

American National Standard

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



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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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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 Ruffin 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 Vitale, M.D., Chairman
Quido Coppilli, 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
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American Ceramic Society	Lyle Rubin
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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
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Optical Laboratory Association.....	Steve Sutherland
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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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Past members of the Subcommittee who made significant contributions to the development or revision of this standard and represented the indicated organization are:

Steve Galbraith
(Johnson & Johnson Vision Care)

Richard Courney
(Johnson & Johnson Vision Care)

Tracy 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)
		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.
	Enhanced oxygen permeable materials (e.g., Silicone Hydrogels)	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