AS ISO 11979.2—2003
ISO 11979-2:1999

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 2: Optical properties and test methods

Standards Australia

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Part 2: Optical properties and test methods

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 11979-2:1999, *Ophthalmic implants—Intraocular lenses—Part 2: Optical properties and test methods.*

The objective of this Standard is to specify requirements and test methods for certain optical properties of non-toric, monofocal intraocular lenses intended for implantation into the anterior segment of the human eye, excluding corneal implants.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

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References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
11979	Ophthalmic implants—Intraocular lenses	11979	Ophthalmic implants—Intraocular lenses
11979-1	Part 1: Vocabulary	11979.1	Part 1: Vocabulary

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INTRODUCTION

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 those interested in information about UV transmission and in specific situations, e.g. when using laser light sources for medical diagnosis and treatment.

Extensive interlaboratory testing has been carried out before setting the limits specified. Some basic problems were encountered.

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 have been made from poly(methyl methacrylate) (PMMA), and 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 an eye model, 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 arises which is the absolute lowest limit that is compatible with good vision. 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.

NOTE It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-2 and EN ISO 11979-2). For those parts where no identical versions exist, it is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

AUSTRALIAN STANDARD

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).

It is applicable but not limited to non-toric, monofocal intraocular lenses intended for implantation into the anterior segment of the human eye, excluding corneal implants.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6328: —[1)], *Photography — Photographic materials — Determination of ISO resolving power.*

ISO 9334:1995, *Optics and optical instruments — Optical transfer function — Definitions and mathematical relationships.*

ISO 9335:1995, *Optics and optical instruments — Optical transfer function — Principles and procedures of measurement.*

ISO 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary.*

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

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 9334 and ISO 11979-1 apply.

NOTE Some definitions from ISO 11979-1 are reproduced for information in annex G.

1) To be published. (Revision of ISO 6328:1982)

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