DRAFT INTERNATIONAL STANDARD ISO/DIS 11979-2

ISO/TC **172**/SC **7** Secretariat: **DIN**

Voting begins on **2012-07-05** Voting terminates on **2012-12-05**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Ophthalmic implants — Intraocular lenses —

Part 2:
Optical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —

Partie 2: Propriétés optiques et méthodes d'essai

[Revision of first edition (ISO 11979-2:1999) and ISO 11979-2:1999/Cor.1:2003]

ICS 11.040.70

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

Contents

Page

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.

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, and by Technical Committee CEN/TC 170, *Ophthalmic optics* in collaboration.

This second edition cancels and replaces the first edition (EN ISO 11979-2:1999+Cor.1:2003), which has been technically revised.

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*

— *Part 7: Clinical investigation*

— *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 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. Thus the general clinical experience is associated with this level. 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 spherical, aspheric, toric, multifocal, and 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 optical instruments — Optical transfer function — Definitions and mathematical relationships*

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

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

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

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

U.S. Mil Std 150-A-1961, *Photographic lenses*

3 Terms and definitions

Terms and definitions stated in ISO 11979-1 and ISO 9334 apply to this standard.

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 all optical properties are retained 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 image quality requirements.

4.2 Dioptric power

4.2.1 General

The spherical dioptric power 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, P

Nominal spherical dioptric power range[a] (D)	Tolerance limits on spherical dioptric power (D)
$0 < P \le 15$	± 0,3
$15 < P \le 25$	± 0,4
$25 < P \le 30$	± 0,5
$30 < P \le 34$	± 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 or the spherical equivalent power shall be within the tolerance limits for dioptric power specified in Table 1. Additionally, the cylinder power calculated as the absolute difference in orthogonal meridional powers shall be within the cylindrical power tolerance limits specified in Table 2.

Table 2 — Tolerance limits on cylinder dioptric power, P

Nominal cylinder dioptric power range (D)	Tolerance limits on cylinder dioptric power (D) <25 D	Tolerance limits on cylinder dioptric power (D) 25 D to 34 D
$0 < P \le 2{,}5$	± 0,3	± 0,4
$2{,}5 < P \le 4{,}5$	± 0,4	± 0,4
$4{,}5 > P$	± 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°. The angle difference shall be accepted as being less than or equal to 5,0° if the lens conforms to the image quality requirements using the toric null lens methods described in Annexes B and C with the null lens aligned with the physical axis indicator. The tolerances in Table 1 apply.

4.2.3 Dioptric power for multifocal IOL (MIOL)

Methods A.1 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 if it is used.

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 as result of the accommodative action shall be determined in a model eye and reported.

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 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 sub-clauses 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 following requirements:

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 configuration of model eye with IOL 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 1 The approval 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].

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

Manufactures shall justify alternate spatial frequencies used to characterize IOLs with dioptric powers below +10 D.

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 Multifocal IOL (MIOL)

4.3.3.1 Imaging quality

The imaging quality specifications apply in all meridians, unless the MIOL also comprises a cylinder component, in which case the considerations of 4.3.4 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) small aperture (2 mm to 3 mm), 25 mm^{-1} and 50 mm^{-1}, for the near dioptric power(s) or power range;

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

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 minimum MTF specification shall be set such that it results in an acceptable visual outcome, verifiable, or to be verified, by clinical data.

NOTE It is acceptable to have a different imaging quality specification for each combination of test aperture and focus.

4.3.4 Toric IOL (TIOL)

4.3.4.1 Resolution efficiency

When the null lens method described in Annex B is used, the general resolution efficiency requirements in 4.3.2.1 shall apply to the combined system of toric IOL and null lens.

4.3.4.2 MTF

The MTF requirements described in 4.3.2 shall apply to the meridians of highest and lowest dioptric power.

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

For toric accommodating lenses the image requirements of 4.3.4 and 4.3.5 apply.

