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Ögonimplantat – Intraokulära linser –
Del 2: Optiska egenskaper och provningar (ISO 11979-2:2014)

Ophthalmic implants – Intraocular lenses –
Part 2: Optical properties and test methods (ISO 11979-2:2014)

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Europastandarden EN ISO 11979-2:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11979-2:2014.

Denna standard ersätter SS-EN ISO 11979-2, utgåva 1.

The European Standard EN ISO 11979-2:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 11979-2:2014.

This standard supersedes the Swedish Standard SS-EN ISO 11979-2, edition 1.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 11979-2:2014/ Relations to other parts under the same general title - Extract from the Foreword of ISO 11979-2:2014

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*

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Denna standard är framtagen av kommittén för Ögonoptik, SIS/TK 336.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-2

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Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 2: Propriétés optiques et méthodes d'essai (ISO 11979-2:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 2: Optische Eigenschaften und Prüfverfahren (ISO 11979-2:2014)

This European Standard was approved by CEN on 25 July 2014.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN ISO 11979-2:2014) 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 February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

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This document supersedes EN ISO 11979-2:1999.

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Endorsement notice

The text of ISO 11979-2:2014 has been approved by CEN as EN ISO 11979-2:2014 without any modification.

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:

$$c/\text{degree} = 0{,}297 * c/\text{mm}$$

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