

Ophthalmic instruments - Corneal topographers (ISO 19980:2012)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 19980:2012 sisaldb Euroopa standardi EN ISO 19980:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 19980:2012 consists of the English text of the European standard EN ISO 19980:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kätesaadavaks 01.04.2012.	Date of Availability of the European standard is 01.04.2012.
Standard on kätesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.70

Standardite reproduutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 19980

April 2012

ICS 11.040.70

Supersedes EN ISO 19980:2005

English Version

Ophthalmic instruments - Corneal topographers (ISO
19980:2012)

Instruments ophtalmiques - Topographies de la cornée (ISO
19980:2012)

Ophthalmische Instrumente - Hornhauttopographen (ISO
19980:2012)

This European Standard was approved by CEN on 31 March 2012.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 19980:2012) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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 October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 19980:2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19980:2012 has been approved by CEN as a EN ISO 19980:2012 without any modification.

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	9
4.1 Area measured	9
4.2 Measurement sample density	9
4.3 Measurement and report of performance	9
4.4 Colour presentation of results	9
5 Test methods and test devices	9
5.1 Tests	9
5.2 Test surfaces	9
5.3 Data collection — Test surfaces	11
5.4 Analysis of the data	11
6 Accompanying documents	13
7 Marking	13
Annex A (informative) Test surfaces for corneal topographers (CTs)	14
Annex B (normative) Standardized displays for corneal topographers (CTs)	16
Annex C (normative) Calculation of area-weighting values	19
Annex D (normative) Test methods for measuring human corneas	21
Bibliography	22

Ophthalmic instruments — Corneal topographers

1 Scope

This International Standard specifies minimum requirements for instruments and systems that fall into the class of corneal topographers (CTs). It also specifies tests and procedures to verify that a system or instrument complies with this International Standard and thus qualifies as a CT according to this International Standard. It also specifies tests and procedures that allow the verification of capabilities of systems that are beyond the minimum requirements for CTs.

This International Standard defines terms that are specific to the characterization of the corneal shape so that they may be standardized throughout the field of vision care.

This International Standard is applicable to instruments, systems and methods that are intended to measure the surface shape of the cornea of the human eye.

NOTE The measurements can be of the curvature of the surface in local areas, three-dimensional topographical measurements of the surface or other more global parameters used to characterize the surface.

It is not applicable to ophthalmic instruments classified as ophthalmometers.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

corneal apex

location on the corneal surface where the mean of the local principal curvature is greatest

3.2

corneal eccentricity

e_c

eccentricity, e , of the conic section that best fits the corneal meridian of interest

NOTE If the meridian is not specified, the corneal eccentricity is that of the flattest corneal meridian (see Table 1 and Annex A).

3.3

corneal meridian

θ

curve created by the intersection of the corneal surface and a plane that contains the corneal topographer axis

NOTE 1 A meridian is identified by the angle θ , that the plane creating it makes to the horizontal (see ISO 8429).

NOTE 2 The value of θ , for a full meridian, ranges from 0° to 180° .