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American National Standard

for Ophthalmics –

Devices for Low Vision

ANSI Z80.9-2020

Approved American National Standard

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American National Standard
for Ophthalmics –

Devices for Low Vision

Secretariat

The Vision Council

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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 Z80.9-2020.)

This American National Standard specifies optical and mechanical requirements and test methods as applied to optical and electro-optical devices used by persons with low vision. With the wide variety of interpretations applied to commonplace terms, such as magnification, it is important to define terms and outline appropriate use of terms to reduce confusion.

ANSI Z80.9-2020 was adapted by a group of experts within the ANSI ASC Z80 Instruments and Low Vision Devices Subcommittee under the chair of Charles Campbell. It is a performance standard.

This document is an extensive revision of this standard and is based in great part on work that has recently gone on in the International Standards Organization where the standards ISO 15253 and ISO 15254 are in process of being combined into a single standard to be designated ISO 15253. In this respect, the new ISO standard will have the form of the current version of ANSI Z80.9, which essentially combines these two standards, as is noted below. This standard originated in 1998, when the ANSI ASC Z80 Committee approved adoption of ISO 15253, Optical Devices for Low Vision, as ANSI Z80.9-1998. In 2004, upon review of ANSI Z80.9-1998, the Z80 Committee further approved inclusion of ISO 15254, Electro-Optical Devices for Low Vision, into the revision of ANSI Z80.9, thus creating a single standard that includes all classes of devices for Low Vision.

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:

Carl Tubbs, M.D., Chairman
Nick Mileti, Vice-Chair
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

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Organization Represented	*Name of Representative*
Advanced Medical Technology Association	Michael Pfleger
American Academy of Ophthalmology	Carl Tubbs
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	William Benjamin
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	Nick Tarantino
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
ISO TC172/SC7	Michael Vitale

The Subcommittee on Ophthalmic Instruments, which modified this American National Standard, had the following members:

Charles Campbell, Chair
William L. Brown
Karl Citek
Bruce Drum
Henry Greene
Sanjeev Kasthurirangan
Eli Peli
Mark Mattison-Shupnick
Stephen Klyce
David Loshin
David Sliney

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Introduction

In 1998, the Z80 Committee approved adoption of ISO 15253, Optical Devices for Low Vision, as ANSI Z80.9-1998. In 2004, upon review of ANSI Z80.9-1998, the Z80 Committee further approved inclusion of ISO 15254, Electro-Optical Devices for Low Vision, into the revision of ANSI Z80.9-2004, thus creating a single standard that includes all classes of devices for Low Vision.

This 2020 revision incorporates further expansion and updating of the ANSI Z80.9 standard:

- The Scope now specifically excludes implanted low vision devices;
- Most Terms and Definitions have been updated and expanded, 11 previous Terms have been removed and 9 new Terms and 2 new Figures have been added. Terms are now also grouped in specific categories;
- Definitions and Requirements are now included for devices that:
    - o alter light transmittance (e.g., tints, filters);
    - o alter image location (e.g., prisms, mirrors); and
    - o alter field size (e.g., field expanders, minifiers);
- Definitions and requirements for electro-optical devices are updated for modern display units that no longer employ cathode ray tube (CRT) technology;
- Classification of devices is updated; and
- An informative Annex is included, describing the procedure for determining lateral variation of magnification for optical devices.

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American National Standard
for Ophthalmics –

Devices for Low Vision

1 Scope

This Standard applies to optical and electro-optical devices specified by the manufacturer for use by visually impaired persons as low-vision devices. It specifies optical and mechanical requirements and test methods. It includes devices with optical and/or electrical and/or electronic components used for image capture or display.

Implanted low vision devices are excluded.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 Z80.1, *Ophthalmics – Prescription Ophthalmic Lenses – Recommendations*

ANSI Z80.3, *Ophthalmics – Nonprescription Sunglass and Fashion Eyewear – Requirements*

ANSI Z80.36, *Ophthalmics – Light Hazard Protection for Ophthalmic Instruments*

EN 55022, *Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement* (IEC/CISPR 22:2005, modified + A1:2005)

EN 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

EN 62321, *Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)*

ISO 12870, *Ophthalmic optics – Spectacle frames – General requirements and test methods*

ISO 14971, *Medical devices – Application of risk management to medical devices*

ISO 15004-1, *Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments*

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

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*