

American National Standard

*for Ophthalmics –
Laser Systems
for Corneal Reshaping*



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ANSI Z80.11-2012

American National Standard
for Ophthalmics –

Laser Systems for Corneal Reshaping

Sponsor

The Vision Council

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American National Standard

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Contents

	Page
Foreword.....	iv
1 Scope and purpose	1
2 Normative references.....	1
3 Definitions	3
4 Mechanical, thermal, and environmental requirements	5
4.1 Combination of different devices.....	5
4.2 Materials	5
4.3 Resistance to transport and storage conditions.....	5
5 Safety requirements.....	6
5.1 Protection against contaminants.....	6
5.2 Protection against toxins and allergens	6
5.3 Photobiological hazards.....	6
5.4 Thermal hazards.....	6
5.5 Mechanical hazards.....	6
5.6 Electrical safety.....	7
5.7 Radiation safety	7
5.7.1 Light hazards	7
5.8 Gas safety (for gas lasers).....	7
5.9 Safety in use	7
5.10 System hazard analysis.....	8
6 Optical requirements.....	8
6.1 Alignment system.....	8
6.2 Fail safe monitoring.....	8
6.3 System calibration.....	8
7 System control and performance	9
7.1 Software.....	9
8 Clinical evaluation	9
8.1 Clinical investigation plan.....	9
8.2 Surgical procedure.....	9
8.3 Reporting periods and evaluations	9
8.4 Adverse events	10
9 Test methods	10
9.1 Verification of alignment system accuracy.....	10
9.1.1 Materials	10
9.1.2 Procedure	10

	Page
9.2	Verification of cylinder axis alignment..... 10
9.2.1	Materials 10
9.2.2	Procedure 11
10	Accompanying documents..... 11
11	Marking 11
Annexes	
A	Spectral weighting function for ultraviolet radiation hazard analysis . 12
B	Methods for system calibration 14
B.1	Plastic plate ablation and measurement..... 14
B1.1	Materials 14
B.1.2	Procedure 14
B.2	Laminated calibration plate method..... 14
B.2.1	Materials 14
B.2.2	Procedure 15
C	Characterization of laser ablation beams and treatment patterns 16
C.1	Ablation characteristics of the beam..... 16
C.2	Mathematical models and simulations 17
C.3	Validation of ablation algorithm software 17
D	Guidance on clinical study design of refractive procedures that use laser systems for corneal reshaping 18
D.1	General 18
D.2	Study objectives..... 18
D.3	Design of clinical study 19
D.4	Study duration..... 19
D.5	Enrollment of subjects 19
D.6	Inclusion and exclusion for subject selection..... 20
D.6.1	Inclusion criteria 20
D.6.2	Exclusion criteria..... 20
D.7	Examination schedule..... 21
D.8	Evaluations and methodology..... 23
D.8.1	Visual acuity and manifest refraction 23
D.8.2	Measurement of intraocular pressure 24
D.8.3	Subject questionnaire 25
D.8.4	Mesopic pupil size 25
D.8.5	Contrast sensitivity..... 25
D.8.5.1	Grating contrast sensitivity testing 25

	Page
D.8.6	Low contrast letter acuity testing..... 26
D.8.7	Specular microscopy..... 27
D.9	Adverse device effects / Adverse events 29
E	Statistical sample size considerations..... 30
E.1	Statistical symbols and definitions 30
E.2	Calculation of necessary sample sizes 31
E.2.1	Sample size based on safety estimates..... 31
E.2.2	Sample size based on effectiveness estimates using noninferiority hypothesis testing..... 32
E.3	Clinical substudies 34
E.3.1	Sample size for a contrast sensitivity study 34
E.3.2	Sample size for endothelial cell density study..... 34
F	Presentation of results of clinical studies 36
F.1	General 36
F.2	Accountability of subjects..... 36
F.3	Refractive stability 38
F.4	Safety 39
F.5	Effectiveness..... 39
F.6	Retreatment 40
G	Bibliography 41
Tables	
D.1	Recommended postoperative examination schedule 22
E.1	Symbol definitions 30
E.2	Normal quantiles to use in equations 31
F.1	Accountability by post-operative visit 37

Foreword (This foreword is not part of American National Standard ANSI Z80.11-2012 (R2017).)

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

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American Glaucoma Society.....	Herbert Hoover (Alt.) Steven Gedde
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National Association of Optometrists & Opticians.....	Nick Mileti Doug Pelkey (Alt.) Franklin Rozak (Alt.)
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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

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John Townsend
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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*