American National Standard

for Ophthalmics –

Corneal Topography and Tomography Systems – Standard Terminology, Requirements

ANSI Z80.23-2018

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Contents

Page

Foreword ii

1 Scope and purpose 1

1.1 Scope 1

1.2 Purpose 1

2 Normative references 1

3 Terminology 2

4 Requirements 2

4.1 Area measured 8

4.2 Measurement sample density 8

4.3 Measurement and report of performance 8

5 Test methods and test devices 8

5.1 Types of test 8
5.1.1 Accuracy 8
5.1.2 Responsibility 8

5.2 Test surfaces 9
5.2.1 Reflection-based systems 9
5.2.2 Luminous surface systems 9
5.2.3 Optical sectioning systems 9
5.2.4 Interference-based systems 9
5.2.5 Specification of test surfaces 9
5.2.6 Verification of test surfaces 10
5.2.7 Type testing using test surfaces 10

5.3 Data collection 12
5.3.1 Test surfaces 12
5.3.2 Human corneas 12

5.4 Analysis of the data 12
5.4.1 Structure of the accuracy data set 12
5.4.2 Structure of the repeatability data set 12
5.4.3 Analysis of the paired data sets 13
5.4.3.1 Special considerations for the comparison of corneal elevation values 13
5.4.4 Report of performance 14
5.4.4.1 Accuracy 14
5.4.4.2 Repeatability 14

6 Accompanying documents 14

7 Marking 15

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Page

Tables

1 Conic section descriptors 7

2 Test surfaces for type testing 11

3 Tolerance levels for test surface measurements 11

4 Analysis zones for accuracy and repeatability testing 13

Figures

1 Illustration of axial curvature, K_a, axial radius of curvature, r_a, meridional curvature, K_m, and meridional radius of curvature, r_m 7

2 Illustration of the corneal vertex and the apex 7

Annexes

A Test surfaces for corneal topographers and corneal tomographers 16

B Standardized displays for corneal topographers and corneal tomographers 18

C Calculation of area weighting values 21

D Pre-processing of axial elevation data prior to analysis of paired data sets 23

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Foreword (This foreword is not part of American National Standard ANSI Z80.23-2018.)

This American National Standard continues to address the expressed needs of those members of the ophthalmic community who use corneal topography in clinical settings, those who manufacture corneal topographers and those who teach others in the use of the information collected by corneal topographers. In particular, there continues to be a need for standardization of the terms and definitions used in the field, for standardization of the methods used for characterizing the performance of these instruments and for standardization of displays of corneal topographical information. The experts who worked together to initially create this standard felt that, at the time, there was not sufficient consensus within the ophthalmic community to set performance requirements for these instruments beyond those for minimum area measured and measurement sample density. Later, in working with international experts in the field, it was decided that instruments should be tested on a selected set of test surfaces to ensure that the calibration to set their scale factors had been done correctly. The standard continues to address standardization of the methods for testing these instruments, for assessing their performance, and for reporting the results thus obtained.

The number and type of test surfaces to be used has been changed to include only test surfaces for which the results can be verified. When these surfaces are tilted or rotated the expected surface measurements are easy to predict. These surfaces were considered to be adequate as minimum verification surfaces for corneal topographers; if a corneal topography system can measure these surfaces well, it will be a clinically useful instrument. The method for standardization of color maps has been changed in an effort to improve the user's ability to discern just-noticeable differences in corneal topography. The user always has the option of using a scale with less resolution but with greater range, as long as the scale recommended in this document is available to be used.

This standard contains four annexes. Annex A is informative and is not considered part of this standard. Annexes B through D are normative and are considered part of this standard.

This standard was created by a special working group created by the Z80 Subcommittee on Ophthalmic Instruments and included experts in the field of corneal topography from the clinical, manufacturing and academic areas of the ophthalmic community. Suggestions for improvement of this standard will be welcome. They should be sent to the Vision Council, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmics, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z80 Committee had the following members:

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Neal Roche, Vice-Chairman
William Benjamin, O.D., Secretary
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1 Scope and purpose

1.1 Scope

This American National Standard applies to instruments, systems and methods that are intended to measure the shape of the cornea of the human eye over a majority of its area. The measurements of the anterior and/or posterior surface in local areas may be of curvature and/or three dimensional topographical measurements of the surface. The measurements may be used to derive more global parameters used to characterize the surfaces. Instruments classified as ophthalmometers or keratometers are not covered by this standard.

1.2 Purpose

This standard defines certain terms that are peculiar to the characterization of the corneal shape so that they may be standardized throughout the field of vision care and have common meaning for all those who have occasion to participate in this area.

This standard sets forth minimum requirements for instruments and systems that fall into the class of corneal topographers.

This standard sets forth tests and verification procedures that will verify that a system or instrument complies with the standard and so qualifies as a corneal topographer or corneal tomographer in the meaning of this standard.

This standard sets forth certain tests and verification procedures that will allow the verification of capabilities of systems that are beyond the minimum required for corneal topographers or corneal tomographers.

2 Normative reference

The following standard contains provisions that, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

ANSI Z80.20-2004, *Ophthalmics – Contact Lenses – Standard terminology, tolerances, measurements and physicochemical properties*[1)]

ANSI Z80.28-2017, *Ophthalmic Instruments – Methods for reporting optical aberrations of eyes* [1)]

ISO 8429:1986, *Optics and optical instruments – Ophthalmology – Gradual dial scale*[1)]

[1)] For electronic copies of some standards, visit ANSI's Electronic Standards Store (ESS) at www.ansi.org. For printed versions of all these standards, contact Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112-5704, (800) 854-7179.

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