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Ophthalmic implants — Intraocular lenses —

Part 2: Optical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —

Partie 2: Propriétés optiques et méthodes d'essai

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11979-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11979-2:1999), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11979-2:1999/Cor.1:2003.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

— *Part 1: Vocabulary*
— *Part 2: Optical properties and test methods*
— *Part 3: Mechanical properties and test methods*
— *Part 4: Labelling and information*
— *Part 5: Biocompatibility*
— *Part 6: Shelf-life and transport stability testing*
— *Part 7: Clinical investigations*
— *Part 8: Fundamental requirements*
— *Part 9: Multifocal intraocular lenses*
— *Part 10: Phakic intraocular lenses*

Introduction

This part of ISO 11979 initially addressed monofocal IOLs and now has been revised to include the requirements and test methods for spherical monofocal, aspheric monofocal, toric, multifocal, and accommodative IOLs. This part of ISO 11979 contains several test methods for which associated requirements are given and one test method for which no requirement is formulated. The former are directly connected to the optical functions of intraocular lenses. The latter, the test for spectral transmittance, has been provided for information about UV transmission and in specific situations, e.g. when using laser light sources for diagnosis and treatment.

For the original spherical monofocal IOLs, extensive interlaboratory testing was carried out before setting the limits specified. During this testing some basic problems were encountered as described in Reference [1]. The accuracy in the determination of 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] gives further discussion on this subject.

The majority of lenses hitherto implanted were qualified using the method described in Annex B or Annex C (model eye 1). The method in Annex B is limited in its applicability, however. The limits for the more general method in Annex C have been set in terms of MTF in a model eye, following two approaches. The first is by correlation to the method and limit in Annex B. Further discussion can be found in Reference [2]. The second is set as a percentage of what is calculated as theoretical maximum for the design, with the rationale that a minimum level of manufacturing accuracy be guaranteed. For common PMMA lenses, these two limits correspond well with each other. For lenses made of materials with lower refractive index, or with certain shape factors, or for extreme power lenses in general, the latter limit is lower than the former. However, such lenses are already in use, indicating clinical acceptance. The question of which is the absolute lowest limit that is compatible with good vision arises. No definite answer can be found, but following clinical data presented to the working group, an absolute lower limit has been set for the calculation method.

Ophthalmic implants — Intraocular lenses —

Part 2:
Optical properties and test methods

1 Scope

This part of ISO 11979 specifies requirements and test methods for certain optical properties of intraocular lenses (IOLs) with any of spherical, aspheric, monofocal, toric, multifocal, and/or accommodative optics. The generic descriptor 'IOL' used throughout this document also includes phakic intraocular lenses (PIOL).

2 Normative references

The following referenced documents are indispensable for the application 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 6328:2000, *Photography — Photographic materials — Determination of ISO resolving power*

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 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

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.

4 Requirements

4.1 General

The manufacturer shall demonstrate 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* conditions or equivalent following surgical manipulation and recovery. See ISO 11979-3 for more detail.

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

4.2 Dioptric power

4.2.1 General

The dioptric power of spherical or aspheric lenses as stated by the manufacturer in the IOL labelling shall be within the tolerance limits specified in Table 1. For rotationally symmetric lenses, these tolerances apply in all meridians.

Table 1 — Tolerance limits on spherical dioptric power, S

Nominal spherical dioptric power range[a] D	Tolerance limits on spherical dioptric power D
$0 \le S \le 15$	±0,3
$15 < S \le 25$	±0,4
$25 < S \le 30$	±0,5
$30 < S$	±1,0

[a] The ranges apply to positive as well as negative dioptric powers.

4.2.2 Dioptric power for toric IOL (TIOL)

When determined by any of the methods in Annex A, the dioptric power in the meridians of highest and lowest dioptric power and 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 range D	Tolerance limits on cylindrical dioptric power D SE < 25 D	Tolerance limits on cylindrical dioptric power D SE ≥ 25 D
$0 < C \le 2,5$	±0,3	±0,4
$2,5 < C \le 4,5$	±0,4	±0,4
$4,5 < C$	±0,5	±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°.

4.2.3 Dioptric power for multifocal IOL (MIOL)

Methods A.2 to A.4 can be applied to MIOL for determining the far power and any distinct near powers. When using A.2, dioptric power must be justified as a calculation based only on spherical surfaces. The dioptric power of the far power shall be within the tolerance limits specified in Table 1 and the dioptric power of the addition power(s) shall be within the tolerances in Table 3.

Table 3 — Tolerance limits on addition dioptric power, *A*

Nominal addition dioptric power range D	Tolerance limits on addition dioptric power D far power < 25 D	Tolerance limits on addition dioptric power D far power ≥ 25 D
$0 < A \leq 2,5$	±0,3	±0,4
$2,5 < A \leq 4,5$	±0,4	±0,4
$4,5 < A$	±0,5	±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 change of the lens or system in the eye resulting from the accommodative action shall be determined in a theoretical or laboratory eye model.

4.3 Determination of imaging quality

4.3.1 General

Imaging quality is dependent upon compatibility between the optical design and conditions that are used to evaluate optical performance. Imaging quality can be specified either as resolution efficiency or as the modulation transfer function (MTF) value at a specified spatial frequency. Resolution efficiency is determined according to the method described in Annex B. MTF is measured according to the method in Annex C.

MTF determined with the method described in Annex C is dependent on the compatibility between the optical design and model eye that is used to evaluate optical performance. For the method described in Annex C, example model eye specifications are given. 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 be provided. The imaging quality specifications apply to all available powers, unless stated otherwise.

NOTE 1 Optical resolution is expressed in spatial frequency. In Annex B, by tradition, resolution is in line-pairs per millimetre (lp/mm) and in Annex C in cycles per millimetre (c/mm or mm^{-1}). In the ophthalmic literature, cycles per degree is often used. For the eye, assuming a nodal point distance of 17 mm in image space, the conversion between the two is:

$$c/degree = 0,297 * c/mm$$

NOTE 2 The test apertures given in the subclauses of 4.3 and in Annexes A, B, and C represent the exposed central area of the IOL under test, which can differ from the aperture stop of the test system.

4.3.2 Monofocal lenses

4.3.2.1 General

Imaging quality for monofocal IOLs shall fulfil one of the requirements in 4.3.2.2, 4.3.2.3 or 4.3.2.4.

4.3.2.2 Resolution efficiency

If determined in accordance with Annex B, the resolution efficiency of the IOL shall be no less than 60 % of the diffraction limited cut-off spatial frequency for a 3 mm aperture. In addition, the image shall be

virtually free of detectable aberrations except due to spherical aberration normally expected for the lens design.

4.3.2.3 MTF using model eye 1

If determined in accordance with Annex C using model eye 1 (C.3.1), the MTF value of the model eye with IOL configuration shall at 100 mm^{-1} meet either of the two requirements given below:

a) be greater than or equal to 0,43;

b) be greater than or equal to 70 % of the maximum theoretically attainable modulation for the specific IOL design, but in any case be greater than or equal to 0,28.

NOTE The acceptance levels given in 4.3.2.2 and 4.3.2.3 a) correspond well with each other for PMMA lenses in the range of 10 D to 30 D[2].

4.3.2.4 MTF using model eye 2

If determined in accordance with Annex C using model eye 2 (C.3.2), the MTF value of the configuration of model eye with IOL shall at 100 mm^{-1} be greater than or equal to 70 % of the maximum theoretical attainable MTF for a 3 mm aperture, but in any case greater than or equal to 0,28.

4.3.3 Toric IOL (TIOL)

4.3.3.1 General

Imaging quality for toric IOLs shall fulfil one of the requirements in 4.3.3.2 or 4.3.3.3.

4.3.3.2 Resolution efficiency

When the null lens method described in Annex B is used, the general resolution efficiency requirements in 4.3.2.2 shall apply to the combined system of toric IOL and null lens.

4.3.3.3 MTF

The MTF requirements described in 4.3.2.3 or 4.3.2.4 shall apply to the meridians of highest and lowest dioptric power.

4.3.4 Multifocal IOL (MIOL)

4.3.4.1 MTF

The imaging quality specifications apply in all meridians, unless the MIOL also comprises a cylinder component, in which case the considerations of 4.3.6 apply. The imaging quality of a MIOL shall be evaluated by modulation transfer function (MTF) testing in one of the model eyes described in Annex C with the following additions:

The method in Annex C is modified such that best focus for the dioptric power under evaluation is obtained by maximizing the MTF at 50 mm^{-1} with a 3,0 mm ± 0,1 mm aperture. Using that focus, record the MTF values at the following conditions:

a) small aperture (2 mm to 3 mm), 25 mm^{-1} and 50 mm^{-1}, for the far dioptric power;

b) large aperture (4 mm to 5 mm), 25 mm^{-1} and 50 mm^{-1}, for the far dioptric power;

c) small aperture (2 mm to 3 mm), 25 mm^{-1} and 50 mm^{-1}, for the near dioptric power(s) or power range.

In order to best control the MTF performance of the MIOL, the small and large apertures used for testing shall be chosen and defined for the lens model over the range of apertures provided above with a tolerance of ± 0,1 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. The MTF shall be greater than or equal to 70 % of the maximum theoretically attainable modulation for the specific IOL design. Alternatively, the minimum MTF specification shall be set such that it results in an acceptable visual outcome, verifiable, or to be verified, by clinical data.

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

For toric multifocal and toric accommodating lenses, the general imaging requirements for all principles in 4.3.3 apply along with the special test requirements in 4.3.4 and 4.3.5, respectively.

For multifocal accommodating lenses the imaging 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 and low power lenses in conjunction with the model eye described, the manufacturer shall justify any alternate spatial frequencies and criteria applied.

4.4 Spectral transmittance

4.4.1 Measurement of spectral transmittance

The spectral transmittance in the range 300 nm to 1 100 nm shall be recorded by a UV/Visible spectrophotometer with a 3 mm aperture in aqueous, or be corrected for specular reflection if measured in air. The measurement should be accurate to ± 2 % transmittance and the resolution should not be less than 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 IOL and having undergone the same production treatment as the finished IOL including sterilization.

4.4.2 Cut-off wavelength

Designate UV cut-off as UV(XXX) where XXX is the wavelength in nanometres at which the spectral transmission is below 10 % when measured according to 4.4.1.

NOTE Guidance for the measurement of spectral transmittance can be found in ISO 18369-3:2006[3].

Annex A
(normative)

Measurement of dioptric power

A.1 General

Multiple methods of determining IOL dioptric power are given below. The specific methods and requirements for spherical and aspheric monofocal, toric, or multifocal IOL measurement are described in this annex where applicable.

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 ± 0,1 mm in diameter is used.

NOTE 1 For more details about optical measurement and calculations, see Reference [4] or similar textbooks on optics.

NOTE 2 A modified bench (e.g. additional converging lens, a microscope objective of appropriate numerical aperture, etc.) may be needed 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 surface radii over a region of approximately 3 mm diameter using a radius meter, interferometer, or optical coherence tomograph (OCT)[5]. Measure the lens thickness with a micrometer or equivalent device. Calculate the dioptric power, using the Equation:

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

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.