American National Standard

for Ophthalmics

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

ANSI Z80.20-2010

Developed by

*Where **IT** all begins*

ANSI
Z80.20-2010
Revision of
ANSI Z80.20-2004

American National Standard
for Ophthalmics –

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

Secretariat

The Vision Council

Approved December 6, 2010

American National Standards Institute, Inc.

American National Standard

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Developed by

The Accredited Committee Z80 for Ophthalmic Standards

The Vision Council
Z80 Secretariat
225 Reinekers Lane
Alexandria, VA 22314

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Foreword (This foreword is not part of American National Standard ANSI Z80.20-2010.)

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 (Insert names) 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 insure 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 four informative annexes, which are not considered part of this standard.

Suggestions for improvement of this standard will be welcome. They should be sent 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 Standards, 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 C. White, M.D., Chairman
Quido A. Cappelli, P.E., Vice-Chairman
Robert Rosenberg, O.D., Secretary

Organization Represented	*Name of Representative*
Advanced Medical Technologies Association	Douglas Fortunato
	Richard Courtney (Alt.)
	Glenn Davies (Alt.)
	Bernie Liebler (Alt.)
American Academy of Ophthalmology	Thomas White
	Carl Tubbs (Alt.)
	Pradeep Ramulu (Alt.)
	Rebecca Hyder (Alt.)
American Academy of Optometry	David S. Loshin
American Ceramic Society	Lyle Rubin
	Herbert Hoover (Alt.)
American Glaucoma Society	Steven Gedde
	Douglas Rhee (Alt.)

Organization Represented	*Name of Representative*
American Optometric Association	Jeffrey Weaver
	Robert Rosenberg (Alt.)
	William Benjamin (Alt.)
	William Brown (Alt.)
American Society of Cataract and Refractive Surgery	Steven Klyce
	Jack Holladay (Alt.)
Contact Lens Institute	Stan Rogaski
	Peter Mathers (Alt.)
Contact Lens Manaufacturer's Association	Quido Cappelli
	Jan Svochak (Alt.)
	John Walfoort (Alt.)
Department of Veterans Affairs	John Townsend
	Sharon Atkin (Alt.)
Federated Cornea Societies/ASCRS	Michael Belin
	David Glasser (Alt.)
Food & Drug Administration	Don Calogero
	Robert James (Alt.)
National Association. of Optometrists & Opticians	Nick Mileti
	Joe Dezenzo (Alt.)
	Franklin Rozak (Alt.)
National Academy of Opticianry	James Elkins
Optical Laboratory Association	Daniel Torgersen
	Virginia (Susie) Lesher (Alt.)
	Richard Tinson (Alt.)
	Robert Dziuban (Alt.)
Opticians Association of America	Tom Hicks
	Chris Allen (Alt.)
Sunglass Association of America	Kenneth Frederick
	Scott MacGuffie (Alt.)
	Rick Van Arnam (Alt.)
US Leader to ISO TC 172/SC7	Charles E. Campbell
The Vision Council	Jeff Endres
	Steve Drake (Alt.)
	Neil Roche (Alt.)
	Dick Whitney (Alt.)
	Ken Wood (Alt.)

The Subcommittee for Contact Lenses, which developed this standard, is composed of two groups having areas of interest as follows:

- Contact lens parameters; Methods of measuring contact lens parameters; Physical and chemical properties of contact lens materials; Methods of measurement of physical and chemical properties.

- Contact lens care products.

The working group that coordinated the development of this revision and harmonization with ISO standards in progress was headed by Doug Fortunato.

The Subcommittee had the following members:

Quido A. Cappelli, Chairman
William Benjamin
Glen Davies
Doug Fortunato
Steve Galas
David Meadows
Mary Mowrey McKee
Ralph Stone

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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 preocular 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 1 Materials not containing silicone or fluorine
		Group 2 Materials containing silicone but not fluorine
		Group 3 Materials containing silicone and fluorine
		Group 4 Materials containing fluorine but not silicone
Soft	Hydrogel	Group 1 (low water (< 50%), non-ionic)
		Group 2 (high water (>/= 50%), non-ionic)
		Group 3 (low water, (< 50%), ionic)
		Group 4 (high water, (>/= 50%), ionic)
	Enhanced oxygen permeable materials (e.g., Silicone Hydrogels)	Group 5 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.