SLOVENSKI STANDARD
SIST EN ISO 11985:2000

01-januar-2000

Oļ esna optika - Kontaktne leļ e - Staranje leļ z izpostavljanjem ģarkom UV in vidnemu sevanju (metoda in vitro) (ISO 11985:1997)

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

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

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

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Ta slovenski standard je istoveten z: **EN ISO 11985:1997**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11985

December 1997

ICS 11.040.70

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

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

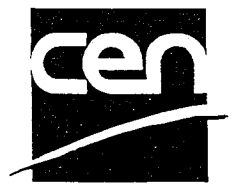
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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same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

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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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.

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INTERNATIONAL STANDARD

ISO 11985

First edition
1997-12-15

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

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

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Reference number
ISO 11985:1997(E)

SIST EN ISO 11985:2000

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.

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

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SIST EN ISO 11985:2000

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

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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.

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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.

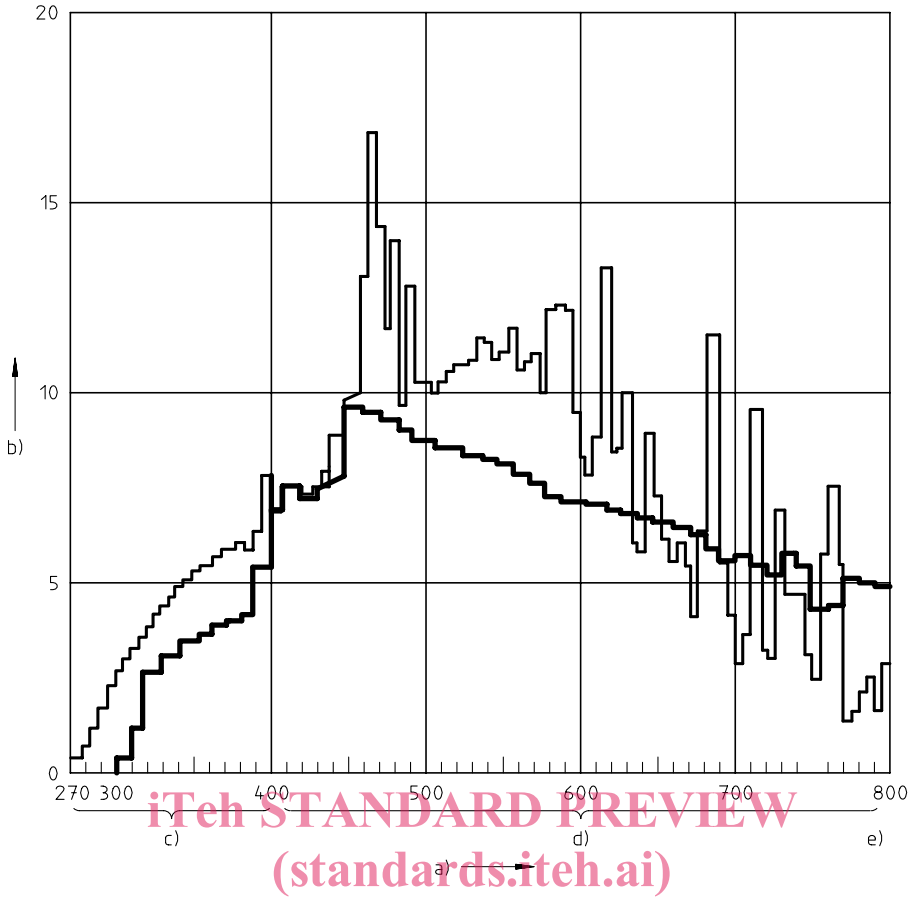
NOTE 1 An example of such a lamp is shown in figure 1.

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.

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Xenon lamp spectrum

Global solar spectrum at sea level (D_{65} illuminant)

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a) Wavelength, in nm

b) Spectral irradiance, in $W/(m^2 \cdot 5\ nm)$

c) UV

d) visible

e) IR

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.

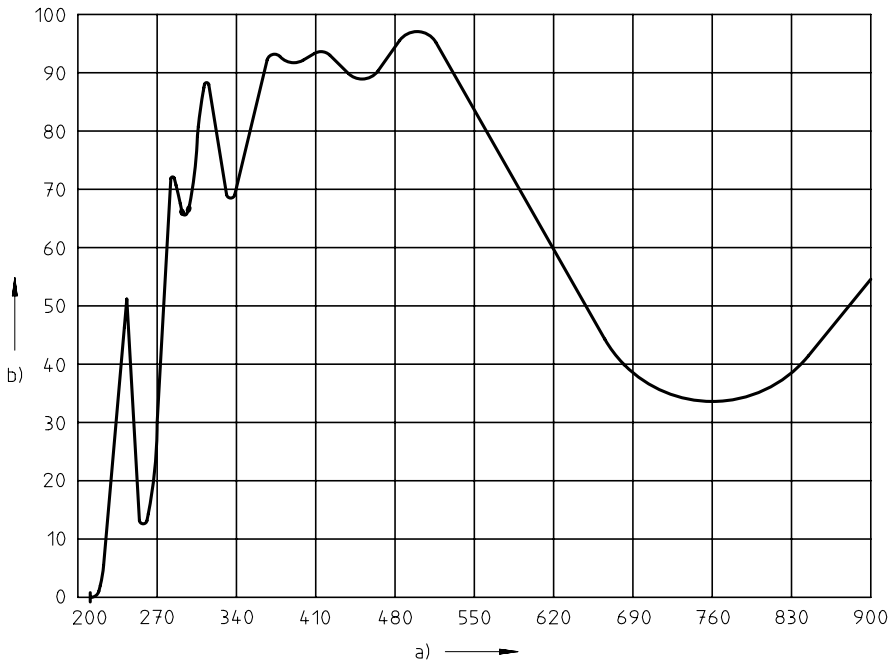
4.4 Mirrors, two, capable of reflecting UV and visible radiation.

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.

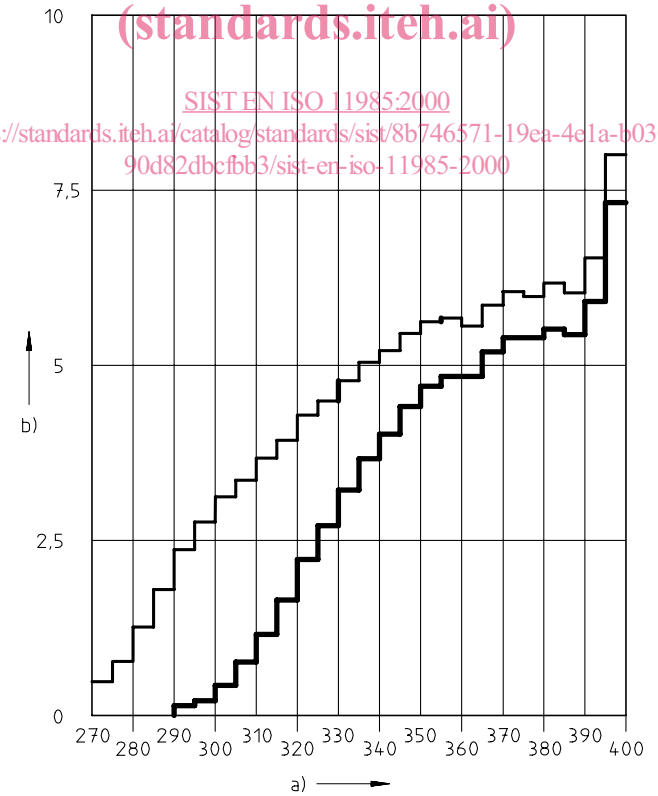
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a) Wavelength, in nm
b) % Transmittance

Figure 2 — IR filter transmittance

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Without UV filter
With UV filter
a) Wavelength, in nm
b) Spectral irradiance, in W/(m^2 · 5 nm)

Figure 3 — UV domain of xenon lamp