

ANSI Z80.38-2017

American National Standard

*for Ophthalmics –
Light Hazard from Operation Microscopes
Used in Ocular Surgery*



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ANSI®
Z80.38-2017

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for Ophthalmics –
Light Hazard from Operation Microscopes
Used in Ocular Surgery

Secretariat
The Vision Council

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American National Standard

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Developed by

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Foreword (This foreword is not part of American National Standard ANSI Z80.38-2017.)

This American National Standard specifies requirements and test methods for optical radiation hazards from operation microscopes that are used during ocular surgery.

ANSI Z80.36-2017 was adapted by a group of experts within the ANSI ASC Z80 Instruments and Low Vision Devices Subcommittee under the chair of William L. Brown, O.D., Ph.D. It is a performance standard.

This document was developed in 2016 when changes were made to ISO 15504-2, *Light hazard protection*, that resulted in recommendations for levels of radiant exposure for retinal photochemical hazard that were unacceptable to the US delegation to the ISO. Since ISO 10936-2, *Light hazard from operation microscopes used in ocular surgery*, refers to ISO 15004-2 for radiation levels, it was decided that an American National Standard was needed.

Suggestions for improvement of this standard are 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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Neil Roche, Vice-Chair
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1 Scope

ANSI Z80.38 specifies requirements and test methods for optical radiation hazards from operation microscopes that are used during ocular surgery.

NOTE – General requirements for operation microscopes and test methods for these requirements are specified in ISO 10936-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ANSI Z80.36, *Light hazard protection for ophthalmic instruments*

ISO 10936-1, *Optics and optical instruments - Operation microscopes - Part 1: Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

Group 1 instrument

ophthalmic instrument for which no potential light hazard exists and that can be shown to fulfill the requirements of 5.2 in ANSI Z80.36

3.2

Group 2 instrument

ophthalmic instrument for which a potential light hazard exists and that does not fulfill the requirements of 5.2 in ANSI Z80.36

3.3

retinal protection device

mechanism placed in the path of illumination to increase the time to reach the recommended maximum retinal exposure limit