American National Standard

for Ophthalmics –
Ophthalmic Instruments – Tonometers

ANSI Z80.10-2018

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Z80.10-2018
Revision of
ANSI Z80.10-2014

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Secretariat

The Vision Council

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American National Standard

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Foreword (This foreword is not part of American National Standard ANSI Z80.10-2018.)

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 Charles E. Campbell. 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 specified to be 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. In Annex B, Clause B.2.3 was added to add the requirement that the same examiner shall make the measurements on an eye with the tested and the reference tonometer. The final paragraph of Clause B.5.3 has been removed so that repeated measurements on the same eye for eyes with pressure in excess of 23 mmHg are no longer allowed as means to obtain sufficient measurements in this pressure range group. The minimum number of eyes to be tested specified in B.5.3 was corrected to read 120. It was clarified that additional eyes in each pressure group are only needed for instruments that are claimed to measure eyes with high astigmatism.

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:

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Neal Roche, Vice-Chairman
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

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1 Scope

This standard, together with ISO 15004-1:2006, *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 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 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 15004-1:2006, *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*