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Ophthalmic instruments — Corneal topographers

Instruments ophtalmiques — Topographes de la cornée

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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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).