INTERNATIONAL STANDARD

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Ophthalmic optics — Contact lenses — Determination of rigid lens flexure and breakage

Optique ophtalmique — Lentilles de contact — Détermination de la flexion et de la rupture des lentilles de contact rigides

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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 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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11984 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lenses — Determination of rigid lens flexure and breakage

1 Scope

This International Standard describes a method for determining the flexural properties of finished rigid contact lenses when tested under specified conditions.

The existence of this International Standard does not imply in any way that the testing of contact lenses for flexure and breakage is a requirement.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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.

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ISO 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols.*

ISO 9337-1, *Contact lenses — Determination of back vertex power — Part 1: Method using focimeter with manual focusing.*

ISO 9337-2, *Contact lenses — Determination of back vertex power — Part 2: Measurement on contact lenses immersed in saline.*

ISO 9338:1996, *Optics and optical instruments — Contact lenses — Determination of diameters.*

ISO 9339-1, *Optics and optical instruments — Contact lenses — Determination of thickness — Part 1: Rigid contact lenses.*

ISO 10338:1996, *Optics and optical instruments — Contact lenses — Determination of curvature.*

ISO 10344:1996, *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8320 apply, together with the following.

3.1
flexural deformation
reduction of the diameter of the contact lens due to a load applied to the edge of the contact lens, perpendicular to the lens axis, to induce flexure

NOTE It is expressed as a percentage of the original lens diameter.

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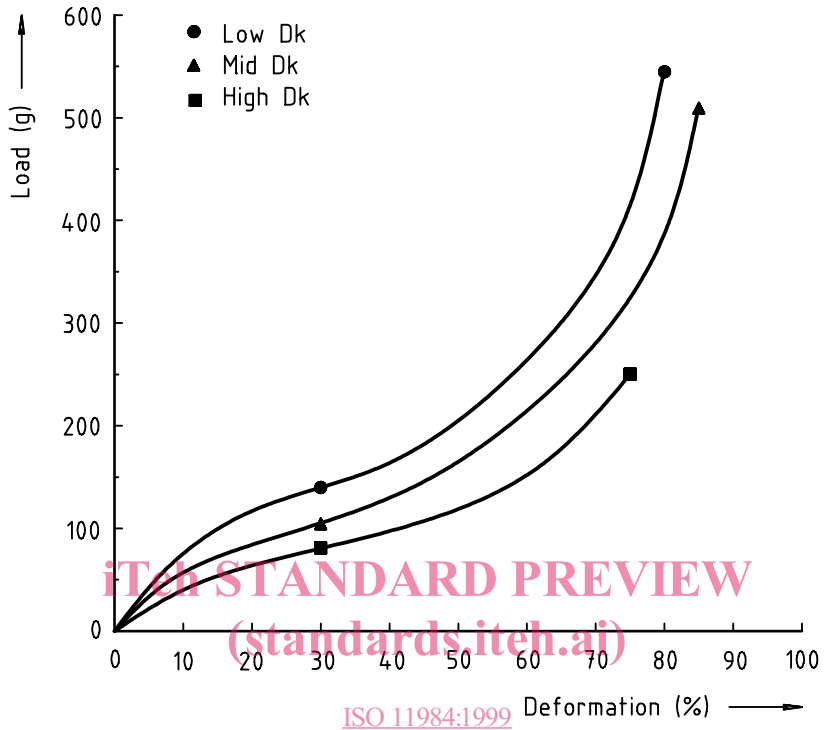
3.2
flexural load-deformation curve
curve obtained by plotting loads as ordinates against corresponding deformations as abscissae for the entire course of a deformation loading test

See Figure 1.



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Dk = oxygen permeability
Contact lens design: 8,00/plano/9,5/0,20, edge R 0,1 mm
Velocity: 20 cm/min

Figure 1 — Flexural load-deformation curve

3.3
flexural deformation strength
load applied at the contact lens edge at a specific point during a flexural loading test

NOTE For the purposes of this International Standard, the flexural deformation strength at rupture and at a 30 % deformation of the contact lens are of primary importance.

3.4
conditioning
procedure intended to bring a sample or test specimen into a state of equilibrium with regard to hydration and temperature

3.5
vertex sphere
imaginary spherical surface touching the back vertex of the lens

NOTE The radius of curvature of the vertex sphere is the same as the back optic zone radius (r_0) or the apical radius of a contact lens with an aspheric back optic zone (ISO 8320).

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4 Test method

4.1 Principle

The test, which is a destructive test, applies an increasing load at the edge of a rigid contact lens across the total diameter until ultimately the test sample fractures. The test is carried out in an apparatus which allows the load and flexural deformation to be monitored continuously. Both the flexural deformation strength and flexural deformation at rupture are determined, as well as flexural deformation strength at 30 % deformation. The latter is derived from the flexural load-deformation curve. Both normal production and specially constructed rigid contact lenses can be tested.

4.2 Sampling

4.2.1 General requirements

In order to demonstrate the degree of resistance to breakage by the material, general samples for testing shall be normal, commercially available rigid, single-vision contact lenses and shall not have been specially treated or adjusted.

Contact lenses which have toroidal zones or truncations shall not be used.

The specified back vertex power (F'_v) shall be the same for all samples and shall be between +0,50 D and –0,50 D.

The specified back optic zone radius (r_0), or radius of the vertex sphere, shall be the same for all samples and shall be between 7,75 mm and 7,85 mm.

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4.2.2 Samples for material comparison

When special samples are prepared in order to compare materials, the contact lenses shall have the following specifications:

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— front surface: single cut, radius of curvature 8,00 mm ± 0,025 mm

— back surface: single cut, radius of curvature 7,80 mm ± 0,025 mm

— total diameter 9,5 mm ± 0,1 mm

— centre thickness: 0,20 mm ± 0,01 mm

— edge thickness: 0,24 mm ± 0,01 mm

— edge form: rounded

— maximum prismatic error: 0,5 Δ

The method of manufacture shall be stated in the test report.

4.2.3 Quantity

When the samples are commercially available contact lenses, three contact lenses from each of three different lots (a total of nine contact lenses) shall be tested where a claim is made regarding flexure or strength.

In the case of custom-made lenses or samples, a minimum of five contact lenses made with the same specification shall be tested where a claim is made regarding flexure or strength.

4.3 Preparation of samples

Samples shall be stored in saline solution conforming to ISO 10344 for at least 48 h prior to testing. The temperature of this saline solution shall be 20 °C ± 5 °C, in accordance with ISO 9337-2.

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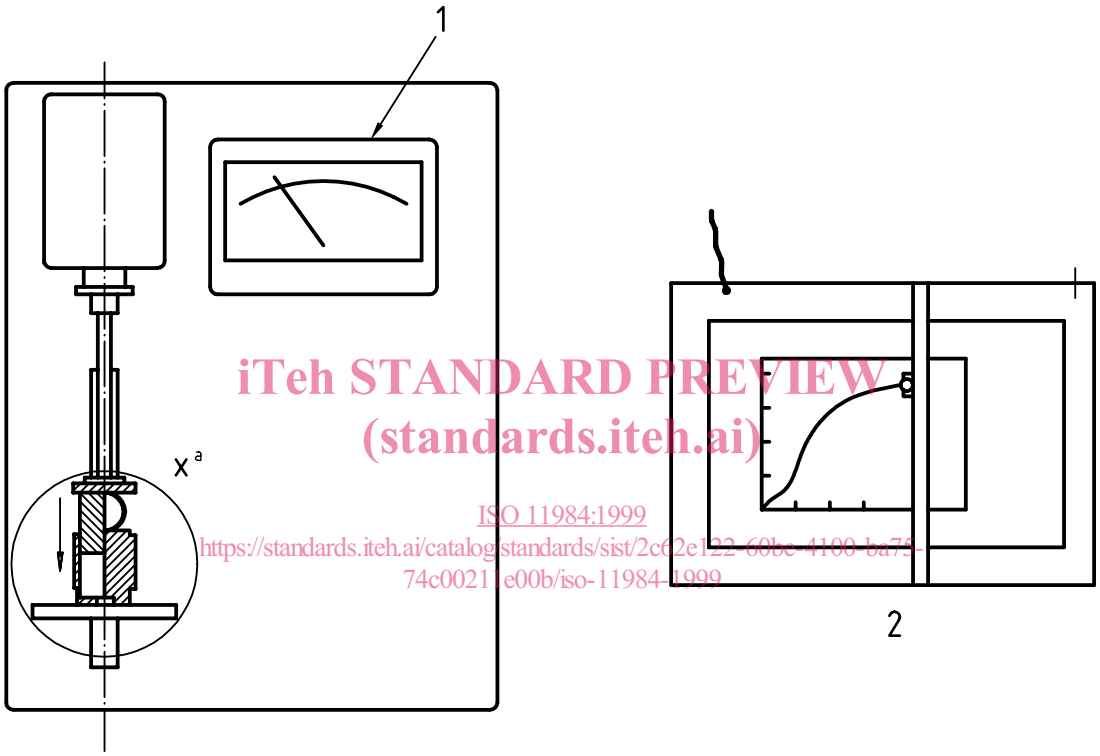
4.4 Apparatus

4.4.1 **Testing machine** (see Figure 2)

The apparatus applies a load to the sample at a fixed rate in either the horizontal or vertical plane. It is composed of the following units:

a) Sample holding jig

The jig (Figure 3) applies the load to the edge of the sample. The sample is set at the centre of the upper and lower contact faces so that the whole load is applied in the plane containing the edge. The contact faces are constructed so that the load is the only force applied to the sample.



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Key

1 Load indicator

2 Recorder

a See details in Figure 3.

Figure 2 — Testing machine

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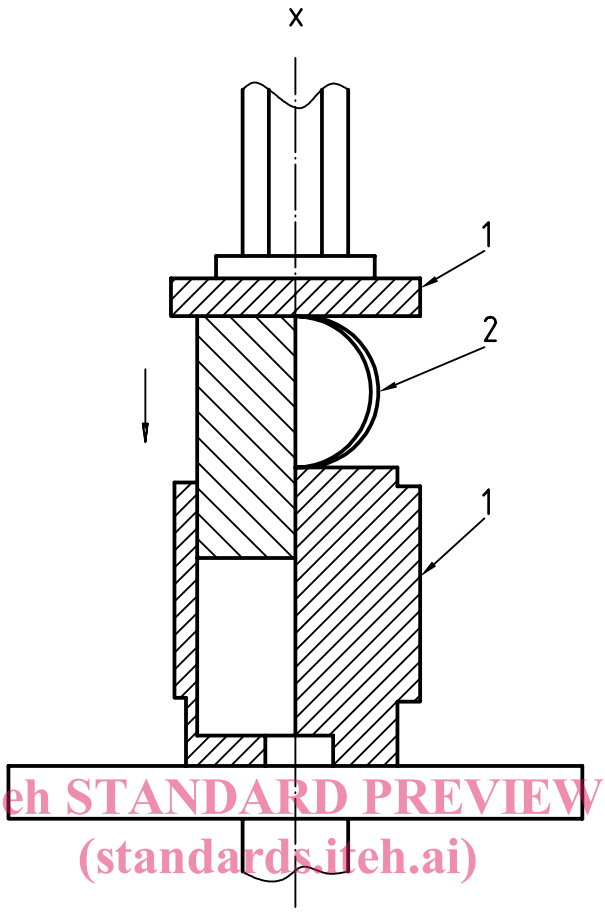

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Key

1 Test specimen setting jig
2 Test specimen

Figure 3 — Test specimen setting jig

b) Load indicator

The apparatus is fitted with a load-indicating device capable of indicating the total load applied to the sample.

c) Data recorder

The apparatus is connected to a data recorder which, after commencement of application of the load to the sample, provides a recording of the total load applied to the sample as a function of time. Although it is conventional to use a paper-strip (chart) recorder, other devices can be utilized. If a paper-strip recorder is used, a minimum paper speed of 1 cm/s is recommended.

4.5 Procedure

Confirm the correct operation and calibration of the apparatus.

Carry out the test at an ambient temperature of 20°C ± 5°C.

Remove the conditioned sample from the saline solution and dry it carefully.

Measure the back optic zone radius, total diameter, centre thickness and back vertex power in accordance with ISO 10338, ISO 9338, ISO 9339-1 and ISO 9337-1 or ISO 9337-2 respectively.

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