American National Standard

for Ophthalmics –
Laser Systems for Corneal Reshaping

ANSI Z80.11-2012

Approved American National Standard
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for Ophthalmics –

Laser Systems for Corneal Reshaping

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The Vision Council

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American National Standard

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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 Z80.11-2012.)

This American National Standard was developed to address the expressed needs of those members of the ophthalmic community who correct the refractive errors of the human eye using laser refractive correction procedures, those who manufacture the lasers systems for corneal reshaping utilized to perform these procedures, and those who protect the public interest by ensuring that such systems are made in such a way so that they reliably perform their function in a safe and effective manner when used correctly by skilled operators.

It must be realized that correcting the refractive error of the human eye with laser corrective surgery is a medical procedure involving not only a laser system for corneal reshaping but also (1) the assessment of the refractive state of the eye prior to surgery, (2) decisions on the best approach to take for treatment that involve not only the judgment of the physician but the desires of the patient, (3) other devices used during surgery, (4) the postsurgical care, and (5) the effects of healing, known and unknown. This standard only addresses the laser system for corneal reshaping and makes no attempt to standardize the procedure itself.

However, in response to a perceived need, informative annexes have been included in the standard to give guidance on types of clinical testing deemed to be adequate to ensure that the entire procedure is safe and effective. It was felt that a service would be performed for those in the field if this information were to be placed in a public document where it would be readily available for reference.

While it is true that the outcome of a laser refractive procedure will not prove acceptable if the laser system for corneal reshaping used to perform it is not adequate for the task, it cannot be assumed that a laser system is inadequate if outcomes are not acceptable, as this may be the result of deficiencies in other important parts of the overall medical procedure. Thus, no claim is made such that, if a laser system for corneal reshaping complies with this standard for the tasks it is designed to perform, that surgical procedures performed with the laser will have acceptable outcomes.

This standard was created by a special working group created by the Z80 Subcommittee on Medical Ophthalmic Devices and included experts in the field of laser refractive correction from the clinical, manufacturing and academic areas of the ophthalmic community and by experts from the regulatory agency given oversight in this field in the United States of America.

This standard contains seven annexes. Annexes A and B are normative and are considered part of the standard. Annexes C through G are informative and are not considered part of this standard.

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 it approved this standard, the Z80 Committee had the following members:

Thomas C. White, M.D., Chairman
Quido Cappelli, Vice-Chairman
Robert Rosenberg, O.D., Secretary
Jeff Endres, Secretariat

Organization Represented	*Name of Representative*
Advance Medical Technologies Association	Paul Ludington
	Richard Courtney (Alt.)
	Glenn Davies (Alt.)
	Bernie Liebler (Alt.)
American Academy of Ophthalmology	Tom White
	Carl Tubbs (Alt.)
	Pradeep Ramulu (Alt.)
	Shannon Curtis (Alt.)
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
	Herbert Hoover (Alt.)
American Glaucoma Society	Steven Gedde
	Douglass Rhee (Alt.)
American Optometric Association	Karl Citek
	Robert Rosenberg (Alt.)
	William Benjamin (Alt.)
	William Brown (Alt.)
American Society of Cataract and Refractive Ophthalmology	Stephen Klyce
	Jack Holladay (Alt.)
Association for Research in Vision & Ophthalmology (ARVO)	Jan Bergmanson
	Gerald McGwin (Alt.)
	Elmer Y. Tu (Alt.)
Contact Lens Institute	Stan Rogaski
	Peter Mathers (Alt.)
Contact Lens Manufacturers Association	Quido Cappelli
	Troy Miller (Alt.)
Department of Veterans Affairs	John Townsend
	Michael White (Alt.)
Federated Cornea Societies/ASCRS	Michael Belin
	David Glasser (Alt.)
Food & Drug Administration CDRH/ Division of Federal Agencies	Don Calogero
	Robert James (Alt.)
	Dexiu Shi (Alt.)
National Association of Optometrists & Opticians	Nick Mileti
	Doug Pelkey (Alt.)
	Franklin Rozak (Alt.)
Optical Laboratories Association	Richard Tinson
	Virginia Lesher (Alt.)
	Jonathan Schwartz (Alt.)
Opticians Association of America	Tom Hicks
	Chris Allen (Alt.)
Sunglass Association of America	Kenneth Frederick
	Scott MacGuffie (Alt.)
	Rick Van Arnam (Alt.)
The Vision Council	Jeff Endres
	Neil Roche (Alt.)
	Dick Whitney (Alt.)
	Mike Vitale (Alt.)
U.S. Assistant TAG Leader to ISO TC 172/SC7J	Jeff Endres

The working group for Laser Systems for Corneal Reshaping, which falls under the Medical Ophthalmic Devices Subcommittee, had the following members who worked on the writing of this standard:

Carl Tubbs MD, WG Chair
Charles E. Campbell, Subcommittee Chair

Michael W. Belin MD
Karl Citek
John Townsend
Thomas C. White, MD

American National Standard
for Ophthalmics –

Laser Systems for Corneal Reshaping

1 Scope and purpose

This standard applies to any laser system whose primary intended use is to alter the shape of the cornea through the removal of corneal tissue, resulting in the improvement of visual performance.

This standard addresses the vocabulary, performance requirements, labeling, and clinical investigations necessary for this type of device.

2 Normative references

The following standards contain provisions that, 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. Members of the IEC and ISO maintain registers of currently valid International Standards.

ANSI Z136.1-2000, *Safe Use of Lasers*

ANSI Z136.3-2005, *Safe Use of Lasers in Health Care Facilities*

IEC 60601-1:2001, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

IEC 60601-1-1:2000, *Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems*

IEC 60601-1-2:1993, *Medical Electrical Equipment – Part 1: General Requirements for Safety – 2. Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*

IEC 60601-1-4:2000, *Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems*

IEC 60601-2-22:1995, *Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment*

IEC 60825-1:2001, *Safety of Laser Products – Part 1: Equipment Classification, Requirements and User's Guide*

ISO 8598:1996, *Optics and optical instruments – Focimeters*