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Očesni vsadki (implantati) - Intraokularne leče - 2. del: Optične lastnosti in preskusne metode (ISO/DIS 11979-2:2023)

Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO/DIS 11979-2:2023)

Ophthalmische Implantate - Intraokularlinsen - Teil 2: Optische Eigenschaften und Prüfverfahren (ISO/DIS 11979-2:2023)

Implants ophtalmiques - Lentilles intraoculaires - Partie 2: Propriétés optiques et méthodes d'essai (ISO/DIS 11979-2:2023)

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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

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 committees has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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

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 the this document due to advancements in optical designs and the availability of modulation transfer function (MTF) imaging quality measurement methods;
- A new normative annex, Annex C IOL – Characterization, has been added with associated requirements for all IOL categories;
- Clarified description of UV cut-off wavelength;
- 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 part of ISO 11979 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 1) 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; 2) optical characterization testing that informs potential optical design risks and guide 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 1) Air Force target-based resolution efficiency or 2) MTF using a minimal spherical aberration model eye, or 3) 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 section (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. No additional optical characterization is required for lens models approved under previous standard editions.

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

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

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia*

ISO/TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

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 for more detail.

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.

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. For rotationally symmetric lenses, these tolerances apply in all meridians. Manufacturers shall consider measurement precision in establishing release specifications for all IOLs.

Table 1 — Tolerance limits on spherical dioptric power, S

Nominal spherical dioptric power [a] D	Tolerance limits on spherical dioptric power D
$0 \le \lvert S \rvert \le 15$	±0,3
$15 < \lvert S \rvert \le 25$	±0,4
$25 < \lvert S \rvert \le 30$	±0,5
$30 < \lvert S \rvert$	±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 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 simultaneous vision IOL (SVIOL)

Methods A.3 to A.4 can be applied to SVIOL 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