SLOVENSKI STANDARD
SIST EN ISO 9913-1:2000

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Optika in optiļ ni instrumenti - Kontaktne leļ e - 1. del: Ugotavljanje prepustnosti za kisik in prenosa kisika z metodo FATT (ISO 9913-1:1996)

Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility by the FATT method (ISO 9913-1:1996)

Optik und optische Instrumente - Kontaktlinsen - Teil 1: Bestimmung der Sauerstoff-Permeabilität und - Transmissibilität nach dem Verfahren nach FATT (ISO 9913-1:1996)

Optique et instruments d'optique - Lentilles de contact - Partie 1: Détermination de la perméabilité a l'oxygene et de la transmissibilité de l'oxygene avec la méthode FATT (ISO 9913:1996)

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Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility by the FATT method (ISO 9913-1:1996)

Optique et instruments d'optique - Lentilles de contact - Partie 1: Détermination de la perméabilité à l'oxygène et de la transmissibilité de l'oxygène avec la méthode FATT (ISO 9913:1996)

Optik und optische Instrumente - Kontaktlinsen - Teil 1: Bestimmung der Sauerstoff-Permeabilität und -Transmissibilität nach dem Verfahren nach FATT (ISO 9913-1:1996)

This European Standard was approved by CEN on 25 April 1998.

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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 from ISO/TC 172 „Optics and optical instruments" of the International Organization for Standardization (ISO) has been taken over as a European Standard by the 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 November 1998, and conflicting national standards shall be withdrawn at the latest by November 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 9913-1:1996 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 9913-1

First edition
1996-11-01

Optics and optical instruments — Contact lenses —

Part 1:
Determination of oxygen permeability and transmissibility by the FATT method

Optique et instruments d'optique — Lentilles de contact —

Partie 1: Détermination de la perméabilité à l'oxygène et de la transmissibilité de l'oxygène avec la méthode FATT

Reference number
ISO 9913-1:1996(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 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.

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 9913-1 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

ISO 9913 consists of the following parts, under the general title *Optics and optical instruments — Contact lenses:*

— *Part 1: Determination of oxygen permeability and transmissibility by the FATT method*

— *Part 2: Determination of oxygen permeability and transmissibility by the coulometric method*

Annex A forms an integral part of this part of ISO 9913. Annexes B and C are for information only.

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Optics and optical instruments — Contact lenses —

Part 1:
Determination of oxygen permeability and transmissibility by the FATT method

1 Scope

This part of ISO 9913 describes a polarographic method for the determination of oxygen permeability of contact lens materials and oxygen transmissibility of contact lenses. It specifies the procedures for making the measurements and establishes the conditions under which measurements are made.

It is applicable for determining permeability (Dk) in the range 0 to 75 × 10^{-11} (cm^2/s) [ml O_2/(ml·hPa)].

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9913. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9913 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 10339:—[1)], *Optics and optical instruments — Contact lenses — Determination of water content of soft lenses.*

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

3 Definitions

For the purposes of this part of ISO 9913, the definitions given in ISO 8320 and the following definitions apply.

3.1 dark current (I_d)**:** Current passing through a cell when an impermeable barrier is placed in between the electrodes.

3.2 oxygen permeability (Dk)**:** Rate of oxygen flow under specified conditions through a unit area of contact lens material of unit thickness when subjected to unit pressure difference.

NOTES

1 Oxygen permeability is expressed in units of (cm^2/s) [ml O_2/(ml·hPa)]. An alternative expression for the units is cm^3 O_2·(cm/cm^2)/(s·hPa).

2 Oxygen permeability is a physical property of the material. It is not a function of the shape or thickness of the material sample.

3 To convert the units of Dk for use with mmHg instead of hectopascals (hPa), multiply the numerical value of Dk by 1,333 22.

1) To be published.

3.3 oxygen transmissibility (Dk/*t*)**:** Value for oxygen permeability divided by the thickness (measured in centimetres) of the measured sample under specified conditions.

NOTES

4 Oxygen transmissibility is not an absolute physical property; it is dependent upon the sample thickness.

5 The reciprocal of oxygen transmissibility (Dk/*t*) is called electrical resistivity (*t*/Dk).

3.4 thickness (*t*)**:** Either the thickness at a specified point or the harmonic mean thickness of the specified area of the lens or sample.

4 Principle

The polarographic method directly measures the number of oxygen molecules diffusing through a piece of test material by electrochemically removing the molecules from solution as soon as they pass through the material. For full details of the theoretical background, see annex C.

5 Reagents

5.1 Oxygen, commercial grade, in a steel cylinder.

5.2 Nitrogen, commercial grade, oxygen free, in a steel cylinder.

6 Apparatus

The test cell shall have the following characteristics.

6.1 The cathode shall be made of 24 carat gold or 99,9 % (*m*/*m*) platinum (min.), shall be located centrally under the test sample, shall have a diameter of 4 mm to 7,2 mm and shall have a polished surface.

6.2 The anode shall be made of silver [99,9 % (*m*/*m*) min.], shall be concentric to the cathode and shall have an area greater than that of the cathode.

6.3 The apparatus shall be capable of maintaining a potential difference between the electrodes of (0,75 ± 0,05) V.

6.4 The electrode face to be used for measuring samples of rigid lens material shall be a smooth spherical surface with a radius of curvature in the range 7,70 mm to 8,30 mm.

6.5 The electrode face to be used for measuring flat samples and hydrogel lenses shall be plane.

6.6 The apparatus shall include a device (see figure B.1) by which the test sample may be pressed against the electrode. The device shall allow oxygen to pass freely into the sample.

6.7 The apparatus shall be capable of maintaining the test sample at 35 °C ± 0,5 °C in an atmosphere with a relative humidity of not less than 95 %.

6.8 If a bath of oxygen saturated water is needed as the oxygen source, then a means of stirring or mixing the water shall be incorporated in the apparatus. The stirrer shall ensure that a minimal but constant stagnant boundary layer is maintained at the sample surface.

6.9 A temperature monitoring device having good thermal contact with the test sample shall be mounted. This device shall be capable of measuring the temperature with an accuracy of 0,5 °C.

NOTE 6 For examples of apparatus, see annex B.

6.10 An ammeter having a range from 0,0 µA to 10,0 µA.

7 Test samples

7.1 The test samples shall have parallel or near-parallel (see note) anterior and posterior surfaces.

NOTE 7 The thickness of the sample used for measurement should be as uniform as possible. In the case of manufactured lenses, the near-parallel condition would correspond to dioptric powers within the range + 0,50 to − 0,50.

7.2 The back optic zone radii of the test samples shall be within the range 7,40 mm to 8,60 mm.

7.3 The surfaces of test samples shall be clean and polished to the quality acceptable in normal lens production for human use.

7.4 In the case of hydrogel material, the samples shall be stored in saline test solution in accordance with ISO 10344 for a minimum of 24 h prior to testing and shall be equilibrated for at least 2 h at test temperature.

8 Test procedure

8.1 Dark current/zero-point correction

Determine the dark current of the cell by placing a barrier between anode and cathode consisting of two Polymethylmethacrylate (PMMA) lenses with an aluminium foil disc between them and measuring the current.

NOTES

8 As this barrier will not transmit oxygen, the equilibrium current is the dark current (I_d) which is the reference for material of zero permeability.

9 Necessary characteristics of the barrier are that it should transmit no oxygen, that it should fit tightly against the anode so that no oxygen can pass around its edge and under it to the cathode and that it should be an electrical non-conductor.

10 If the oxygen-saturated water bath method is used, it will be necessary to carry out the zero-point adjustment (or "correction") using oxygen-free nitrogen gas.

8.2 Measurement of *t*/Dk

Bring the test equipment to 35 °C ± 0,5 °C and allow the temperature to stabilize. Remove the sample from the saline solution, blot and place the lens on the test cell. If the sample is made of material that does not incorporate water in its molecular structure, place a piece of saturated paper, e.g. cigarette paper, on the surface of the cell and place the sample thereon. Firmly clamp the sample to the surface of the electrode. If the source of oxygen is a water bath, fill the electrode assembly with electrolyte (for example, standard saline solution in accordance with ISO 10344), establish the gas flow, activate the stirring mechanism and ensure that an equilibrium condition has been reached before proceeding.

Allow the current reading to stabilize and record the measurement. Remove the sample from the test cell and measure the centre thickness to an accuracy of ± 0,005 mm.

Repeat the procedure for at least four samples with thicknesses of approximately 0,10 mm, 0,17 mm, 0,24 mm and 0,30 mm.

NOTES

11 Samples should be no thicker than 0,40 mm.

12 Accuracy may be improved by making multiple independent measurements on each sample. Independent measurements are made by removing the sample from the apparatus, re-equilibrating it and repeating the procedure.

9 Expression of results

NOTE 13 For the theoretical background, see annex C.

9.1 Calculate the value of *t*/Dk (total) for each test sample using the following equation:

$$t/\mathrm{Dk} = p_{O_2}/F$$

with

$$p_{O_2} = (p_{bar} - p_{H_2O}) \times 0{,}209;$$

$$F = (I - I_d) \times 5{,}804 \times 10^{-2}/A.$$

where

- p_{O_2} is the partial pressure of oxygen above the cell in hectopascals (hPa);
- F is the oxygen flux in hundreds of metres per cubic centimetre second [$m \times 10^2/(s \times cm^2)$];
- p_{bar} is the barometric pressure in hectopascals (hPa);
- p_{H_2O} is the vapour pressure of water in the atmosphere in hectopascals (hPa);
- 20,9 is the percentage oxygen in the atmosphere in air at 0 % humidity (if the percentage of oxygen is other than 20,9 %, that value is used);
- I is the measured electric current in amperes;
- I_d is the dark current of the cell, in amperes, i.e. the current which flows in the absence of the O_2 flux;
- A is the area of the central electrode (cathode) in square centimetres.

The area of the cathode when using electrodes with spherical surfaces is given by the equation

$$A = 2\pi r(r - \sqrt{r^2 - D^2/4})$$

where

- D is the diameter of cathode, in millimetres;
- r is the radius of curvature of the surface, in millimetres.

The area of a cathode with a flat surface is given by the equation

$$A = \pi(D/2)^2$$