Smart532™

Solid-State 532-nm Green Laser

Operator Manual

Lumenis®
Energy to Healthcare

In the US:
Caution: Federal law restricts this device to sale by or on the order of a physician.

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Revision C

Use of this Manual:

The Smart532 laser device is designed to meet international safety and performance standards. Personnel operating the device must have a thorough understanding of the proper operation of the device.

This manual has been prepared to aid medical and technical personnel to understand and operate the device. Do not operate the device before reading this manual and gaining a clear understanding of the operation of the device. If any part of this manual is not clear, please contact your Lumenis representative for clarification.

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the Smart532 laser device. Such training should include a review of published literature, seminars, workshops and appropriate preceptorships. Please contact your Lumenis representative for current information on available training.

This manual should always accompany the device, and its location must be known to all personnel operating the device. Additional copies of this manual are available from your Lumenis distributor.

Device and accessory specifications subject to change without notice.

For further information about Lumenis, visit the Lumenis Website: http://www.Lumenis.com or send email to information@Lumenis.com

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Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual treatment and recovery at an approved recycling facility.

By returning waste electrical and electronic equipment via the correct segregated disposal channel, users can ensure the environmentally sound treatment and disposal of the waste equipment, thereby reducing the potential for any environmental or health risks that could arise as a result of incorrect disposal.

Lumenis provides web-based collection, recycling and reporting arrangements to the business end-user for equipment marked with the crossed-out wheelie bin. Please visit www.lumenis.com/Homepage/About2/Recycle to understand what arrangements Lumenis has made in each EU Member State.

Table of Contents

CHAPTER 3 System Description **Page**

CHAPTER 4 System Installation and Initial Setup **Page**

CHAPTER 5 Operating Instructions Page

CHAPTER 6 Maintenance and Troubleshooting Page

APPENDIX A Clinical Guide Page

List of Illustrations

List of Tables

Chapter 1

Overview

1.1. Introduction

The Smart532-nm green laser system is indicated for ophthalmic applications; ear, nose and throat applications; dentistry and dermatologic applications. Complete and detailed lists of the system's clinical indications appear in Appendix A of this manual – **Clinical Guide**.

The Smart532 laser system is shipped directly from the factory to your site. A Lumenis-certified field engineer will initially uncrate, inspect, set up and install the laser to ensure that it is ready for use. In addition, Lumenis provides in-service training to ensure that your staff is experienced with the operation and safety considerations of the laser.

Thereafter, you or the staff at your facility will perform the daily maintenance routines associated with the laser and with any delivery systems and/or accessories used during surgery, including inspecting and cleaning the laser and delivery systems; sterilizing and connecting/ disconnecting the accessories. These procedures are detailed in this manual or in the appropriate operator manuals of the delivery systems and accessories.

Most nursing staff prefer to inspect the laser and delivery systems daily, usually prior to scheduled cases and before patients are admitted and prepped. Doing so will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care.

1.2. Scope of This Manual

This manual is intended to provide the surgeon, private practitioner and other personnel who operate or maintain the system with information regarding the operating principles, controls, safety precautions, installation and maintenance of the system. While this manual is intended to aid in the use and care of the equipment, it does not serve as a substitute for proper training in the clinical applications of medical laser devices.

This operator's manual incorporates the following chapters:

Chapter 1:	**Overview**	Contains a general introduction to the system.
Chapter 2:	**Laser Safety and Regulatory**	Contains explanations and directions concerning safety measures for operating the system. This chapter also includes regulatory information and requirements.

Chapter 3:	**System Description**	Contains a detailed overview of the system and its various components, controls, displays and connections. Includes detailed specifications of all facets of the system.
Chapter 4:	**System Installation and initial setup**	Lists electrical, space and environmental requirements for installation of the system and basic installation & setup instructions.
Chapter 5:	**Operating Instructions**	Explains how to operate the system.
Chapter 6:	**Maintenance and Troubleshooting**	• Provides a detailed review of how to maintain the system. • Lists the system's error messages that might occur during operation, their probable causes and what actions to take.
Appendix A:	**Clinical Guide**	Offers information about staff training, indications and contraindications for use, recommended setup parameters and suggested professional reference literature.

1.3. Manual Conventions

Throughout this manual, notes, cautions and warnings and are used to provide critical information needed before the device is used.

Examples:

Note

A **Note** is a statement that alerts the operator to particularly important information.

Caution

A **Caution** is a statement that alerts the operator to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, and damage to the device or other property. The caution statement includes the precaution that should be taken to avoid the hazard.

> ***Warning***
>
> A **Warning** is a statement that alerts the operator to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the device.

1.4. Physician Responsibility

Federal (USA) law restricts prescription medical devices to sale by or on the order of a physician, or properly licensed practitioner.

The properly licensed practitioner will be responsible for the use and operation of the device and for all user qualifications. Lumenis makes no representations regarding federal, state or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

1.5. Maintenance

The Smart532 laser system is a precision, technical medical device that requires routine service. All service must be performed by a Lumenis technician and all parts must be purchased from Lumenis. Failure to obtain service and parts through Lumenis voids all warranties, expressed and implied. Please call Lumenis or your local representative for details.

1.6. Modification of the Device

Unauthorized modification of the hardware, software or specifications of the Smart532 voids all warranties, expressed and implied. Lumenis takes no responsibility for the use or operation of such a device.

> ***Caution***
>
> Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

1.7. Resale Inspection

If any Lumenis device is resold by anyone other than an authorized sales representative, Lumenis offers a resale inspection by a Lumenis technician to assure that the device is working in accordance with manufacturer's specifications. Using the device after it has been resold and before it has been inspected is a misuse of the device, which may result in injuries and voids all warranties, express and implied.

Lumenis also offers service contracts and extended warranties for its devices. For more information about the services or about the costs of inspections or service calls, please call Lumenis or your local representative.

1.8. Abbreviations and Acronyms

µm	Microns
°C	Degrees Celsius
cm^2	Centimeters squared
°F	Degrees Fahrenheit
ANSI	American National Standards Institute
CE	European Directives Compliance Marking
CFR	Code of Federal Regulations
cm	Centimeters
FCC	Federal Communications Commission (USA)
FDA	Food & Drug Administration (USA)
ESF	Eye Safety Filter
EU	European Union
GUI	Graphic User Interface
J/cm^2	Joules per square centimeter
Kg	Kilogram(s)
Lbs.	Pounds
LCD	Liquid Crystal Display
LIO	Laser Indirect Ophthalmoscope
m	Meters
mm	Millimeters
ms	Milliseconds
mW	MilliWatts
NHZ	Nominal Hazard Zone
NOHD	Nominal Ocular Hazard Distance
nm	Nanometers
OD	Optical Density
PRP	Pan-Retinal Photocoagulation
RoHS	Restriction of Hazardous Substances Directive (RoHS) Compliance Marking
Sec	Seconds
UL	Underwriters Laboratories
USB	Universal Serial Bus
VAC	Volts, Alternating Current
VDC	Volts, Direct Current
W	Watts
WEEE	Waste Electrical and Electronic Equipment
W/cm^2	Watts per square centimeter

Chapter 2

Laser Safety and Regulatory

2.1. Introduction

Operators must take precautions to prevent exposure of laser energy to the eyes and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Lumenis does not make recommendations regarding the practice of medicine. Laser treatment parameters are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

Patient safety should always be the clinician's first concern. This chapter of the manual includes the minimum information required to operate the system safely. In addition to the guidelines presented here, follow all applicable institutional procedures. Read this chapter completely before attempting a procedure with the Smart532 laser system.

This chapter includes:

- Basic institutional requirements, including responsibilities of the Laser Safety Officer.
- Detailed information concerning the safety eyewear required when using the Smart532 laser system and its associated delivery systems.
- Hazards associated with unsafe laser use.
- Safety features of the Smart532 laser system.
- Compliance with regulatory standards and regulatory labels adhered to the Smart532 laser system.

2.2. Training and Institutional Requirements

Caution

No one should use the Smart532, or any other medical laser, without specific training in both medical laser use and laser safety.

Both operator and safety training is available from Lumenis. Contact your Lumenis representative to inquire about seminars in your area.

2.2.1. Laser Safety Officer

Large institutions are following the prescriptions of ANSI 136.3 and EN 207 by setting up Laser Safety Committees and appointing Laser Safety Officers to manage laser use. Even the smallest office should have one person to act in the capacity of Laser Safety Officer.

ANSI Z136.3 and EN 207 require the Laser Safety Officer to fulfill the following responsibilities:

1. Classify, or verify classification of, lasers and laser systems.

2. Evaluate hazards of laser treatment areas.

3. Assure that the prescribed control measures are in effect and recommend or approve alternates when the primary ones are not feasible.

4. Approve operational procedures, including any procedural checklists.

5. Recommend or approve protective equipment, and assure that it is periodically inspected to ensure proper working order.

6. Approve wording on signs and equipment labels.

7. Approve installation and equipment prior to use, and modifications to existing equipment and facilities.

8. Assure adequate safety education and training is provided for all personnel.

The Laser Safety Officer may also assume other responsibilities, such as keeping laser use and maintenance logs. The Laser Safety Officer should become familiar with the periodic maintenance requirements in the **Maintenance** chapter of this manual.

For detailed information refer to Section 2.10. - **Compliance with International Standards**.

2.2.2. *Laser Treatment/ Operating Area*

According to ANSI Z136.3, the Laser Safety Officer is responsible for the area in which laser treatments are carried out. In meeting this requirement, the Laser Safety Officer should ensure that:

1. The surroundings are safe for both the patient and the operator.
2. The floor is uncluttered and clear access is maintained to the footswitch. Cables are secure and not crimped.
3. The operating area is occupied only by authorized personnel.
4. Appropriate warning signs are posted in the operating area and just outside of it. The Smart532 is a Class IV laser; the door warning sign for the Smart532 is shown in Figure 2-1.

Figure 2-1: Laser Treatment Room Warning Sign

2.3. Laser Safety Eyewear

Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1-2014, ANSI Z136.3-2011, or International Standard IEC 60825-1: 2014.

The following formula was used to calculate the *worst case* NOHD for Lumenis Smart532 lasers and compatible delivery systems:

$$NOHD = Z + \frac{1}{\theta}\sqrt{\frac{4}{\pi}\frac{\Phi}{MPE}\,Pf - a^2}$$

Where:

Z = the distance of the beam waist from the laser system;

a = the beam waist diameter ($1/e^2$ of axial irradiance for Gaussian beam);

θ = minimum full angle beam divergence ($1/e^2$ of axial irradiance for Gaussian beam);

e ≈ 2.7182818285, the base of natural logarithms;

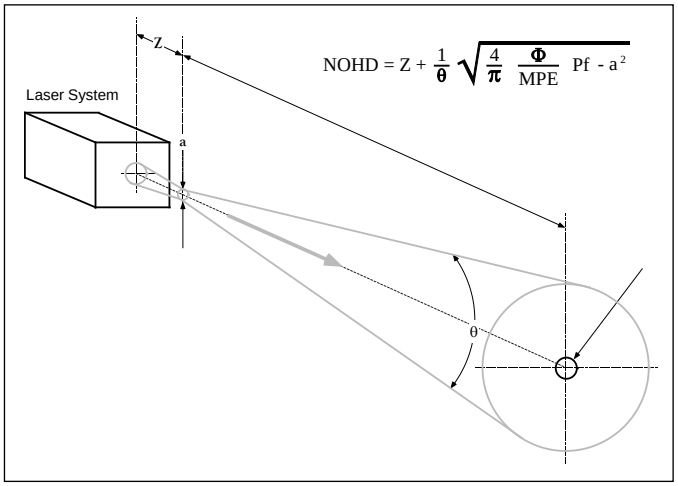
Φ = maximum energy of one laser pulse or maximum CW laser power;

Pf = the profile correction factor (1 for uniform profile or 2 for Gaussian irradiance);

MPE = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);

NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture;

= the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

	θ (rad)	*Φ (W)*	*MPE (W/cm²)*	*Pf*	*a (cm)*	*Z (cm)*
LaserLink HS	0.020	2.5	0.00137	1	0.050	5.7
LaserLink Z	0.010	2.5	0.00137	1	0.100	9.8
LIO Keeler	0.024	2.5	0.00137	2	0.096	37
LIO Heine	0.022	2.5	0.00137	2	0.107	36
Endoprobe	0.140	2.5	0.00137	2	0.02	0
Lumenis 1000	0.010	2.5	0.00137	1	0.100	9.8
Insight	0.010	2.5	0.00137	1	0.100	9.8
Array LaserLink	0.010	2.5	0.00137	1	0.100	9.8

Which results in a worst case NOHD of:

	NOHD [m]
LaserLink HS	24.2
LaserLink Z	48.3
LIO Keeler	28.8
LIO Heine	31.3
Endoprobe	4.87
Lumenis 1000	48.3
Insight	48.3
Array LaserLink	48.3

Calculated OD value is OD=3.7 for all delivery types.

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a *minimum* optical density (**OD**) of:

LaserLink HS	OD 4+
LaserLink Z	OD 4+
LIO Keeler	OD 4+
LIO Heine	OD 4+
Endoprobe	OD 4+
Lumenis 1000	OD 4+
Insight	OD 4+
Array LaserLink	OD 4+

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure as per ANSI Z136.1-2007, section 4.6.2 and Appendix C. For operators who must comply with EN 207, the safety eyewear must have a protection class of **LB6**.

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room or the controlled area:

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser.
3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

Note

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

2.3.1. Additional Ocular Protection

Warning

- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, except for therapeutic purposes, nor any optical fiber, probe, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.

2.4. Additional Safety Considerations

- When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Never deliver the treatment beam to the target tissue if the aiming beam is not visible; the fiber optic cable or the delivery device may be damaged. A damaged cable or device may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.
- Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, and power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- Laser beam integrity checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; contact your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.
- To prevent accidental laser discharge, always place the laser in Standby mode before connecting the delivery system.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution pressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch pressed is the correct one to avoid accidental laser exposure.
- Laser equipment not in use should be protected against unqualified use by ensuring that the access password is not accessible to unqualified personnel.

In the US: Caution

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- Do not use the device in environment with known sources of Electromagnetic Interference (EMI) such as; Magnetic Resonance Imaging (MRI), Computerized-axial Tomography (CT), Diathermy, Radio Frequency Identification (RFID) and electromagnetic security systems (e.g., metal detectors).
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

2.5. Fire Hazards

Personnel in operating rooms, private and out-patient clinics should be aware of the following safety considerations and potential fire hazards when using laser equipment:

- Laser energy can ignite most non-metallic materials.
- Use fire-retardant drapes and gowns.
- A UL or CE approved or equivalent fire extinguisher and water should be readily available.

Warning

- Do not use this device in an oxygen-rich environment and in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion or fire could occur.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.

2.6. Electrical Hazards

Because the Smart532 contains high-voltage components, there is a danger of severe shock if its covers are taken off by other than trained personnel.

To guarantee both operator and patient safety, operator service is limited to the items described in the **Maintenance** chapter of this manual. Other service must be performed only by Lumenis trained personnel.

Warning

- Never open the laser console protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation. Only Lumenis-certified service technicians are qualified to service the system.
- To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cables are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis' recommendations and institutional standards.

2.6.1. Grounding the System

Proper grounding is essential for safe operation. The system is grounded through the grounding conductor in the power cable. To ensure grounding reliability, always plug the power cable into a properly wired hospital grade power receptacle.

> ***Warning***
>
> Use the system only when it is properly grounded via the ground wire lead in the power cable supplied with the Smart532 system.

2.7. Operating Safety Cautions & Warnings

2.7.1. Cautions

Training – do not use the Smart532 laser system in clinical, office or surgical procedures unless you have been trained:

- In general laser safety, including operator and patient protection.
- By a qualified mentor in hands-on situations.
- On the Smart532 system.

Before Performing Procedures – read this manual before performing any patient procedures. The information in this manual should be used in conjunction with, not as a substitute for, formal training.

Power Settings – Lumenis suggests that you begin new or unfamiliar procedures at the lowest recommended power settings and gradually increase the setting until you see the desired effect.

Console Cleaning – when cleaning the console, use a dampened cloth. Avoid saturating the exterior panel areas and electrical input area.

Warranty Void – internal maintenance by unqualified service technicians may cause system damage. This damage is not covered under warranty.

2.7.2. Warnings

Class IV Laser – the Smart532 system contains a Class IV laser which produces a visible beam of high energy radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV devices.

To Avoid Injury or Fire – observe all warning and other labels on the equipment. Failure to do so could result in injury or fire.

Inadvertent Lasing – when not actively lasing, set the system to **Standby** mode.

Laser Emission – in **Ready** mode laser energy will be emitted through the laser aperture when the footswitch is pressed.

2.8. System Safety Features

The Smart532 laser system is equipped with various built-in safety features to provide maximum protection for both clinician and patient. Before using the system for the first time, become familiar with these features and how they operate.

2.8.1. Password Protection

Entry to the system's surgical operating program is protected by a password (see Chapter 5). If the password is not keyed in, the operating system is not accessible and laser beam emission will not be available.

2.8.2. Self-Testing at Start Up

When the Smart532 is turned on, the system computer automatically executes system self-testing. Self-testing checks the following:

- Ability of the system to generate lasing power.
- Functionality of the electronic components.
- Safety monitoring circuits.

If the self-test is successfully completed, the system enters **Standby** mode. The test circuits continuously monitor the operation of the system during treatment.

2.8.3. Safety Shutter

The automatic safety shutter blocks the laser beam to prevent accidental lasing.

The safety shutter opens only when the laser is in **Ready** mode and the footswitch is pressed. The safety shutter remains closed when the system is turned off, during self-test at system turn on, when the system is placed in Standby mode, or when the safety monitor detects a fault.

2.8.4. Door Interlock Connector

The door interlock connector plug must be inserted into the proper receptacle on the system's rear panel in order for the laser to operate. It can be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

2.8.5. Location of Controls

Operation and adjustment controls are all located on the system's front panel and touch-screen display so that the operator will enjoy the system's built-in ease-of-use design and ergonomic characteristics of the accessories.

2.8.6. Laser Emergency Stop Button

This red knob is designed for emergency shut-down of laser energy emission. When pressed it immediately disables the laser.

To disengage the emergency shut-off button, press it again.

2.8.7. Continuous Internal System Monitoring

The system's computer continually monitors internal system status. The following are among the items monitored:

2.8.7.1. System Faults

If a fault is detected an appropriate error message is displayed on the LCD monitor. If the error is non-recoverable lasing is disabled until the fault is corrected. If the error is recoverable, follow instructions on the screen. A complete discussion of system faults may be found in the **Trouble-shooting** chapter of this manual.

2.8.7.2. Internal Power Monitoring

To prevent accidental delivery of excessive energy to tissue, laser energy is monitored continuously. An appropriate error message is displayed on the LCD monitor if a ±20% deviation in the laser output is detected, the system returns to **Standby** mode and issues an error message.

2.8.7.3. Temperature

If the system begins to overheat, an appropriate error message will be displayed on the LCD monitor (refer to the **Troubleshooting** chapter of this manual).

2.9. Laser Beam Emission Indicators

The system features two laser emission indicators: a blue LED-illuminated line located between the system display and buttons and a built-in speaker.

The blue LED has three modes of operation

- **Low level continuous** - When the system is turned on, and in **Standby** mode.
- **Medium level blinking** - When the system is in **Ready** mode.
- **High level continuous** - During laser emission (footswitch pressed).
- The speaker emits an audible indicator during laser emission.

2.10. Compliance with International Standards

Lumenis lasers and delivery systems comply with the current revision of 21 CFR Part 1040, Chapter I, Subchapter J (Performance Standards for Light-Emitting Products), as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

CE-labeled devices comply with all appropriate performance standards as specified in Annex II of the European Medical Device Directive MDD 93/42/EEC.

The Smart532 laser system is classified as Class IV lasers by the Center for Devices and Radiological Health of the Food and Drug Administration and as Class 4 by the International Standard IEC 60825.

Refer to the current revisions of the American National Standard (ANSI) publications Z136.3, ANSI Z136.1 and EN 207 for recommendations on the safe use of lasers in health care facilities.

The current revisions of the American National Standards Institute specification ANSI Z136.3 & Z136.1 and EU standard EN 207 include very thorough discussions of laser safety and guidelines for medical laser use. These standards were developed in the earliest days of lasers and are routinely revised to keep up with growing technology. ANSI Z136.3 and EN 207 are written specifically for the use of lasers in medicine. While non-binding, the guidelines are excellent guides for an office or institution seeking to set up a formal safety program.

Lumenis strongly recommends that operators read these two ANSI and EN 207 standards before using a laser in clinical practice.

The Smart532 system is designed to comply with current revisions of the following international standards:

- IEC 60601-1: 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 Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-2-22: Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1: Safety of Laser Products - Part 1: Equipment Classification and Requirements.
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability.

- ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in the Risk Management Process.
- RoHS: Restriction of Hazardous Substances DIRECTIVE 2011/65/EU.
- REACH: Registration, Evaluation, Authorization and Restriction of Chemicals.
- WEEE Waste Electrical and Electronic Equipment Directive.

In compliance with these standards, the system is equipped with:

- Laser emission indicators
- Beam shutter
- Power display
- Laser emergency stop button
- Door interlock connector
- Proper labeling

In accordance with the regulations, a recommended routine inspection and maintenance schedule is provided in the **Maintenance** chapter of this manual.

2.11. Warning, Certification and Identification Labels

Figure 2-2 displays the labels affixed to the system:

1. ***Identification and Certification*** – the label contains the following information:
   - System's model name and part number.
   - Serial number and date of manufacture.
   - Manufacturing series number of the system.
   - The system's electrical requirements.
   - CSA compliance symbol.
   - CE marking.
   - – Follow instructions for use.
   - **Rx Only** – **Caution:** Federal law restricts this device to sale by or on the order of a physician.
   - WEEE symbol – directs that the electrical/electronic product be disposed of in an environmentally safe way as the directive sets collection, recycling and recovery targets for all types of electrical goods.
   - Details of the manufacturer and of the authorized representative in the European Community.
2. ***Laser Emission Danger*** – the label contains the following information:
   - Warns against possible exposure to laser beam radiation and specifies the type and classification of laser beams present.
   - System's electrical requirements.
3. ***Laser Aperture*** – indicates laser beam exit port, located next to the fiber connection ports on the front and rear panels of the system.
4. ***Type B/BF Equipment*** – type BF relates only to the probe.
5. ***Standard & Smart Footswitches IP Rating*** – the watertight level of these footswitches conform to the **IP68** standard
6. ***PowerEase Footswitch IP Rating*** – the watertight level of this footswitch conforms to the **IP28** standard.
7. ***Emergency Stop Switch –*** pressing this switch immediately disables laser energy emission. Turn the switch 1/4 turn clockwise to reset it.
8. ***Upper Window Port Labels –*** displays the labels describing the connection ports in the upper window of the rear panel, including electrical specifications.
9. ***Lower Window Port Labels –*** displays the labels describing the connection ports in the lower window of the rear panel.

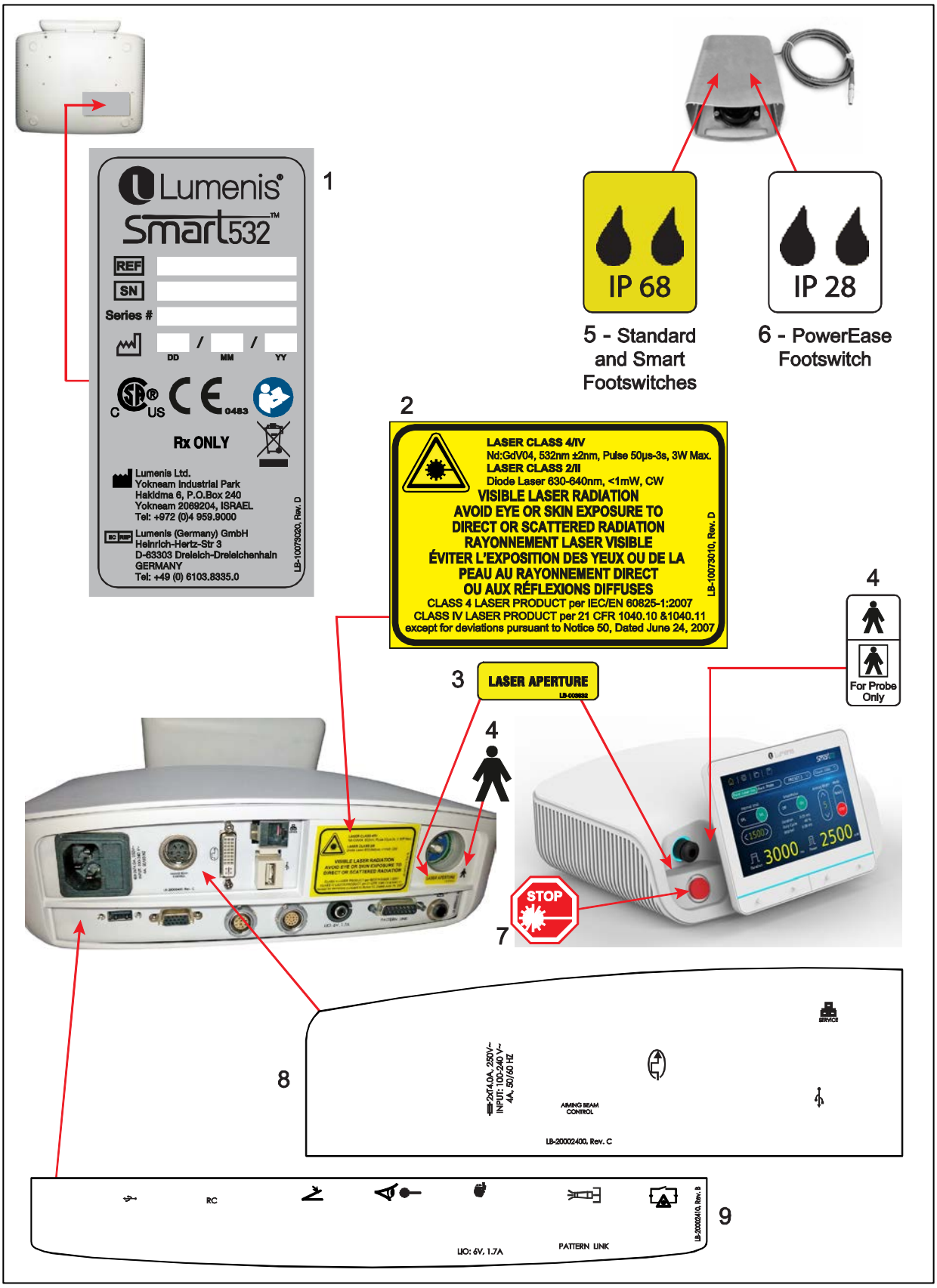
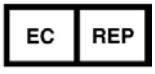
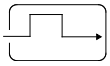
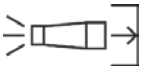


Figure 2-2: System Regulatory Labels

2.12. Symbol Descriptions

The following table provides a key to the symbols displayed on the Smart532 laser system:

Symbol	Description
	Danger: Laser Radiation
	Emergency Stop
	Type B Equipment
	Type BF Equipment
	Follow Instructions for Use
	CE Compliance
	CSA Compliance
	Serial Number
	Catalog Number
	Legal Manufacturer
	Date of Manufacture
	Waste of Electrical and Electronic Equipment (WEEE) Compliance
	Authorized Representative in the European Community

Symbol	*Description*
2xT4.0A, 250V~ INPUT: 100-240 V~ 4A, 50/60 HZ	Electrical and Fuses Requirements
	Auxiliary Monitor Connection Port
	Service (Ethernet) Connection Port
	USB Connection Port
	Footswitch Connection Port
	Eye Safety Filter Connection Port
	LIO Connection Port
	Pattern Link Connection Port
	Remote Interlock Connection Port
	Water Ingress Protection Level – Standard & Smart Footswitches
	Water Ingress Protection Level – PowerEase Footswitch

2.13 EMC Guidance and Manufacturer's Declaration

2.13.1 Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Smart532 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [A or B]	Class A
Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	Complies
	[See 5.2.2.1 c) and Figure 1]	The Smart532 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

2.13.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smart532 requires continued operation during power mains interruptions, it is recommended that the Smart532 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

2.13.2 Electromagnetic Immunity (continued)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)			
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Smart532, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smart532 is used exceeds the applicable RF compliance level above, the Smart532 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smart532. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

2.13.3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Medical Equipment or Medical System

Recommended separation distances between portable and mobile RF communications equipment and the M22 with ResurFX			
The Smart532 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Smart532 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smart532 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.334
10	3.689	3.689	7.378
100	11.667	11.667	23.334
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Chapter 3

System Description

3.1. Introduction

The Smart532-nm green laser system is indicated for ophthalmic applications; ear, nose and throat applications; dentistry and dermatologic applications. Complete and detailed lists of the system's clinical indications appear in Appendix A of this manual – **Clinical Guide**.

Lumenis' complete line of delivery systems and accessories further extends the versatility of the Smart532 laser system.

Lumenis lasers and delivery systems are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser or delivery system, contact your Lumenis representative.

Warning

Lasers generate a highly concentrated energy beam that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.

3.1.1. Characteristics of the 532-nm Green Laser Beam

The 532-nm wavelength falls in the green region of the electromagnetic spectrum. Visible or invisible laser energy can cause tissue damage; therefore, eye safety precautions must be taken by the physician, patient, and any observers in the room. A low-power, visible aiming beam that is coaxial with the treatment beam is used to target tissue.

Green light energy is readily absorbed by melanin, hemoglobin, and oxyhemoglobin in the eye, but avoids macular xanthophyll. These characteristics allow for effective laser photocoagulation of ocular tissue.

3.1.2. *Smart532 Laser System Components*

The Smart532 laser system is comprised of (see Figure 3-1):

1. A laser console with a touch-screen control panel.
2. All electrical cables necessary for proper connection.
3. Remote interlock connection plug.
4. A footswitch.
5. Safety eyewear.

> ***Note***
>
> Delivery devices, including integrated slit lamps and slit lamp tables may be purchased separately.

Figure 3-1: Smart532 Laser System Components

3.1.2.1. Laser Console

The laser console houses the touch-screen control panel, laser emergency stop button, control electronics, laser source with associated optics and power supply. The laser console is the central unit to which the laser components and delivery devices are attached.

3.1.2.2. Remote Interlock Connection Plug

The remote interlock plug must be inserted into the external interlock connection port on the laser console's rear panel for the laser to operate. The plug may be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

3.1.2.3. Footswitch

The footswitch activates the laser treatment beam when you press it while the laser is in **Ready** mode. Three different types of footswitch are available for the Smart532 system[1]:

- **Standard Footswitch** – press the footswitch to emit laser energy.
- **Smart Footswitch** – the **Smart** footswitch engages the automatic eye safety filter when you place your foot inside of the footswitch housing while the laser is in **Ready** mode.
- **PowerEase Footswitch** – adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.

3.1.2.4. Delivery Systems

Delivery systems for a variety of applications may have been shipped with your Smart532 laser system laser. Refer to the operator manuals included with those delivery systems for specific descriptions and operating instructions.

Compatible delivery systems include probes, fibers, laser indirect ophthalmoscopes (LIO), LaserLinks and slit lamps.

[1] Depending on the Lumenis purchase agreement.

3.1.3. *System Description – Front Panel*

The front panel of the Smart532 laser system is shown in Figure 3-2.

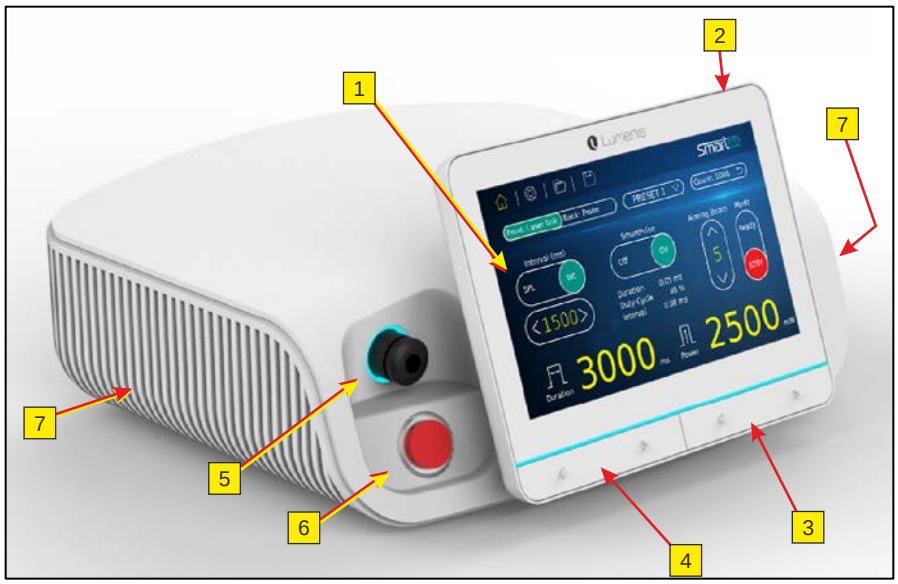


Figure 3-2: Smart532 Laser System – Front Panel

#	***Description***
1	Touch-screen control panel
2	Main on/off button
3	Power setting ▲ and ▼ buttons
4	Pulse duration setting ▲ and ▼ buttons
5	Fiber connection port (SMA-906)
6	Laser emergency stop button
7	Cooling grids

3.1.4. *Laser Emergency Stop Button*

In an emergency, press the laser emergency stop button on the front of the laser console to immediately turn off the laser.

Note

- When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, unplug the main power plug from the wall socket, or turn off the main electrical service (wall circuit breaker).
- The laser emergency stop button turns all power to the laser off, but does not turn off the CPU board or the control panel. When the button is pressed, a message will appear on the control panel, and the system will be in **Standby** mode. To clear the error, press the laser emergency stop button again to disengage it.

3.1.5. *System Description – Rear Panel*

The rear panel of the Smart532 laser system is shown in Figure 3-3:

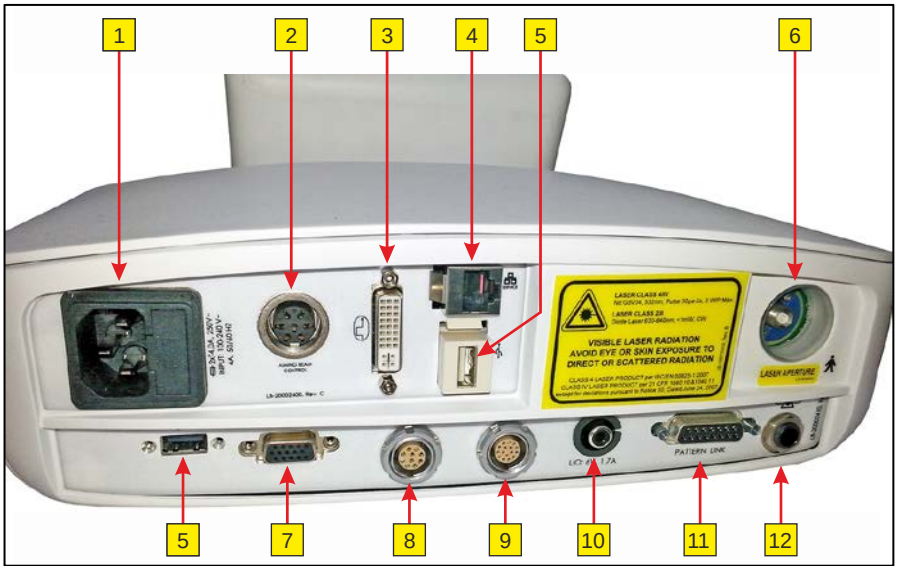


Figure 3-3: Smart532 Laser System – Rear Panel

#	***Description***
1	Power cable connection port and fuse housing
2	Array connection port to aiming beam
3	DVI connection port
4	Ethernet connection port
5	USB connection ports
6	Fiber connection port (FC)
7	Disabled
8	Footswitch connection port
9	Eye safety filter (ESF) connection port
10	LIO illumination connection port
11	Array data connection port
12	Remote interlock connection port

Note

The USB connection ports are normally utilized by Lumenis-authorized service engineers for servicing the system and for uploading periodical software upgrades.

3.1.6. Touch-Screen LCD Control Panel

The Smart532 system is controlled by pressing the buttons on the touch-screen. Figure 3-4 presents a sample control screen; all aspects of the operating system will be discussed in the **Operating Instructions** chapter later in this manual.

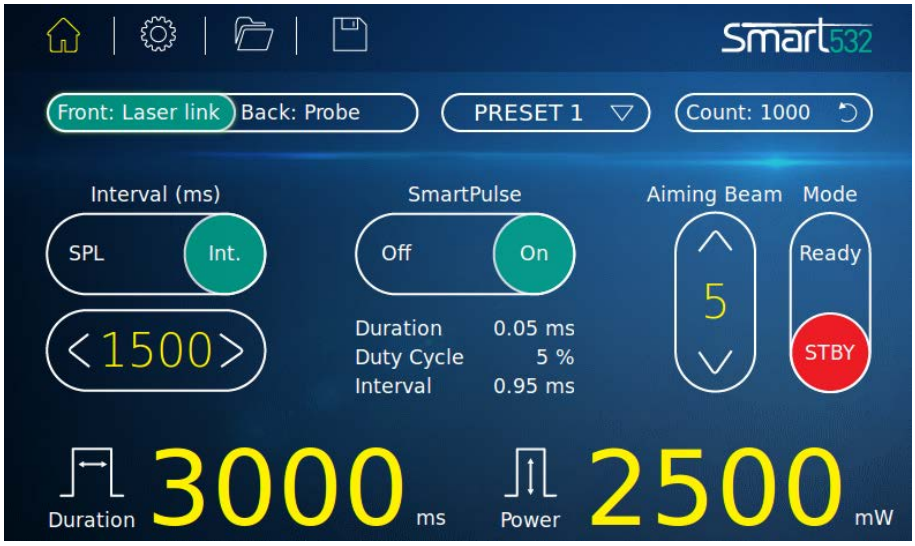


Figure 3-4: Touch-Screen LCD Control Panel

3.1.7. Optical Bench Assembly

The optical bench assembly is comprised of the optical resonator that generates the 532-nm green laser beam, the laser shutter assembly, the photodiodes, the aiming beam assembly and the beam combiner.

The aiming beam is a low-powered 635 nm diode laser with an adjustable intensity control.

The beam combiner combines the 532-nm green laser and the aiming beam coaxially, and guides them into the laser output aperture.

3.1.8. System Specifications

3.1.8.1. Outputs

Treatment Laser

- Type: Frequency-doubled Nd:gdVO4, diode-pumped solid-state
- Wavelength: Green: 532 nm ±2 nm
- Nominal Laser Peak Power[1]: 50 to 2,500 mW
- Exposure Duration: Single pulse[2] /Continuous Waveform: 5.0 to 3,000 ms
  SmartPulse Waveform: 0.05 to 1.0 ms
- Exposure Interval: Continuous Waveform: 10 to 1,500 ms
  SmartPulse Waveform: 0.5 to 10 ms

Aiming Laser

- Type: Red diode laser
- Wavelength: 635 nm ±5 nm
- Intensity: 7 settings from minimal to 1 mW max.
- Operational mode: Continuous

3.1.8.2. Operation and Control

Control

- Microprocessor based, touch screen, high resolution, multicolor GUI.
- Presets storing and display capability.

Laser Emission Control

- Footswitch

Laser Emission Indicators

- Blue LED
- Audible indicator

[1] At **Repeat** mode the peak power is limited by duty cycle limitation (refer to the Power Setting section).

[2] **Single Pulse** is a sub set of Continues one, with all the supporting work ranges, but where the interval is zero.

3.1.8.3. Compatible Accessories

- Lumenis Slit Lamps - 1000, 980, 990, SL130, 30SL
- Lumenis Array LaserLink (On-Axis or Off-Axis)
- Lumenis Trio
- LaserLink Z
- LaserLink HS
- ESF for all LaserLinks Listed, green 532nm
- Single and Dual Endo Kits for Zeiss and Leica/Wild microscopes
- LIO (both Keeler and Heine models)
- Standard, PowerEase or Smart Footswitch

3.1.8.4. Electrical Requirements

- 100-240 VAC, 4A, 50/60 Hz, single phase

3.1.8.5. Physical Specifications

Dimensions and Weight

• Height:	13.7 centimeters	(5.4 inches)
• Width:	29.5 centimeters	(11.6 inches)
• Depth:	26.3 centimeters	(10.4 inches)
• Weight:	3.5 kilograms	(7.75 pounds)

3.1.8.6. Environmental Specifications

Ambient Temperature

- Operating: 10 to 30°C (50 to 86°F)
- Storage: (-20) to 55°C [(-4) to 131°F]

Relative Humidity

- Operating: 10 to 75% relative humidity, non-condensing.
- Shipping & Storage: 10 to 90% relative humidity, non-condensing.

Max. Altitude / Atmospheric Pressure

- Operating: 2,240 m (7,500 ft.) / 78 kPa
- Storage: 2,240 m (7,500 ft.) / 78 kPa

3.1.8.7. System Classifications

Degree of Protection against Electric Shock for Applied Parts

- Type B Equipment

CDRH Classification

- Class IV

European MDD Laser Classification

- Class 4

Suitability for use in Presence of Flammable Mixture

- Not suitable

Protection against Ingress of Water

- IPX0 – water spillage protection for operation room
- IP68 – footswitch types: Standard footswitch & Smart footswitch
- IP28 – footswitch type: PowerEase footswitch

Chapter 4

System Installation and Initial Setup

4.1. Introduction

The Smart532 laser system has passed full quality assurance testing before shipment and should be operational upon delivery.

Your local Lumenis representative initially uncrates, inspects, sets up and installs the laser to ensure that it is working properly. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced with the performance and safety considerations of the laser.

Thereafter you, or the nursing staff at your facility, will perform the daily maintenance routines associated with the laser and delivery devices, including inspecting and cleaning the laser and delivery devices, connecting and disconnecting the delivery devices, and verifying the aiming beam. These procedures are detailed in this manual and in the delivery device operator manuals.

Note

In Canada this instrument must be installed and operated according to CAN/CSA-Z386-08: Laser Safety in Health Care Facilities.

4.2. Unpacking the System

The Smart532 system is shipped in a shockproof container. Contents may vary according to the purchase agreement with Lumenis, but the parts and accessories generally shipped in the container are:

- Smart532 system console
- Safety eyewear
- Footswitch
- Door interlock connector plug
- Laser danger sign(s)
- Power cable
- Operator's manual CD

To unpack the Smart532 system, carefully remove all components from the shipping container. Save all packaging materials in case repacking and shipping becomes necessary at a later date.

Note

Any damage to the packaging or to the system found prior to opening the packaging, or during unpacking and installation of the system, should be immediately reported to your Lumenis representative and to the insurance carrier.

4.3. Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections.

4.3.1. Space and Positioning Requirements

Space should be allocated with adequate ventilation and free air flow. The working area for the system should be prepared according to the dimensions shown in Figure 4-1. In order to guarantee proper ventilation, always keep the sides of the system at least 0.5 m (20") from the wall or from other obstructions to air flow.

Figure 4-1: Physical Dimensions

4.3.2. Electrical Requirements

The system is equipped with a universal power supply module. Accordingly, the system will require a separate line supply of:

- 100-240 VAC, 6A, 50/60 Hz, single phase

Input power lines should be free of transients, voltage and current spikes, sags and surges. Consequently, the system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc.

It is strongly recommended that the system be connected to a separate power line with separate circuit breakers. Lumenis cannot guarantee adequate performance unless the system is connected to a dedicated circuit.

4.3.3. Environmental Requirements

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Temperature:

To ensure that the system performs optimally, it is recommended to maintain ambient room temperature between 10-30°C (50-86°F) and relative humidity of 10-75% non-condensing. When the system is used intensively it will emit heat. Therefore, it is recommended that the treatment room be air-conditioned.

4.4. Installation and Setup

The system has passed full quality assurance testing before shipment and should be operational upon delivery.

The front panel of the Smart532 laser system is shown in Figure 4-2.

Figure 4-2: Smart532 Laser System – Front Panel

#	*Description*
1	Touch-screen control panel
2	Main on/off button
3	Power setting ▲ and ▼ buttons
4	Pulse duration setting ▲ and ▼ buttons
5	Fiber connection port (SMA-906)
6	Laser emergency stop button
7	Cooling grids

The rear panel of the Smart532 laser system is shown in Figure 4-3:

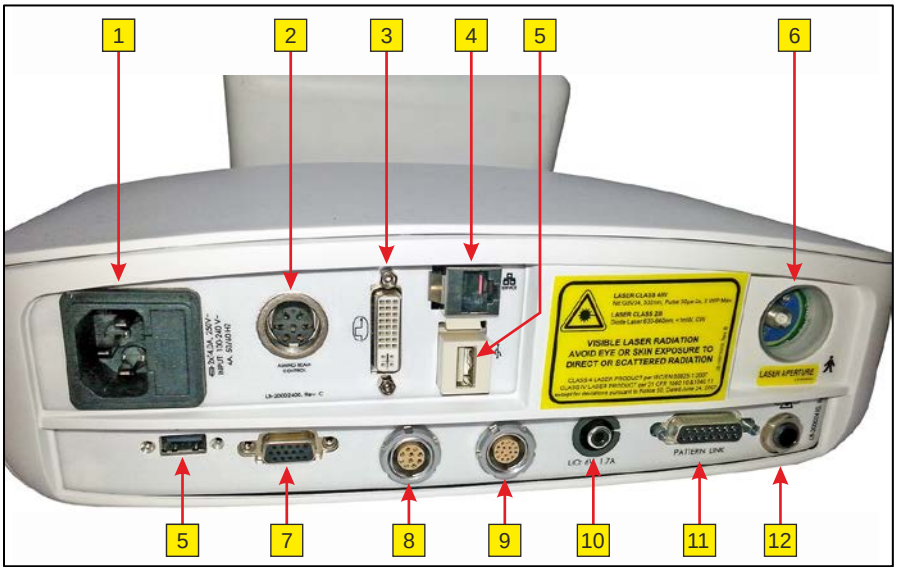


Figure 4-3: Smart532 Laser System – Rear Panel

#	Description
1	Power cable connection port and fuse housing
2	Array connection port to aiming beam
3	DVI connection port
4	Ethernet connection port
5	USB connection ports
6	Fiber connection port (FC)
7	Disabled
8	Footswitch connection port
9	Eye safety filter (ESF) connection port
10	LIO illumination connection port
11	Array data connection port
12	Remote interlock connection port

4.5. Connection Instructions

Before connecting the laser components, inspect the individual components, cables and electrical connections for dirt, debris or damage. Ensure that the electrical cables are not frayed or split. Inspect all delivery devices as instructed in the appropriate delivery device operator manual. Contact your Lumenis representative if any component appears damaged.

> ***Caution***
>
> Do not touch any optical lens; finger oils may damage the delicate coatings.

4.5.1. Connect the Footswitch

Insert the footswitch plug into the footswitch connection port on the system's rear panel (see Figure 4-4). If the footswitch is not properly connected when the laser is turned on, an error message will display on the control panel until the footswitch is properly connected.

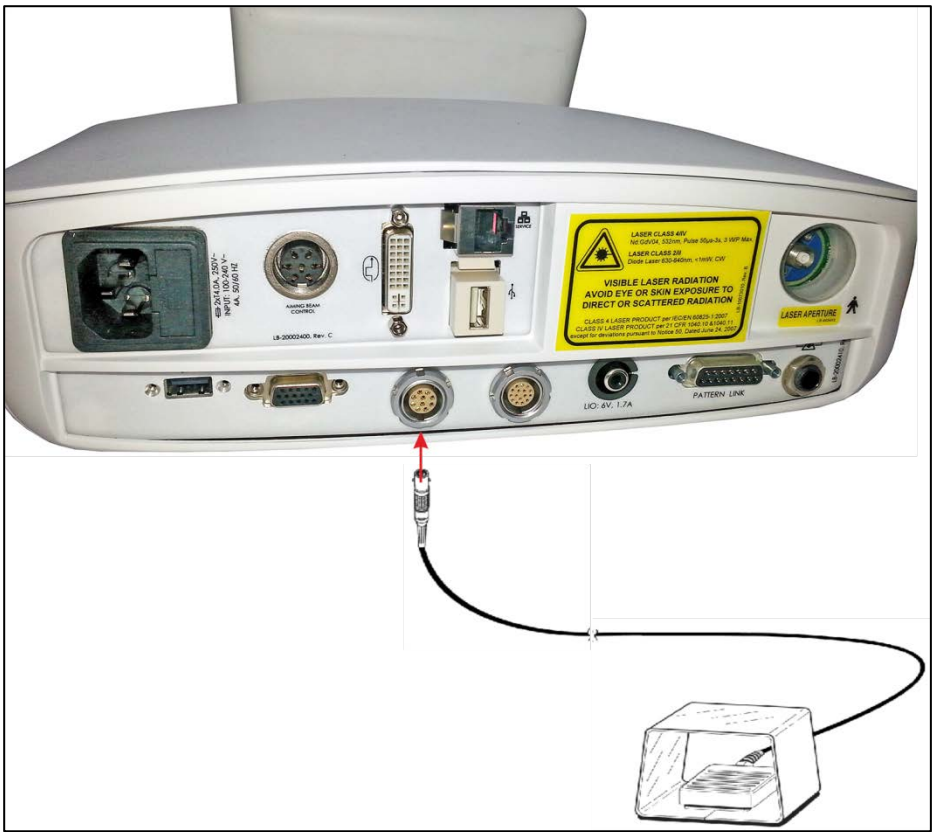


Figure 4-4: Connecting the Footswitch

4.5.2. Connect the Remote Interlock

The remote interlock is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed.

Use of a remote interlock is optional; however, an interlock plug must be inserted into the remote interlock connection port (see Figure 4-5) whether or not you are using a remote interlock. The laser will be inoperative unless the plug is inserted into the receptacle. For your convenience, the Smart532 laser system is delivered from the factory with an interlock plug pre-installed.

A remote interlock is required for this system. When using a remote interlock, the laser automatically disables and returns to **Standby** mode if the treatment door is opened or the interlock plug is removed. An appropriate error message will appear on the control panel. To resume treatment, close the treatment room door or reinsert the interlock plug, and transition the system to **Ready**.

Figure 4-5: Remote Interlock Plug Connection

4.5.3. Connect the Main Power Cable

Insert the power cable plug into the Power cable connection port on the system's rear panel (see Figure 4-6).

Insert the other end of the power cable into the wall socket and ensure that the plug is secured.

The supplied hospital-grade power cable should be used with a hospital-grade wall outlet. The power cable shipped with the system will vary according to local electrical requirements.

Figure 4-6: Connecting the Main Power Cable

4.5.4. Connect a Delivery System

Warning

- To avoid possible damage to the laser, use only qualified, compatible Lumenis delivery systems. Using after-market devices may jeopardize safe operation or damage the laser and will void your Lumenis warranty or service contract.
- When using a fiber-optic delivery system always inspect the fiber-optic cable to ensure that it has not been kinked, punctured, fractured or otherwise damaged. The fiber-optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber-optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Carefully inspect any delivery system's sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system.

A variety of delivery systems[1] are compatible with the Smart532 laser system. To connect a delivery system, attach the device's laser connector to an available fiber connection port on the system's front or rear panel (see Figure 4-2 or Figure 4-3). Attach any additional connectors to the appropriate accessory connection port. Refer to the appropriate delivery system's operator manual for detailed connection and operating instructions.

When a delivery system is properly connected, the name of the device will be displayed on the control panel (see Chapter 5).

If the delivery system is not properly connected, an error message will be displayed on the control panel. Verify that the delivery system is properly connected to the appropriate connection ports before turning the laser system on. If the delivery system is not compatible with the Smart532 laser system, an error message will be displayed on the control panel.

[1] Optional purchase equipment

4.5.5. Eye Safety Filters

4.5.5.1. Installing the Eye Safety Filter(s)

When using a LaserLink, a Lumenis slit lamp or Acculite delivery system, you must install a compatible automatic or fixed eye safety filter onto the slit lamp or operating microscope. The eye safety filter protects the physician's eyes from exposure to laser energy while looking through the slit lamp or operating microscope.

If the eye safety filter is not properly connected to the Smart532 laser system, or if the eye safety filter is not compatible with the system, an error message will be displayed on the control panel.

Refer to the appropriate delivery system operator manual for detailed eye safety filter installation instructions.

Warning

During treatment the eye safety filter must be attached to the slit lamp or operating microscope. Failure to use an eye safety filter could result in ocular injury. In addition some slit lamps and microscopes require an auxiliary eye safety filter to protect persons observing the procedure through an observation tube. To determine if an auxiliary eye safety filter is required, review your slit lamp or microscope operator's manual or contact its manufacturer.

4.5.5.2. Connecting an Automatic Eye Safety Filter to the Laser

When using an automatic eye safety filter, you must connect the eye safety filter to the Smart532 laser system using the extension cable provided with your eye safety filter.

To connect the eye safety filter to the laser, connect the filter plug to the system as instructed in the appropriate delivery system operator's manual.

Insert the extension cable plug into the laser system's appropriate connection port.

4.5.5.3. Connecting a Fixed Eye Safety Filter to the Laser

If you are using a fixed eye safety filter, then you must insert an emulation plug[2] into the laser system's eye safety filter connection port.

Note

The LIO delivery system has an integrated eye safety filter. When using an LIO inserting an emulation plug is not necessary.

[2] Supplied with the Fixed ESF kit.

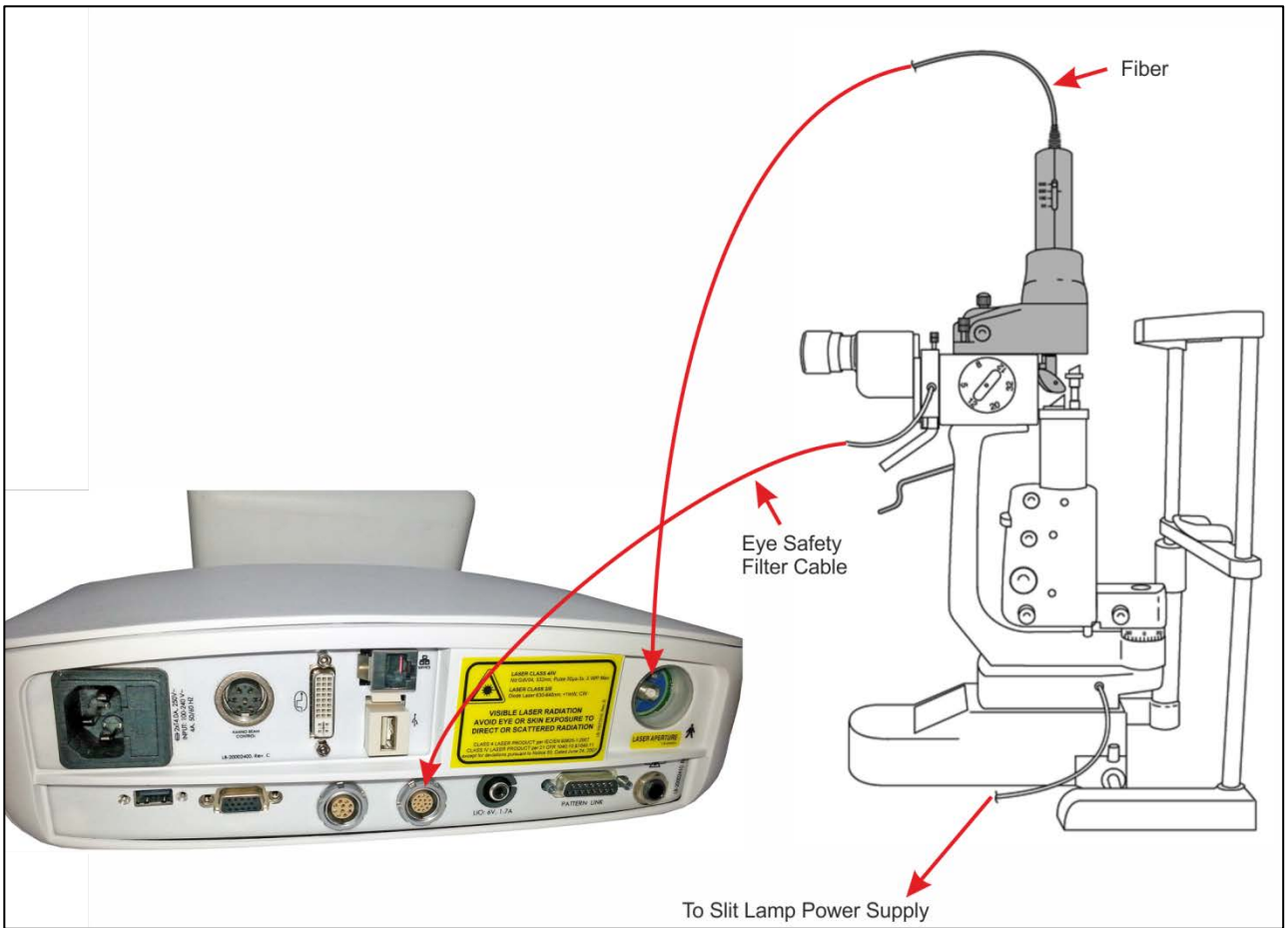


Figure 4-7: Connecting a Delivery System (for illustration purposes only)

4.6. Transporting and Storage

Prepare the system for transport as follows:

1. Set the system to **Standby** mode and power it down by unplugging it from the wall outlet.
2. Disconnect the delivery system(s) from the laser system. If the delivery device is single-use dispose of it properly. Otherwise, inspect and clean the delivery system(s) as instructed in the appropriate operator's manual(s).
3. Disconnect the footswitch from the laser.
4. Disconnect the remote interlock or the remote interlock emulator.
5. Clean the exterior surfaces of the laser as instructed in the **Maintenance** chapter of this manual.

Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.

Chapter 5

Operating Instructions

5.1. *Safety Considerations*

Read Chapter 2 before attempting any procedures. Be aware of the hazards when using lasers and take appropriate protective measures. Some important reminders:

1. Restrict access to the laser operating area. Post the laser warning sign before beginning any procedure.
2. Make sure that the laser operating area is safe and secure. Any flammable materials should be moistened, or should be beyond contact of the laser beam. All assisting staff in the room should wear protective goggles or glasses.
3. Remember that the footswitch is enabled (allowed to operate the system) when the system is in **Ready** mode. The footswitch is disabled (not allowed to operate the system) when the system is in **Standby** mode. When not actively lasing, set the system to **Standby** mode.

5.2. *Starting the System*

1. Press the On/Off switch on top of the system's control panel; the system starts its initialization process, during which a splash screen is displayed on the LCD.
2. The **Login** screen will now appear (see Figure 5-1) and a self-test routine starts that tests the system; insert the password by pressing the 4-digit password (**1 2 3 4**) on the screen's virtual keypad. If you pressed a wrong button by mistake, press the button with the ← icon – this will clear the last character entered.
3. Press the **Enter** key; if a fault is detected, the system issues an appropriate error message (see Chapter 6). Once the system satisfactorily completes the self-test routine, it is ready for operation and displays the **Main Treatment** screen (see Figure 5-2).

Figure 5-1: Login Screen

5.3. Main Treatment Screen Elements

The elements of the **Main Treatment** screen are described in the following illustration and following table. Each of the elements is described in detail in the following sections.

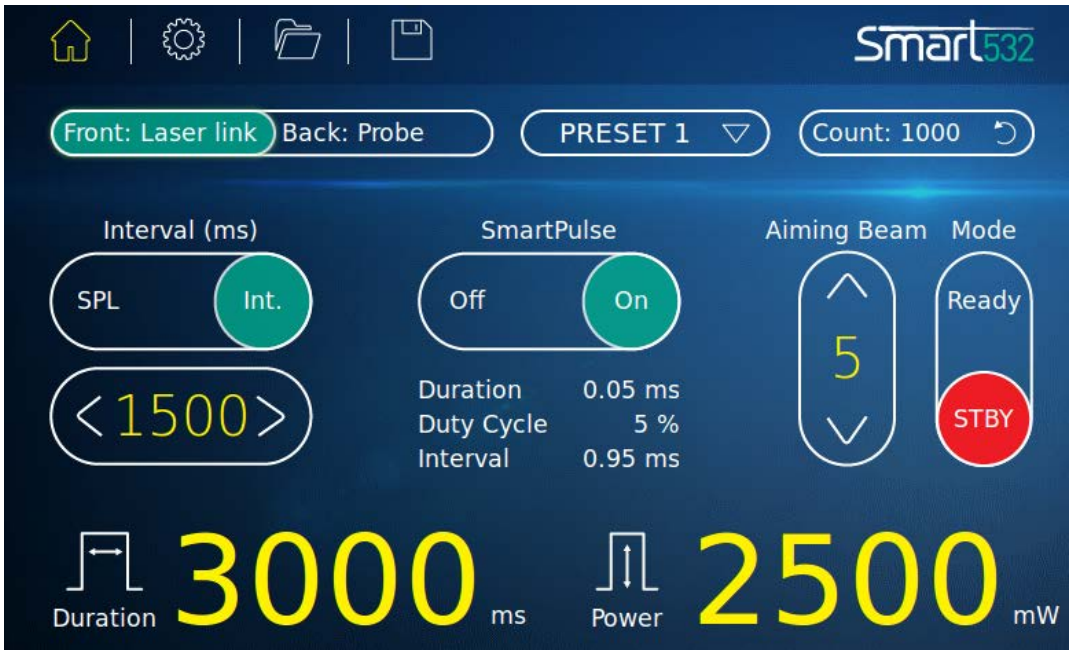


Figure 5-2: Main Treatment Screen

#	*Description*	*See Section:*
1	Delivery system selection buttons	5.3.1
2	Power setting display	5.3.2
3	Exposure time setting (pulse duration)	5.3.3
4	Pulse interval display	5.3.4
5	Aiming beam adjustment	5.3.5
6	SmartPulse[1]	5.3.6
7	Pulse counter	5.3.7
8	Standby/Ready mode selection	5.3.8
9	Selected preset name	5.3.9
10	Save new preset	5.3.10
11	Open Presets screen	5.3.10
12	Open Options screen	5.3.12
13	Return to Main Treatment screen	5.25.3

[1] Optional product configuration

Caution

Always verify that the desired treatment parameters are displayed on the control panel before initiating treatment. If there is no change in display values when you press the selectors on the control panel, or if the control panel appears otherwise erratic, do not use the laser system. Contact your Lumenis representative.

5.3.1. *Delivery System Selection*

Select one of two connected delivery systems by pressing the appropriate button on the screen; the highlighted delivery system and port (**Front** or **Back**) is the active one.

Warning

Always ensure that a compatible eye safety filter is properly connected for the selected delivery system. Failure to properly use an eye safety filter for those delivery systems that require them can result in serious eye injury. Refer to the appropriate delivery system operator manual for additional compatibility and safety information.

5.3.2. *Power Setting*

The available power level settings are from 50 mW up to 2,500 mW when:

- Between 50 to 100 mW the increments are 5 mW.
- Between 100 to 300 mW the increments are 10 mW.
- Between 300 to 500 mW the increments are 20 mW.
- Between 500 to 1,000 mW the increments are 50 mW.
- Between 1,000 to 2,500 mW the increments are 100 mW.

The available power settings are detailed in the Specifications section in Chapter 3 of this manual.

At a duty cycle of more than 50%, the average power will be limited to 1,250 mW and the peak power on the screen will change accordingly.

Note

If you are using the PowerEase footswitch, you can also adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.

Warning

Always inspect the optics and delivery system as described in this manual to ensure that the system is clean and undamaged. Never use a system that appears damaged or dirty. Doing so may dangerously reduce the delivered power and result in unintended, adverse tissue effects.

5.3.3. *Exposure Time Setting*

Set the exposure time (pulse duration) by pressing the ◄ or ► buttons on the left side under the LCD.

The available exposure time settings are detailed in the **Specifications** section in Chapter 3 of this manual.

5.3.4. *Pulse Interval Selection*

The pulse interval is the time between laser pulses. Single and repeat pulse modes are available. In single pulse mode, the laser delivers a single pulse each time you press the footswitch. In repeat pulse mode, the laser delivers repeated pulses at a specified interval until you release the footswitch.

The available interval time settings are detailed in the Specifications section in Chapter 3 of this manual.

Note

Not all interval settings are available at higher power and exposure time settings. If you attempt to select an interval that is unavailable at the existing power and exposure time settings, the laser changes to meet the duty cycle requirements for that power setting. You must reduce the power or exposure time setting to make available the desired interval. Conversely, if you select the minimum interval for the existing power and exposure time settings, and then you increase the power or exposure time setting, the interval automatically increases to the minimum setting for the new power and exposure time settings.

- Ensure that the **Int.** (Interval) button is selected.
- Set the pulse interval by pressing the **<** or **>** buttons on the LCD screen.
- If the Single Pulse option is selected (**SPL** button pressed), the Pulse Interval Selection function is disabled.

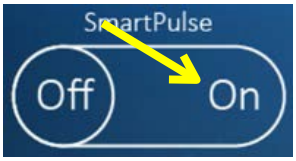
5.3.5. *Aiming Beam Intensity Adjustment*

Set the aiming beam intensity by pressing the **^** or **v** buttons on the selector icon.

The available aiming beam intensity settings are detailed in the Specifications section in Chapter 4 of this manual.

During some procedures, the aiming beam may obstruct the view of the treatment site while lasing. The aiming beam can be either on or off while lasing. To turn the aiming beam off, press the **v** selector to the lowest setting.

5.3.6. SmartPulse Mode



SmartPulse[2] mode allows the operator to apply greater fine-tuning to the system's operating parameters; proceed as follows:

- Press the **SmartPulse On** button; the **SmartPulse** parameter selection pop-up appears (see Figure 5-3).

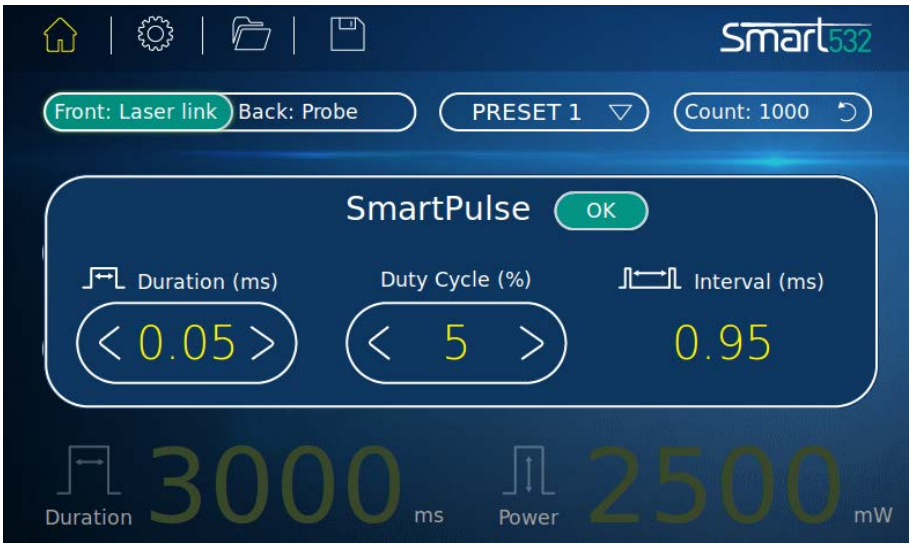
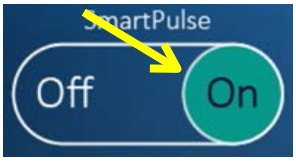


Figure 5-3: SmartPulse Parameter Selection Pop-Up

- Reconfigure the parameter levels of the **Duration** and/or **Duty Cycle** and/or **Interval** by pressing the **<** or **>** buttons in each of the parameters.



- Press the **OK** button; the pop-up will close and return to the **Main Treatment** screen. The **SmartPulse Off/On** button will be **On** and the selected parameters will be displayed on the screen.

- At any time during treatment the operator may press the **Pencil** button to display the **SmartPulse** parameter selection pop-up to further fine-tune the parameters.

[2] Optional product configuration

5.3.7. *Pulse Counter*

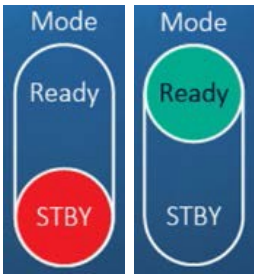
The pulse counter displays the total number of treatment pulses delivered since the reset button was last pressed. The range on the Smart532 laser system display is 0-10,000 pulses. It can be reset to zero by pressing the **Reset** button. The pulse count will reset to **0** (zero) when the laser system is powered down.

The count display will incrementally show the number of pulses delivered.

5.3.8. *Standby/Ready Mode Selection*

Warning

- Except during actual treatment, the system must always be in **Standby** mode. Maintaining the system in **Standby** mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to **Ready** mode.



When the Smart532 laser system is turned on and has finished warming up, it defaults to **Standby** mode. The aiming beam is present but the footswitch is disabled and the treatment laser cannot be activated.

Press the **Ready** button to transition the system from **Standby** to **Ready** mode; the **Ready** icon turns green. The system beeps to indicate the start of a two-second delay, after which the treatment beam can be activated by pressing the footswitch.

When the footswitch is pressed the eye safety filter will engage (if using an automatic eye safety filter) and the treatment beam will be activated. While the treatment beam is being delivered, an audible tone is emitted.

Note

- If the laser is not used for five minutes, the system automatically defaults to **Standby** mode.
- If the laser cannot be set to **Ready** mode, an error message displays on the control panel.

5.3.9. *Preset Name*

This area of the screen displays the name of the currently-selected preset. Press the ▼ button to open a drop-down menu of the last four presets that were used during a treatment.

5.3.10. Save a New Preset

You may add your own proprietary treatment setting protocols as presets to the Smart532 laser system.

Adjust the treatment parameters on the touch-screen – power, exposure time, interval and other parameters – in the manner that you desire, and press the **Save** icon; a virtual keyboard will appear on the screen where you may assign a name to the new preset and save it to the system.

Press the **Done** button; a new screen will appear and on it all of the selected parameters will be displayed (see Figure 5-4).

Figure 5-4: Preset Screen

5.3.11. Edit, Delete or Select an Existing Preset

Press the **Preset name** button and select the desired preset:

- Press the **Edit** button to readjust the names and/or the parameters of the preset.
- Press the **Delete** button to remove the selected preset from the system's memory.
- Press the **Done** button on the virtual keyboard to transition to the **Main Treatment** screen for treatment with the selected preset's parameters.

5.3.12. Open Options Screen

To configure the Smart532 system's software and hardware preferences, press the **Options** button on any screen; the **Options** screens will appear (see Figure 5-5).

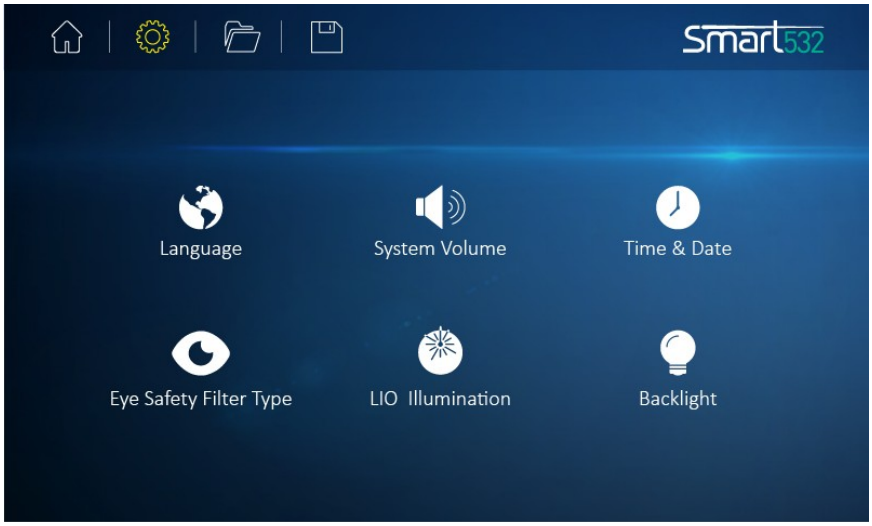


Figure 5-5: Options Screen

Pressing any of the **Options** icons in the screen will navigate the system to that particular Option screen. Pressing the ► or ◄ button at the top-left or top-right corner of the screen will navigate the system to the next or previous Option screen.

Press the **Home** button at any time to exit the **Options** screens and return to the **Home** screen.

Press the **Options** button at any time to exit the particular option screen and return to the **Options** screen (see Figure 5-5).

5.3.12.1. LIO Illumination Setting Screen

In this screen (see Figure 5-6) you may adjust the illumination level of the connected laser indirect ophthalmoscope (LIO) by pressing the ► or ◄ buttons.

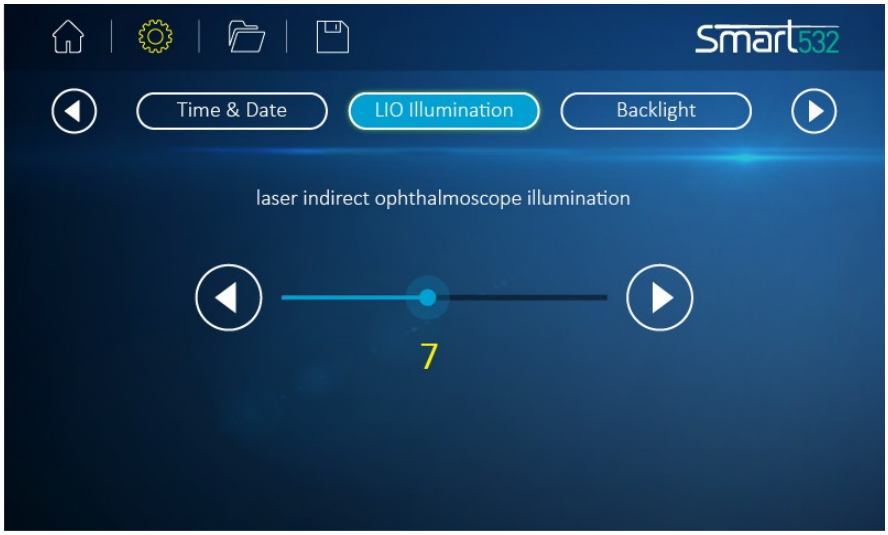


Figure 5-6: Option Screen: Adjust LIO Illumination

5.3.12.2. Time & Date Settings Screen

In this screen (see Figure 5-7) you may adjust the system's time and date settings by pressing the ▲ or ▼ buttons above or below each of the appropriate parameters.

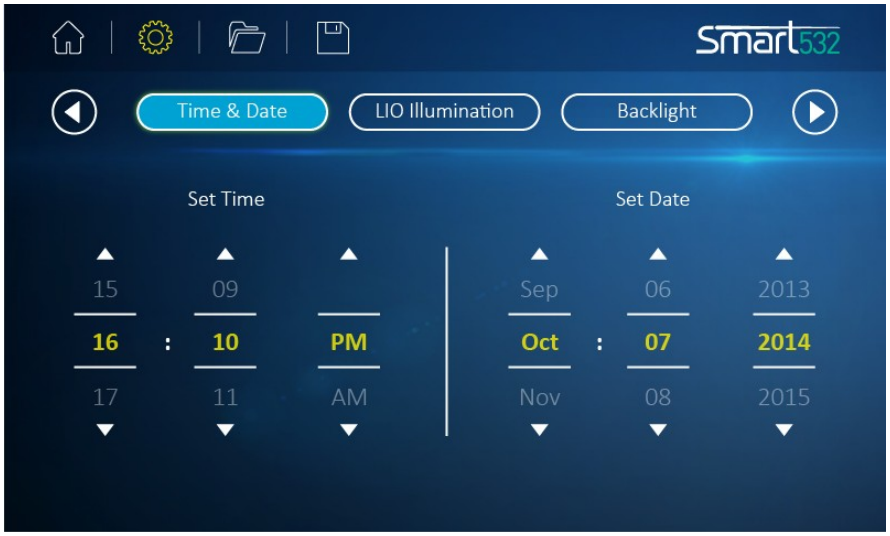


Figure 5-7: Option Screen: Time & date Settings

5.3.12.3. Language Setting Screen

In this screen (see Figure 5-8) you may select the user interface language by pressing the appropriate language icon on the screen. The available language selection is English, Italian, German, Japanese, Simplified Chinese, Russian, French, Spanish, Dutch and Portuguese.

Figure 5-8: Option Screen: Language Setting

5.3.12.4. Volume Setting Screen

In this screen (see Figure 5-9) you may adjust the volume of the system's feedback by pressing the ► or ◄ buttons.

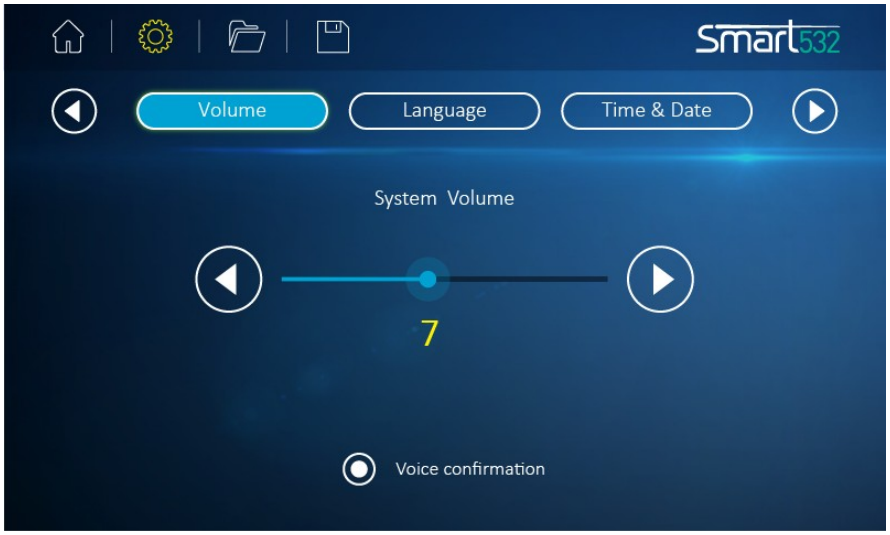


Figure 5-9: Option Screen: Volume Setting

5.3.12.5. Backlight Setting Screen

In this screen (see Figure 5-10) you may adjust the backlight illumination level of the user interface screen by pressing the ► or ◄ buttons. You can set the backlight separately for **Standby** and **Ready** system modes.

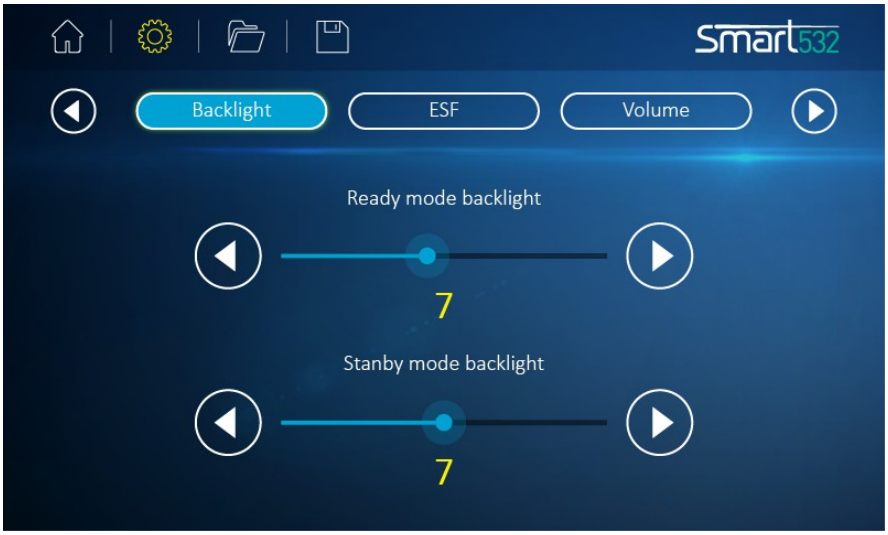


Figure 5-10: Option Screen: Backlight Setting

5.3.12.6. *Eye Safety Filter (ESF) Mode Selection Screen*

In this screen (see Figure 5-11) you may select the operational mode of the connected ESF by pressing the desired mode on the screen.

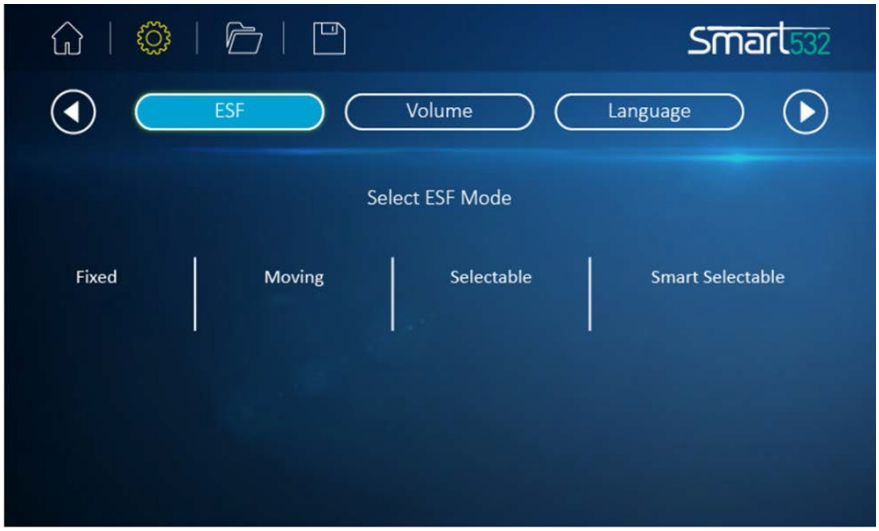


Figure 5-11: Option Screen: Eye Safety Filter (ESF) Selection

One or more of the following eye safety filter modes are available, depending upon the type of footswitch, delivery system(s), and eye safety filter(s) that you have connected to the laser:

- **Fixed**: the eye safety filter is always in position.
- **Moving**: the eye safety filter moves into position when you press the footswitch while the laser is in ready mode (available only with automatic eye safety filters).
- **Selectable**: the eye safety filter moves into position when you place the laser in Ready mode (available only with automatic eye safety filters).
- **Smart Selectable**: the eye safety filter moves into position when you place your foot inside the Smart footswitch housing while the laser is in Ready mode (available only with automatic eye safety filters and the Smart footswitch).

Note

If you are using a fixed eye safety filter, or if you are using a delivery system with an integrated fixed filter, such as the LIO, the eye safety filter mode is automatically set to **Fixed**; no other modes are available.

5.4. Pre-Operative Instructions

1. Verify that the laser system is properly connected as instructed in this manual.
2. Verify that the delivery system is properly connected as instructed in the delivery system operator manual. If using a remote interlock, verify that it is also properly connected.
3. Post the **Laser in Use** warning sign outside the treatment room door.
4. Plug the laser system's main power cable into the wall socket.
5. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See Laser Safety Eyewear in Chapter 2 of this manual for detailed laser safety eyewear information.
6. Turn on the laser system.
7. Perform the aiming beam integrity check as instructed later in this chapter.

Warning

- Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Do not use the delivery system if the aiming beam is set to high intensity and is weak or not visible; the fiber optic cable may be damaged. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Before using the laser, always verify that the displays on the laser console are properly working.

5.4.1. Aiming Beam Integrity Test

Warning

- Refer to the appropriate delivery system manual for important, additional information on laser beam integrity specific to that device.
- When using a fiber delivery device always inspect the fiber to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the fiber with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the fiber. A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient and/or cause fire in the treatment room.

Before beginning treatment, verify the aiming beam integrity by performing the following:

1. Ensure that the delivery system is properly connected to the Smart532 laser as described in the **Connection Instructions** sections earlier in this chapter.

2. Turn on the Smart532 laser system.

3. Verify that there are no error messages displayed on the control panel. If a message is displayed, ensure that the connector is fastened properly to the fiber connection port. If **Incompatible Delivery Device Connected** is displayed, connect a compatible delivery system.

4. Set the aiming beam to the highest intensity.

5. Hold a non-reflective surface, such as a tongue depressor, in front of the probe fiber tip or at the delivery system's focal plane. A red spot (the aiming beam) should appear on the flat surface. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.

Warning

Do not use the delivery system if the aiming beam is set to the highest intensity and is still weak or not visible; the fiber may be damaged. A damaged fiber may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

6. Set the desired laser treatment parameters.

5.5. *Intra-Operative Instructions*

Warning

Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Use extreme caution until you thoroughly understand the biological interaction between the laser energy and tissue.

1. Set the treatment values, as instructed in this manual, and verify that the desired settings are displayed on the control panel.
2. Ensure that the aiming beam is visible and position it on the target tissue.
3. Set the laser system to **Ready** mode.
4. Press the footswitch to deliver the treatment beam to the tissue.
5. The laser emission icon will illuminate on the control panel, and the system will emit a beep for each pulse delivered.
6. If surgery must be interrupted, set the laser system to **Standby** mode to disable the footswitch.

5.6. *Post-Operative Instructions*

1. Set the laser system to **Standby** mode.
2. Turn off the laser system by unplugging it and coiling the power cable to prevent damaging it.
3. Unplug the footswitch and coil the cable to prevent damaging it.
4. If desired, disconnect the delivery system and store the laser and delivery system components, as instructed in this manual and in the delivery system operator manual. Refer to the delivery system operator manual for additional postoperative instructions specific to the delivery system.
5. Disconnect the remote interlock (if used).
6. Clean the exterior surfaces of the laser, as instructed in the **Maintenance** chapter of this manual.

Chapter 6

Maintenance and Troubleshooting

6.1. User Maintenance

6.1.1. Annual Laser Maintenance

Preventative maintenance, safety, power and calibration tests should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance.

6.1.2. Laser System Repair

All laser system repairs should be performed by a Lumenis-certified service engineer. For detailed information contact your Lumenis representative.

6.1.3. Clean the External Surfaces of the Laser Console

Use a cloth dampened with a hospital-grade disinfectant to wipe the external surfaces of the laser console. Dry with a clean cloth or allow to air dry.

6.1.4. Clean the LCD Panel

The LCD panel should be cleaned with a dedicated LCD cleaning liquid, available in most office supply stores.

> ***Caution***
>
> Do not spray or pour cleaning agents directly on the laser console or LCD panel. You may damage the console, screen, and laser system electronics.

6.1.5. Fuse Replacement

1. Ensure that the system is turned off.
2. Unplug the main power cable from both the wall socket and the main power receptacle on the rear of the laser console.
3. Locate the fuse holder directly to the right of the main power receptacle.
4. Unlock and pull out the fuse holder by inserting a small, insulated flathead screwdriver into the slot on the fuse holder cover.
5. Replace the fuses as follows: two fuses rated 250V, 4A, Type T, Slo-Blo (5 x 20 mm)
6. Reinsert the fuse holder.

> ***Note***
>
> Always replace both fuses.

Figure 6-1: Login Screen

6.2. *Professional Maintenance*

This section covers tests, calibrations and maintenance that require internal access to the Smart532 console and special skills.

Warning

These procedures demand specific knowledge, training and use of tools not available to repair personnel outside of Lumenis. Since performing these procedures may expose the user to potential electrical and laser energy hazards, Lumenis requires that these procedures only be performed by trained service personnel.

6.2.1. *Power Meter Calibration*

Regulatory agencies require that manufacturers of US FDA CDRH Class II and IV, and European IEC 60825 Class 2 and 4 medical lasers supply their customers with power calibration instructions.

Power meter check and calibration must be performed by an engineer or technician qualified to work with laser equipment. Questions regarding this procedure should be referred to your Lumenis representative.

Disclaimer warning:

Calibration is a service procedure to be performed only by Lumenis-certified service engineers. Adjustment by anyone other than a trained Lumenis service engineer voids any existing manufacturer's warranty on the instrument. It is company policy not to distribute service tools outside of the Lumenis Service Organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

6.2.2. *Internal Power Meter Test*

The Smart532 laser system incorporates an internal power meter which is used for display and control of lasing energy. The power meter test compares the internal power meter reading to the reading from an external power meter.

Note

Optical components must be clean before the power meter check is performed.

Warning

- All personnel in the immediate area must wear eye protection rated specifically for the 532 nm laser.
- An out-of-calibration power meter will cause power delivery to tissue to be different than that displayed.

6.3. Warranty Information

For specific and detailed warranty information for this instrument, please refer to the first page of your **Purchase Agreement** and the last page of the **Terms and Conditions of Sale**.

> ***Caution***
>
> Improper use or adjustment of this system may invalidate the service warranty agreement. Please contact your Lumenis representative before attempting to troubleshoot this system in any manner other than those specified in this manual.

6.4. Decontamination of Returned Equipment

In order to comply with postal and transportation laws, equipment shipped to the supplier's offices for return or repair must first be decontaminated. To communicate that the returned equipment has been properly decontaminated, a signed **Decontamination Certificate** (obtained from Customer Service) must be enclosed in the shipping package.

Failure to enclose the Decontamination Certificate will cause the supplier to assume the product is contaminated. The supplier will assess the customer with cleaning costs. Any decontamination inquiries should be directed to Customer Service.

6.5. Lumenis Customer Support

Lumenis Center	*Address*	*Telephone/Fax*
Lumenis Ltd.	Yokneam Industrial Park 6 Hakidma Street P.O.B. 240 Yokneam 2069204, Israel	Tel: + 972.4.959.9000 Fax: + 972.4.959.9050
Lumenis, Inc.	2033 Gateway Place, Suite 200 San Jose, CA 95110, USA	Tel: + 1.408.764.3000 Fax: + 1.408.764-3999
Lumenis (Germany) GmbH	Heinrich Hertz Str. 3 D-63303 Dreieich-Dreieichenhain Germany	Tel: + 49 (0) 6103.8335.0 Fax: + 49 (0) 6103.8335.300
Lumenis Co. Ltd., Japan	1-14-3 K-3 building 5F Oi Shinagawa-ku, Tokyo 140-0014 Japan	Tel: + 81.3.4431.8300 Fax: + 81.3.4431.8301
Lumenis Ltd. China	4th floor, South Tower, Kerry Centre, No.1 Guang Hua Road Beijing 100020, China	Tel: +86.10.5737.6677 Fax: +86.10.5737.6767

6.6. Troubleshooting Guide

Table 6-1 provides a list of error messages that may appear on the touch-screen control panel that include possible remedies that may be attended to by clinic staff. The operator has the option of correcting the problem, setting the system back to **Ready** mode and continuing with normal operation.

Table 6-2 provides a list of 'Fatal' error messages that may appear on the touch-screen control panel that will disable further use of the system. In the event of such a message, shut down the system, restart it and try to resume normal operation. If the situation persists, shut down the system and contact Lumenis Service. Report the error number and text to them and follow their advice.

Table 6-3 lists some possible system symptoms that indicate malfunctions that do not appear on the control panel. If the corrective action listed in the table does not solve the problem, contact Lumenis-authorized service personnel.

If any error situation cannot be resolved, or if an error message returns repeatedly, contact Lumenis Service.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to authorized service personnel.

Table 6-1: Troubleshooting Guide: Error Messages with Corrective Actions

#	*Error Message Text*	*Corrective Action*
4	**Internal Communication Error (C-S)**	Restart system and try again; If error persists, shut down the system and contact Lumenis Service.
8, 11	**System Warm-Up, Please Wait.**	Wait until the system warms up sufficiently before attempting to operate.
14	**Eye Safety Filter (1) Identification Error**	Incompatible ESF connected. Connect compatible accessories.
15	**Eye Safety Filter (2) Identification Error**	Incompatible ESF connected. Connect compatible accessories.
16	**Eye Safety Filter (1) Error**	ESF failure; replace accessory and retry.
17	**Eye Safety Filter (2) Error**	ESF failure; replace accessory and retry.
18	**Eye Safety Filter (1) is not connected**	Check cable connection and retry.
19	**Eye Safety Filter (2) is not connected**	Check cable connection and retry.
21	**Footswitch Disconnected**	Check cable connection and retry.
22	**Footswitch Pressed While Entering Ready Mode**	Release the footswitch and press the **Ready** button again.
23	**Footswitch Error**	Footswitch failure; check cable connection and retry, replace or repair footswitch.

Table 6-1: Troubleshooting Guide: Error Messages with Corrective Actions (continued)

#	*Error Message Text*	*Corrective Action*
24	**Footswitch Error**	**Smart** footswitch failure; check cable connection and retry, replace or repair footswitch.
25	**Footswitch Error**	**Power Ease** footswitch failure; check cable connection and retry, replace or repair footswitch.
30	**Power Converge Error (SubP)**	System could not generate requested power. Restart system and try again; If error persists, shut down the system and contact Lumenis Service.
32.	**Door Open (Interlock)**	Close the interlocked door or connect the interlock plug. Access **Ready** mode and continue normal operation.
33	**Emergency Button Pressed**	Pull the laser emergency stop button out and restart the system.
34	**On/Off Button Pressed**	Release the button and resume normal operation.
35	**Invalid Password**	Enter the correct login password and resume normal operation.
39	**Temperature Range Error (System)**	The ambient temperature in the treatment room is outside of the system's specs. Adjust the room temperature and restart the system.
42	**Front Port: Accessory Identification Error**	Incompatible delivery device connected.
43	**Rear Port: Accessory Identification Error**	Incompatible delivery device connected.
44	**No Delivery Device Connected**	Connect a compatible delivery device and resume normal operation.
45	**Two LIOs connected**	Disconnect one of the LIOs and resume normal operation.
46	**Two Laser Links connected**	Disconnect one of the laser links and resume normal operation.
47	**Two Probes connected**	Disconnect one of the probes and resume normal operation.

Table 6-2: Troubleshooting Guide: Error Messages Requiring Contact with Lumenis Service

#	*Error Message Text*
1	Software Version Error
2	Internal Communication Error (G-C)
3	Internal Communication Error (C-F)
5	Aiming Beam Not Calibrated
6	Aiming Beam Error
7	Display Press-Buttons Error
9	Temperature Error (LBO)
10	Temperature Range Error (LBO)
12	Temperature Error (Diode)
13	Temperature Range Error (Diode)
20	Internal Clock Error
26	Shutter Error
27	Diode Error (Current)
28	Diode Error (Check)
29	Diode Error (Power)
31	Timing Error
36	Voltage Error (12V)
37	Voltage Error (3.3V)
38	Voltage Error (1.9V)
40	Port Selection Error
41	Power Calibration Error
48	Parameters Error
49	Diode Temperature Error
50	Diode Temperature Error
51	Diode (LBO) Temperature Error

Table 6-3: Undisplayed System Malfunctions Troubleshooting Guide

Symptom	*Probable Cause*	*Corrective Action*
System does not function when plugged in and turned on.	1. No AC power from wall outlet. 2. Tripped power circuit breaker (operating room power supply).	1. Check if AC power is available from wall outlet, and power cable is properly plugged into AC outlet. 2. Reset power circuit breaker.
System will not switch to **Ready** mode.	1. Footswitch or delivery system not connected properly. 2. Footswitch malfunction. 3. System malfunction.	1. Check external connections according to warning message. 2. Contact Lumenis Service. 3. Contact Lumenis Service.
Laser emission does not occur when footswitch is pressed.	1. System is not in **Ready** mode. 2. Damaged delivery system. 3. Footswitch malfunction. 4. System malfunction.	1. Set system to **Ready** mode. 2. Replace delivery system. 3. Contact Lumenis Service. 4. Contact Lumenis Service.
System not responding to touch-screen commands	Control panel's touch-screen is out of calibration.	Contact Lumenis Service.
Inadequate treatment beam or tissue effect.	The treatment or aiming beam is not properly aligned.	Contact Lumenis Service.
System does not turn on. Display does not illuminate.	1. The laser is not plugged in. 2. The building power (main electrical service) is turned off. 3. The electrical outlet is defective. 4. Blown surge-protection fuse(s).	1. Plug the power cord into the laser and into an appropriate outlet. 2. Turn on the building power. 3. Use another outlet or have the outlet professionally tested and, if appropriate, repaired 4. Replace fuses.

Appendix A

Clinical Guide

A.1. General Information

Warning

- The Indications for Use and Safety and Regulatory sections of this operator manual should be carefully read and comprehended in their entirety before attempting to use the laser system. Particular attention should be given to all cautions and warnings pertaining to the safe use of the laser.
- The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.

Successful clinical use of the laser depends upon the interaction of a number of variables. These variables include the type of tissue, the amount of tissue pigmentation, spot size, delivered power, pulse duration, and incidence angle of the laser beam onto the target tissue.

A.1.1. Tissue effects

Tissue effects are caused by the absorption of electromagnetic laser radiation and its conversion to heat. Diffusion of heat through the tissue depends on the thermal properties of the irradiated material. Pulse parameters such as duration, interval, frequency and power may be optimized for a desired tissue effect.

The irradiance (power density) required to elicit a specific tissue effect depends on a multitude of factors, such as, but not limited to:

- Reflection coefficient at air/water interface with target tissue.
- Density and type of pigmentation at target tissue
- Opacities of media preceding target tissue
- Wavelength of the laser beam
- Spot size of the laser beam at target tissue
- Time dependent parameters (e.g., pulse duration)
- Blood flow
- Other factors that may influence heat diffusion

Tissue effects include, in incremental order: expression of heat shock proteins[1], denaturation of proteins, photocoagulation, vaporization and ablation[2]. For Smart532, the effect of interest is photocoagulation. Analysis of clinical and laboratory experience indicates that irradiance of ~ 100-500 W/cm^2 , corresponding to heating the tissue by ~12-25°C above body temperature, is required for photocoagulation of tissues[2,3].

A.1.2. General Warnings and Precautions

Warning

- Lumenis and/or related entities assume no responsibility for parameters, techniques, methods or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, i.e. technique, proper power settings, intervals, durations, etc.
- Physicians should seek formal training from established courses on the use of the laser and its accessories. Any information given in this text is not intended to provide such instructions, and is not to be considered a substitute.

Caution

- The laser unit should be handled carefully. Maintenance and service should be performed only by Lumenis trained personnel.
- In using any delivery devices or accessories, attention must be paid to the specific instructions and precautions applicable to those devices. This manual and the appropriate delivery device operator manual should be carefully read and comprehended before use.

A.1.3. Adverse Effects (AEs)

Warning

Complications of laser therapy are the same as complications for any other surgical procedure. Some of these complications may be serious and could result in death or permanent blindness.

[1] C. Sramek, M. Mackanos, R. Spitler, L. Leung, H. Nomoto, C. Contag and D. Palanker, "Non-damaging retinal phototherapy: dynamic range of heat shock protein expression". *Invest. Opthalmol. Vis. Sci*., vol. 52, no. 3, pp. 1780-7, 2011.
[2] G. Kulkarni, "Laser-tissue interaction studies for medicine," *Bull Materials Sci*, vol. 11, pp. 239-44, 1988.
[3] J. Krauss and C. Puliafito, "Lasers in ophthalmology," *Lasers Surg Med*, vol. 17, no. 2, pp. 102-59, 1995.

A.1.3.1. Pain

Delivery of laser energy is occasionally associated with pain or discomfort. During the procedure, pain may be reduced by topical anesthesia or retrobulbar block. The extent and duration of pain following laser therapy are usually minimal.

A.1.3.2. Infection

The possibility of infection must be considered and treated accordingly, especially when laser energy is delivered via endoprobes.

A.1.3.3. Bleeding

The possibility of postoperative bleeding must be considered, and post-operative follow-up is advised. Laser irradiation may cause the regression newly formed vessels, thereby producing vitreous and subhyaloid hemorrhage. If laser application is applied close to the macula and with high power setting, there is a risk of disrupting the pigment epithelium and compromising the Bruch's membrane, thereby giving rise to foci of choroidal neovascularization which can bleed[4,5].

A.1.3.4. Visual Function

In some cases, extensive photocoagulation may cause a reduction in visual acuity secondary to macular edema, a reduction in peripheral vision, a reduction in the power of accommodation, loss of color vision (especially in the blue spectrum), loss of contrast sensitivity, a scotoma or photophobia[6,7,8]. Visual function may also be compromised by inadvertent delivery of laser energy to the fovea and parafoveal areas.

A.1.4. Non-Contact and Free-Beam Devices

Tissue effect may be controlled by altering the distance between hand-held fiber-optic delivery devices and the target tissue.

Once the treatment is completed, routine post-operative care is indicated according to the procedure done.

All recommendations for safe use of your laser system should be followed. Users should be aware of the recommended practices for the safe use of

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[4] A. Obana, B. Lorenz, A. Gassler and R. Birngruber, "The therapeutic range of chorioretinal photocoagulation with diode and argon lasers: an experimental comparison," *Lasers Light Ophthalmol*., vol. 4, pp. 147-56, 2009.
[5] P. Romero-Aroca, J. Reyes-Torres, M. Baget-Bernaldiz and C. Blasco-Suñe, "Laser treatment for diabetic macular edema in the 21st century," *Curr. Diabetes Rev*., vol. 10, no. 2, pp. 100-12, 2014.
[6] H. McDonald and H. Schatz, "Visual loss following panretinal photocoagulation for proliferative diabetic retinopathy," *Ophthalmology*, vol. 92, pp. 388-93, 1985.
[7] J. Evans, M. Michelessi and G. Virgili, "Laser photocoagulation for proliferative diabetic retinopathy," *Cochrane Database Syst. Rev*., 2014doi:10.1002/14651858.CD011234.pub2.
[8] F. P. A. Bandello, M. Del Borrello, N. Zemella and M. Isola, "“Light” versus “classic” laser treatment for clinically significant diabetic macular oedema.," *Br J Ophthalmol*, vol. 89, no. 7, pp. 864-70, 2005.

lasers in health care facilities, as described in ANSI Z136.3[9] and ANSI Z136.1[10]. Laser applications performed with non-contact devices are indicated throughout this manual by the icon shown on the left.

Laser applications using free-beam devices, such as slit lamps or laser indirect ophthalmoscopes, are indicated by the icon shown on the left.

A.2. Indications for Use

The Smart532 is intended for use in the treatment of ocular, otolaryngological, dermatologic and dentistry indications as listed below.

A.2.1. Ophthalmology

The indications for use in ophthalmology are:

- Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy
- Proliferative Diabetic Retinopathy (PDR)
- Retinal Tear
- Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO).
- Choroidal Neovascularization (CNV) secondary to Age-related Macular Degeneration (AMD)
- Central Serous Chorioretinopathy (CSCR)
- Trabeculoplasty for Primary Open Angle Glaucoma (POAG)
- Iridotomy / Iridoplasty for Angle-Closure Glaucoma (CAG)

A.2.2. Ear, Nose and Throat (ENT)

The indications for use in ear, nose and throat are:

- Stapedectomy
- Stapedotomy
- Myringotomies
- Lysis of Adhesions
- Control of Bleeding
- Removal of Acoustic Neuromas
- Soft Tissue Adhesion in Micro/Macro Otologic procedures.

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[9] American National Standards Institute. “Safe Use of Lasers in Health Care Facilities” ANSI Standard Z-136.3. New York: ANSI, 1430 Broadway, 1996.
[10] American National Standards Institute “Safe Use of Lasers” ANSI Standard Z-136.1. New York: ANSI, 1430 Broadway, 1993.

A.2.3. Dermatologic Applications

The indications for use in dermatology are:

- Pigmented lesion, including soar lentigines
- Vascular lesions, including cherry hemangiomas and angiokeratomas
- Extremities telangiectases, including facial and Leg telangiectases
- Cutaneous lesions
- Flat warts
- Dermatosis
- Papulosa Nigra

A.2.4. Dentistry Applications

The indications for use in dentistry are

- Frenectomy
- Treatment of oral mucous cyst
- Treatment of benign vascular lesions:
  - Capillary hemangioma
  - Hemorrhagic hereditary telangiectasia
  - Capillary/cavernous hemangiomas
  - Lymphangioma
  - AV malformation of the tongue
  - Hemangio-lymphangiomas
- Photocoagulation of superficial vessels
- Vaporization of superficial blood or lymph containing vessels.
- Treatment of superficial tongue lesions
- Tissue management and hemostasis for crown and bridge impressions.
- Incision and drainage for abscess
- Gingivoplasty/Gingivectomy
  - Operative procedures
  - Crown and bridge, gingival reduction
  - Crown lengthening
- Hyperplasia (Drug, irritation, Epulus).
- Hemostasis during dental procedures
- Operculectomy (Operculotomy)
- Excisional biopsy
- Free Ginvical Graft (Adjunct):
  - Hemostasis of donor site

- Hemostasis of graft site
- Vestibuloplasty
- Soften Gutta Percha
- Treatment of canker sores, herpetic lesions, and aphthous ulcers
- Laser-assisted bleaching/whitening

A.2.5 Device energy delivery options

Energy Delivery Option	Indication
SmartPulse	Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy, Proliferative Diabetic Retinopathy (PDR), Central Serous Chorioretinopathy (CSCR), Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO)
CW (Continuous Wave)	All Indications

A.3. Ophthalmic Photocoagulation

The Smart532 system emits a laser beam with a wavelength of 532 nm (green). This type of energy can be used to treat several ocular conditions in both the anterior and posterior segments of the eye. It is particularly well suited for treating the eye because it is not absorbed in aqueous media and has minimal effect on transparent tissues and materials. Hence the laser energy can efficiently penetrate the cornea, aqueous humor, lens, and vitreous humor to target tissues of interest such as the retina in the posterior segment and the trabecular meshwork in the anterior segment.

Laser energy can be delivered by means of a slit lamp, a laser indirect ophthalmoscope or an endoprobe.

A.3.1. Ophthalmology Indications for Use

See Section A.2.1.

A.3.1.1. Clinical conditions and associated treatment

Condition	Treatment
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy	Focal/Grid laser
Proliferative Diabetic Retinopathy (PDR)	Pan-retinal photocoagulation
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO).	Grid, sectoral or pan-retinal photocoagulation
Central Serous ChorioRetinopathy (CSCR)	Focal/Grid laser
Choroidal Neovascularization (CNV) secondary	Focal/Grid laser

to Age-related Macular Degeneration (AMD)	
Retinal Tear	Barrage laser treatment
Primary Open Angle Glaucoma (POAG)	Trabeculoplasty
Angle-Closure Glaucoma (ACG)	Iridotomy/Iridoplasty

A.3.2. Contraindications in Ophthalmology

Laser treatment is contraindicated when an appropriate procedure cannot be performed safely. This could occur when tissue targets cannot be visualized properly. Corneal opacities, cataract formation and vitreous hemorrhage can all interfere with the physician's view of target tissues, possibly leading to inadvertent photocoagulation of tissues/structures adjacent to the tissue/structure of interest. Treatment should be delayed until the ocular media problem resolves or is treated. If it is not possible, an alternative form of therapy should be considered.

A.3.3. Slit Lamp

Laser energy is most commonly delivered to the eye by means of a slit lamp that has been specially adapted for use as a laser delivery system. In this case, the delivery system includes a lens system that focuses the laser energy and changes the size of the laser spot in the slit lamp observation plane. It may include a mechanism that manipulates the position of the laser beam without moving the slit lamp. The laser energy is delivered to the slit lamp by means of a flexible fiber optic.

For most procedures, a contact lens is used to direct the laser energy to the part of the eye being treated. The contact lens may have mirrors so that laser energy can reach peripheral areas of the retina or the irido-corneal angle (e.g., the trabecular meshwork). The contact lens is also instrumental in order to inhibit eye movements and to prevent eyelid closure, so that laser energy can be delivered effectively and safely.

A.3.4. Laser Indirect Ophthalmoscope (LIO)

In young children or in physically impaired, disabled or unconscious patients, the delivery of laser energy through a slit may not be possible. In these cases, examination is done in the supine position, using a laser indirect ophthalmoscope (LIO).

A.3.5. Endoprobe

Media opacities such as a non-transparent cornea, a dense cataract or a vitreal hemorrhage can obstruct the delivery of laser energy through a slit lamp or an LIO. A solution is to circumvent these media opacities by delivering the laser energy via an endoprobe (a disposable fiber optic). In addition, laser delivery via an endoprobe is often employed in the operation room, as an adjunct to vitreo-retinal surgery.

The endoprobe is inserted in the ocular globe via a scleral incision done at the pars plana level. The size of the laser burn can be controlled by changing the distance from the tip of the endoprobe to the target: the closer the tip probe is from the retina, the smaller and more fluent (i.e., higher energy density) is the spot of influence.

A.3.6. Ophthalmology Precautions

The following precautions should be taken when using laser energy in ophthalmic procedures:

- Excessive power density (power/area) may cause unwanted target tissue damage. Hence, caution must be exercised when reducing the spot size, as the spot size is inversely related to the power density: decreasing the spot diameter by 1/x multiplies the power density by x^2. For example, halving the spot diameter quadruples the power density.
- Approximate power settings are usually found by titration using a continuous waveform at a peripheral location, starting from low values and gradually increasing the power, until the desired endpoint (such as blanching in posterior segment indications) is achieved. Once power settings P_{vis} are identified through titration with a continuous waveform, if the user desires to operate in SmartPulse Mode then the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references)
- Increased pigment density can increase the absorption of laser energy, thereby increasing the thermal effect. Physicians should take account of this fact when intending to treat areas of increased pigmentation, either by reducing the power setting, or by treating areas with less pigmentation.
- Opacities in the ocular media may absorb the laser light and cause inadvertent and undesirable thermal damage to the tissues in which the opacities are located. Opacities in a patient's ocular media include makeup remnants in the corneal tear film, corneal lesions, pigment or blood on the surfaces of the crystalline lens, and cataract formation. Prior to laser therapy, debris should be removed from the patient's tear film.
- Direct treatment of vascular or vascularized structures can cause intraocular bleeding that can impair a patient's vision as well as the physician's ability to complete the laser procedure. Vascular/vascularized structures should be treated with caution, using treatment patterns and parameters appropriate for the specific indication and conditions.

A.3.7. Ophthalmology Warnings

- Only appropriate tissue targets should be subject to photocoagulation.
- Attention should be paid to avoid treating major retinal vessels, as vitreous hemorrhage and serious visual loss could occur.
- The optic nerve head should not be coagulated, as severe and permanent visual loss could occur.
- Inadvertent macular photocoagulation, especially close to the fovea (within 300-500µm), can cause severe and permanent visual loss.
- Excessively high power settings should not be used, as they can cause damage to tissues adjacent to the target of interest.

A.4. Treatment Parameters in Ophthalmology

Ophthalmic problems are successfully treated with laser photocoagulation. Treatment parameters such a power, duration of the pulse and spot size depend on a variety of factors including the type of tissue to be treated, the intensity of the lesion desired, and the individual pigmentation of tissue targets.

Smart532 comes with two types of waveforms: Continuous waveform (CW) and SmartPulse.

A.4.1. Parameters in continuous waveform (CW)

In CW, the stimulus is a single square pulse of duration 10-500 msec. The appropriate power is usually found by titration: the power is initially set to a low level and then increased gradually until the desired tissue effect is obtained. Table A-1 lists recommended clinical treatment parameters for intended medical conditions using CW pulse:

Table A-1: Recommended clinical treatment parameters in CW for intended medical conditions

Treatment (Mode)	*Power (mW)*	*Required Tissue Reaction*	*Exposure duration (sec)*	*Spot size (µm)*
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy[11]	100-300	mild grey-white burn	0.05-0.5	50-200
Proliferative Diabetic Retinopathy (PDR)[12,13]	250-750	Whitening	0.02-0.1	100-500
Central Serous ChorioRetinopathy (CSCR)[14]	150-400	Light grayish	0.02-0.2	50-200
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO)[12]	175-410	Grey-white	0.02-0.2	100-400
Retinal Tear[15]	175-575	Grey-white	0.01-0.4	200-400
Iridotomy for angle closure (Stretch)[16]	500	Stroma at the iridotomy site becomes thin and tense	0.2	500
Iridotomy for angle closure (Penetration) [16]	1000	Penetration , until a hole of 0.2 mm in the iris is formed	0.02-0.2	50
Trabeculoplasty for primary open angle glaucoma[17]	400-600	Blanching	0.1	50
CNV[18]	200	Mild whitish	0.2	150-250

[11] P. Romero-Aroca, J. Reyes-Torres, M. Baget-Bernaldiz and C. Blasco-Suñe, "Laser treatment for diabetic macular edema in the 21st century," *Curr. Diabetes Rev.*, vol. 10, no. 2, pp. 100-12, 2014.

[12] Y. Paulus and M. Blumenkranz, "Proliferative and nonproliferative diabetic retinopathy," *One Network*, 2013.

[13] C. Sanghvi, R. McLauchlan, C. Delgado, L. Young, S. Charles, G. Marcellino and P. Stanga, "Initial experience with the Pascal photocoagulator: a pilot study of 75 procedures.," *Br J Ophthalmol*, vol. 92, no. 8, pp. 1061-4, 2008.

[14] L. Ficker, G. Vafidis, A. While, P. Leaver, "Long-term follow-up of a prospective trial of argon laser photocoagulation in the treatment of central serous retinopathy", *Br J Ophthalmol*, vol 72, pp. 829-34, 1988

[15] M. Muqit, C. Sanghvi, R McLauchlan, C. Delgado, LB Young, SJ Charles, GR Marcellino and PE. Stanga. "Study of clinical applications and safety for Pascal_ laser photocoagulation in retinal vascular disorders". *Acta Ophthalmologica* 90:155-161, 2012

[16] R. Harrad, K. Stannard and J. Shilling, "Argon laser iridotomy," *Br J Ophthalmol*, vol. 69, no. 5, pp. 368-72, 1985.

[17] E. Rosenfeld, G. Shemesh and S. Kurtz, "The efficacy of selective laser trabeculoplasty versus argon laser trabeculoplasty in pseudophakic glaucoma patients," *Clin Ophthalmol*, vol. 6, pp. 1935-40, 2012.

[18] L.V. Angioletti, P.J. Colquhoun, A.D. Kulik, E.H. Malpica , "Indirect photocoagulation of subfoveal choroidal neovascularization in age-related macular degeneration", *Bull N Y Acad Med*, vol. 67(4), pp. 389-98, 1991

A.4.2. Parameters in SmartPulse

In SmartPulse, the stimulus is a train of brief pulses (see Table A-2). The characteristic use of SmartPulse is when a sub-visible tissue reaction is requested. In such a case, power is estimated by titration done at a peripheral retinal location: at this location, using a continuous waveform the power is gradually increased to P_{vis}, until a barely visible burn is obtained. In SmartPulse, the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references).

Because the tissue reaction is sub-visible, physicians might not recognize if an area has been treated, leading to under-treatment (not treating an area) or over-treatment (treating over an area which was previously treated). Different strategies may be employed to address this issue.

For example, visible landmarks (e.g., light gray burns) obtained with continuous waveforms could delimit an area to be treated (for example, the corners of a square). The area within the delimited area could be then filled with sub-visible spots.

Another possibility is for the physician to draw a treatment plan before the actual treatment, clearly marking the fovea, the major arcades, the arterioles and an outline of the area to be treated. During treatment, treated areas could then be marked on the outlined areas in the treatment plan, thereby preventing the physician from treating the same areas twice, and indicating him which areas were not yet treated.

With gathering more experience using the system, physicians that treat in the sub-visible range will typically adopt their own strategies.

Table A-2 lists recommended clinical treatment parameters for intended medical conditions using SmartPulse:

Table A-2: Recommended clinical treatment parameters in SmartPulse for intended medical conditions

Indication	*Power (mW)*	*References (links)*	*SmartPulse duration (ms)*	*SmartPulse interval (ms)*	*Exposure duration (sec)*	*Spot size (µm)*
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy[19]	1.2 X test burn CW power	Lavinsky et al 2011	0.1	1.9	0.3	125
		Kwon et al 2014	0.2	1.8	0.02	100
		Laursen et al 2004	0.1	1.9	0.1	125
		Lutrull et al 2005	0.1	1.9	0.3	125
		Nakamura et al 2010	0.3	1.7	0.2	200
		Ohtman et al 2014	0.3	1.7	0.3	75-125
		Vujosevic et al 2010	0.1	1.9	0.2	100
		Range:	**0.1-0.3**	**1.7-1.9**	**0.02-0.3**	**75-200**
		Most commonly used value:	**0.1**	**1.9**	**0.3**	**125**
Proliferative Diabetic Retinopathy (PDR) [20]	2.0 X test burn CW power	Desmettre et al 2006	0.3	1.7	0.2	125
		Luttrull et al 2008	0.3	1.7	0.2	500
		Moorman & Hamilton 1999	0.1-0.3	1.7-1.9	0.1-0.3	200-500
		Range:	**0.1-0.3**	**1.7-1.9**	**0.1-0.3**	**125-500**
		Most commonly used value:	**0.3**	**1.7**	**0.2**	**200**
Central Serous Chorio Retinopathy (CSCR) [21]	2.0 X test burn CW power	Koss et al 2012	0.3	1.7	0.2	125
		Breukink et al 2015	0.1	1.9	0.2	125
		Bandello et al 2003	0.2-0.3	1.8-1.9	0.2	200
		Range:	**0.1-0.3**	**1.7-1.9**	**0.2**	**125-200**
		Most commonly used value:	**0.3**	**1.7**	**02**	**125**
Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO) [22]	2.0 X test burn CW power	Inagaki et al 2014	0.3	1.7	0.3	200
		Ohkoshi et al 2010	0.3	1.7	0.2	125-200
		Moorman & Hamilton 1999	0.1-0.3	1.7-1.9	0.1-0.3	200-500
		Parodi et al 2006				
		Range:	**0.1-0.3**	**1.7-1.9**	**0.1-0.3**	**125-500**
		Most commonly used value:	**0.3**	**1.7**	**0.3**	**200**

[19] D. Lavinsky, J.A. Cardillo, L.A.S. Meli, A. Dare, M.E. Farah, and R. Belfort Jr., "Randomized Clinical Trial Evaluating mETDRS versus Normal or High-Density Micropulse Photocoagulation for Diabetic Macular Edema" , *IOVS*, vol. 52(7), pp. 4314-23, 2011

[20] T.J. Desmettre, S.R. Mordon, D.M. Buzawa, and M.A. Mainster "Micropulse and continuous wave diode retinal photocoagulation: visible and subvisible lesion parameters" , *Br J Ophthalmol*, vol. 90, pp. 709-12, 2006

[21] M.J. Koss, I. Berger, F.H. Koch, "Subthreshold diode laser micropulse photocoagulation versus intravitreal injections of bevacizumab in the treatment of central serous chorioretinopathy", *Eye*, Vol. 26, pp. 307-14, 2012

[22] K. Inagaki, K. Ohkoshi, S. Ohde, G.A. Deshpande, N. Ebihara and A. Murakami, Subthreshold Micropulse Photocoagulation for Persistent Macular Edema Secondary to Branch Retinal Vein Occlusion including Best-Corrected Visual Acuity Greater Than 20/40", *J Ophthalmol*, Epub 2014, Sep 4, 2014

A.5. Posterior Segment Laser Procedures

Note

- Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.
- Refer to the Ophthalmology references in this chapter for literature regarding the use of the laser in retinal laser procedures.

A.5.1. Adverse Effects and Complications

Warning

- The most common complication is increased macular edema secondary to pan-retinal photocoagulation, usually with a concurrent decrease in visual acuity. Visual acuity loss is the result of redirection of the blood flow from the shunting vessels in the mid-periphery toward the macular region. In addition, blowout hemorrhages from areas of neovascularization, particularly on the optic nerve, have been observed. These may be caused by an increase in peripheral resistance secondary to photocoagulation, or by an inadvertent Valsalva maneuver by the patient.
- Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician.

Macular striae and increases in vitreoretinal traction are occasionally observed, particularly in advanced diabetic retinopathy. These areas, as well as zones along the vitreous base, should be observed closely so that pars plana vitrectomy can be used, if necessary, to alleviate excessive vitreoretinal traction caused by pan-retinal photocoagulation.

In rare cases, rapidly maturing cataract or lenticular opacities developed as a result of photocoagulation[23].

[23] Straub W. Complications after photocoagulation and cryotherapy. *Klin Monbl Augenheikd* 171:317-21, 1977.

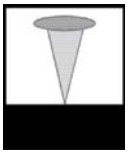
A.5.2. Patient Warnings

Warning

- Following photocoagulation, patients should be cautioned against any activity that could increase the venous pressure in head, neck, or eyes, such as straining, lifting, or holding their breath. Patients should be advised to sleep with the head of their bed elevated 15 to 20°.
- Patients should be cautioned against stifling a sneeze, as this may raise ocular blood pressure to a high level. Vigorous nose blowing should also be discouraged. Rubbing the eyes following photocoagulation may disrupt blood vessels inside the eyes. Sneezing and coughing should be controlled with cough syrup or other medications.
- Patients should be cautioned, however, against the use of medications such as nose drops, sprays, inhalators, or other medications that contain ephedrine or epinephrine, because these drugs tend to elevate systemic pressure.
- Immediately following treatment, patients should avoid altitudes over 2,400 m / 8,000 ft. (commercial aircraft cabins are pressurized below this altitude).

A.5.3. Guidelines for Use

- For retinal laser treatments, the pupil should be dilated.
- Topical anesthetic is normally adequate, but occasionally a retrobulbar block is needed.



- A contact lens specifically designed for use with laser energy is placed on the eye (note: a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard both to the patient and the physician). Such a contact lens allows the physician to visualize and treat peripheral areas of the retina which otherwise cannot be reached.
- The power setting depends on a multitude of conditions, such as spot size, pulse duration, pigmentation and turbidity of the vitreous. The standard procedure is to find the approximate power by titration using a continuous waveform, done at a peripheral retinal location: titration is started with a low power that produces no visible reaction. The power is then gradually increased until a blanching (faint whitening) of the retinal spot occurs. Power setting for retinal procedures is usually 250-750 mW, though lower (down to 50 mW) or higher (up to 1,000 mW) are sometimes used. Once power settings P_{vis} are identified through titration using a continuous waveform, if the user desires to operate in SmartPulse Mode then the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references)
- Tissue reaction depends also on pulse duration: longer pulse durations result in more thermal energy and more temperature increases. For

procedures performed on slit lamp or LIO, the pulse duration should be kept at 0.5 sec or less, to ensure that during treatment the patient does not move.

- Spot sizes are usually 200-1000 µm. In some cases, such as when treating close to the center of the macula, smaller spot size such as 50-100 µm should be used, so as to prevent inadvertent targeting of the fovea.

- For treatment of diabetic retinopathy in advanced (proliferative) stages, pan-retinal photocoagulation (PRP) is performed: The ischemic conditions characteristic of this condition are alleviated by confluent photocoagulation of 30-50% of the retina. Care should be taken to exclude the macula. Laser burns should be applied in a checker-board pattern, usually with spacing of 0.6-1.0 spot size between adjacent burns. This procedure requires ~1000-2000 burns. It may be split in two or more consecutive sessions.

-

A.6. Anterior Segment Laser Procedures

Note

- Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.
- Refer to the Ophthalmology references in this chapter for literature regarding anterior chamber laser procedures.

A.6.1. Uses

Other uses of the laser in ophthalmology involve the anterior segment of the eye. The most common procedures are performed to reduce the intraocular pressure in angle closure glaucoma (with iridotomy) and in open angle glaucoma (with trabeculoplasty).

A.6.2. Warnings

Warning

- Following iridotomy or trabeculoplasty, intraocular pressure (IOP) should be closely monitored.
- Hemorrhage from the trabecular meshwork occasionally occurs and is manifested as an ooze of blood from Schlemm's canal to the site of laser impact. This can be easily stopped by increasing the pressure of the gonioprism to the cornea.
- Pupillary distortion may be encountered if the iris root or peripheral iris has been treated. This distortion may or may

not be permanent, depending on the severity of the accidental damage.

- Medical therapy should be continued following laser Trabeculoplasty[24].
- Peripheral anterior synechiae may occur when the posterior portion of the trabecular meshwork or other structures posterior to the meshwork are treated. These are best avoided by meticulous delivery of a well-focused laser beam.

Transient corneal epithelial burns have reportedly resolved within 1 week without scarring. Endothelial burns are rarely encountered when careful focusing is employed.

A.6.3. Adverse Effects

A "snuff out" of the central visual acuity has been reported as a complication of an intraocular pressure spike. Patients with advanced field loss should be carefully treated and monitored. Progressive field loss following laser trabeculoplasty is possible, even in the presence of seemingly adequately controlled intraocular pressure[25].

Rarely, severe iritis may occur, related to either an unusual patient response or improper spot location.

[24] J. Wise, "Errors in laser spot size in laser trabeculoplasty," *Ophthalmology*, vol. 91, no. 2, pp. 186-90, 1984.
[25] D. Spiegel, E. Wegscheider and O. Lund, "Argon laser trabeculoplasty: long-term follow-up of at least 5 years," *Ger J Ophthalmol*, vol. 1, no. 3-4, pp. 156-8, 1992.

A.6.4. Guidelines for Use

A.6.4.1. Iridotomy

Iridotomy is performed for treatment of angle- closure glaucoma. The photocoagulator can be used to thin a thick iris before perforation, where perforation can be done with Nd:YAG or with a green laser with a small spot size. The desired result is a perforation of approximately 150-200 µm (diameter) through the iris. The aqueous humor can then flow through this perforation, thereby relieving the intraocular pressure (IOP).

1. A rosette of 4-5 burns, approximately 500 µm in diameter, are made on the iris about 2/3 of the distance from pupillary border to the iris root. These burns are made with a typical power of 500 mW and a typical pulse duration of 0.2-0.5 sec. The purpose of these large burns is to soften the iris and to find a good site for the smaller, penetrating burn for finalizing the perforation

2. At the chosen site for final perforation, the iris is penetrated with either Nd:YAG laser or, if unavailable, with green laser (50 µm spot size, a power setting of 1200-1500 mW and a pulse duration of 0.2 -1.0 sec).

Warning

Glaucoma medications should be continued post-operatively. Occasionally, following iridotomy the intraocular pressure may briefly rise (a phenomenon termed IOP spike). In extreme cases the IOP spike the intraocular pressure to dangerous levels. For this reason, the patient should be closely monitored after the procedure, and glaucoma medications should be continued.

A.6.4.2. Trabeculoplasty

Trabeculoplasty is used to control open angle glaucoma. Laser burns are scattered around the trabecular meshwork. The mechanism of action is believed to be the scarring and shrinking of tissue at the laser burns, so that the trabecular meshwork between the laser burns is stretched. This mechanical stretching is thought to increase the outflow through the affected trabecular meshwork, thereby reducing the IOP.

1. Laser burns are placed at the border of the pigmented and the non-pigmented meshwork. Typical settings are a 50 μm spot size, a power setting of 300-1000 mW and a pulse duration of 0.1 sec. The immediate result of the laser burn should be a depigmentation of the trabecular meshwork and/or minimal bubble formation at the site of the laser burn.

2. Typically, 50 burns are homogenously spaced along 180° of the trabecular meshwork. Usually the inferior 180° are treated first, since this portion tends to be more pigmented and laser energy is hence better absorbed.

3. IOP should decrease within several weeks. Usually, this decrease is maintained for 1-2 years or more.

A.7. Ophthalmology Bibliography

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A.8. Ear, Nose and Throat (ENT) Laser Applications

> ***Note***
>
> Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.

The laser is indicated in procedures where color-specific absorption, small spot size, and high power densities are required. The laser beam may be used to photocoagulate, vaporize, or cut tissue by utilizing the appropriate beam delivery accessory and varying spot size, output power, and pulse duration.

A.8.1. Indications

- The laser is indicated in procedures where color-specific absorption, small spot size, and high power densities are required. The laser beam may be used to photocoagulate, vaporize, or cut tissue by utilizing the appropriate beam delivery accessory and varying spot size, output power, and pulse duration.
- The laser has been shown to achieve satisfactory results in stapedotomy, stapedectomy, tympanoplasty with fascia graft[26], myringotomies[27], control of bleeding, lysis of adhesions, and soft tissue adhesion ("spot welding")[28].

A.8.2. Contraindications

- One investigator reported that the laser was not indicated in the removal or vaporization of cortical bone or dense bone as found in obliterative otosclerosis[26].
- Uninflamed mastoid cases, such as endolymphatic sac surgery and cochlear implants do not benefit from the laser.

A.8.3. Uses

- The laser is indicated in both micro- and macro-otologic procedures.
- The selective absorption of the laser wavelength by color permits the surgeon to work on closely-approximated soft tissue which is colored red, but the laser is reflected and/or transmitted by adjacent non-red tissue.
- The laser may be used for procedures done in the hospital for in-patient or out-patient procedures. The use of the laser is not a

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[26] L.H. Escudero L, A.O. Castro, M. Drumond, S.P. Portom D.G. Bozinis, A.F. Penna, and E. Gallego Lluesma, "Argon Laser in Human Tympanoplasty", *Arch Otolaryngol* 105(5):252-3, 1979

[27] J.R. DiBartolomeo, and M. Ellis, "The Argon Laser in Otology", *Laryngoscope* 90(11 Pt 1):1786-96, 1980

[28] T.M. McGee, "The Argon Laser in Surgery for Chronic Ear Disease and Otosclerosis", *Laryngoscope* 93(9):1177-82, 1983

contributing factor in deciding if a procedure is done on an in- or an out-patient basis.

A.8.4. Warnings

Warning

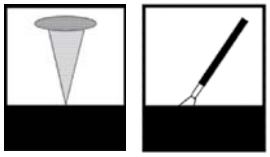
- The physician should be well acquainted with standard operating procedures and the use of the operating microscope. Formal instruction in these areas is available through established programs.
- Although hemostasis is to be expected from use of the laser, coagulation may prove difficult in highly vascular lesions and the use of means other than the laser may be needed.

A.8.5. Precautions

- Blood should not be allowed to contaminate or color the perilymph surface. A bloodless field will help prevent absorption of the laser energy by the clear perilymph[29].
- The usual precautions observed for general anesthesia for any purpose, and for otological procedures specifically, are to be followed.

A.8.6. Guidelines for Use

Formal instruction in operative procedures is the responsibility of the physician and should be obtained on a formal basis from recognized sources.



Caution

The operator should be aware of the irradiances required for specific tissue effects as are outlined throughout this manual, as well as detailed in the appropriate delivery system operator manual.

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[29] J.R. DiBartolomeo, "The Argon and CO_2 Lasers in Otolaryngology: Which One and Why?", *Laryngoscope* 91(9 Pt 2 Supp 26): 1-16, 1981

- J.R. DiBartolomeo, “The Argon and CO_2 Lasers in Otolaryngology: Which One and Why?”, *Laryngoscope* 91(9 Pt 2 Supp 26): 1-16, 1981

A.10. Delivery Devices and Accessories

A.10.1. Filters

Lumenis offers fixed and moving physician’s filters for integrated slit lamps, indirect ophthalmoscope attachments, and microscopes. These filters shield the physician's or observer's eyes from laser light and allow a normal field of view when the laser is in the Ready mode. The filters contain high quality optical elements for high visibility and easily attach to operating room microscopes. For a list of available filters, contact your local Lumenis representative.

A.10.2. Acculite Endoprobe

Fiber-optic endoprobes, such as the Lumenis Acculite endoprobe, are useful for photocoagulation of the posterior segment, in procedures such as pan-retinal photocoagulation, barrage of retinal tears, and treatment of choroidal neovascularization secondary to age-related macular degeneration.

Spot sizes delivered through the Acculite endoprobes vary, depending on the distance of the Acculite endoprobe tip from the treatment site. Power requirements vary from 300-1000 mW, depending on the type of treatment and the desired tissue effect.

Endoprobes are supplied pre-packaged and sterile for one-time use only. Fibers are precision-cut and polished to rigid optical specifications to provide maximum energy delivery. An exterior jacket protects the fiber from damage. Fibers and probes attach to the fiber port on the front panel of the laser.

Fibers can be damaged or can injure a patient if not used carefully; therefore, the physician should make the following checks before activating the laser:

- Ensure that the fiber is fully inserted into the laser aperture. This will allow the best efficiency through the laser fiber.
- Care must be taken when handling the optical fiber not to bend or kink it excessively since this could fracture the fiber allowing laser light to emerge from the fracture site.
- Identify all tissues that lie in the potential path of the laser beam to avoid laser exposure to tissues other than those undergoing treatment.
- Carefully identify and protect all relevant anatomic structures from possible undesired exposure.
- Ensure that the probe tip does not come into direct contact with tissue when treating; if it does, the optical efficiency of the fiber will be compromised.
- Use a suction tip in the treatment area to evacuate the laser plume.

A.10.3. Fluence of laser energy delivered by endoprobe

Fluence is the measurement of energy delivered in relation to the area of the treatment beam or energy density. Irradiance is the measurement of power delivered in relation to the area of the treatment beam or power density. This measurement is helpful in determining the power setting to use for a particular treatment. Fluence and irradiance for various power and duration settings can be calculated using the following equations:

$$F = \frac{E}{A}$$

$$I = \frac{P}{A}$$

$$E = P \ T_S$$

$$A = \pi \left(\frac{d}{2}\right)^2 = 0.7854 d^2$$

Where:

F = Fluence (J/cm^2)

I = Irradiance (W/cm^2)

E = Energy (J)

P = Power (W)

T_S = Pulse duration (sec)

A = Spot area (cm^2)

d = Spot diameter (cm)

Table A-3 lists resulting spot sizes using approximate irradiance and fluence for a delivery power of 1 W, pulse durations of 0.5 s and 1.0 sec, and a fiber diameter of 300 or 600 µm.

Table A-3: Irradiance and Fluence at 1 W and 0.5 Sec and 1.0 Sec Delivered

Fiber Diameter (µm)	Spot Size (mm)	Spot Size Area (cm^2)	Irradiance (W/cm^2)	Fluence at 1 Sec (J/cm^2)	Fluence at 0.5 Sec (J/cm^2)
300	0.3	0.000707	1415	1415	707
	3.0	0.0707	14	14	7
600	0.6	0.00283	354	354	177
	3.0	0.0707	14	14	7

Figure A-1 shows the spot size as a function of distance from the fiber. Figure A-2 illustrates the relationship between irradiance and the distance from the fiber tip.

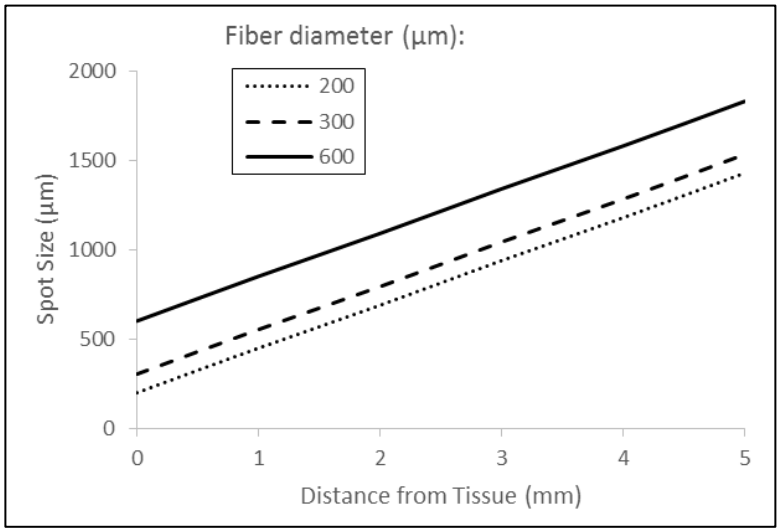

Figure A-1: Spot Size versus Distance of fiber tip from Tissue

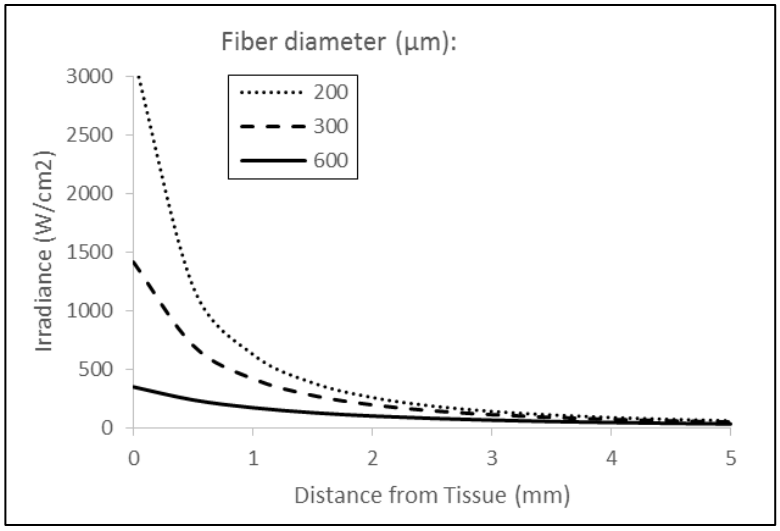

Figure A-2: Irradiance versus Distance of Fiber Tip from Tissue

Table A-4 lists the irradiance obtained at 1 W delivered power for 200, 300 and 600 µm diameter fiber optic accessories held from 0 to 5 mm from the tissue target. Taking into consideration the irradiance which is effective for each procedure, the user can determine the different laser power settings.

Table A-4: Spot Size and Irradiance at 1 W Delivered

Fiber Optic	*Distance from tissue (mm)*	*Spot Size (mm)*	*Irradiance (W/cm^2)*
200 µm	0	0.20	3183
	1	0.45	628
	2	0.69	267
	3	0.94	145
	4	1.18	91
	5	1.43	62
300 µm	0	0.30	1415
	1	0.55	421
	2	0.79	204
	3	1.04	118
	4	1.28	78
	5	1.53	54
600 µm	0	0.60	354
	1	0.85	176
	2	1.09	107
	3	1.34	71
	4	1.58	51
	5	1.83	38

A.10.4. Laser Indirect Ophthalmoscope (LIO)

Note

Users should be aware of the general laser warnings, precautions, and adverse effects out-lined in the **General Information** section in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

A.10.5. Uses

The LIO is used for treatment of retinal lesions in the peripheral fundus, anterior to the equator. Other uses include extending pan-retinal photocoagulation further anterior than can conveniently be reached with a conventional slit lamp laser photocoagulator, retinal photocoagulation in patients with media opacities where conventional photocoagulation with a slit lamp is difficult or impossible, and treatment of patients limited to the supine position.

A.10.6. Warnings

- Precautions pertaining to laser safety should be carefully observed: requiring the wear of laser safety goggles by all individuals present in the room, posting warning signs at all entrances to the area where the laser is being used, and using only nonflammable drapes and anesthetics.
- The LIO should be carefully inspected before each use to be sure that it is not damaged.

A.10.7. Guidelines for Use

- The LIO can be configured at the factory for use with a Lumenis argon laser, krypton laser, or diode-green (Smart532) laser. Only the filter material and electrical characteristics differ.
- The LIO consists of an indirect ophthalmoscope that has been modified with a fixed laser safety filter and a lens system to focus the laser beam.
- Like an unmodified indirect ophthalmoscope, the LIO is mounted on a headband. The LIO is connected to the laser by a fiber-optic which is plugged into the laser in the same way that any Lumenis fiber-optic is connected to the laser.
- The LIO is designed to conveniently deliver laser energy to the far periphery of the fundus. With the indirect ophthalmoscope, the doctor has a clearer view of the areas of the fundus which are anterior to the equator of the eye than can be obtained using a slit lamp.
- Another advantage is the ability to position the patient to take advantage of gas bubbles that are injected into the eye during pneumatic retinopexy to force the retina into the proper position (so that it is resting against the choroid). If the laser treatment can be performed when the retina is in this position, the retina can be attached using the laser and may be less likely to detach again. If the patient can be positioned so that the retina can be treated without the laser beam

having to pass through the gas bubble, it makes the laser treatment easier.

- A third potential advantage over conventional slit lamp delivery systems is the fact that the LIO does not employ a contact lens to direct the laser beam. Because there is no contact with the eye, it may be possible to treat eyes that are injured and cannot have any force exerted on them.
- The LIO can also be used with scleral depression in place of, or as an adjunct to cryotherapy. It has been theorized that the use of cryotherapy scatters cells from the retinal pigment epithelium, which may lead to proliferative vitreoretinopathy. There is no evidence that laser treatment scatters these cells, and so it may be an improved treatment modality for retinal reattachment procedures.
- The laser spot size can be changed by varying the distance between the LIO and the condensing lens, and by varying the distance from the condensing lens to the retina. Both of these distances are limited if a clear view of the fundus is to be obtained. However, the ability of the user's eyes to accommodate changing focal length can have an effect on the laser spot size if the user is not aware of this phenomenon while adjusting the image of the retina.
- Because this condensing lens is the last optical element that the laser beam passes through, the power and position of this lens will have an effect on the laser beam in terms of spot size and the focus of the image of the laser beam on the retina.
- For most eyes, the image of the retina formed by the hand-held lens is real, inverted, and located a few centimeters above the hand-held lens.

The magnification, **M**, of the two-lens system created by the hand-held lens and the eye is:

$$M = \frac{60\ Diopter}{Power\ of\ hand-held\ lens}$$

Where 60 diopter is the refractive power of a “standard” eye. The magnification of an indirect ophthalmoscope using a 20-diopter hand-held lens is 3X, and the magnification of the system when using a 30-diopter lens is 2X.

Because the laser beam is a converging beam, the size of the laser beam in the retinal image plane can be varied by moving the point of focus of the laser beam out of the laser beam's object plane (retinal image plane). Figure A-1 shows how altering working distance affects retinal spot size. Note that because the laser beam divergence angle of small spot sizes is greater than the laser beam divergence angle of large spot sizes, working distance has a greater effect on the small spot sizes.

A.10.8. Slit Lamps and LaserLinks for Slit Lamps

Note

Users should be aware of the general laser warnings, precautions, and adverse effects out-lined in the **General Information** section in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

A.10.9. Description

Several integrated slit lamp models are available from Lumenis, as are LaserLinks for adapting your existing diagnostic slit lamp to the Smart532. LaserLinks are available for Zeiss and Haag-Streit, as well as most third-party equivalent slit lamps.

The integrated slit lamp with laser delivery system is designed to project a focused laser beam into the focal plane of the microscope. The delivery system provides spot size zooming over a range of 50 - 1000 µm. It also incorporates an internal protective physician's filter.

A.10.10. Guidelines for use

Refer to the appropriate delivery system operator manual for specific instructions regarding the use of a slit lamp.

A.11. Indirect Ophthalmoscope Bibliography

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