

INTERNATIONAL STANDARD

ISO
11984

First edition
1999-12-01

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*



Reference number
ISO 11984:1999(E)

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Printed in Switzerland

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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.

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*.

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.

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

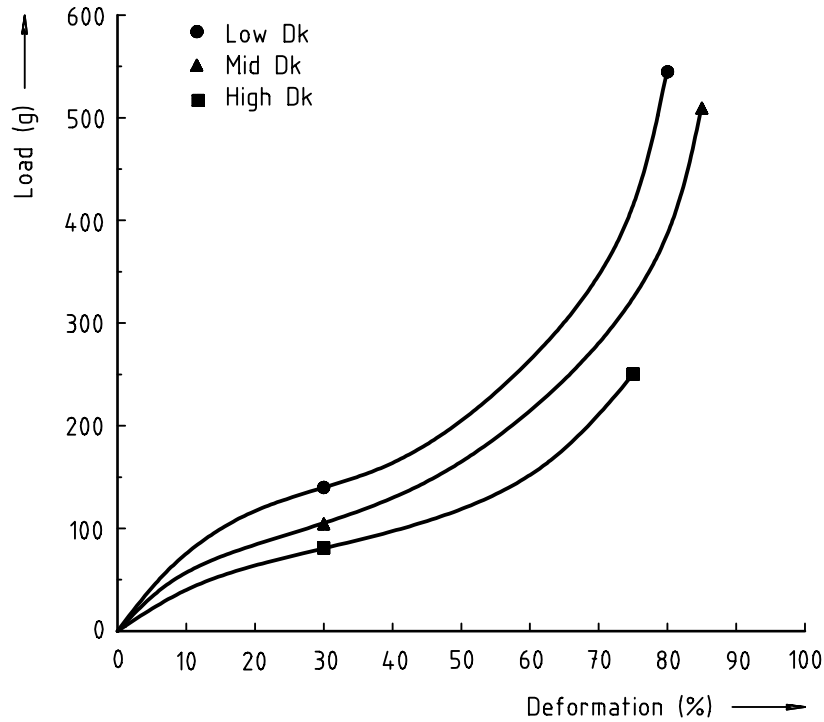
reduction of the diameter of the contact lens due to a load applied to the edge of the contact lens, perpendicular to the lens axis, to induce flexure

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

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.



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).

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.

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:

- front surface: single cut, radius of curvature 8,00 mm \pm 0,025 mm
- back surface: single cut, radius of curvature 7,80 mm \pm 0,025 mm
- total diameter 9,5 mm \pm 0,1 mm
- centre thickness: 0,20 mm \pm 0,01 mm
- edge thickness: 0,24 mm \pm 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 \pm 5 °C, in accordance with ISO 9337-2.

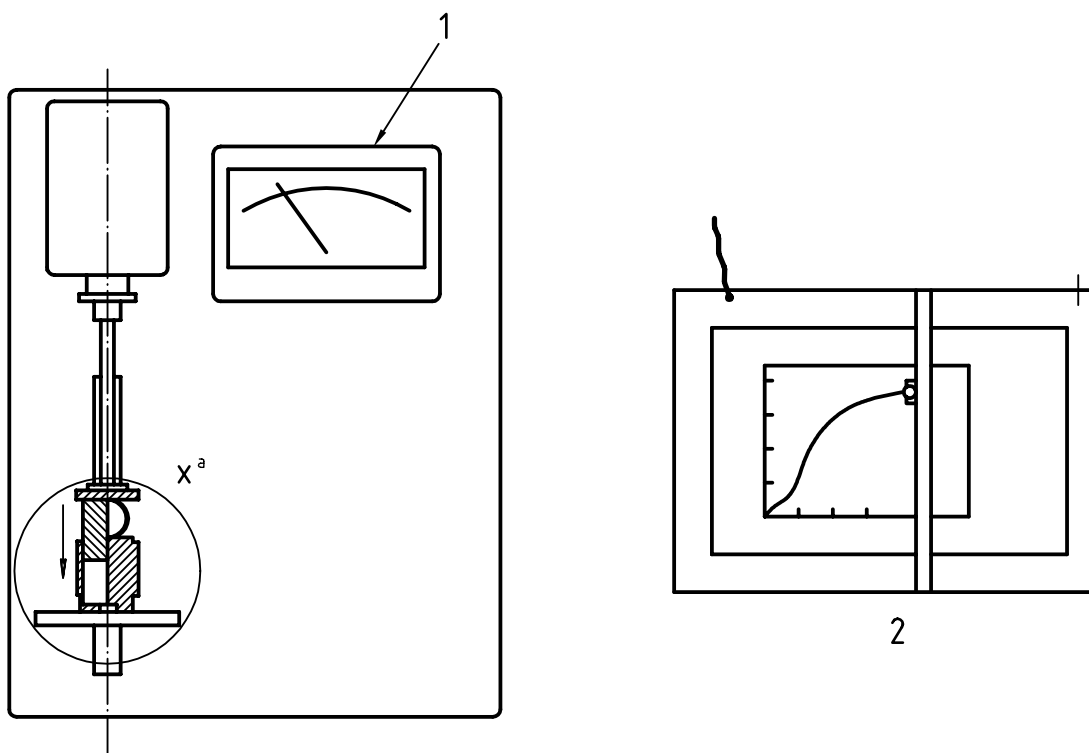
4.4 Apparatus

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

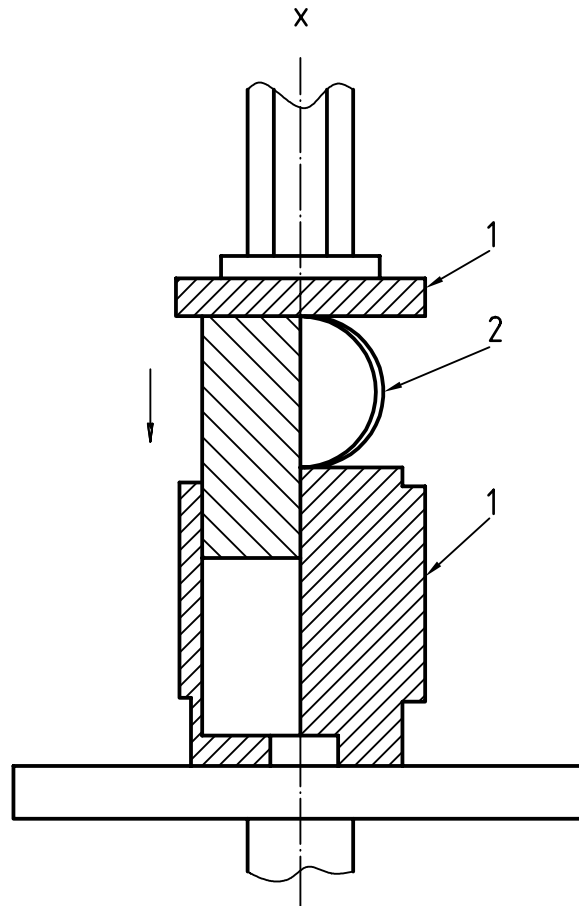
The jig (Figure 3) applies the load to the edge of the sample. The sample is set at the centre of the upper and lower contact faces so that the whole load is applied in the plane containing the edge. The contact faces are constructed so that the load is the only force applied to the sample.



Key

- 1 Load indicator
- 2 Recorder
- a See details in Figure 3.

Figure 2 — Testing machine



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 $20^{\circ}\text{C} \pm 5^{\circ}\text{C}$.

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.

Position the sample in the jig so that the upper and lower edges of the sample lie along the centreline of the upper contact face (Figure 3). Set the velocity of the moving contact face to 20 cm/min (3,33 mm/s) \pm 10 %.

NOTE The sample and jig may be set horizontally or vertically. If a horizontal system is used, it is necessary to verify in advance of the test that results do not differ from those obtained using a vertical system.

Start the data recorder and then commence applying the load to the sample. Stop applying the load when the lens ruptures. Record the load, in grams, at which rupture occurred. Repeat the test with each of the test samples.

4.6 Results

4.6.1 General

It should be noted that variability in the test results may also result from inconsistencies in contact lens manufacturing methods and may not necessarily be indicative of the material itself.

4.6.2 Flexural deformation strength at rupture

The flexural deformation strength at rupture is the load indicated at the moment of rupture during the test.

4.6.3 Flexural deformation at rupture

From the time of rupture and the rate of loading at this time, calculate the distance (d) between the contact faces when rupture occurred. Express the deformation as a percentage of the total diameter (\varnothing_T) of the sample, i.e.

$$\frac{100 \cdot d}{\varnothing_T}$$

4.6.4 Flexural deformation strength at 30 % deformation

From the rate of loading, calculate the time at which the total diameter of the sample has decreased by 30 % (see example) and determine the load, in grams, that was being applied at that time. The load can also be derived from the flexural load-deformation curve (Figure 1).

EXAMPLE

Total diameter of the contact lens is 9,6 mm;
velocity of the moving contact face is 20 cm/min (3,33 mm/s);
30 % deformation = 2,9 mm;
time taken for the moving contact face to cover 2,9 mm is 0,865 s.
The value needed is the applied load 0,865 s from the start of deformation.

4.7 Test report

The test report shall include at least the following information:

- a) date of the test;
- b) name of the test laboratory;
- c) name and signature of the person collecting the data;
- d) name and signature of the author of the report and his/her position;
- e) method of conditioning;
- f) ambient temperature during the test;

- g) identification of the product tested or, if a special sample, identification of the material;
- h) method of manufacture;
- i) moving-face velocity used for the test;
- j) a statement that the samples were tested in the vertical or horizontal position, as appropriate;
- k) results of the test, expressed as the arithmetic mean values together with the standard deviation (see Note), for the:
 - 1) flexural deformation strength at rupture, expressed in grams;
 - 2) flexural deformation at rupture, expressed as a percentage of the initial total diameter;
 - 3) flexural deformation strength at 30 % deformation, expressed in grams.
- l) The test report shall include the following details of each contact lens tested:
 - 1) contact lens design;
 - 2) batch or lot number;
 - 3) back optic zone radius or vertex sphere radius;
 - 4) back vertex power;
 - 5) centre thickness;
 - 6) total diameter.

NOTE The estimated standard deviation (σ) is given by the expression

$$\sigma = \sqrt{\left(\frac{\sum [x - \bar{x}]^2}{n - 1}\right)}$$

where

- x is the value of a single result;
- \bar{x} is the arithmetic mean ($\sum x / n$);
- n is the number of samples in the data set.

Bibliography

- [1] ISO 291:1997, *Plastics — Standard atmospheres for conditioning and testing.*
- [2] ISO 604:1993, *Plastics — Determination of compressive properties.*

ICS 11.040.70

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