INTERNATIONAL STANDARD

**ISO 9337-1**

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# Contact lenses — Determination of back vertex power —

## Part 1:
Method using focimeter with manual focusing

*Lentilles de contact — Détermination de la puissance frontale arrière —*
*Partie 1: Méthode utilisant un frontofocomètre à mise au point manuelle*



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## Contents







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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 committee 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

International Standard ISO 9337-1 was prepared by ISO/TC 172, *Optics and optical instruments,* 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 on contact lenses immersed in saline.*

## Introduction

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

The method as applied to rigid contact lenses does not differentiate between contact lenses which are stored wet and those which are stored dry. The test procedure allows for wet storage by specifying that wet contact lenses require blotting before measurement. It is considered that the measured value of back vertex power of rigid contact lenses is not influenced by wet storage.

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 1:
Method using focimeter with manual focusing

## 1 Scope

This part of ISO 9337 describes test methods for the determination of back vertex power of both rigid and hydrogel contact lenses in air using a focimeter with manual focusing. It is applicable to finished contact lenses.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9337. 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 9337 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 8320-1, *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses.*



ISO 10344, *Ophthalmic optics — Contact lenses — Saline solution for contact lens testing*.

## 3 Terms and definitions

For the purposes of this part of ISO 9337, the terms and definitions given in ISO 8320-1 apply, together with the following.

**3.1**
**back vertex power**
$F'_v$
reciprocal of the paraxial value of the back vertex focal length, measured in metres

**3.2**
**dioptre**
**D**
unit of focusing power of a lens or surface, or of the vergence (refractive index divided by the radius) of a wavefront

NOTE 1 Commonly used symbols for dioptre are D, dpt and δ.

NOTE 2 Dioptre is expressed in reciprocal metres ($m^{-1}$).

**3.3**
**repeatability**
closeness of agreement between mutually independent test results obtained under repeatability conditions

[ISO 3534-1]

**3.4**
**repeatability conditions**
conditions where mutually independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time

[ISO 3534-1]

**3.5**
**repeatability value**
*r*
value below which the absolute difference between two single test results obtained under repeatability conditions may be expected to lie with a probability of 95 %

[ISO 3534-1]

**3.6**
**reproducibility**
closeness of agreement between mutually independent test results obtained under reproducibility conditions

[ISO 3534-1]

**3.7**
**reproducibility conditions**
conditions where mutually independent test results are obtained with the same methods on identical test material in different laboratories with different operators using different equipment

[ISO 3534-1]



**3.8**
**reproducibility value**
*R*
value below which the absolute difference between two single test results obtained under reproducibility conditions may be expected to lie with a probability of 95 %



[ISO 3534-1]

## 4 Determination of back vertex power

### 4.1 Principle

The back vertex power of rigid and hydrogel contact lenses in air is measured using the focimeter.

### 4.2 Apparatus and reagent

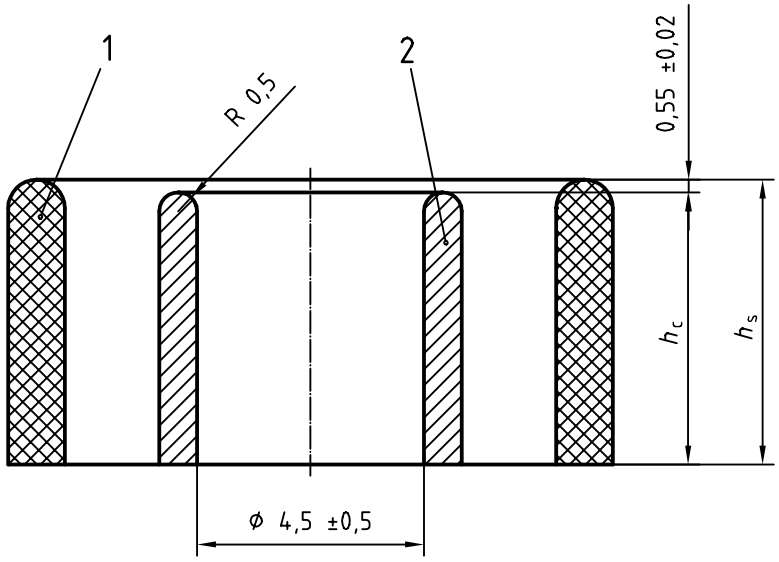
**4.2.1 Focimeter**, provided with a contact lens support.

NOTE 1 Manually focusing focimeters conforming to ISO 8598 may be used. Other focimeters may be used provided that the readings derived are shown to be equivalent to those of a manually focusing focimeter.

The contact lens support shall be designed so that the contact lens rests on the supporting ring only. Figure 1 shows an example of a suitable support design. Its central aperture has a diameter of 4,50 mm ± 0,50 mm and projects 0,55 mm ± 0,02 mm less than the spectacle lens support which it replaces.

NOTE 2 This change in projection provides accurate power readings on lenses with a back optic zone radius of 8,00 mm. Lenses with back optic zone radii substantially different from this may require further vertex distance correction.

Dimensions in millimetres




**Key**

1 Spectacle lens support, height $h_s$
2 Contact lens support, height $h_c$

**Figure 1 — Example of a contact lens support in comparison with the spectacle lens support which it replaces**



**4.2.2 Six spherical test lenses** having nominal back vertex power 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 respectively. The back vertex powers of the test lenses shall be traceable to a national or International Standard.



NOTE Test lenses conforming to ISO 9342 may be used.

**4.2.3 Standard saline solution** conforming to ISO 10344.

## 4.3 Conditioning of contact lenses prior to testing

Condition each contact lens prior to testing as follows.

a) For rigid contact lenses, maintain at a temperature of 20°C ± 5°C for 30 min.

b) For hydrogel contact lenses, immerse in a vial filled with standard saline solution (4.2.3) and maintain at a temperature of 20,0 °C ± 0,5 °C for 30 min.

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

## 4.4 Procedure

### 4.4.1 Calibration

At a temperature of 20°C ± 5°C and using the spherical test lenses (4.2.2), calibrate the focimeter fitted with its spectacle lens support.

Place each test lens centrally with its back surface against the spectacle lens support, and focus the focimeter to obtain the clearest possible image. Record the focimeter reading. Take three independent readings within 30 s and record the mean. Plot the results on a calibration curve.

NOTE 1 The term ‘independent’ means that the test lens is removed from the instrument and remounted between each reading.

NOTE 2 The preferred method of plotting a calibration curve is to use a quadratic best-fit.

#### 4.4.2 Measurement of back vertex power of rigid contact lenses

If necessary, blot the contact lens between two layers of tissue to remove all visible surface liquid.

Place the lens with its back surface centrally on the contact lens support and focus the focimeter to obtain the clearest possible image. Record the focimeter reading.

NOTE Before measuring back vertex power, the contact lens should have passed a test of optical quality.

Take four independent readings (see note 1 to 4.4.1) of the back vertex power, calculate the mean and, using the calibration curve (4.4.1), determine the corrected mean.

#### 4.4.3 Measurement of back vertex power of hydrogel contact lenses

Transfer the contact lens to a lint-free tissue using a lens lift. Blot the lens between two layers of tissue to remove all visible surface liquid. Make sure the contact lens is not everted.

Place the lens with its back surface centrally on the contact lens support. Focus the focimeter to obtain the clearest possible image. Record the focimeter reading.

NOTE 1 These actions should be carried out in the shortest possible time, in order to minimize dehydration of the lens.

If the image is not clear, recondition the contact lens in standard saline solution and repeat the above procedure.

NOTE 2 Before measuring back vertex power, the contact lens should have passed a test of optical quality.

For spherical contact lenses, take five independent readings (see note 1 to 4.4.1) of the back vertex power, calculate the mean and, using the calibration curve (4.4.1), determine the corrected mean.



For toric hydrogel contact lenses:



a) take 19 independent readings to determine spherical power to within ± 0,25 D;

b) take17 independent readings to determine cylinder power to within ± 0,25 D; and

c) take 7 independent readings to determine axis direction to ± 5°.

NOTE 3 These criteria for toric contact lenses have been established by means of an international interlaboratory test. However, fewer readings may be taken if the values are not required to the above precision.

## 5 Expression of results

The back vertex power of the contact lens, in dioptres, shall be reported as follows:

a) for rigid contact lenses, the corrected mean value determined as described in 4.4.2;

b) for hydrogel contact lenses, the corrected mean value determined as described in 4.4.3.

## 6 Precision data

Precision data for the measurement of back vertex power of rigid and hydrogel contact lenses are given in annex A

## 7 Test report

The test report shall contain at least the following information:

a) the name of the laboratory carrying out the test;

b) all necessary details for the identification of the contact lens tested;

c) a reference to this part of ISO 9337;

d) details of how the optical quality of the contact lens has previously been determined;

e) the back vertex power of the contact lens, in dioptres;

f) the date on which the test was carried out.