ANSI Z80.20-2004
(Editorially Revised: December 2005)

AMERICAN NATIONAL STANDARD

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

ANSI Z80.20-2004

ANSI
Z80.20-2004
(Revision of
ANSI Z80.20-1998)

American National Standard
for Ophthalmics –

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

Secretariat

Optical Laboratories Association

Approved September 9, 2004
Editorially Revised December 5, 2005

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Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

Optical Laboratories Association
Z80 Secretariat
P. O. Box 2000
Merrifield, VA 22116-2000

Published by

Optical Laboratories Association
P. O. Box 2000
Merrifield, VA 22116-2000

Printed in the United States of America

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Foreword (This foreword is not part of American National Standard ANSI Z80.20-2004.)

The Z80 Standards Committee for Ophthalmic Lenses was organized in 1956. Through the years, a number of changes in the scope of the committee were made to include subcommittees that apply to ophthalmic lenses, to contact lenses and their accessories for use; equipment, instruments and to processes used in the final fabrication level which may affect their performance; to ophthalmic frames, sunglasses, and fashion eyewear; to intraocular implant lenses; to low vision aids and ophthalmic procedures and vision evaluation.

In 1982, the Optical Laboratories Association (OLA) assumed the responsibilities of the Secretariat, and in 1985 the Z80 Committee became an accredited standards committee. Currently, ophthalmic standards are drafted by subcommittees of the Z80 committee which in turn may establish working groups to address specific detailed areas of interest.

In 1998, the Subcommittee for Contact Lenses published the revision of its earlier contact lens standards to reflect new areas of interest, the addition of new materials and the changing state-of-the-art and issuing one standard that would contain all applicable provisions for modern day contact lens reference. This revision contains the latest technical review of methods of measuring oxygen permeability and is also intended to reflect the provisions that have been in the process of formulation by the International Standards Organization.

Suggestions for improvement of this standard will be welcome. They should be sent to the Optical Laboratories Association, P.O. Box 2000, Merrifield, VA 22116-2000.

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*
American Academy of Ophthalmology	Thomas White
American Academy of Optometry	David S. Loshin
American Ceramic Society	Ron Klimek
American Optometric Association	Donald Pitts
	William J. Benjamin (Alt.)
	Robert Rosenberg (Alt.)
	Gregory Stephens (Alt.)
American Society of Cataract and Refractive Surgery	John Alpar
	Jack Holladay (Alt.)
	Stephen Johnson (Alt.)
AR Council of America	Scott Reickert
	Nick Milletti (Alt.)
Contact Lens Institute	Ed Schilling
Contact Lens Manaufacturer's Assn	Quido Cappelli
Department of Veterans Affairs	John Townsend
	Sharon Atkin (Alt.)
Food & Drug Administration	David Wipple
	Ashley Boam (Alt.)
	Don Calogero (Alt.)
	Robert Landry (Alt.)

Organization Represented	*Name of Representative*
National Assn. of Optometrists & Opticians	Arthur Newman
National Academy of Opticianry	James Elkins
Optical Laboratory Association	Daniel Torgersen
	Henry Hart (Alt.)
Optical Society of America	F. Dow Smith
	Richard Phillips (Alt.)
Opticians Association of America	Mike Robey
Prevent Blindness of America	Tod Turriff
Sunglass Association of America	Kenneth Frederick
	David Elliott (Alt.)
	Thomas Loomis (Alt.)
	James Pritts (Alt.)
US Leader to ISO TC 172/SC7	Charles E. Campbell
Vision Council of America	Kenneth O. Wood
	Steve Drake (Alt.)
	Darryl Meister (Alt.)
	Richard Waido (Alt.)
	Dick Whitney (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 William Joe Benjamin.

The Subcommittee had the following members:

Quido A. Cappelli, Chairman

William Joe Benjamin
Glen Davies
Douglas Fortunato
Michael Miller
Mary Mowrey-Mckee
Arthur Newman
Michael Pfleger
Barry VanDuzee
Karen Warburton
David Whipple

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 which are devices worn over the front surface of the eye in contact with the preocular tear film. The standard covers rigid (hard) intracorneal and haptic (scleral) contact lenses, as well as flexible paralimbal contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Flexible lenses are easily deformable and may require support for proper shape. A very large subset of flexible lenses are so-called "soft" (hydrophilic) contact lenses, which are made of transparent hydrogels containing water in concentrations greater than or equal to 10%. Flexible lenses can also be made of non-hydrogel materials, e.g., flexible polysiloxanes (silicone elastomers).

1.2 Purpose

This standard is applicable for determining allowable tolerances of parameters and properties important for proper functioning of contact lenses. The standard includes tolerances for single-vision contact lenses, bifocal lenses, lenses that alter the optical density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UVR-blocking lenses). The standard covers lenses designed with spherical, toric, and conoidally aspheric surfaces and recommended methods for the specification of contact lenses.

The purpose of this standard is to incorporate tolerances for all contact lenses in a single standard and to provide, as much as possible, for standards in development by the International Standards Organization (ISO) for rigid and soft contact lenses.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were 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 Z80.2-1989, *Ophthalmics - Rigid Contact Lenses - Requirements*[1]

ANSI Z80.3-2001, *Ophthalmics - Non-Prescription Sunglasses and Fashion Eyewear - Requirements*[1]

[1] Available from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036.