

ICS 11.040.70

CCS C 40



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 38455-2019

Ophthalmic instruments - Ophthalmometers

Issued on: December 31, 2019

Implemented on: January 1, 2022

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

Foreword

1 Scope

2 Normative references

3 terms and definitions

Foreword

All technical contents of this standard are mandatory.

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces YY0579-2016 Ophthalmic Instrument Corneal Curvature Meter. Compared with YY0579-2016, except for editorial changes

The main technical changes are as follows.

- Added the term and definition of "corneal refractive constant" (see 3.5);
- Deleted the term and definition of "front surface corneal power" (see 3.5 in the.2016 edition)
- Added the term and definition of "corneal diopter" (see 3.6);
- Increased general requirements for electrical safety and electromagnetic compatibility (see 4.1);
- Modified the curvature radius measurement range and measurement tolerance requirements of A-type corneal curvature meter, B-corneal curvature meter curvature radius measurement allowance

Poor requirements (see 4.2, 4.2 of.2016 version).

This standard uses the redrafting method to modify and adopt ISO 10343..2014 "Ophthalmic Instrument Corneal Curvature Meter".

Compared with ISO 10343..2014, this standard has some structural adjustments.The international standard 5.2 has been changed to this standard 5.2.1 and added.

5.2.2 and 5.3.

There are technical differences between this standard and ISO 10343..2014, and the terms related to these differences have passed through the margins on the outer margins

The installed vertical single line (I) is marked.

The technical differences between this standard and ISO 10343..2014 and the reasons are as follows.

--- Regarding normative references, this standard has made adjustments with technical differences to suit China's technical conditions and the situation of adjustment.

The situation is reflected in Chapter 2 "Regulatory Reference Documents", and the specific adjustments are as follows.

* Replaced IEC 60601-1 with GB 9706.1 equivalent to the international standard (see 4.1, Chapter 6, Chapter 7);

* Added reference to YY0505 (see 4.1).

--- Added the data processing method of Chapter 5 test method to make the test method operable (see 5.2.2, 5.3.2).

Please note that some elements of this document may involve patents. The issuer of this document is not responsible for identifying these patents.

This standard is proposed and managed by the State Drug Administration.

This standard was drafted. Zhejiang Medical Device Inspection Institute.

1 Scope

This standard specifies the terms and definitions, requirements and test methods of continuous or digital indicating corneal curvature meters.

This standard applies to continuous or digital indication corneal curvature meter.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article

Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment Part 1. General requirements for safety (GB 9706.1-2007, IEC 60601-1. 1988, IDT)

YY0505 Medical electrical equipment-Part 1-2. General requirements for safety. Collateral standard. EMC requirements and tests

(YY0505-2012, IEC 60601-1-2..2004, IDT)

ISO 8429 Optics and Optical Instruments Ophthalmology Dial Scales

(Optics and optical instruments - Ophthalmology - Graduated dial scale)

ISO 15004-1:2006 Basic requirements and test methods for ophthalmic instruments. Part 1. General requirements for ophthalmic instruments

instruments - Fundamental requirements and test methods - Part 1. General requirements applicable to ophthalmic instruments)

3 terms and definitions

The following terms and definitions apply to this document.

3.1

Corneal curvature meter

An instrument used to measure the radius of curvature and the axial direction of the principal meridian in the central area of the human cornea and/or contact lens.

3.2

Distance-dependent ophthalmometer

A corneal curvature meter whose measurement results are affected by the distance between the instrument and the surface being measured.

3.3

Toroidal surface

A surface formed by a circular arc rotating about an axis in the same plane but not passing through the center of curvature of the arc, having two orthogonalities

The round, "main meridian", one largest and one smallest.

3.4

Principal curvature direction

The direction of the smallest or largest radius of curvature of the reflecting surface to be measured.

3.5

Keratometric constant

The constant 337.5 is used to convert corneal curvature from the inverse of millimeters (mm^{-1}) to corneal refractive power.

[ISO .19980..2012, definition 3.11]

chinastandards.org · PREVIEW