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**Ophthalmic optics —  
Contact lenses —  
Ageing by exposure to UV  
and visible radiation  
(in vitro method)**

The European Standard EN ISO 11985 : 1997 has the status of a  
British Standard

ICS 11.040.70

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## National foreword

This British Standard is the English language version of EN ISO 11985 : 1997. It is identical with ISO 11985 : 1997.

The UK participation in its preparation was entrusted by Technical Committee CH/78, Ophthalmic optics, to Subcommittee CH/78/4, Physical properties of contact lenses, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

### Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled 'International Standards Correspondence Index', or by using the 'Find' facility of the BSI Standards Electronic Catalogue.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

### Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword page, the EN title page, page ii, pages 1 to 6, an inside back cover and a back cover.

### Amendments issued since publication

Amd. No.	Date	Text affected

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 April 1998

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Descriptors: see ISO document

English version

Ophthalmic optics - Contact lenses - Ageing by exposure to UV  
and visible radiation (in vitro method) (ISO 11985:1997)

Optique ophtalmique - Lentilles de contact - Vieillessement  
des lentilles de contact par exposition aux rayonnements  
UV et visible (méthode in vitro) (ISO 11985:1997)

Augenoptik - Kontaktlinsen - Alterung durch Einwirkung von  
ultravioletter und sichtbarer Strahlung (in vitro-Verfahren)  
(ISO 11985:1997)

This European Standard was approved by CEN on 4 December 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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EUROPÄISCHES KOMITEE FÜR NORMUNG

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**Foreword**

The text of the International Standard ISO 11985:1997 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

**Endorsement notice**

The text of the International Standard ISO 11985:1997 was approved by CEN as a European Standard without any modification.

INTERNATIONAL  
STANDARD

**ISO**  
**11985**

First edition  
1997-12-15

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**Ophthalmic optics — Contact lenses —  
Ageing by exposure to UV and visible  
radiation (*in vitro* method)**

*Optique ophtalmique - Lentilles de contact - Vieillessement par exposition  
aux rayonnements UV et visible (méthode in vitro)*

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Reference number  
ISO 11985:1997(E)

## 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 organisations, 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.

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 11985 was prepared by ISO/TC 172 *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

**Descriptors:** optics, optical equipment, ophthalmic equipment, contact lenses, ageing (materials), ageing tests (materials), artificial light tests, solar radiation, ultraviolet radiation.

# Ophthalmic optics — Contact lenses — Ageing by exposure to UV and visible radiation (*in vitro* method)

## 1 Scope

This International Standard describes an *in vitro* method which simulates the ageing of rigid (hard) and soft lenses in daylight.

The existence of this International Standard does not imply in any way that the testing of contact lenses for ageing by ultraviolet (UV) and visible radiation is a requirement.

## 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of the publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

## 3 Principle

One aspect of the ageing of contact lenses in normal use is simulated by exposure to an intense source of light.

## 4 Apparatus

**4.1 High pressure xenon lamp**, with a quartz envelope and with filters giving a spectral distribution corresponding to that of solar radiation.

NOTE 1 An example of such a lamp is shown in figure 1.

NOTE 2 High intensity UV sources present radiation hazards if not properly shielded and safety hazards if not properly maintained.

**4.2 Infrared (IR) filter**, with a transmittance of less than 50 % of the incident radiation in the range 650 nm to 850 nm.

NOTE — An example of the transmittance of an IR filter is shown in figure 2.

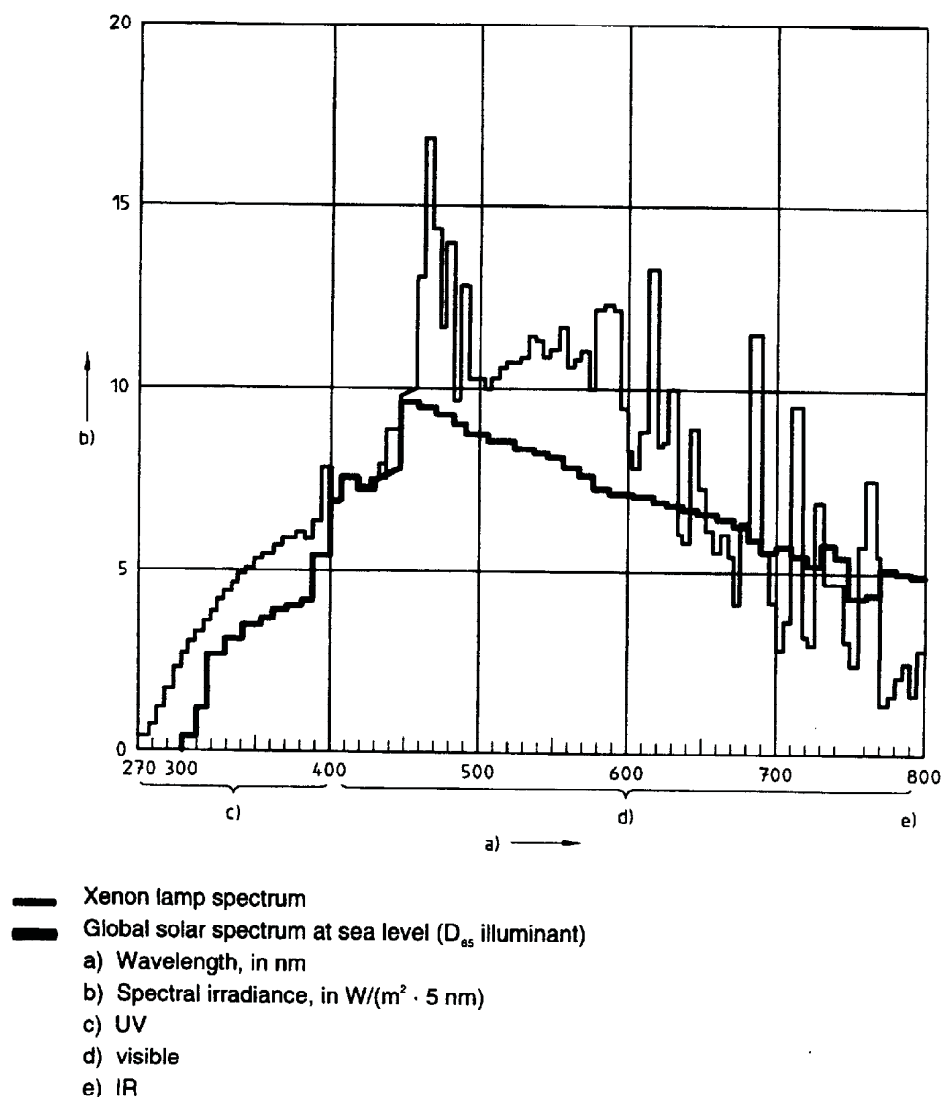


Figure 1 — Energy distribution

**4.3 Ultraviolet (UV) filter**, with a transmittance corresponding to solar radiation. The transmittance shall be 0 % below a wavelength of 290 nm and greater than 90 % between wavelengths of 380 nm and 750 nm.

NOTE — An example of the effect of such a UV filter is shown in figure 3.

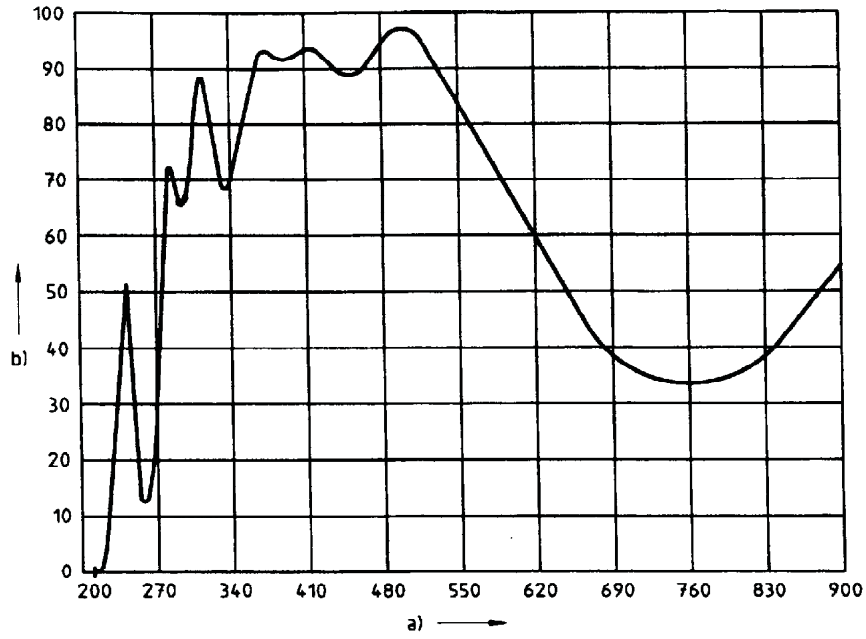
**4.4 Mirrors**, two, capable of reflecting UV and visible radiation.

**4.5 Radiation source**, comprising a xenon lamp (4.1), IR filter (4.2), UV filter (4.3), mirrors (4.4) and parabolic reflector assembled as shown in figure 4.

**4.6 Cuvette**, manufactured from quartz and designed to hold contact lens(es). It shall be provided with a silicone rubber seal retained in position using a suitable clamp. When filled with standard saline solution (ISO 10344), the cuvette shall not absorb more than 2 % of incident radiation between the wavelengths 290 nm and 750 nm.

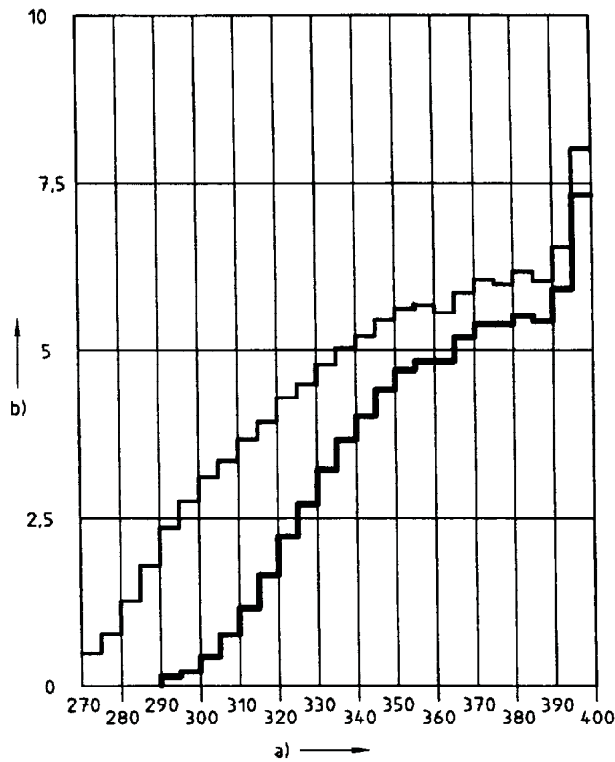
NOTE — Such an arrangement retaining two cuvettes is shown in figure 5.





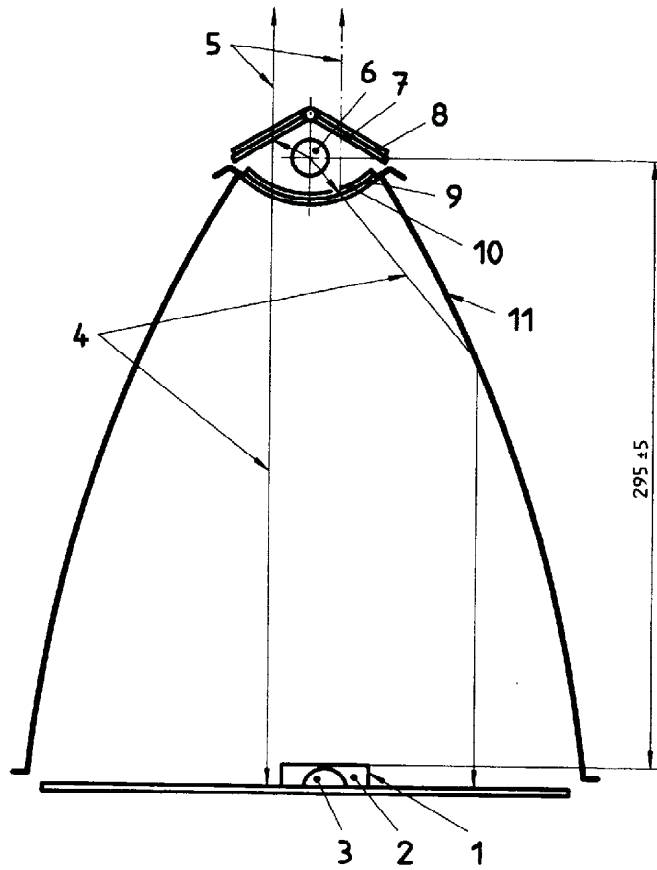
a) Wavelength, in nm  
 b) % Transmittance

Figure 2 — IR filter transmittance



— Without UV filter  
 — With UV filter  
 a) Wavelength, in nm  
 b) Spectral irradiance, in  $W/(m^2 \cdot 5 \text{ nm})$

Figure 3 — UV domain of xenon lamp

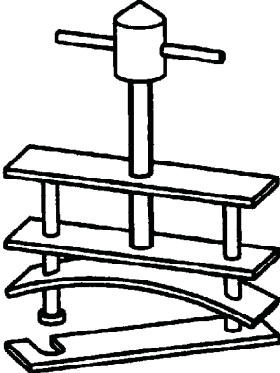
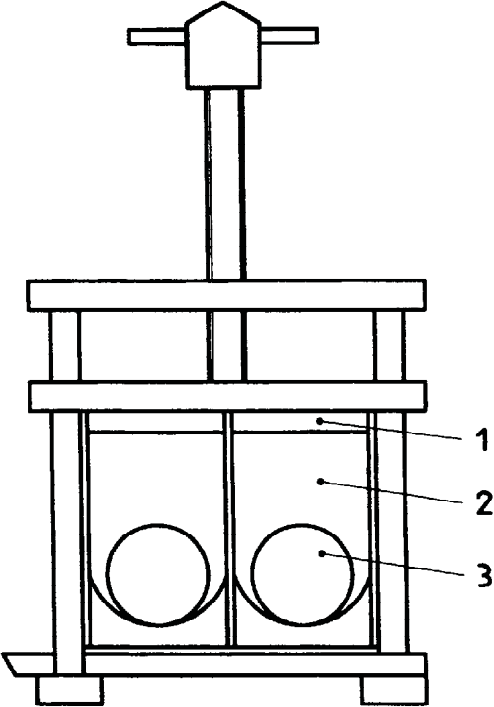


- 1 Cuvette (see cuvette assembly shown in figure 5)
- 2 Saline solution
- 3 Contact lens
- 4 UV - visible rays
- 5 IR rays
- 6 Xenon lamp
- 7 UV reflecting mirror
- 8 Visible reflecting mirror
- 9 IR filter
- 10 UV filter
- 11 Parabolic reflector

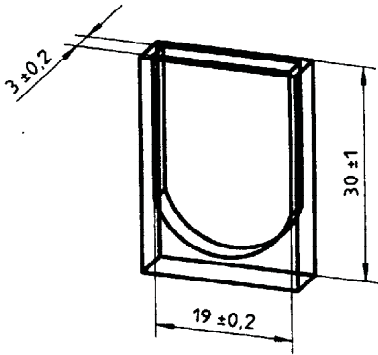
Figure 4 — Radiation source and apparatus

Dimensions in millimetres

- 1 Silicone rubber seal
- 2 Saline solution
- 3 Contact lens



Cuvette holder



Cuvette

Figure 5 — Cuvette assembly

## 5 Samples

Take the new unused contact lenses from the normal production process. Ensure that no lens has been specially treated or conditioned prior to the test.

## 6 Procedure

**6.1** Place one sample lens in each cuvette (4.6). Fill the cuvette with the saline solution conforming to ISO 10344. Place the silicone rubber seal on the tip of the cuvette. Ensure that there are no air bubbles. Fix the seal in position with the clamp.

**6.2** Ensure that the total irradiance between 300 nm and 800 nm is 240 W/m<sup>2</sup> to 260 W/m<sup>2</sup> and that, if more than one lens is exposed simultaneously, each lens is subjected to the same irradiation. Ensure that the irradiation is essentially perpendicular to the surface on which the sample rests.

Expose the samples to the light source (see 4.5) at a distance of  $(295 \pm 5)$  mm for  $\left(20 \begin{smallmatrix} +1 \\ 0 \end{smallmatrix}\right)$  h unless otherwise specified by the manufacturer. During the exposure, ensure that the temperature of the saline solution in the cuvette remains below 40 °C.

## 7 Test report

The test report shall contain at least the following information :

- a) a reference to this International Standard, i.e. ISO 11985;
- b) the identification of the contact lens submitted to the procedure;
- c) the date of submission of the contact lens to the procedure.

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