AMERICAN NATIONAL STANDARD

for Ophthalmic Istruments –
Fundamental Requirements and Test Methods

OLA®

ANSI®
Z80.25-1996 (R2002)

American National Standard
for Ophthalmic Instruments –

Fundamental Requirements and Test Methods

Secretariat

Optical Laboratories Association

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Contents

Foreword (This foreword is not part of American National Standard Z80.25-1996

This is a standard for ophthalmic instruments which specifies characteristics which are common to many such instruments, such as: safety issues, environmental use conditions, electrical requirements, storage and transport conditions, radiation hazards, marking requirements, accompanying documents and others. Since these characteristics are common to many ophthalmic instruments it is economical to standardize them in a single horizontal standard rather than include these characteristics in each of the individual instrument standards.

In 1982, the Optical Laboratories Association (OLA) assumed the responsibility of the Secretariat; and in 1985 the Z80 Committee became an accredited standards committee. The scope of the Z80 committee is for the establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and to processes used in the final fabrication level which affect their performance; to ophthalmic frames, sunglasses, and fashion eyewear; to contact lenses and accessories for their use; to intraocular implant lenses; to low vision aids and ophthalmic contact devices in addition to contact lenses; and to optical instrumentation used in ophthalmic procedures and vision evaluation.

The current ophthalmic standards are drafted by subcommittees of the Z80 committee. These subcommittees may, in turn, establish working groups, as needed, to address detailed areas in the assigned project.

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, 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:

David E. Eifrig, Chairman
F. Dow Smith, Vice Chairman
Robeert Rosenberg, Secretary

Organization Represented	*Name of Representative*
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American Academy of Optometry	David S. Loshin
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	David Sliney (Alt.)
United States Air Force	Bob Buckingham
United States Navy	David Mazur
	Stanley Freed (Alt.)
Veterans Health Administration	Charles F. Mullen

The Z80 subcommittee on Ophthalmic Instruments, which developed this standard, had the following members:

James E. Sheedy, Chairman

David Eifrig
Charles Campbell
John J. Alpar
Rick Ambler
Bernard Grolman
David A. Hsieh
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Jeffrey S. Kosh
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Donald H. Winfield

American National Standard
for Ophthalmics –

Instruments – Fundamental Requirements and Test Methods

1 Scope and purpose

1.1 Scope

This standard is applicable to non-invasive, active and non-active ophthalmic instruments. This standard includes low vision aids and tonometers, but excludes other instruments which are used in contact with the globe of the eye. This standard is not applicable to operation microscopes, endoscopes and devices intended for laser treatment (surgery) of the eye. This standard takes precedent over the corresponding requirement of the other general standards quoted in clause 2, if differences exist. In addition to the requirements of this standard, the supplementary or modified requirements specified in the relevant product-related standards will apply. They are listed in annex D.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7944:1984 *Optics and optical instruments - Reference wavelength* [1)]

ISO 9022-2:1994 *Optics and optical instruments - Environmental test methods, Part 2: Cold, heat, humidity* [1)]

ISO 9022-3:1994 *Optics and optical instruments - Environmental test methods, Part 3: Mechanical stresses* [1)]

ISO 9022-5:1994 *Optics and optical instruments - Environmental test methods, Part 5: Combined cold, low air pressure* [1)]

IEC 601-1:1988 *Safety of medical-electrical equipment, Part 1: general requirements* [1)]

IEC 825:1993 *Radiation safety of laser products, equipment classification, requirements and user's guides* [1)]

3 Definitions

For the purpose of this standard the following definition shall apply:

3.1 Corneal plane

The plane that is perpendicular to the optic axis of the instrument and that is tangential to the corneal surface closest to the instrument when in normal use.

3.2 Non-invasive ophthalmic instrument

Ophthalmic instrument which does not in whole or in part penetrate inside the body, either through a body orifice or through the surface of the body.

3.3 Active ophthalmic instrument

Any ophthalmic instrument connected to or equipped with a source of electrical energy.

3.4 Manufacturer

The natural or legal person, who places the instrument on the market.

1) Available from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036.