INTERNATIONAL STANDARD

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Contact lenses — Determination of back vertex power —

Part 2: Measurement of contact lenses immersed in saline

Lentilles de contact — Détermination de la puissance frontale arrière —

Partie 2: Mesurage des lentilles de contact immergées dans une solution saline

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Foreword

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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 9337-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 9337 consists of the following parts, under the general title *Contact lenses — Determination of back vertex power*:

— *Part 1: Method using focimeter with manual focusing*

— *Part 2: Measurement of contact lenses immersed in saline*

Introduction

It is intended that the test methods described in this part of ISO 9337 should be used by contact lens manufacturers, practitioners and other interested parties.

It has been assumed in drafting this part of ISO 9337 that the execution of its provisions will be entrusted to appropriately qualified and experienced people.

Contact lenses — Determination of back vertex power —

Part 2:
Measurement of contact lenses immersed in saline

1 Scope

This part of ISO 9337 describes test methods for the determination of back vertex power of soft contact lenses immersed in saline. It is applicable to finished contact lenses.

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 8320-1, *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses*

ISO 8320-2, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products*

ISO 10344, *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8320-1 and ISO 8320-2 apply.

4 Test methods

The test methods specified in Annex A are listed in Table 1, together with a statement of their reproducibility when applied to spherical or toric soft contact lenses. Reproducibility of a method should be half or less of the product tolerance in order to verify the tolerance.

Table 1 — Test methods

Test method	Application	Reproducibility, R
Moiré deflectometer	Spherical soft lenses	0,252 8 D
	Toric soft lenses:	
	Sphere power	0,442 1 D
	Cylinder power	0,260 4 D
	Axis direction	3,416°
Hartmann method	Spherical soft lenses	0,070 8 D
	Toric soft lenses:	
	Sphere power	0,181 7 D
	Cylinder power	0,243 9 D
	Axis direction	5,644 8°

Annex A
(normative)

Determination of back vertex power of contact lenses immersed in saline

A.1 Scope

This annex specifies a method for determining the back vertex power of soft contact lenses immersed in saline using: (1) the Moiré deflectometer and (2) the Hartmann method.

A.2 Principle

The **Moiré deflectometer** is a quantitative instrument for mapping ray deflections of a beam passed through or reflected off a test object. The technique is based on the Moiré effect, a phenomenon that causes a fringe pattern to appear when two gratings are placed at a small angle to each other. The fringe pattern is detected by a CCD camera and digitized. Digital information relating to the fringe pattern is relayed through the electro-optical interface to the control software for analysis. The resulting image is displayed on a visual display unit.

The system is calibrated so that when there is no contact lens in the cuvette, the beam is collimated and straight vertical fringes are observed. When a contact lens is inserted in the cuvette, the fringes deviate from the vertical. The laser light source is translated by means of a servomotor under software control until the fringes are restored to the vertical. The power of the cuvette-contact lens combination is determined from the distance the laser travels, from which the dioptric power of the lens being measured is calculated. It is necessary to calculate the back vertex power of the contact lens in air based on the parameters of the cuvette, saline and contact lens.

The **Hartmann instrument** is used to measure the power-related components of optical elements that are placed in the path of a beam of light that then passes through a screen containing a number of microlenses. Typically, the screen consists of an array of microlenses arranged in a square matrix. The measuring system is arranged so that a reference image is taken before the optical element to be measured is placed in the system. The image produced by the microlenses is memorized; this acts as the reference image. The optical element to be measured is then introduced to the system. The image of the microlenses is altered by the power-related parameters of the element being measured. It can be shown that the transverse aberrations of the image of the microlenses are a function of the power-related parameters of the element being measured. An algorithm is used to calculate the power-related parameters of the element being measured.

A.3 Apparatus and reagent

A.3.1 Moiré deflectometer or **Hartmann instrument**, having the following capabilities:

A.3.1.1 The diameter of the central aperture through which the power is measured shall be adjustable and at least be capable of being set to 4,50 mm ± 0,50 mm.

A.3.1.2 The instrument shall have a measuring range of at least – 25,00 D to + 25,00 D.

NOTE This requirement should apply to the powers in air; suitable allowance should be made in the system for the power of lenses immersed in saline.

A.3.1.3 The instrument shall have a positioning mechanism for the cuvettes containing the contact lenses, designed so that the lens being measured is located centrally in the measuring system.

A.3.2 Eight spherical test lenses, with the nominal back vertex power of each test lens being within one dioptre of – 20,00 D, – 15,00 D, – 10,00 D, – 5,00 D, + 5,00 D, + 10,00 D, + 15,00 D and + 20,00 D. The powers of the test lenses shall be traceable to a national or International Standard. The following parameters shall be known for each of the test lenses, to the accuracy given:

— centre thickness to ± 0,01 mm;

— base curve to ± 0,05 mm;

— diameter to ± 0,05 mm;

— refractive index correct to 3 places of decimals.

NOTE Test lenses conforming to ISO 9342-2 may be used.

A.3.3 Calibrated cuvettes, such that the optical properties of the cell walls of the cuvettes used in the measurement shall not influence the outcome of the test.

A.3.4 Standard saline solution conforming to ISO 10344. The refractive index of the saline solution shall be known correct to 3 places of decimals.

A.4 Procedure

A.4.1 Conditioning of lenses prior to testing

Condition each test lens prior to testing as follows.

Immerse in a vial filled with standard saline solution (A.3.4) and maintain at a temperature of 20 °C ± 0,5 °C for 30 min.

NOTE If 30 min is not sufficient time for the lens polymer to equilibrate, the lens manufacturer should state the time required.

A.4.2 Calibration

A.4.2.1 At a temperature of 20 °C ± 5 °C and using the spherical test lenses (A.3.2) arranged in calibrated cuvettes (A.3.3), follow the manufacturer's instructions to calibrate the instrument.

NOTE The average measured power for each lens should be within ± 0,04 D of the nominal value.

A.4.2.2 Take three independent readings and record the mean.

NOTE "Independent reading" means a reading that is obtained in a manner not influenced by any previous reading; the test lens should be removed from the instrument between each reading.

A.4.2.3 Plot the results on a calibration curve.

NOTE The preferred method of plotting a calibration curve is to use a linear least squares best fit.

A.4.3 Measurement of back vertex power

A.4.3.1 Transfer the lens from its equilibrating vial to a cuvette filled with standard saline solution (A.3.4) using a lens lift.

A.4.3.2 Make sure the lens is not everted.

A.4.3.3 Place the cuvette in the positioning mechanism (see A.3.1.3) as specified by the instrument manufacturer.

A.4.3.4 Follow the instrument manufacturer's instructions to obtain a reading of the back vertex power of the lens being measured.

A.4.4 Number of readings required

A.4.4.1 General

The number of readings required for spherical soft lenses is given in Tables A.1 or A.3 according to the instrument used. The number of readings required for each of the power-related dimensions of toric soft lenses is given in Tables A.2 or A.4.

NOTE The number of readings required will depend on the tolerance limit of the dimension being measured and the precision of the test method as assessed by an inter-laboratory test. Tables A.1, A.2, A.3 and A.4 are based on the outcome of inter-laboratory tests as given in A.5.

A.4.4.2 Spherical lenses

Take a number of independent readings (see note to A.4.2.2) of the back vertex power as specified in Table A.1 and calculate the mean. Use the calibration curve (see A.4.2.3) to determine the corrected mean.

A.4.4.3 Toric lenses

The number of independent readings required will depend on the power-related parameter being measured and is specified in Table A.2. Take the specified number of independent readings of the toric power-related parameters and calculate the mean. In the case of sphere and cylinder powers, use the calibration curve (see A.4.2.3) to determine the corrected mean.

Table A.1 — Number of readings required for spherical lenses: Moiré deflectometer

Parameter	Tolerance limit	Number of measurements
Back vertex power		
0 to ± 10 D	± 0,25 D	2
over ± 10 D to ± 20 D	± 0,50 D	1
over 20 D	± 1,00 D	1

Table A.2 — Number of readings required for toric soft lenses: Moiré deflectometer

Parameter	Tolerance limit	Number of measurements
Sphere power		
0 to ± 10 D	± 0,25 D	7
over ± 10 D to ± 20 D	± 0,50 D	2
over 20 D	± 1,00 D	2
Cylinder power		
up 2,00 D	± 0,25 D	2
over 2,00 D to 4,00 D	± 0,37 D	1
over 4,00 D	± 0,50 D	1
Axis direction	± 5°	2