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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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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.

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.