

ANSI Z80.23-2008

American National Standard

*for Ophthalmics –
Corneal Topography Systems –
Standard Terminology, Requirements*



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ANSI®
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American National Standard
for Ophthalmics –
Corneal Topography Systems –
Standard Terminology, Requirements

Secretariat
The Vision Council

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American National Standards Institute, Inc.

American National Standard

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The Accredited Committee Z80 for Ophthalmic Standards -

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Foreword (This foreword is not part of American National Standard ANSI Z80.23-2008 (R2013).

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 regarding 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 create this standard felt that at this time there is not sufficient consensus within the ophthalmic community to set performance requirements for these instruments beyond those for minimum area measured and measurement sample density. 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 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.

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

Suggestions for improvement of this standard will be welcome. They should be sent to the Vision Council, 225 Reinekers Lane, 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:

Thomas White, M.D., Chairman
Quido Cappelli, Vice-Chairman
Robert Rosenberg, O.D., Secretary
Daniel Torgersen, Secretariat

<i>Organization Represented</i>	<i>Name of Representative</i>
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<i>Organization Represented</i>	<i>Name of Representative</i>
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William L. Brown, O. D., Ph.D, Chairman	Charles E. Campbell
	Robert Landry
	David Loshin
	Robert Rosenberg
	Thomas White

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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 central anterior surface. The measurements may 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. 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 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.

2 Normative references

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 Z80.20-1998, *Ophthalmics – Contact Lenses – Standard terminology, tolerances, measurements and physicochemical properties*¹⁾

ANSI Z80.28-2004, *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.