AMERICAN NATIONAL STANDARD

OLA®

for Ophthalmics –

Ophthalmic Instruments – Tonometers

ANSI®
Z80.10-2003
Revision of
ANSI Z80.10-1994

American National Standard
for Ophthalmics –

Ophthalmic Instruments – Tonometers

Secretariat

Optical Laboratories Association

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American National Standards Institute, Inc.

American National Standard

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Foreword (This foreword is not part of American National Standard ANSI Z80.10-2003.)

This American National Standard is, for the most part, a modification of ISO 8612.2, *Ophthalmic Instruments - Tonometers*. However, the American National Standard covers tonometers specifically intended for routine clinical use in the estimation of intraocular pressure *for the detection, diagnosis, and management of ocular abnormalities* and excludes uses such as monitoring induced high intraocular pressure for refractive surgery.

ANSI Z80.10-2003 was adapted by a group of experts within the ANSI Ophthalmic Instruments Subcommittee under the chair of David S. Loshin, O.D., Ph.D. This new modified standard has been changed significantly from the previous ANSI tonometer standard, which was specific to instrumentation, rather than a performance standard. This standard defines the tolerable range of intraocular pressure (IOP) readings as compared to reference measurements made by an applanation tonometer such as the Goldmann Tonometer.

This standard contains three annexes. Annexes A and B are normative and are considered part of the standard. Annex C is informative and is not considered part of the standard.

Suggestions for improvement of this standard will be welcome. They should be sent to the Optical Laboratories Association, P.O. Box 200, Merrifield, VA 22116-2000.

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 White, M.D., Chairman
F. Dow Smith, Ph.D., Vice-Chairman
Robert Rosenberg, O.D., Secretary

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

David S. Loshin, O.D., Ph.D., Chair

John Alpar
Charles E. Campbell
Robert Landry
Robert Rosenberg
Daniel Torgersen
Tom White

American National Standard
for Ophthalmics –

Ophthalmic Instruments – Tonometers

1 Scope

This standard, together with ISO 15004, specifies minimum requirements and the design compliance procedure for tonometers intended for routine clinical use in the estimation of intraocular pressure (IOP) for the detection, diagnosis, and management of ocular abnormalities.

NOTES

1) The true intraocular pressure is seldom directly measured since it would require invasion of the eye. Since the true IOP cannot be known, the instrument (Annex A) and method (Annex B) for determining a reference IOP are established.

2) Clinical tonometers may employ different parameters or correlates in the indirect assessment of measured IOP. The manufacturer states the exact design parameters of the specific tonometer, and then, on the basis of design compliance testing as specified in 5.3, demonstrates that the specific design performs acceptably compared to the reference method. This process is referred to as certification.

The manufacturer also demonstrates, by methods specified in 5.4, that individual manufactured instruments perform the same as (within defined limits) the test tonometer. This process is referred to as verification.

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 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.

ISO 15004, *Ophthalmic Instruments - Fundamental Requirements and Test Methods*

IEC 601-1:1988, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

3 Definitions

For the purpose of this standard, the following definitions apply.

3.1 intraocular pressure (IOP): The pressure within the eye in millimeters of mercury (mmHg).

NOTE - 1 mmHg = 1.333 hPa

3.2 reference IOP: The IOP that is measured with the reference tonometer (Annex A) in accordance with the procedures given in Annex B.

3.3 measured IOP: The IOP reading provided by the instrument when used in accordance with the manufacturers instructions.

3.4 reference tonometer: A tonometer as described in Annex A

3.5 test tonometer: The verified tonometer used in design compliance testing.