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Optics and optical instruments — Contact lenses — Determination of refractive index of contact lens materials

Optique et instruments d'optique — Lentilles de contact — Détermination de l'indice de réfraction des matériaux des lentilles de contact

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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.

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 9914 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Optics and optical instruments — Contact lenses — Determination of refractive index of contact lens materials

1 Scope

This International Standard specifies a test method for determining the refractive index of contact lens materials. The test method described is given as a reference method. Alternative methods may be used provided that repeatability and accuracy are at least equal to those specified herein for the refractive index of the specimen under test according to ISO 5725[1].

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7944:1984, *Optics and optical instruments — Reference wavelengths.*

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

ISO 10344:—[2], *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing.*

3 Definitions

For the purposes of this International Standard the definitions given in ISO 8320 and the following definition apply.

3.1 refractive index (of a contact lens material): Ratio of the sine of the angle of incidence to the sine of the angle of refraction when a ray of light of defined wavelength passes from air into the contact lens material maintained at a constant temperature.

4 Principle

The refractive index is determined by measuring the angle at which total internal reflection occurs when light passes from the prism surface of the refractometer into the contact lens material. It is necessary to use a contacting fluid between the contact lens material and the refractometer prism for all materials except hydrogels.

5 Apparatus

5.1 Abbe refractometer, or refractometer of similar design, calibrated using one of the reference wavelengths specified in ISO 7944 and having a precision of at least ± 0,000 5.

A refractometer calibrated for a wavelength other than the reference wavelength may be used only if an accurate conversion to the desired wavelength is available.

Refractometers designed to measure the solids content of sugar solutions may be used only if an accu-

1) ISO 5725:1994, *Accuracy (trueness and precision) of measurement methods and results.*

2) To be published.

rate conversion to the refractive index of the scale readings in percent solids is available.

5.2 Contacting fluid, with a refractive index greater than that of the specimen and which is not harmful to the specimen material or to the refractometer prism assembly.

NOTE 1 As the refractive index of contact lens materials generally does not exceed 1,55, a contacting fluid with a refractive index of at least 1,55 is sufficient. Organic solvents should not be used. Aqueous solutions, such as saturated zinc bromide ($n_d = 1,564$, density $\rho = 2,510$ g/ml), have been found to be suitable.

5.3 Light source, of the chosen reference wavelength (see 5.1) may be produced either by using a monochromatic light source or by using a white light source and placing a transmission filter for the desired wavelength in the light path of the refractometer.

NOTE 2 If a refractometer with a chromatic correction prism is employed, a transmission filter centred at a wavelength other than the design wavelength of the correction prism should not be used. It is generally better to use a white light source with such refractometers.

6 Procedure

6.1 Calibration

Calibrate the refractometer as described in the manufacturer's instructions for use.

6.2 Preparation of test specimen

NOTE 3 With tinted materials, the light transmitted may be insufficient to enable a sharp image to be formed. If this occurs and if the material was not tinted before polymerization, the determination should be carried out with a specimen of the same material which has not been tinted.

6.2.1 Rigid and non-water bearing materials

Prepare a test specimen of a size that will fit on the face of the fixed half of the refractometer prism, having one surface optically flat and polished (the measurement face). If it is necessary to bring light into the system through an edge of the specimen, ensure that this edge is optically flat and is polished perpendicular to the measurement face.

NOTES

4 Specimens of soft non-water bearing materials, such as silicones, may consist of actual contact lenses.

5 A convenient shape for the test specimen is a rectangle of thickness 0,5 mm to 3,0 mm, which is slightly smaller than the face of the refractometer prism.

6.2.2 Hydrogel materials

Check that the surface of the test specimen in contact with the prism (the measurement face) is smooth and that the thickness of the specimen is approximately constant. Stabilize the state of hydration of the specimen by maintaining it at (20 ± 0,5) °C in a saline solution complying with ISO 10344 for at least two hours before the test.

NOTE 6 Contact lenses of approximately constant thickness provide the most convenient form of test specimen for hydrogel materials.

6.3 Measurement

6.3.1 Rigid and non-water bearing materials

Ensure that both the specimen and refractometer are at an ambient temperature of (20 ± 5) °C. Place a drop of contacting fluid on the fixed refractometer prism and firmly press the specimen against the prism with the polished edge, if used, towards the light source.

NOTE 7 Satisfactory contact between the test specimen and the prism is indicated by a sharp and straight dividing line appearing between the light and dark portions of the field of view.

For direct-reading non-compensated refractometers, read the refractive index (or solids content) directly at the dividing line between the light and dark field. For refractometers with an external scale, read the refractive index after adjusting the index arm of the refractometer, so that the dividing line between the light and dark fields is coincident with the eyepiece hairline. If the refractometer has chromatic compensating prisms, adjust these to remove all colour from the field before reading the refractive index.

6.3.2 Hydrogel materials

With the refractometer at an ambient temperature of (20 ± 5) °C, remove the specimen from its hydrating solution, blot off excess fluid and immediately press the measurement face firmly against the refractometer fixed prism. Compensate for colour and measure the refractive index as described in 6.3.1.

NOTE 8 Satisfactory contact between the test specimen and the prism is indicated by a sharp and straight dividing line appearing between the light and dark portions of the field of view. If the specimen is not pressed firmly enough against the prism, a faint secondary line may be seen

somewhat removed from the sharp line. This is caused by the hydrating fluid and will give a refractive index of 1,336.

6.3.3 Anisotropic materials

If the specimen is known to have different refractive indices in different areas or if it is desired to check for this possibility, mask the measurement surface of the specimen so that the refractive index can be measured in selected areas.

6.4 Expression of results

The result of testing for each sample tested shall be given as the average of at least three independent measurements of the sample. If more than three independent measurements are taken and used in the average, this shall be stated in the test report under 7e). If the refractometer scale is marked in percent solids or if the refractometer is calibrated at a wavelength other than the chosen reference wavelength, correct the reading to give the refractive index at the reference wavelength.

6.5 Precision

The precision of measurement expected with this method is 0,001.

7 Test report

The test report shall contain at least the following information:

a) a reference to this International Standard (ISO 9914);

b) identification of the material tested;

c) the results of the test, as required by 6.4;

d) the wavelength of the light used;

e) any deviation, by agreement or otherwise, from the described test method;

f) the date of the test.

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