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American National Standard

for Ophthalmics –

Slit-Lamp Microscopes

ANSI Z80.37-2017

Approved American National Standard
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Secretariat

The Vision Council

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American National Standard

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Contents

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Foreword (This foreword is not part of American National Standard ANSI Z80.37-2017.)

This American National Standard specifies requirements and test methods for optical radiation hazards from slit-lamp microscopes.

ANSI Z80.37-2017 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 2017 after 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 U.S. 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 for slit-lamp microscopes was needed.

Suggestions for improvement of this standard are welcome. They should be sent to the Vision Council, 225 Reinkers 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 C. White, M.D., Chair
Neil Roche, Vice-Chair
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
Advanced Medical Technology Association	Michael Pfleger
American Academy of Ophthalmology	Thomas White
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	Karl Citek
American Society of Cataract and Refractive Surgery	Stephen Klyce
Contact Lens Institute	Stan Rogaski
Contact Lens Manufacturers Association	Martin Dalsing
Cornea Society	Michael Belin
Department of Veterans Affairs	John Townsend
Food & Drug Administration CDRH/Division	Don Calogero
Individual	Ralph Stone
Johnson & Johnson Vision	Leonard Borrman
National Association of Optometrists & Opticians	Nick Mileti
Optical Laboratory Association	Steve Sutherlin
Opticians Association of America	Tom Hicks
Sunglass Association of America	Tibor Gross
The Vision Council	Michael Vitale
U.S. ISO TC 172/SC7	Michael Vitale

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The Subcommittee on Instruments and Low Vision Devices, which developed this American National Standard, had the following members who contributed to this document:

Charles Campbell, Chair
William L. Brown, OD, PhD
Bruce Drum
Sharon Miller
Robert Rosenberg, OD
Dexiu Shi
David Sliney
Thomas White, MD

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American National Standard
for Ophthalmics –

Slit-Lamp Microscopes

1 Scope

This American National Standard, together with ISO 15004-1 and ANSI Z80.36, specifies requirements and test methods for slit-lamp microscopes to provide slit illumination and observation under magnification of the eye and its adnexa.

This American National Standard is not applicable to microscope accessories, e.g. photographic equipment and lasers.

This American National Standard takes precedence over ISO 15004-1 and ANSI Z80.36, if differences exist.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 15004-1, *Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1:2005, + Amd.1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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

3.1

slit-lamp microscope
instrument consisting of a microscope and a swivelling illumination system providing a slit image

3.2

magnification
ratio of the viewing angle of an object, when observed through a magnifying system with the image at infinity, to that of the object, when observed by the naked eye at a reference viewing distance of 250 mm

NOTE 1 The magnification, M, can be calculated using the following equation:

$$M = \frac{tan\ \sigma'}{tan\ \sigma}$$

where

σ' is the angle at which an object is seen through the microscope;

σ is the angle at which the same object is seen without any instrument at a viewing distance of 250 mm.

NOTE 2 The magnification of the microscope comprises the magnifications of the complete system.

3.3

high eye point eyepiece
eyepiece in which the exit pupil is of sufficient clearance from the eyepiece to allow spectacles to be worn