

AMERICAN NATIONAL STANDARD



*for Ophthalmics –
Contact Lens Care Products –
Vocabulary, Performance Specifications
and Test Methodology*

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Z80.18-2003

American National Standard
for Ophthalmics –
Contact Lens Care Products –
Vocabulary, Performance Specifications
and Test Methodology

Secretariat

Optical Laboratories Association

Approved May 1, 2003

American National Standards Institute, Inc.

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Foreword (This foreword is not part of American National Standard ANSI Z80.18-2003.)

The Z80 Committee for Ophthalmic Standards was organized in 1956, and the committee's initial standard was issued in 1964 as *American National Standard Institute Requirements for First Quality Glass Ophthalmic Lenses*, ANSI Z80.1-1964. Through the years, a number of changes in the scope of the committee were made. Subsequently the scope of the subcommittee has been broadened to the establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and to processes used in the final fabrication level that may affect their performance; to ophthalmic frames, sunglasses, and fashion eyewear; to contact lenses and their accessories for use; 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 the past decade, the Subcommittee for Contact Lenses has provided delegates to the International Standards Organization to represent the American National Standards Institute's role in developing and approving contact lens care products standards for the international community. During the many sessions to accomplish this task, it became apparent to these delegates that an approved American position regarding standards for contact lenses and contact lens products is a necessity before an international standard can be approved by these delegates. As a result of this observation, the delegates began the task of supplying information to the various ISO working groups and, at the same time, including this information and other information that will appear in ISO standards in an American document that would receive the consensus approval of the Z80 Committee on Ophthalmic Standards. The culmination of this dual project is seen here as ANSI Z80.18-2003. Future reviews or revisions of this standard will ensure that the continued participation of American delegates to ISO will be supported by a document that has received a consensus by Z80 Committee for Ophthalmic Standards.

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, U.S.A.

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
 Guido A. Cappelli, P.E., Vice-Chairman
 Robert Rosenberg, O.D., Secretary

<i>Organization Represented</i>	<i>Name of Representative</i>
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Advance Medical Technologies Association	Douglas J. Fortuna Carolyn Jones (Alt.) Glenn Davies (Alt.) Stanley J. Ronas (Alt.)
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Veterans Administration	John Townsend Sharon R. Atkin (Alt.)
Vision Council of America	Kenneth O. Wood Steve Drake (Alt.) Michelle Princi (Alt.) Neil Roche (Alt.) Dick Whitney (Alt.)

The subcommittee on Ophthalmic Instruments, which modified the ISO standard, had the following members:

Quido A. Cappelli, Chairman

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William Joe Benjamin
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American National Standard
for Ophthalmics –

Contact Lens Care Products – Vocabulary, Performance Specifications and Test Methodology

1 Scope

This American National Standard applies to contact lens care products (CLCP) that are marketed for use with hard (PMMA), rigid gas permeable (RGP), and soft hydrophilic contact lenses. These products are intended for use in the care of contact lenses: e.g., rinsing, storing, disinfection, conditioning, neutralization, cleaning, hydration, and/or for alleviating discomfort of lens wear and improving lens tolerance by physical means.

This standard provides test methodology to be used in developing performance specifications of CLCP by function and, where appropriate, provides acceptable performance specifications for specific products. It also addresses general requirements for CLCP based upon physical state of the marketed product (solutions, granules, and tablets), the packaging configuration (including conventional plastic container, aerosol container, form-fill-seal or blister pack), and mode of use (unit dose or multi-dose).

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 standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid standards.

ANSI Z80.20-1998, *Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

ANSI/AAMI/ISO 11134:1993, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ANSI/AAMI/ISO 11135:1993, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ANSI/AAMI/ISO 11137:1995, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ISO 8320-2:2001, *Contact lenses and contact lens care products - Vocabulary - Part 2: Contact lens care products*

ISO 9363-1:1994, *Optics and optical instruments – Contact lenses – Determination of cytotoxicity of contact lens material – Part 1: Agar overlay test and growth inhibition test*