

# 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**

Approved December 6, 2016  
Published March 20, 2017

**American National Standards Institute, Inc.**

# American National Standard

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## *Developed by*

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## *Published by*

The Vision Council  
1700 Diagonal Road  
Suite 500  
Alexandria, VA 22314

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Printed in the United States of America

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**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>
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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
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Department of Veterans Affairs .....	Dr. John Townsend
Federated Cornea Societies/ASCRS .....	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 (American Optometric Association)	Angelo Green (U.S. Food and Drug Administration)	Michael Pflieger (Alcon Laboratories)
Roya Borazjani (Cooper Vision Corporation)	Denise Hampton (U.S. Food and Drug Administration)	Samuel Puig (Cooper Vision Corporation)
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Glenn Davies (Bausch & Lomb, Inc.)	Carol Lakkis (Johnson & Johnson Vision Care)	Karen Sentell (Alcon Laboratories)
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Past members of the Subcommittee who made significant contributions to the development or revision to this standard and represented the indicated organization are:

Steve Galas  
(Johnson & Johnson Vision Care)

Richard Courtney  
(Johnson & Johnson Vision Care)

Troy Miller  
(Contact Lens Manufacturers Association)

American National Standard  
for Ophthalmics –

# Contact Lenses – Standard Terminology, Tolerances Measurements and 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 paralimbal 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