# **INTERNATIONAL STANDARD**



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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 19980 was prepared by Technical Committee ISO/TC 172, Optics and photonics, Subcommittee SC 7, Ophthalmic optics and instruments.

This second edition cancels and replaces the first edition (ISO 19980:2005), which has been technically revised.

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## **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

 $\theta$ 

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  $\theta$ , that the plane creating it makes to the horizontal (see ISO 8429).

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