

ANSI Z80.20-2016

# American National Standard

*for Ophthalmics –  
Contact Lenses –  
Standard Terminology,  
Tolerances, Measurements and  
Physicochemical Properties*

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**ANSI**<sup>®</sup>  
**Z80.20-2016**  
Revision of  
ANSI Z80.20-2010

American National Standard  
for Ophthalmics –

**Contact Lenses –  
Standard Terminology,  
Tolerances, Measurements and  
Physicochemical Properties**

Secretariat  
**The Vision Council**

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## American National Standard

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## Contents

|   | Page |
|---|------|
| Foreword .....  | iii  |
| <b>1</b> Scope and Purpose .....  | 1    |
| <b>2</b> Normative References .....   | 2    |
| <b>3</b> Contact Lens Terminology.....  | 4    |
| <b>4</b> Nomenclature and Classification of Contact Lens Materials .....  | 16   |
| <b>5</b> Standard Tolerances of Finished Contact Lenses.....  | 22   |
| <b>6</b> Physicochemical Properties of Contact Lens Materials .....   | 27   |
| <b>7</b> Standard Measurement Methods for Contact Lenses .....  | 28   |
| <b>8</b> Test Report.....   | 83   |
| <b>Tables</b>   |      |
| <b>1</b> Contact Lens Materials.....  | 1    |
| <b>2</b> Symbols for Parameters and Linear Dimensions .....   | 4    |
| <b>3</b> Tolerances for Corneal and Paralimbal Contact Lenses .....   | 22   |
| <b>4</b> Tolerances for Scleral (Haptic) Contact Lenses .....   | 24   |
| <b>5</b> Tolerance Limits of Material and Contact Lens Physical Properties .....  | 25   |
| <b>6</b> Physicochemical Properties: Repeatability, Test Methods,<br>and Units of Measure .....   | 28   |
| <b>7</b> Summary of Sagittal Depth Equations in Terms of<br>Apical Radius of Curvature ( $r$ ), Eccentricity ( $e$ ),<br>Chord Diameter ( $2h$ ), and Lens Diameter ( $D$ ) ..... | 35   |
| <b>8</b> Specifications for a V-Groove Diameter Gauge .....   | 44   |
| <b>Figures</b>  |      |
| <b>1</b> Linear Dimensions of a Corneal Contact Lens .....  | 5    |
| <b>2</b> Qualitative Specification of Edge Thickness<br>and Shape for Rigid Contact Lenses .....  | 26   |
| <b>3</b> Optical System of a Microsphereometer .....  | 29   |
| <b>4</b> Optical System of an Ophthalmometer .....  | 33   |
| <b>5</b> Measurement of Sagittal Depth of a Soft Lens .....   | 36   |
| <b>6</b> Annular Cylinder Contact Lens Support for the Focimeter .....  | 37   |
| <b>7</b> Contact Lens Resting on an Annular Cylinder Contact Lens Stop .....  | 38   |
| <b>8</b> Paddle Contact Lens Support (Stop) for the Focimeter.....  | 39   |
| <b>9</b> Contact Lens Resting on a Paddle Contact Lens Stop .....   | 39   |
| <b>10</b> V-Groove Diameter Gauge .....   | 43   |
| <b>11</b> Principle of the Projection Comparator.....   | 45   |
| <b>12</b> Measurement of Center Thickness with a Dial Gauge .....   | 49   |

|                |  |     |
|----------------|--|-----|
| <b>13</b>      | Apparatus for Determination of Spectral and Luminous Transmittance .....   | 54  |
| <b>14</b>      | Specimen Dimensions for Testing of Flexural Strength,<br>Dimensions in Millimeters .....   | 59  |
| <b>15</b>      | Fixture Holding Specimen for Testing of Flexural Strength,<br>Dimensions in Inches.....  | 60  |
| <b>16</b>      | Hydrogel Sample between Sensor and Retaining Mesh .....  | 66  |
| <b>17</b>      | Clamping Mechanism for Polarographic Measurement. ....   | 66  |
| <b>18</b>      | Polarographic Cell Body .....  | 67  |
| <b>19</b>      | Nonhydrogel Sample between Sensor and Retaining Mesh .....   | 67  |
| <b>20</b>      | Coulometric Apparatus .....  | 71  |
| <b>21</b>      | Diffusion Cell for Coulometric Method .....  | 71  |
| <b>22</b>      | Measurement of Bulk Material with Prism-Coupling Device .....  | 77  |
| <b>Annexes</b> |  |     |
| <b>A</b>       | Conformance Criteria for Testing Products.....   | 84  |
| <b>B</b>       | Measurement Systems Requirements.....  | 87  |
| <b>C</b>       | Example of Calculating Gauge Repeatability and Reproducibility .....   | 89  |
| <b>D</b>       | Determination of Label Back Vertex Power of Soft Contact Lenses<br>Immersed in Saline using the Moire Deflectometer or Shack-Hartmann<br>Methods ..... | 96  |
| <b>E</b>       | Bibliography .....   | 101 |

**Foreword** (This foreword is not part of American National Standard ANSI Z80.20-2016.)

The Z80 Committee for Ophthalmics was organized in 1956, and the committee's initial standard on ophthalmic lenses was issued in 1964. In the ensuing years the committee expanded its scope and organization into a number of subcommittees, each charged with specific areas of responsibility. One of these, The Subcommittee for Contact Lenses, has published two standards Z80.18 Contact Lens Care Products-Vocabulary, Performance Specifications, and Test Methodology and Z80.20 Contact Lenses- Standard Terminology, Tolerances Measurements and Physiochemical Properties which are dutifully reviewed on a five-year basis to include any newly established information.

Since 1980, the Subcommittee for Contact Lenses has provided delegates to the International Standards Organization to represent the American Standards Institute's role (for the United States) in developing and approving contact lens and contact lens care products standards for the international community. In providing this service for ANSI it became apparent that the role of the delegates continued to require reaffirmation from the American community as a whole to support their input. Thus in addition to providing information to the international forum the Subcommittee for Contact Lenses continues to process all available information through its ANSI network.

This latest version of Z80.20 was written to include provisions for newer contact lenses and materials now on the public market and to ensure that the US standard is in conformance with the International Standard. Thus, this revision of Z80.20 and future reviews or revisions of this standard will ensure that the continued participation of American delegates to ISO will be supported by an America standard that has received a consensus by the Z80 Committee for Ophthalmic standards in addition to other American interests.

This standard contains five informative annexes, which are not considered part of this standard.

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 Ophthalmic Optics, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time of approval of this standard, the Z80 Committee consisted of the following members:

Thomas White, M.D., Chairman  
Quido Cappelli, Vice-Chairman  
William Benjamin, O.D., Secretary  
Michael Vitale, Secretariat

| <i>Organization Represented</i>                               | <i>Name of Representative</i> |
|---|-------------------------------|
| Abbott Medical Optics.....                                    | Leonard Borrmann              |
| Advance Medical Technologies Association.....                 | Michael Pflieger              |
| American Academy of Ophthalmology .....                       | Dr. Thomas White              |
| American Academy of Optometry.....                            | Dr. David Loshin              |
| American Ceramic Society .....                                | Lyle Rubin                    |
| American Glaucoma Society .....                               | Dr. Steven Gedde              |
| American Optometric Association .....                         | Dr. Karl Citek                |
| American Society of Cataract and Refractive Ophthalmology ... | Dr. Stephen Klyce             |
| Contact Lens Institute.....                                   | Stan Rogaski                  |
| Contact Lens Manufacturers Association .....                  | Quido Cappelli                |
| Department of Veterans Affairs .....                          | Dr. John Townsend             |
| Federated Cornea Societies/ASCERS .....                       | Dr. Michael Belin             |
| Food & Drug Administration .....                              | Don Calogero                  |
| National Association of Optometrists & Opticians .....        | Nick Mileti                   |
| Optical Laboratory Association.....                           | Steve Sutherland              |
| Opticians Association of America .....                        | Tom Hicks                     |
| Sunglass Association of America .....                         | Tibor Gross                   |
| The Vision Council.....                                       | Michael Vitale                |
| U.S. TAG Leader to ISO TC 172/SC7 .....                       | Michael Vitale                |

The working group that coordinated the development of this revision and harmonization with ISO Standards was headed by William J. Benjamin, assisted by Ralph Stone and Paul Ludington.

As of the date of publication of this revision the Subcommittee had the following active members:

Quido A. Cappelli, Chairman  
(Contact Lens Manufacturers Association)

|   |   |   |
|---|---|---|
| William J. Benjamin<br>(American Optometric Association)    | Angelo Green<br>(U.S. Food and Drug Administration)   | Michael Pflieger<br>(Alcon Laboratories)        |
| Roya Borazjani<br>(Cooper Vision Corporation)               | Denise Hampton<br>(U.S. Food and Drug Administration) | Samuel Puig<br>(Cooper Vision Corporation)      |
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| Glenn Davies<br>(Bausch & Lomb, Inc.)                       | Carol Lakkis<br>(Johnson & Johnson Vision Care)       | Karen Sentell<br>(Alcon Laboratories)           |
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Steve Galas  
(Johnson & Johnson Vision Care)

Richard Courtney  
(Johnson & Johnson Vision Care)

Troy Miller  
(Contact Lens Manufacturers Association)



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for Ophthalmics –

Contact Lenses –  
Standard Terminology, Tolerances  
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Physicochemical Properties

**1 Scope and Purpose**

**1.1 Scope**

This American National Standard applies to contact lenses worn over the front surface of the eye in contact with the precorneal tear film. The standard covers rigid intracorneal and haptic (scleral) contact lenses, as well as soft paralingual contact lenses. Table 1 provides a high-level list of materials used for both rigid and soft contact lenses.

**Table 1 – Contact Lens Materials**

| Type  | Subtype  | Material   |
|-------|--|--|
| Rigid | Traditional  | PMMA (polymethyl methacrylate), CAB  |
|       | Non-hydrogel   | Group I - Materials not containing silicone or fluorine  |
|       |  | Group II - Materials containing silicone but not fluorine  |
|       |  | Group III - Materials containing silicone and fluorine   |
|       |  | Group IV - Materials containing fluorine but not silicone  |
| Soft  | Hydrogel   | Group I - (low water (< 50%), non-ionic)   |
|       |  | Group II - (high water (>= 50%), non-ionic)  |
|       |  | Group III - (low water, (< 50%), ionic)  |
|       |  | Group IV - (high water, (>= 50%), ionic)   |
|       | Enhanced oxygen permeable materials (e.g., Silicone Hydrogels) | Group V - Materials having a Dk greater than 40 Dk units (using mmHg) and having a Dk greater than that expected on the basis of the materials' water content alone. |
|       |  | Group VA - Group 5 materials containing an ionic monomer or oligomer at pH 6-8   |
|       |  | Group VB - Group 5 non-ionic material containing $\geq$ 50% water  |
|       |  | Group VC - Group 5 non-ionic material containing < 50% water   |