

# American National Standard

*for Ophthalmics –  
Slit-Lamp Microscopes*

---





**ANSI®**  
**Z80.37-2017**

American National Standard  
for Ophthalmics –  
**Slit-Lamp Microscopes**

Secretariat  
**The Vision Council**

Approved December 11, 2017  
Published January 11, 2018

**American National Standards Institute, Inc.**

# American National Standard

Approval of an American National Standard requires review by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgement of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made towards their resolution.

The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards.

The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

**CAUTION NOTICE:** This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

## *Developed by*

The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council  
Z80 Secretariat  
225 Reinekers Lane  
Suite 700  
Alexandria, VA 22314

## *Published by*

The Vision Council  
225 Reinekers Lane  
Suite 700  
Alexandria, VA 22314

Copyright © 2018 by The Vision Council  
All rights reserved.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America

## Contents

|   | Page |
|---|------|
| Foreword .....  | ii   |
| <b>1</b> Scope.....   | 1    |
| <b>2</b> Normative references.....                            | 1    |
| <b>3</b> Terms and definitions.....                           | 1    |
| <b>4</b> Requirements.....                                    | 2    |
| 4.1 General .....   | 2    |
| 4.2 Optical requirements.....                                 | 2    |
| 4.3 Construction and function .....                           | 4    |
| 4.3.1 General .....   | 4    |
| 4.3.2 High eye point eyepiece.....                            | 4    |
| 4.4 Optical radiation hazard with slit-lamp microscopes ..... | 4    |
| <b>5</b> Accompanying documents.....                          | 5    |
| <b>6</b> Marking .....  | 5    |
| <b>Table</b>  |      |
| <b>1</b> Requirements for optical properties.....             | 3    |
| <b>Figure</b>   |      |
| <b>1</b> Explanation of criterion no. 5 .....                 | 4    |
| <b>Annex</b>  |      |
| <b>A</b> Bibliography.....                                    | 6    |

**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

| <i>Organization Represented</i>                           | <i>Name of Representative</i> |
|---|-------------------------------|
| Advanced Medical Technology Association .....             | Michael Pflieger              |
| 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 Sutherland              |
| 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                |

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



# 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

$\sigma'$  is the angle at which an object is seen through the microscope;

$\sigma$  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