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Optics and optical instruments — Contact lenses —

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

Optique et instruments d'optique — Lentilles de contact —

Partie 2: Détermination de la perméabilité à l'oxygène et de la transmissibilité de l'oxygène avec la méthode coulométrique

Reference number
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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 part of ISO 9913 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9913-2 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 with the FATT method*

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

Optics and optical instruments — Contact lenses —

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

1 Scope

This part of ISO 9913 describes a coulometric method for the determination of oxygen permeability of both rigid and non-hydrogel flexible contact lens materials and oxygen transmissibility of rigid and non-hydrogel flexible contact lenses. It specifies the procedures for the measurements and establishes the conditions under which measurements are made.

This part of ISO 9913 is applicable to the determination of oxygen transmissibility of rigid and non-hydrogel flexible contact lenses, incorporating various refractive powers and radially symmetric contact lens geometries, and the oxygen permeability (*Dk*) of rigid and non-hydrogel flexible contact lens materials in the form of standardized test samples.

This part of ISO 9913 is especially useful for the determination of permeability values above 75×10^{-11} (cm^2/s) [ml O_2/(ml·hPa)], which fall above the usual range of the standard polarographic method of measurement (FATT method, see ISO 9913-1).

This part of ISO 9913 is not applicable to hydrogel materials or hydrogel contact lenses.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9913. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 9913 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 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results.*

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

ISO 9339-1:1996, *Optics and optical instruments — Contact lenses — Determination of the thickness — Part 1: Rigid contact lenses.*

ISO 9913-1:1996, *Optics and optical instruments — Contact lenses — Part 1: Determination of oxygen permeability and transmissibility with the FATT method.*

3 Terms and definitions

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

3.1
oxygen flux
j
net volume of oxygen gas passing through a unit area of sample contact lens material per unit time under specified conditions, including temperature, sample thickness, and partial pressures of oxygen on both sides of the sample

NOTE A convenient unit of oxygen flux for contact lens materials is µl/(cm^2 · s). In terms of measurement using the coulometric method, *j* is equal to the rate of oxygen flow past the coulometric oxygen sensor q_V divided by the area of sample (*A*) through which the oxygen has passed.

3.2
oxygen permeability
Dk
oxygen flux (*j*) under specified conditions through contact lens material of unit thickness when subjected to unit pressure difference

NOTE 1 Oxygen permeability is stated in traditional units of (cm^2/s) · [ml O_2/(ml · mmHg)], which is equivalent to (cm^3 O_2 · cm)/(cm^2 · s · mmHg). The units are (cm^2/s) · [ml O_2/(ml · hPa)], or (cm^3 O_2 · cm)/(cm^2 · s · hPa) when the hectopascal (hPa) is used instead of mmHg. To express *Dk* units in terms of hPa instead of mmHg, multiply *Dk* magnitudes using mmHg in the denominator by 0,750 06. To express *Dk* units in terms of mmHg instead of hectopascals, multiply *Dk* magnitudes using hectopascals in the denominator by 1,333 22.

NOTE 2 In terms of measurement using the coulometric method, *Dk* is equal to the oxygen transmissibility (*Dk/t*) multiplied by the sample thickness (*t*). Oxygen permeability is a physical property of the material and is not a function of the shape or thickness of the material sample.

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

NOTE 1 Oxygen transmissibility is stated in traditional units of (cm/s) · [ml O_2/(ml · mmHg)], which is equivalent to (cm^3 O_2)/(cm^2 · s · mmHg). The units are (cm/s) · [ml O_2/(ml · hPa)], or (cm O_2)/(cm^2 · s · hPa) when the hectopascal (hPa) is used instead of mmHg. To express *Dk/t* units in terms of hPa instead of mmHg, multiply *Dk/t* magnitudes using mmHg in the denominator by 0,750 06. To express *Dk/t* units in terms of mmHg instead of hectopascals, multiply *Dk/t* magnitudes using hectopascals in the denominator by 1,333 22.

NOTE 2 In terms of measurement using the coulometric method, *Dk/t* is equal to the oxygen flux (*j*) divided by the difference in oxygen tension (partial pressure of oxygen) between atmospheres at the two exposed surfaces of the sample contact lens. Oxygen transmissibility is a property of the lens material and lens thickness; it depends on the design of the contact lens.

3.4
thickness
t
radial thickness within the central area of the test sample, as measured according to ISO 9339-1, or the harmonic mean thickness of the area of test sample exposed to oxygen flow

NOTE To be consistent with other definitions and equations in this part of ISO 9913, *t* should be expressed in centimetres (cm).

3.5
harmonic mean thickness
t_{HM}
⟨rotationally symmetric contact lens⟩ that thickness calculated from a series of (h + 1) radial thickness measurements at intervals of equal annular area from the centre (point 0) to the edge (point h) of the circular area exposed to oxygen flow

See 6.1.1 b).

NOTE The interval between thickness measurements[1)] should allow each successive annulus to be of the same area:

$$t_{HM} = \frac{h+1}{1/t_0 + 1/t_1 + 1/t_2 + 1/t_3 + \ .. \ + 1/t_h} \quad (1)$$

where

t_{HM} is the harmonic mean thickness of rotationally symmetric test sample, in centimetres;

t_0 to t_h are radial thicknesses measured or calculated at intervals of equal area from the centre (t_0) to the edge (t_h) of the exposed sample area, in centimetres.

4 Principle

4.1 Overview

A rigid or non-hydrogel flexible contact lens is placed in the apparatus described in 6.1, with exposed front and rear contact lens surface areas in contact with gas mixtures at eye temperature (35 °C). The gaseous environments at the anterior and posterior contact lens surfaces are separated by the contact lens, which acts as a barrier to the net flow of oxygen from the anterior environment to the posterior environment. The two environments and the contact lens can be purged of all detectable oxygen gas. Once purged, an oxygen-containing gas is allowed to fill the anterior environmental chamber and to diffuse through the contact lens.

An inert carrier gas, initially oxygen-free, is allowed to flow across the posterior environmental chamber at the posterior contact lens surface and to remove oxygen molecules that have crossed the contact lens barrier. The carrier gas, now containing a small concentration of oxygen, is directed to a coulometric sensor which creates a current proportional to the concentration of oxygen flowing past the detector.

With appropriate instrument calibration, such that the concentration of oxygen at the detector is precisely known, the rate of oxygen flow q_V in microlitres per second, past the detector can be determined and recorded.

4.2 Calculated values

Oxygen flux (j), oxygen transmissibility (Dk/t), and oxygen permeability (Dk) can be derived by using equation (2), knowing the area of the contact lens through which oxygen has passed (A, in square centimetres), the thickness of the contact lens or sample (t), the calculated oxygen flux (j) or recorded rate of oxygen flow past the detector q , and the oxygen pressure difference between anterior and posterior environmental chambers during measurement ($P_A - P_P$, in hectopascals, where P_A is approximately 116 hPa and P_P is assumed to be zero).

$$Dk = \frac{t \cdot q_V}{P_A \cdot A} \cdot \frac{\text{ml}}{10^3 \ \mu\text{l}} \quad (2)$$

1) Fatt I., Ruben C.M. *J. Br. Cont. Lens Assoc.*, **17** (4), 1994, pp. 115ff.

where

Dk	is the oxygen permeability of test sample, in (cm^2/s) · [ml O_2/(ml · hPa)];
P_A	is the (barometric pressure – vapour pressure)(0,209), expressed in hectopascals;
t	is the thickness of test sample (measured), expressed in centimetres;
A	is the exposed area of test sample (measured), expressed in square centimetres;
q_V	is the rate of oxygen flow past the detector (measured), expressed in microlitres per second;
0,209	is the oxygen fraction in the oxygenated test gas (if other than 0,209, that value is used).

4.3 Precision of measurement

A single determination of oxygen transmissiblity (Dk/t) and/or oxygen permeability (Dk) shall have a reproducibility value (R) of 10 % of the corrected value, in accordance with ISO 5725.

5 Reagents and materials

5.1 Oxygen-free carrier gas, consisting of nitrogen gas (volume fraction 99,9 % or more) or a mixture of nitrogen gas (volume fraction 97 % to 99,5 %) and hydrogen gas (volume fraction 0,5 % to 3 %). The carrier gas shall be dry and contain not more than a volume fraction of 0,01 % of oxygen. An oxygen trap and a moisture trap shall ensure that the carrier gas is essentially oxygen-free and dry prior to reaching the diffusion cell (6.1.1) and that vapour pressure P_P is zero.

5.2 Oxygenated test gas, comprising either a mixture of oxygen gas (volume fraction 20,9 %) and nitrogen gas (volume fraction 79,1 %), or compressed air, or oxygen gas (volume fraction 99,9 % or greater). A moisture trap dries the test gas prior to introduction into the anterior environmental chamber of the diffusion cell (6.1.1).

5.3 Sealing grease, either a high-viscosity non-silicone stopcock grease or a high-vacuum grease which is nearly impermeable to oxygen. A "sealing grease" is required for sealing the contact lens test sample to the two halves of the diffusion cell, as noted in 6.1.1.

5.4 Standard reference material (SRM), comprising a non-hydrogel flat plastic film, typically used for preliminary calibration of the apparatus, having parallel surfaces and a certified oxygen transmissibility (Dk/t)[2)].

6 Apparatus

6.1 Oxygen gas transmission apparatus, depicted in Figure 1, consisting of a diffusion cell (6.1.1), O-ring, heating unit (6.1.2), flowmeter, coulometric oxygen sensor (6.1.3), load resistor and recorder (6.1.4).

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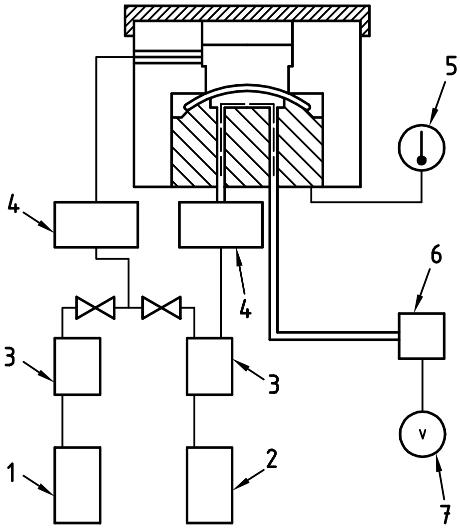
2) SRM 1470, a reference material useful for calibration with respect to testing of contact lenses, has a certified oxygen transmissibility equal to $0{,}072 \times 10^{-9} \pm 0{,}000\,45 \times 10^{-9}$ (cm^3 O_2)/(cm^2 · s · mmHg) and is available from the National Institute for Standards and Technology, Gaithersburg, Maryland, USA 20899.

A series of six rigid non-hydrogel contact lens reference materials may be obtained from the custodian of the Permeability Reference Material Repository. The materials are available in the form of contact lens buttons from single lots, and can be lathed and polished to the appropriate specifications as reference samples for the polarographic and coulometric methods. The custodian of repository reference buttons is presently Dr. William J. Benjamin, University of Alabama at Birmingham, School of Optometry, Birmingham, Alabama, USA, 35294-0010; phone (205) 934-6753, Fax (205) 934-6758.

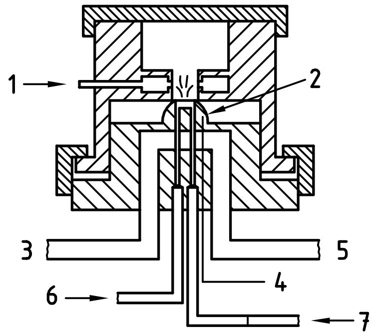
This information is given for the convenience of users of this part of ISO 9913, and does not constitute an endorsement by ISO of these products.

Suitable oxygen-impermeable ports, valves and tubing allow purging of oxygen from each of the two environmental chambers inside the diffusion cell, introduction of oxygenated test gas into the anterior environmental chamber (the upper chamber, in Figure 2), and flow of carrier gas through the posterior environmental chamber (the lower chamber, in Figure 2) to the coulometricoxygen sensor. An oxygen trap ensures that carrier gas is free of oxygen before entering the posterior environmental chamber and moisture traps ensure that the gases are dry.



Key
1 Air
2 Carrier gas
3 Gas dryer
4 Humidifier
5 Temperature controller
6 Coulometric sensor
7 Voltage recorder

a) Device schematic



Key
1 Test gas
2 Contact lens
3 Temperature control loop
4 Thermocouple feed-back loop
5 To temperature control loop
6 Carrier gas
7 Carrier gas to coulometric sensor

b) Lens fixture setup

Figure 1 — Apparatus for measurement of oxygen gas transmission (schematic)

6.1.1 Diffusion cell, shown in Figure 2, impermeable to oxygen and in two halves.

a) Description of cell

When closed around a test sample, the cell houses two environmental chambers separated by the sample. The specific volumes enclosed by each cell half, when clamped, are not critical. These volumes should be small enough, however, to allow for rapid gas exchange, but not so small that an unsupported test sample, which happens to sag or bulge, could contact the top or bottom of the cell. The cell incorporates a thermistor to verify temperature and shall be fitted with a heating unit to maintain the chambers and sample at 35 °C. An appropriately sized annular groove in the anterior half of the diffusion cell (the half that delivers oxygenated test gas to the anterior surface of the sample) retains a neoprene O-ring against the anterior test sample surface. The surface of the posterior cell half has a smooth annular mounting rim in contact with the posterior surface of the sample. The mounting rim shall be free of radial scratches.