SLOVENSKI STANDARD
SIST EN ISO 9913-2:2001

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Optics and optical instruments - Contact lenses - Part 2: Determination of oxygen permeability and transmissibility by the coulometric method (ISO 9913-2:2000)

Optics and optical instruments - Contact lenses - Part 2: Determination of oxygen permeability and transmissibility by the coulometric method (ISO 9913-2:2000)

Optik und optische Instrumente - Kontaktlinsen - Teil 2: Bestimmung der Sauerstoff-Permeabilität und -Transmissibilität nach dem coulometrischen Verfahren (ISO 9913-2:2000)

Optique et instruments d'optique - Lentilles de contact - Partie 2: Détermination de la perméabilité a l'oxygene et de la transmissibilité de l'oxygene avec la méthode coulométrique (ISO 9913-2:2000)

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ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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Optics and optical instruments - Contact lenses - Part 2: Determination of oxygen permeability and transmissibility by the coulometric method (ISO 9913-2:2000)

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 (ISO 9913-2:2000)

Optik und optische Instrumente - Kontaktlinsen - Teil 2: Bestimmung der Sauerstoff-Permeabilität und -Transmissibilität nach dem coulometrischen Verfahren (ISO 9913-2:2000)

This European Standard was approved by CEN on 24 January 2000.

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.

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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

Foreword

The text of the International Standard ISO 9913-2:2000 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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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 9913-2:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

INTERNATIONAL STANDARD

ISO 9913-2

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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

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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.*