reproducibility were about 0,5 % and 1 %, respectively, of the dioptric power as described in Reference [1]. Additionally, for IOLs in the 10 D to 30 D range, the respective expected imaging quality repeatability and reproducibility were 0,09 and 0,16 modulation transfer function values as described in Reference [2]. For other non-monofocal IOL designs, manufacturers should utilize model-specific repeatability and reproducibility precision limits to establish reliable final release criteria.

During the interlaboratory testing, some problems were encountered with measuring dioptric power, as described in Reference [1]. Specifically, the accuracy in determining dioptric power has an error that is not negligible in relation to the half dioptre steps in which intraocular lenses are commonly labelled. The dioptric power tolerances take this fact into account. Hence the limits set may lead to some overlap into the next labelled power, especially for high dioptre lenses. Reference [1] further discusses this subject.

Historically, imaging quality was tested using either

- a) Air Force target-based resolution efficiency, or
- b) MTF using a minimal spherical aberration model eye, or
- c) a manufacturer-defined spherical aberration model eye using modulation transfer function (MTF) testing.

Since the test method with Air Force target-based resolution efficiency is not optimal for quantifying image contrast, and better methods using MTF measurements have become mainstream in the industry, Air Force target-based resolution efficiency is not included in this revision as a reference method. The model eye with manufacturer-defined spherical aberration includes the option of having a model eye with minimal spherical aberration. Therefore, the original model eye with minimal spherical aberration is removed from this document. For lenses that have already been approved using the measurements in the previous edition, it is not necessary to retest these lens models with the method in this document.

[Annex B](#) describes a test method used to establish quality criteria for IOLs. The quality criteria assure consistent IOL optical quality. This document also includes a new normative optical characterization text (see [Annex C](#)), that is meant to provide preclinical assessments to inform of risks and benefits associated with the optical design and guide the design of the potential clinical investigation. The additional optical characterization is required only for lens models to be approved after publication of this document.

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Ophthalmic implants — Intraocular lenses —

Part 2: Optical properties and test methods

1 Scope

This document specifies requirements and test methods for certain optical properties of intraocular lenses (IOLs) with monofocal, toric, simultaneous vision, and/or accommodative optics. The generic descriptor 'IOL' used throughout this document also includes phakic intraocular lenses (PIOL).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes the 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.

ISO 9334, *Optics and photonics — Optical transfer function — Definitions and mathematical relationships*

ISO 9335, *Optics and photonics — Optical transfer function — Principles and procedures of measurement*

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 and ISO 9334 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Requirements

4.1 General

The manufacturer shall assure that the entire range of available powers meets the specifications herein. All optical properties apply at in situ conditions, either by being measured at simulated in situ conditions, or being measured at other conditions and then corrected to in situ conditions.

For IOLs where the optic is intended to be deformed during implantation, it shall be demonstrated that dioptric power and imaging quality are retained at in situ or equivalent conditions following surgical manipulation and recovery. See ISO 11979-3^[3] for more details.

The test methods described in this document are reference methods. Alternative methods that produce equivalent results to those obtained with the reference methods may be used if the manufacturer can demonstrate that the IOLs meet the minimum dioptric power and imaging quality requirements.

For rotationally symmetric IOLs the manufacturer shall assure that lenses meet the requirements in all meridians, for example by selecting an arbitrary meridian for measurement.

4.2 Dioptric power

4.2.1 General

The base power of lenses as stated by the manufacturer in the IOL labelling per ISO 11979-4 shall be within the tolerance limits specified in [Table 1](#). Manufacturers shall consider measurement precision when establishing IOL release specifications.

Table 1 — Tolerance limits on spherical dioptric power, S

Nominal base power ^a D	Tolerance limits on spherical dioptric power D
$0 \leq S \leq 15$	$\pm 0,3$
$15 < S \leq 25$	$\pm 0,4$
$25 < S \leq 30$	$\pm 0,5$
$30 < S $	$\pm 1,0$
^a The dioptric power ranges apply to positive and negative dioptric powers.	

4.2.2 Dioptric power for toric IOL (TIOL)

When determined by any of the methods in [Annex A](#), the spherical equivalent (SE) power shall be within the tolerance limits for dioptric power specified in [Table 1](#). Additionally, the cylindrical power calculated as the absolute difference between the powers of the meridian of highest dioptric power and the meridian of lowest dioptric power shall be within the cylindrical power tolerance limits specified in [Table 2](#).

Table 2 — Tolerance limits on cylindrical dioptric power, C

Nominal cylindrical dioptric power D	Tolerance limits on cylindri- cal dioptric power D $SE < 25 D$	Tolerance limits on cylindri- cal dioptric power D $SE \geq 25 D$
$0 < C \leq 2,5$	$\pm 0,3$	$\pm 0,4$
$2,5 < C \leq 4,5$	$\pm 0,4$	$\pm 0,4$
$4,5 < C$	$\pm 0,5$	$\pm 0,5$

The TIOL shall have a physical axis indicator such as a mark, engraving, or label that aligns with the meridian of lowest dioptric power and is visible to the surgeon during implantation. The angle difference between the physical axis indicator and the meridian with the lowest dioptric power shall be less than or equal to $5,0^\circ$.

4.2.3 Dioptric power for simultaneous vision IOL (SVIOL)

Methods [A.3](#) to [A.4](#) can be applied to SVIOLs for determining the far power and any designed distinct addition power(s). The dioptric power of the far power shall be within the tolerance limits specified in [Table 1](#), and the dioptric power of designed distinct addition power(s) shall be within the tolerances in [Table 3](#). For SVIOLs that do not have designed distinct addition powers, the manufacturer shall develop MTF through-focus response specifications per [4.3.4](#).

Table 3 — Tolerance limits on addition dioptric power, A

Nominal addition dioptric power D	Tolerance limits on addition dioptric power D far power < 25 D	Tolerance limits on addition dioptric power D far power $\geq$ 25 D
$0 < A \leq 2,5$	$\pm 0,3$	$\pm 0,4$
$2,5 < A \leq 4,5$	$\pm 0,4$	$\pm 0,4$
$4,5 < A$	$\pm 0,5$	$\pm 0,5$

4.2.4 Dioptric power for accommodating IOL (AIOL)

The power associated with the far power configuration of an AIOL shall be determined by one of the methods in [Annex A](#). When determined by one of these methods, the dioptric power tolerances specified in [Table 1](#) shall apply to the power associated with the far power configuration of the AIOL. The dioptric power response of the lens or system in the eye shall be determined in a theoretical or laboratory eye model that simulates the intended accommodating mechanism of action.

4.3 Imaging quality

4.3.1 General

Reported imaging quality is dependent upon compatibility between the optical design, manufactured lens quality, and conditions that are used to evaluate optical performance. Imaging quality shall be specified in relation to theoretical lens performance in terms of a modulation transfer function (MTF) value at one or more specified spatial frequencies or the area under the MTF curve between two spatial frequencies for a given aperture. Manufacturers shall consider measurement precision when establishing IOL release specifications.

A method for measuring MTF and example model eye specifications are given in [Annex B](#). Alternatively, the manufacturer can specify an equivalent method or model eye with optical properties for the intended use and design. In this case, the model eye and the method shall be fully described, and a justification for the use thereof be provided. The imaging quality specifications apply to all available powers unless stated otherwise.

NOTE 1 The test apertures given in [4.3](#) and in [Annexes A, B, and C](#) represent the exposed central area of the IOL under test.

NOTE 2 Throughout this document, optical resolution is specified using spatial frequencies that are presented in cycles per millimetre (mm^{-1}). Alternatively, equivalent values for the generally accepted vision science convention of cycles per degree (degree^{-1}) can be used:

- where the document specifies 100 mm^{-1} , alternatively 30 degree^{-1} can be used;
- where the document specifies 50 mm^{-1} , alternatively 15 degree^{-1} can be used;
- where the document specifies 25 mm^{-1} , alternatively $7,5 \text{ degree}^{-1}$ can be used.

If conversion back from these values in degree^{-1} to mm^{-1} is needed for different lens powers, the following approximative conversion can be used, as shown in [Formula \(1\)](#)

with:

- SF = spatial frequency, expressed in degree^{-1} ;
- sf = spatial frequency, expressed in mm^{-1} ;
- $EFL(P)$ = effective focal length of the model eye, with an IOL with power P (in D) in place;
- so that $EFL(20)$ = EFL of the model eye with an IOL of 20 D.

Then:

$$sf(P) = EFL(20)/EFL(P) \times SF/0,3 \quad (1)$$

Other methods for converting between mm^{-1} and degree^{-1} are acceptable if justification can be provided.

4.3.2 Monofocal IOL

In accordance with [Annex B](#) with a 3 mm aperture, the MTF value shall at 100 mm^{-1} meet either of the two requirements given below:

- a) $\geq 0,43$;
- b) ≥ 70 % of the theoretically attainable MTF for the nominal lens design, but in any case $\geq 0,28$.

4.3.3 Toric IOL (TIOL)

In accordance with [Annex B](#) using a model eye with IOL configuration, the MTF requirements described in [4.3.2](#) shall apply to the meridians of highest and lowest dioptric power.

4.3.4 Simultaneous vision IOL (SVIOL)

The SVIOL imaging quality specifications shall be evaluated by MTF testing using the methods and eye model described in [Annex B](#) for the following conditions:

- a) for far dioptric power, record MTF at 25 mm^{-1} and a second spatial frequency in the range from 50 mm^{-1} to 100 mm^{-1} for small and large apertures. The small aperture diameter shall be selected from 2,0 mm, 2,5 mm, or 3,0 mm. The large aperture diameter shall be selected from 4,0 mm, 4,5 mm, or 5,0 mm.
- b) for lens designs that have one or more designed distinct addition powers, for each addition power, record MTF at 25 mm^{-1} and a second spatial frequency in the range from 50 mm^{-1} to 100 mm^{-1} for a small aperture. The small aperture diameter shall be selected from 2,0 mm, 2,5 mm or 3,0 mm.

The manufacturer shall have the option of setting the minimum MTF specification based on the area under the curve between the two spatial frequencies or on the MTF value for each individual spatial frequency. A specification describing the MTF through-focus response shall be developed for designs with no designed distinct addition power(s). The MTF shall be ≥ 70 % of the theoretically attainable MTF for the lens design under the defined test conditions.

4.3.5 Accommodating IOL (AIOL)

The requirements given in [4.3.2](#) shall apply at the far power configuration and configurations associated with the designed range of accommodation. Measurements shall be obtained in 0,5 D or smaller increments over this range if applicable.

4.3.6 Combination of optical principles

Lenses combining optical principles shall meet applicable test requirements such as described in the following examples.

For toric simultaneous vision and toric accommodating lenses, the general imaging requirements in [4.3.3](#) apply along with the test requirements in [4.3.4](#) and [4.3.5](#), respectively.

For simultaneous vision accommodating lenses the imaging test requirements of [4.3.4](#) and [4.3.5](#) apply.

4.3.7 Exceptions

If the criteria specified in [4.3.2](#) through [4.3.6](#), for reasons of theoretical limitation, cannot be applied to negative, low, or high power lenses in conjunction with the model eye described, the manufacturer shall justify any alternative spatial frequencies and criteria.

4.4 Optical characterization

Optical characterization shall be performed in accordance with the methods described in [Annex C](#). The optical characterization contributes to the assessment of potential risks and benefits associated with the optical design and shall serve as input for the design of a potential clinical investigation. The optical characterization does not have quantitative pass/fail criteria.

4.5 Spectral transmittance

4.5.1 Measurement of spectral transmittance

The spectral transmittance in the range 300 nm to 1 100 nm shall be recorded by a spectrophotometer with a 3 mm aperture under simulated in situ conditions or corrected for specular reflection if measured in air. The measurement should be accurate to ± 2 % transmittance and the resolution should be ≤ 5 nm. The test specimen shall be either an actual IOL or a flat facsimile of the IOL optic material, having a thickness equal to the centre thickness of a 20 D spherical equivalent IOL and having undergone the same production treatment as the finished IOL including sterilization.

NOTE For toric lenses, an IOL of SE = 20 D with lowest available cylinder or equivalent non-toric IOL can be used.

4.5.2 Cut-off wavelength

The UV cut-off is the wavelength in nanometres at which the spectral transmission is ≤ 10 % when measured according to [4.5.1](#).

NOTE Guidance for measuring spectral transmittance can be found in ISO 18369-3; see Reference [\[4\]](#).

Annex A (normative)

Measurement of dioptric power

A.1 General

Multiple methods of determining IOL dioptric power are given below. Where applicable, the specific methods and requirements for monofocal, toric, simultaneous vision, and accommodating IOL measurements are described in this annex.

For all IOLs, the value of dioptric power is defined at in situ conditions (see ISO 11979-1) for a light source that has a peak wavelength within ± 10 nm of 546 nm having a full width at half maximum of 20 nm or less. For the methods in [A.3](#) and [A.4](#), an aperture of $3,0 \text{ mm} \pm 0,1 \text{ mm}$ in diameter is used.

NOTE 1 For more details about optical measurement and calculations, see Reference [\[5\]](#) or similar textbooks on optics.

NOTE 2 A modified bench (e.g. additional converging lens, a microscope objective of appropriate numerical aperture, etc.) can be used to quantify the focal length of negative and low dioptric power IOLs.

A.2 Determination of dioptric power by calculation from measured dimensions

A.2.1 Procedure

Measure the optical surface radii of curvature over a region of approximately 3 mm diameter using a radius meter, interferometer, or optical coherence tomograph (OCT), see Reference [\[6\]](#). Measure the lens thickness with a micrometer or equivalent device. Calculate the dioptric power, using [Formula \(A.1\)](#):

$$D = D_f + D_b - (t_c / n_{\text{IOL}}) D_f D_b \quad (\text{A.1})$$

under in situ conditions, where

D is the dioptric power of the IOL;

D_f is the dioptric power of the front surface of the IOL;

D_b is the dioptric power of the back surface of the IOL;

t_c is the central thickness, in metres, of the IOL;

n_{IOL} is the refractive index of the IOL optic material at in situ conditions.

NOTE 1 [Formula \(A.1\)](#) is often referred to as the “thick lens equation”.

NOTE 2 In general, the value of n_{IOL} is influenced by temperature and water uptake by the IOL optic material.

Calculate D_f from [Formula \(A.2\)](#):

$$D_f = (n_{\text{IOL}} - n_{\text{med}}) / r_f \quad (\text{A.2})$$

where

n_{med} is the refractive index of the surrounding medium;

r_f is the surface radius of curvature, in metres, of the front surface of the IOL.

Calculate D_b from [Formula \(A.3\)](#):

$$D_b = (n_{\text{med}} - n_{\text{IOL}}) / r_b \quad (\text{A.3})$$

where r_b is the surface radius of curvature, in metres, of the back surface of the IOL.

NOTE 3 With respect to the incidence of light, a convex radius is positive and a concave radius is negative.

NOTE 4 These formulae assume that there is exact alignment of front and back surfaces along the optical axis.

NOTE 5 ISO 18369-4^[7] describes a method that can be used to determine n_{IOL} , which should be known to the third decimal place.

NOTE 6 If the lens material is flexible, appropriate care is taken when measuring the two lens surfaces to ensure that the two surface measurements are consistent with each other. Any flexing of the lens between the measurements of the two surfaces will affect the results.

Use $n_{\text{med}} = 1,336$, and the dimensions and refractive index of the IOL under in situ conditions to obtain the dioptric power in situ, D_{aq} , from [Formula \(A.1\)](#).

If the measured dimensions and the refractive index of the IOL were not obtained under in situ conditions, apply proper corrections to calculate the corresponding values at in situ conditions.

A.2.2 Applicability

This method as described is only applicable to rotationally symmetric spherical monofocal IOL designs.

A.3 Determination of dioptric power by calculation from measured back focal length or effective focal length

A.3.1 Principle

The method described in [A.3](#) assumes measurement in air but is applicable to measurement at simulated in situ conditions with proper adjustments.

The back focal length (*BFL*) is the distance from the back vertex of the IOL to the focal point with parallel light incident on-axis upon the IOL. This method has historically been used to measure monofocal lenses in air.

The effective focal length (*EFL*) is the distance from the second principal plane to the focal point with parallel light incident on-axis upon the IOL. EFL can be measured with an optical bench equipped with a nodal slide, see Reference [\[5\]](#).

Both methods can be used when appropriate corrections are made as described below.

NOTE 1 The position of the focal point is dependent on the spatial frequency used to find the focal point. It is normally not coincident with the paraxial focal point of the lens under measurement if there is spherical aberration. The focus found is often referred to as “best focus”.

NOTE 2 BFL, EFL, and the corrections are all vector quantities. The positive direction is that of the incident light and is measured along the optical axis.

A.3.2 Apparatus

Optical bench, e.g. as illustrated in Figure A.1, having the following features:

- a) a collimator achromat that is virtually free from aberrations in combination with the light source used, having a focal length preferably at least 10 times that of the IOL being measured;
- b) a spatial frequency target such as the U.S. Air Force 1951 Resolution Target, see Reference [8], diffusely illuminated by a light source in the focal plane of the collimator;
- c) an aperture stop of $3,0 \text{ mm} \pm 0,1 \text{ mm}$ placed maximally 3 mm in front of the IOL being measured;
- d) a surrounding medium of air;
- e) a microscope objective with a numerical aperture greater than that of the test system and capable of magnifying $\times 10$ to $\times 20$;
- f) an eye-piece magnifying about $\times 10$.

NOTE 1 To measure a focal length longer than the testing apparatus, an additional converging lens or microscope objective of appropriate numerical aperture can be used.

NOTE 2 It is a matter of convenience whether to use a straight bench or employ a mirror as illustrated in Figure A.1.

The microscope is connected to a position measuring device so that its position along the optical axis can be determined with a precision of 0,01 mm.

A.3.3 Procedure

A.3.3.1 Mount the IOL on the optical bench just behind the 3 mm aperture.

A.3.3.2 Focus the microscope at the back surface of the IOL and note the position of the microscope.

A.3.3.3 Focus the microscope at the image of the target and note the position of the microscope. The distance from the back vertex of the IOL to the focal point is the back focal length, *BFL*, of the IOL.

If focusing is done using a USAF target element, the group/element that is closest to 0,3 of the IOL's MTF cut-off frequency shall be used. Otherwise, focusing is done at a spatial frequency of $0,3 \pm 0,04$ of the cut-off frequency of the IOL. The procedure given here assumes that measurement is done in air at normal ambient conditions of a laboratory. The calculations assume that the dimensions of the IOL are not appreciably different under in situ conditions. Should that not be the case, *BFL* is measured with the IOL under simulated in situ conditions, with appropriate changes in the calculations.

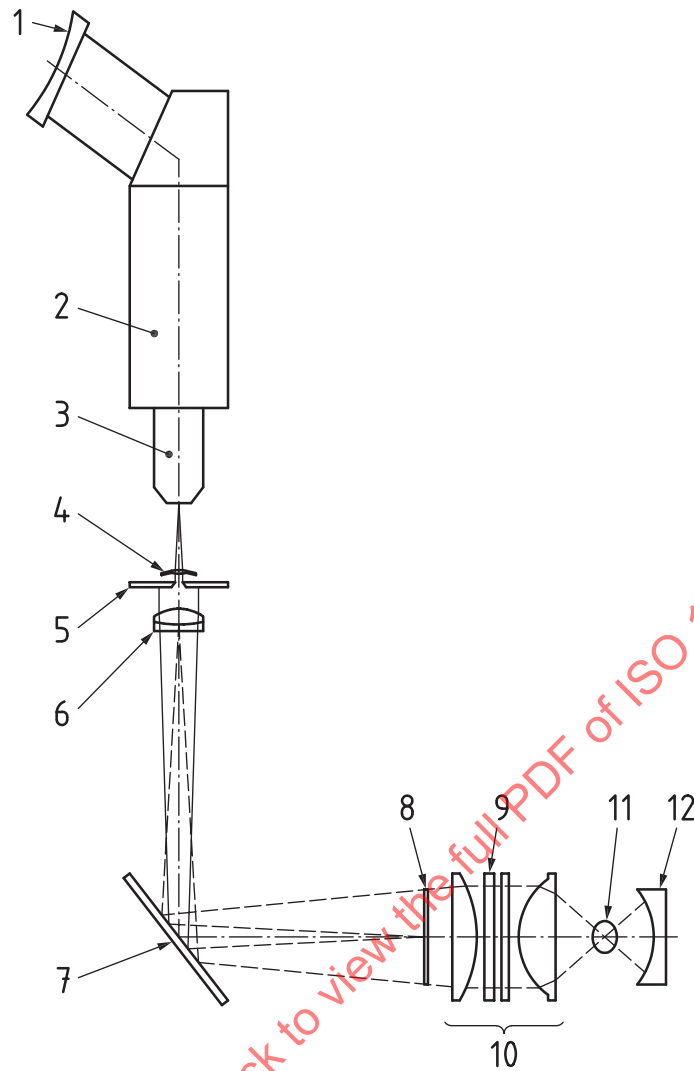
A.3.3.4 Calculate the distance from the back vertex of the IOL to the back principal plane of the IOL, as given by Formula (A.4):

$$-A_2H'' = (D_f / D) \cdot (n_{\text{med}} / n_{\text{IOL}}) \cdot t_c \quad (\text{A.4})$$

where $n_{\text{med}} = 1$ for measurement in air.

NOTE 1 A_2H'' is a vector that can be positive or negative depending on lens shape. The quantity $-A_2H''$ is added to *BFL* as correction.

NOTE 2 This correction does not apply to *EFL*.

**Key**

- 1 eyepiece
- 2 microscope body
- 3 microscope objective
- 4 IOL
- 5 3,0 mm aperture
- 6 collimator doublet

- 7 mirror
- 8 target
- 9 dichroic filter
- 10 condenser lens system
- 11 light source
- 12 retro-reflecting mirror

Figure A.1 — Optical bench with IOL

A.3.3.5 Calculate the longitudinal spherical aberration (*LSA*) as the vector from the paraxial focal point to the intersection of a meridional ray at the pupillary margin with the optical axis, and determine the defocus (*Def*) caused by spherical aberration, as given by [Formula \(A.5\)](#):

$$-Def = -LSA / 2 \quad (A.5)$$

where *LSA* is the longitudinal spherical aberration, expressed in millimetres. It is permissible under this document to calculate *Def* by other procedures, such as those available in optical design calculation

programmes and raytrace software, provided that the correctness of the programme has been verified. Alternatively, the *LSA* may be measured directly by wavefront mapping technology.

NOTE 1 The user of this document is referred to the optics literature for methods on how to calculate *LSA*, see Reference [5].

NOTE 2 *Def* is a vector that can be positive or negative. The quantity $-Def$ is added to *BFL* (or *EFL*) as a correction.

A.3.3.6 If *BFL* is measured, calculate *EFL* as follows in [Formula \(A.6\)](#):

$$EFL = BFL - A_2 H'' \quad (A.6)$$

Calculate the paraxial focal length *f* (in metres), using [Formula \(A.7\)](#):

$$f = EFL - Def \quad (A.7)$$

A.3.3.7 Paraxial focal length, *f*, is converted to dioptric power, *D* (in reciprocal metres), using [Formula \(A.8\)](#):

$$D = n_{\text{med}} / f \quad (A.8)$$

where $n_{\text{med}} = 1$.

A.3.3.8 Compute the conversion ratio, *Q*, using [Formula \(A.9\)](#):

$$Q = D_{\text{aq,nom}} / D_{\text{air,nom}} \quad (A.9)$$

where $D_{\text{aq,nom}}$ and $D_{\text{air,nom}}$ are the respective dioptric powers calculated in situ and air from [Formulae \(A.1\), \(A.2\) and \(A.3\)](#) using nominal dimensions for the IOL, $n_{\text{med}} = 1$ and the appropriate value for n_{IOL} .

A.3.3.9 Finally calculate the dioptric power in situ, D_{aq} , using [Formula \(A.10\)](#):

$$D_{\text{aq}} = D_{\text{air}} \cdot Q \quad (A.10)$$

NOTE If measurement of *BFL* (or *EFL*) is made at simulated in situ conditions, $n_{\text{med}} = 1,336$ in [Formulae \(A.2\), \(A.3\), \(A.4\) and \(A.8\)](#). [Formula \(A.8\)](#) then gives directly D_{aq} .

A.3.4 Applicability

This method is, as described, applicable to rotationally symmetric IOLs.

A.4 Determination of dioptric power from measured magnification

A.4.1 Principle

The concept of lens power relates to the image magnification of a lens. The principle of the focal collimator to measure magnification to determine dioptric power is given here.

A.4.2 Apparatus

An optical bench such as described in [A.3.2](#) with the following modifications:

- a target with a measurable repeating pattern such as the U.S. Air Force 1951 Resolution Target
- an eye-piece with some means, such as a reticle, to measure the corresponding linear dimension in the image.

A.4.3 Procedure

Determine the linear dimension, h_{target} , of the target.

Determine the focal length, F , of the collimator.

NOTE 1 These two determinations need not be repeated every time.

NOTE 2 The ratio F/h_{target} could be obtained by measurement of calibrated lenses in lieu of the IOL.

Mount the IOL on the optical bench just behind the 3 mm aperture.

Focus the microscope on the image and measure the linear dimension, h_{image} , in the image.

Focusing is done at a spatial frequency of $0,3 \pm 0,04$ of the cut-off frequency of the IOL.

Calculate the effective focal length (EFL) of the IOL, by using [Formula \(A.11\)](#):

$$EFL = (F / h_{\text{target}}) \cdot h_{\text{image}} \quad (\text{A.11})$$

Add the spherical aberration corrections from [Formula \(A.5\)](#) to EFL using [Formula \(A.7\)](#) to obtain the paraxial focal length, f_{air} , and continue to calculate the dioptric power in air and aqueous according to [Formulae \(A.8\)](#), [\(A.9\)](#), and [\(A.10\)](#).

A.4.4 Applicability

This method is as described applicable to rotationally symmetric IOLs.

A.5 Determination of dioptric power and error in axis for TIOL

A.5.1 General

For toric IOLs, the methods in this Annex allow the determination of the dioptric power of the principal meridians with the highest and lowest dioptric power and the measurement of the alignment of the axis marks with the meridian with the lowest dioptric power.

A.5.2 Without the use of a null lens

For toric IOLs, the dioptric powers in the two principal meridians are determined as follows:

- If determined in accordance with [A.2](#): calculate the dioptric powers from measured dimensions (including radii) of the two principal meridians;
- If determined in accordance with [A.3](#): calculate the dioptric powers from the measured back focal lengths of the two principal meridians. The principal meridian under measurement and the applied target are aligned in such a way that a sharp image is perceived;
- If determined in accordance with [A.4](#): calculate the dioptric power from the measured magnification of the two principal meridians. The principal meridian under measurement and the applied target are aligned in such a way that a sharp image is perceived.

The spherical equivalent power (SE) is calculated as follows:

$$SE = (\text{dioptric power in high power meridian} + \text{dioptric power in low power meridian})/2.$$

The cylindrical power (CYL) is determined as follows:

$$CYL = \text{dioptric power in high power meridian} - \text{dioptric power in low power meridian}.$$

A.5.3 With the use of a null lens

The optical bench described in [A.3.2](#) can be modified to determine SE and CYL with the addition of a positive or negative cylinder lens (null lens) placed behind or in front of the TIOL being tested.

The null lens is a lens that compensates for the astigmatism of the TIOL. The cylinder axis of the null lens is aligned with the corresponding principal meridian of the TIOL. The lens power and position of the null lens are chosen such that the lens combination of the null lens and the IOL creates a sharp image of the 2-dimensional target. First, the lens power of the uncorrected principal meridian is determined by either method in [A.3](#) or [A.4](#), and then the position of the null lens is measured. The cylinder power can then be calculated from the cylinder power of the null lens and its location relative to the TIOL principal plane of the corrected principal meridian using the lens combination formula, see Reference [\[5\]](#).

A.5.4 Determination of error in axis for TIOL

A.5.4.1 Determination of error in axis without a null lens

The error in the axis is determined using either of the methods [A.5.2 b\)](#) or [A.5.2 c\)](#). When a best focused image for the low power meridian is perceived, determine the angle between the corresponding target principal direction and the toric indicators. This angle is the error in the axis.

A.5.4.2 Determination of error in axis with a null lens

The error in the axis is determined using the method in [A.5.3](#). When a focused image is perceived, determine the angle between the cylinder axis of the null lens or its orthogonal meridian and the toric indicators of the TIOL. The smaller of these is the error in the axis.

NOTE An error of the orthogonality between the meridians of lowest and highest powers will be apparent in the imaging quality.

A.6 Determination of dioptric power for SVIOL

Two alternative methods for the determination of dioptric power can be applied to SVIOL ([A.3](#) and [A.4](#)). Measurements are done for apertures at $3,0 \text{ mm} \pm 0,1 \text{ mm}$. Due to the complexity of the optic surfaces, the method described in [A.2](#) should not be used for SVIOL. Depending on the SVIOL optic design the correction formulae given in this document could be invalid. In such cases the manufacturer should derive and justify corrections that result in dioptric powers that are consistent with power labelling of monofocal IOLs. If the focusing conditions are not appropriate for the particular design, another focusing condition should be developed with justification. If the addition power of an SVIOL is not rotationally symmetric, the manufacturer should justify the LSA correction factor that is used.

For each near image plane, these methods are modified as follows:

- Determination of dioptric power from measured back focal length ([A.3](#)): The microscope is first focused on the back vertex of the SVIOL, and then focused on the far image plane to obtain *BFL* for the far power, and subsequently focused on the near image plane to obtain *BFL* for the near power.
- Determination of dioptric power from measured magnification ([A.4](#)): The microscope is first focused on the far image plane to obtain the linear dimension h_{image} for the far power, and subsequently focused on the near image plane to obtain h_{image} for the near power.
- The manufacturer shall derive and apply a spherical aberration correction according to [A.3.3.5](#).

A.7 Accommodating IOL (AIOL)

A.7.1 Mode of action

Describe the accommodative mode of action in the eye and associated test methods to demonstrate that action.

A.7.2 Determination of dioptric power

Determine dioptric power with either of the methods described in [A.3](#) and [A.4](#).

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Annex B (normative)

Measurement of MTF

B.1 General

This annex describes the principles, apparatus, and methods for MTF measurement of rotationally symmetric monofocal IOLs. Modifications required for other types of IOLs are provided at the end of this annex.

B.2 Principle

The modulation transfer function (MTF) of an IOL is measured using a model eye. A light source with a peak wavelength within ± 10 nm of 546 nm having a full width at half maximum of 20 nm or less is used.

The model eye described in this Annex is used to establish quality criteria for IOLs by means of the limits set in 4.3. No inference should be made to performance in real eyes.

B.3 Apparatus

B.3.1 Model eye

The model eye is defined by:

- a) the converging beam of the model cornea, when exposing a circular area of $5,15 \text{ mm} \pm 0,10 \text{ mm}$ at an axial location that is between 25 mm and 28 mm in front of the focal point of the model cornea itself, taking the refractive index of the image space to be 1,336, produces a wavefront that is characterized by a value for the Zernike coefficient $c(4,0)$ to within $\pm 0,020 \text{ } \mu\text{m}$ of the intended value;

NOTE 1 For the calculation of the location of this plane, the model eye is assumed infinitely deep so that the image falls within the liquid with which the model eye is filled.

- b) the IOL front surface is placed at the axial location specified in a);
- c) the converging beam from the model cornea is stopped down to expose a central circular area of the IOL having a diameter appropriate for the test to a tolerance of $\pm 0,1 \text{ mm}$ by means of an aperture:
 - directly in front of the IOL or
 - in front of the cornea, when testing with a diameter chosen, depending on the cornea, so as to expose the required central circular area of the IOL.

- d) the IOL is placed in a liquid medium contained between two flat windows;
- e) the difference in refractive index between the IOL and the liquid medium is within 0,005 units of that under in situ conditions;

NOTE 2 For practical testing purposes, purified water or physiological saline can be used.

- f) the model cornea incorporates spherical aberration as intended for the IOL design so that resulting imaging quality is due to the IOL;
- g) the image plane falls in air, beyond the last window.

The materials and dimensions of a suitable model eye are described in [Tables B.1](#) and [B.2](#) assuming the model cornea to be made of a material with refractive index 1,493 (PMMA).

NOTE 3 A discussion about model eyes can be found in Reference [9]. A suitable model eye is illustrated in [Figure B.1](#), and many other realizations are possible. With the refractive index 1,493 and the thickness 10 mm for the model cornea, the asphericity, Q , of the front surface can be calculated from [Formula \(B.1\)](#):

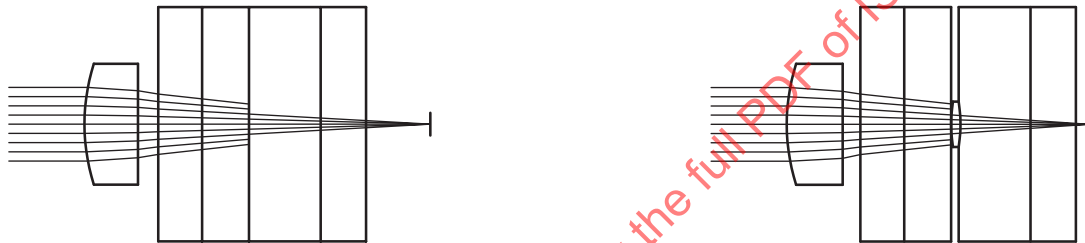
$$Q = -0,9519 \cdot [c(4,0)]^2 + 2,9567 \cdot [c(4,0)] - 0,4809 \quad (\text{B.1})$$

for values of $c(4,0)$ in the range from $-0,2 \mu\text{m}$ to $+0,5 \mu\text{m}$.

The asphericity Q is defined by the equation of a conic aspheric surface, as given by [Formula \(B.2\)](#):

$$z = \frac{\left(\frac{1}{R}\right)r^2}{1 + \sqrt{1 - (Q+1)\left(\frac{1}{R}\right)^2 r^2}} \quad (\text{B.2})$$

where z is the sagittal distance from the vertex, r is the radial distance from the centre, and R is the optical surface radius of curvature.



- a) Without IOL** (as described in [Tables B.1](#) and [B.2](#)) **b) With a 30 D IOL** (The central 3 mm of the IOL are exposed. Note that the image plane moves closer to the last window but remains behind it.)

Figure B.1 — Model eye configuration

Table B.1 — Description of a model eye (with 5,15 mm aperture at surface 5) fulfilling the requirements of [B.3.1](#)

Surface number	Surface radius mm	Q-value to obtain the desired Ze- rnike coefficient $c(4,0)$	Separation space mm	Diameter mm	Refractive index
1	19,332	Formula (B.1)	10,0	16	1,493
2	∞	—	3,0	16	1,000
3	∞	—	6,0	32	1,519
4	∞	—	6,25	32	1,336
5	∞	—	10,0	5,15	1,336
6	∞	—	6,0	32	1,519
7	∞	—	9,45	32	1,000
8	image plane (∞)	—	—	—	—

The model cornea (surfaces 1–2) is assumed cut from PMMA. A model cornea that meets the description in [B.3.1](#) can be realized in many other ways and materials, but there is none commercially available. The choice of glass for the windows (surfaces 3 and 6) is not critical.

Table B.2 — Examples of surface number 1 Q-values calculated by Formula (B.1) to obtain selected $c(4,0)$ values

$c(4,0)$	0,000 μm	0,100 μm	0,200 μm	0,280 μm
Q	−0,481	−0,195	0,072	0,272

NOTE 4 A value of 0,280 μm for the Zernike coefficient $c(4,0)$ is described in Reference [10] for an average human eye with a 6 mm entrance pupil.

NOTE 5 The cornea of the Liou and Brennan model eye shown in Reference [11] provides a value of 0,258 μm for $c(4,0)$ for an entrance pupil of 6 mm, and exposes the central 5,15 mm at the plane of the front surface of its lens, with a theoretical paraxial focus 26,3 mm behind that plane in a medium of refractive index 1,336.

NOTE 6 Model eye is suitable only for an object at infinity. It is inadequate for objects at finite distances because the magnification is not comparable to that of the natural eye. A model eye with physiological dimensions is needed. A practical realization is given in Reference [9].

NOTE 7 A model with zero spherical aberration can be considered appropriate for monofocal IOLs having spherical surfaces.

NOTE 8 The notation for Zernike coefficients follows ISO 24157[12].

B.3.2 Optical bench

The model eye is mounted on an optical bench for measurement of MTF which shall conform to the requirements of ISO 9335.

With the apparatus described, measurement can be carried out at ambient temperature if the IOL dimensions or optical performance do not deviate appreciably from those under in situ conditions. Otherwise, the measurement is carried out at simulated in situ conditions.

B.4 Procedure

Place the model eye (B.3.1) on the optical bench (B.3.2). Ensure that the IOL is in the correct position and that the model eye is well aligned with the optical axis of the bench and focused to obtain maximum MTF at $\geq 50 \text{ mm}^{-1}$ using the specified aperture. Measurements at different apertures shall be performed without re-focusing unless otherwise justified. Record the MTF values at the required spatial frequencies.

B.5 Measurement of MTF for toric IOL (TIOL)

For TIOL, MTF is measured in the highest and lowest dioptric power meridians.

Alternatively, use a null lens to permit MTF measurement as a rotationally symmetric IOL.

B.6 Measurement of MTF for simultaneous vision IOL (SVIOL)

For SVIOL imaging quality specifications, the MTF for the lens is measured under the defined test conditions.

B.7 Measurement of MTF for accommodating IOL (AIOL)

a) Modulation transfer function (MTF) testing:

Generate MTF through-frequency response curves at 3 mm aperture at the far power configuration and configurations associated with the designed range of accommodation in 0,5 D or smaller increments;

b) MTF through-focus response testing:

Generate the MTF through-focus response of the AIOL at 50 mm^{-1} with 3 mm ($\pm 0,1 \text{ mm}$) aperture at the far power configuration. Focus to maximum MTF at 50 mm^{-1} for an object at infinity and then measure MTF

at positions more anterior in image space using 0,1 mm steps up to 1,5 mm The defocus steps shall also be reported in the corresponding dioptric power increments.

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Annex C (normative)

Optical characterization

C.1 Principle

Optical characterizations are meant to inform of potential benefits and risks associated with the particular optical design under evaluation as well as to guide the design of the potential future clinical investigation. The potential benefits and risks are related to the clinical attributes that the IOL is designed to provide as well as to other specific design-related aspects. Given the clinical relevance of the optical characterization, the outcomes of testing performed according to this annex shall be used to include or exclude characteristics to be studied in the potential future clinical investigation designed according to ISO 11979-7^[13] and under the guidance of ISO/TR 22979^[14].

The clauses below provide a summary of the clinical outcomes under the scope of this Annex. Each of these clinical outcomes can be tied to preclinical assessments, that are mentioned in the subsequent clauses. Additional testing can be considered based on the risk assessment conducted for the specific IOL design under evaluation, e.g. unwanted optical/visual effect testing of SVIOLs.

In each case, the performance is compared preferably to that of the monofocal control to be used in the potential future clinical investigation. Optionally, other intraocular lenses of known clinical performance could be included in the comparison. The optical characterization for accommodating IOLs shall be performed in a physical eye model, based on the mechanism of action of the IOL.

For preclinical assessments that include optical bench testing, these shall be performed using the model eye described in [Annex B](#) and modified to allow measurements in white light:

- a) the light spectrum is covering at least the range of 400 nm to 700 nm;
- b) spectral sensitivity of the combination of light source, spectral filter(s), and camera sensitivity shall follow the photopic luminosity function $V(\lambda)$ for the eye, Reference [\[15\]](#);
- c) the model eye has a physiological amount of corneal spherical aberration, Reference [\[10\]](#);
- d) the model eye has a physiological amount of chromatic aberration, References [\[16\]](#) and [\[17\]](#).

NOTE Examples of an alternative model eyes suitable for optical characterization can be found in Annex C of Reference [\[18\]](#). The design of these model eyes, along with detailed test procedures for these model eyes, in addition to the model eye are provided in this document.

C.2 Distance vision

MTF through-frequency testing shall be performed and reported according to the conditions outlined below.

A total of 30 lenses (10 low, 10 medium, and 10 high spherical equivalent power) shall be used. In the case of toric IOLs, a total of 60 lenses shall be used, those representing the highest and lowest cylinder power for each group of spherical equivalent powers.

Use aperture sizes 2 mm, 3 mm and 4,5 or 5 mm ($\pm 0,1$ mm). Focus to give maximum modulation ratio for a spatial frequency in the range from 15 degree⁻¹ to 30 degree⁻¹ for a 3 mm aperture. Alternatively, a spatial frequency in the range from 50 mm⁻¹ to 100 mm⁻¹ may be used. For toric IOLs, MTF is measured in the meridians of highest and lowest dioptric power. Alternatively, use a null lens to permit MTF measurement of a toric IOL as a rotationally symmetric IOL. Report the MTF through-frequency data and the graphs representing the average MTF curves for each power and aperture tested.