



NSAI
Standards

Irish Standard
I.S. EN ISO 19980:2021

Ophthalmic instruments - Corneal topographers (ISO 19980:2021)

I.S. EN ISO 19980:2021

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 19980:2021 is the adopted Irish version of the European Document EN ISO 19980:2021, Ophthalmic instruments - Corneal topographers (ISO 19980:2021)

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EUROPEAN STANDARD

EN ISO 19980

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2021

ICS 11.040.70

Supersedes EN ISO 19980:2012

English Version

Ophthalmic instruments - Corneal topographers (ISO 19980:2021)

Instruments ophtalmiques - Topographes de la cornée
(ISO 19980:2021)

Ophthalmische Instrumente - Hornhauttopographen
(ISO 19980:2021)

This European Standard was approved by CEN on 6 June 2021.

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EN ISO 19980:2021 (E)

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European foreword

This document (EN ISO 19980:2021) 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of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

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

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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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19980:2021 has been approved by CEN as EN ISO 19980:2021 without any modification.

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INTERNATIONAL STANDARD

**ISO
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Third edition
2021-06

Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée



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ISO 19980:2021(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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 19980:2012), which has been technically revised. The main changes compared to the previous edition are as follows:

- a) normative references were updated;
- b) [5.2.6](#) regarding requirements for test surfaces and requirement for testing of accuracy was changed;
- c) in [5.4.3](#), formulae for data analysis have been updated;
- d) Table 4 was deleted;
- e) document editorially revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Ophthalmic instruments — Corneal topographers

1 Scope

This document 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 document and thus qualifies as a CT according to this document. It also specifies tests and procedures that allow the verification of capabilities of systems that are beyond the minimum requirements for CTs.

This document 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 document 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.

This document is not applicable to ophthalmic instruments classified as ophthalmometers.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 + A1:2012 + A2:2020, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

corneal apex

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

Note 1 to entry: See Figure 1.

3.2

corneal eccentricity

e_c

eccentricity, e , of the conic section that best fits the *corneal meridian* (3.3) of interest

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

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