

American National Standard

*for Ophthalmics
Ophthalmic Instruments
Tonometers*



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ANSI®
Z80.10-2014
Revision of
ANSI Z80.10-2009

American National Standard
for Ophthalmics –
Ophthalmic Instruments –
Tonometers

Secretariat
The Vision Council

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American National Standard

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The Accredited Committee Z80 for Ophthalmic Standards -

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Foreword (This foreword is not part of American National Standard ANSI Z80.10-2014.)

This 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 Z80.10-2014 was adapted by a group of experts within the ANSI Ophthalmic Instruments Subcommittee under the chair of William L. Brown, O.D., Ph.D. It is a performance standard.

This standard defines the tolerable range of intraocular pressure (IOP) readings in comparison to measurements made by a reference applanation tonometer such as the Goldmann Tonometer. Normative references have been updated. Allowance is made in this standard for a Goldmann-equivalent measurement, taken with an instrument that meets requirements for a test tonometer when compared to the Goldmann reference tonometer. Such an instrument may present intraocular pressure data in formats other than Goldmann. This standard clarifies that a new tonometer that meets all of the specifications and requirements of annex A is qualified as a reference tonometer, and, therefore, it does not require the clinical validation described in annex B and clause 4.2.1. Added to annex B is clause B.9.3, which modifies requirements for statistical analysis. Allowance for multiple measurements with the reference tonometer during testing with the test tonometer is disallowed in this standard with the deletion of clause B.9.2.

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 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 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
Quido Cappelli, Vice-Chairman
William Benjamin, O.D., Secretary
Jeff Endres, Secretariat

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- William L. Brown, O.D., Ph.D, Chair
- Charles E. Campbell
- Bruce Drum
- David Luce
- Robert Rosenberg

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Ophthalmic Instruments – Tonometers

1 Scope

This standard, together with ISO 15004-1:2009, *Fundamental requirements and test methods – Part 1: General requirements applicable to all instruments – First edition*, 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 correlations 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 4.2, 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 4.3, 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 15004-1:2009, *Fundamental requirements and test methods – Part 1: General requirements applicable to all instruments – First edition*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Third edition*