# Selecta II™

## Frequency-doubled, Q-switched Nd:YAG (532 nm) Ophthalmic Laser Operator Manual

Lumenis®
Energy to Healthcare

Please note that while every effort has been made to ensure that the data given in this document is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.



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# Operation

## Overview

# Introduction

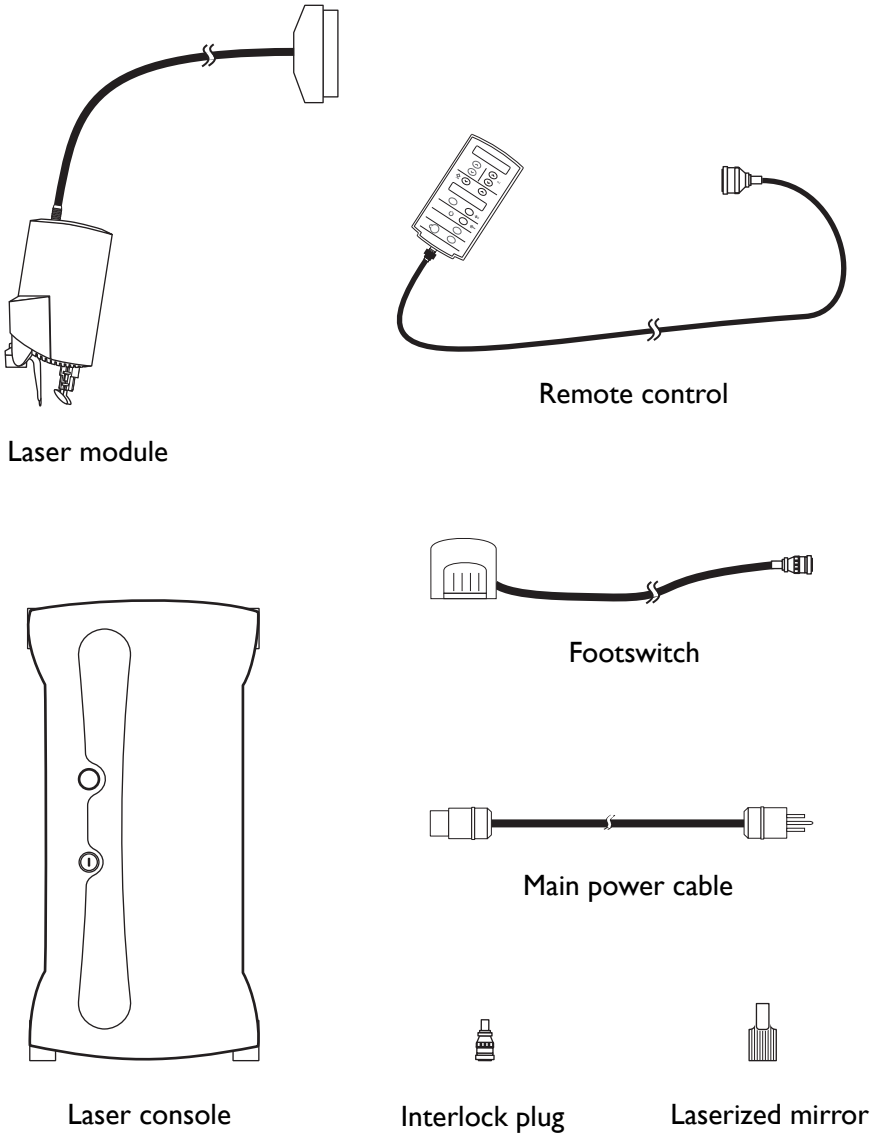
The Lumenis Selecta II laser introduces a new approach to ophthalmic laser surgery for the treatment of patients with open-angle glaucoma. Using an innovative short-pulse technology, the Selecta II delivers the necessary wavelength and energy to perform laser trabeculoplasty. The complete Selecta II system comprises a laser delivery module that mounts to your existing slit lamp, a convenient remote control, and a laser console containing the power supply.

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 local Lumenis representative.

⚠ **WARNING -** Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and 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.

# Selecta II Components

The Selecta II laser system comprises a laser module, a remote control, a laser console, a footswitch, and all of the electrical and fiber optic cables necessary for proper connection. Other components necessary for operation, such as an interlock plug and laserized mirror, are also included.




Selecta II components

## Laser module

The laser module attaches to a standard diagnostic slit lamp, enabling the laser module to be used as a therapeutic laser device. It houses the treatment and aiming beams, laser source, and associated optics.

## Remote control

The remote control is the control panel for the Selecta II laser. The remote control allows you to select treatment settings, such as energy and aiming beam intensity.

## Laser console

The laser console houses the main power key switch, emergency off button, control electronics, and power supply. The laser console is the central unit to which all of the other laser components attach.

## Footswitch

The footswitch activates the laser treatment beam.

## Main power cable

The main power cable connects the laser to the main power source.

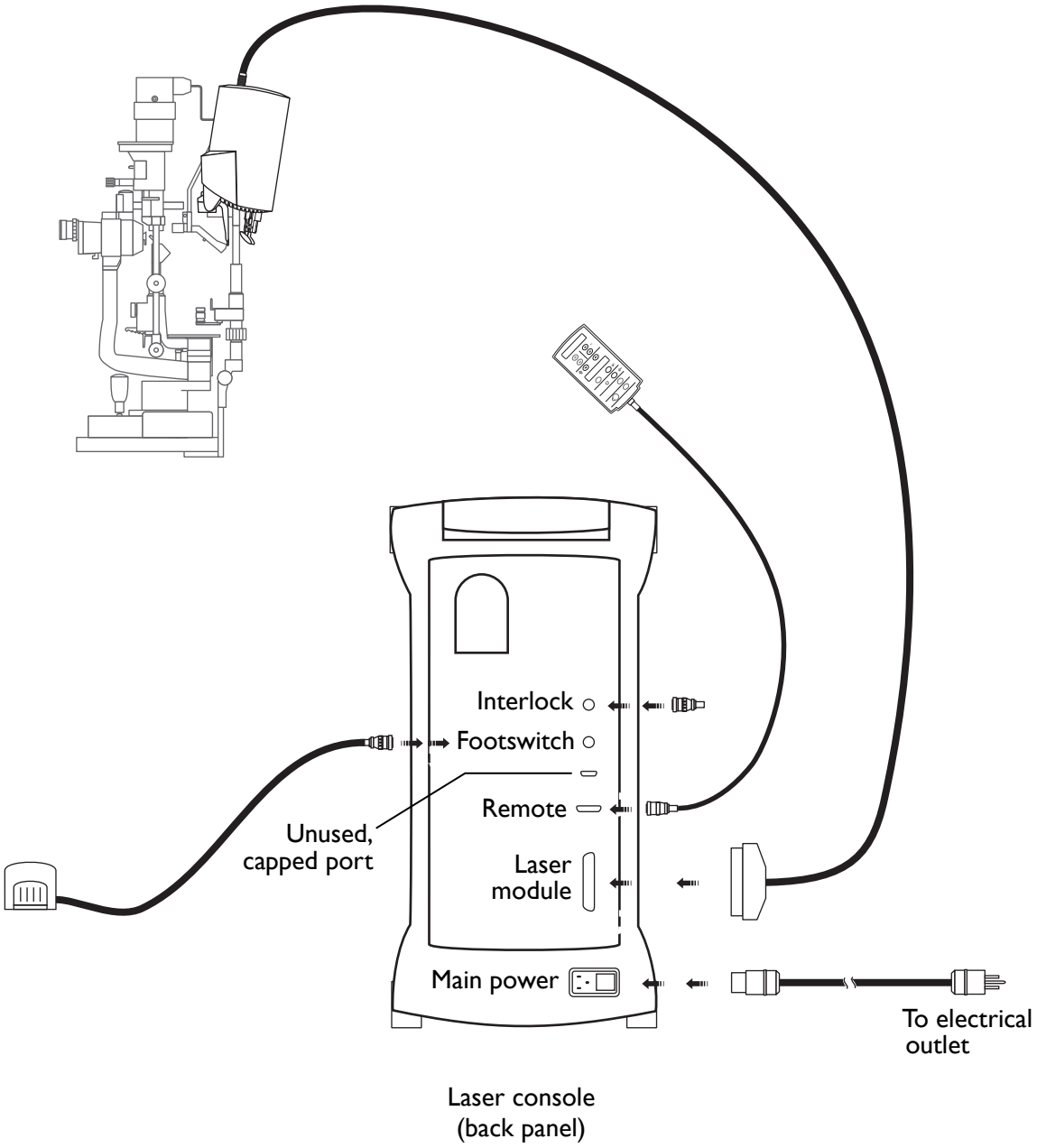
## Door interlock plug

The door interlock is a safety feature that disables the laser if someone opens the treatment room door or removes the interlock plug while the laser is in ready mode.

## Laserized mirror

The Lumenis laserized mirror replaces your standard slit lamp illumination mirror. The laserized mirror has a black, non-reflective coating that eliminates distracting reflections from the backside of the laser delivery mirror. It is three millimeters shorter than a standard illumination mirror, allowing room for eye safety filters, which prevent laser light from reflecting back through the microscope into the surgeon's eyes.

# Connection Diagram




Selecta II connections

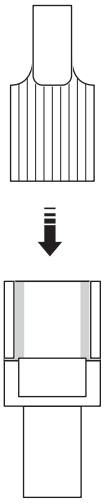
# Connection Instructions

## Inspect the Selecta II components

Before connecting the Selecta II components, inspect the individual components, cables, and electrical connections for evidence of dirt, debris, or damage. Check the electrical cables to ensure that they are not frayed or split.

## Attach the laser module to your slit lamp

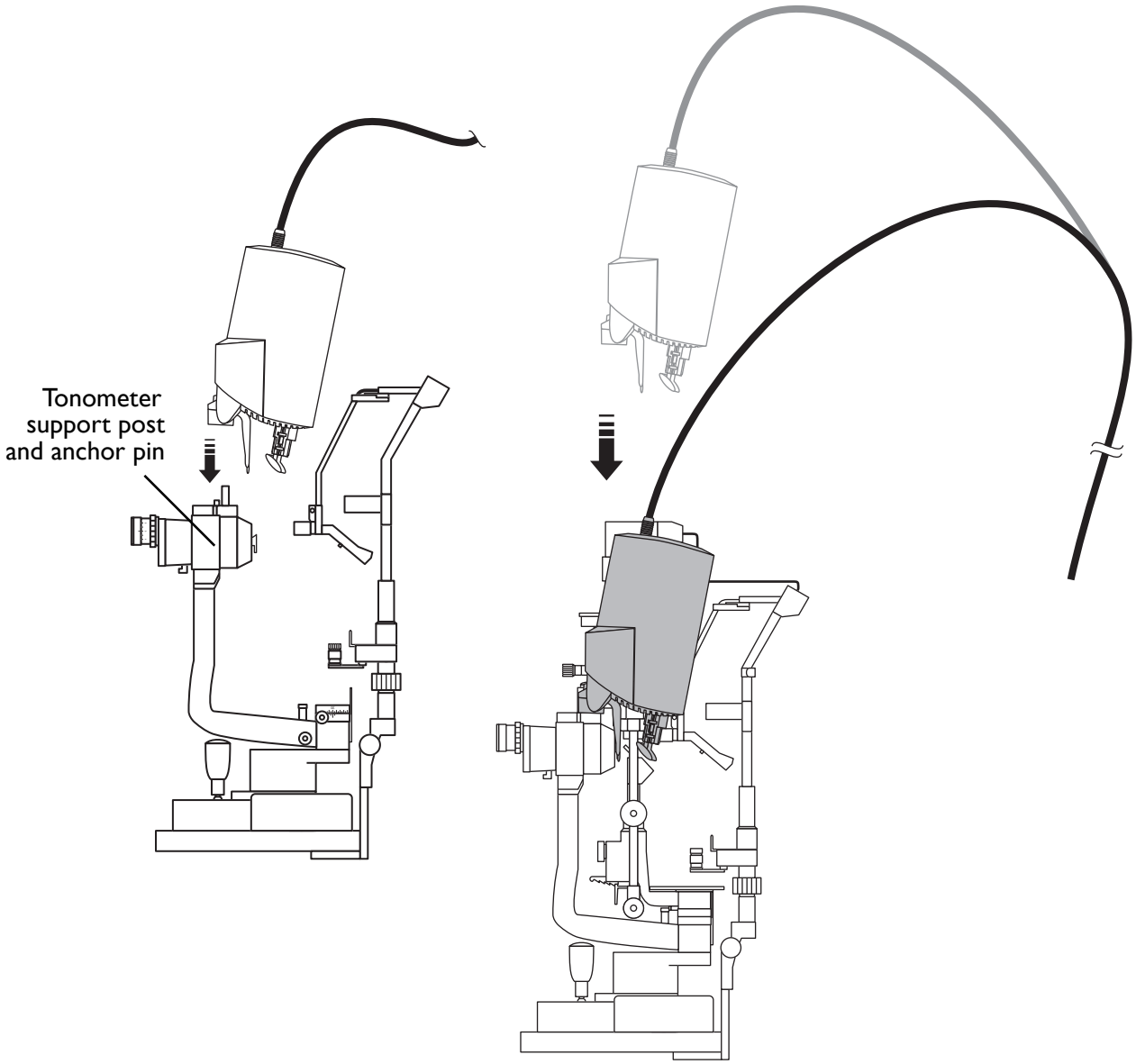
1. Remove the slit lamp applanation tonometer, if it is not already removed.
2. Rotate the slit projector to the left of the eyepieces (as viewed from the physician's side).
3. Remove the slit lamp illumination mirror by sliding it out of the mirror holder.
4. Insert and slide the Lumenis laserized illumination mirror, wide-end first, into the mirror holder; avoid touching the surface of the mirror.



Insert the Lumenis laserized mirror into the mirror holder

5 Position the laser module so that the eye safety filter is parallel to the slit lamp magnification optics housing, as shown.

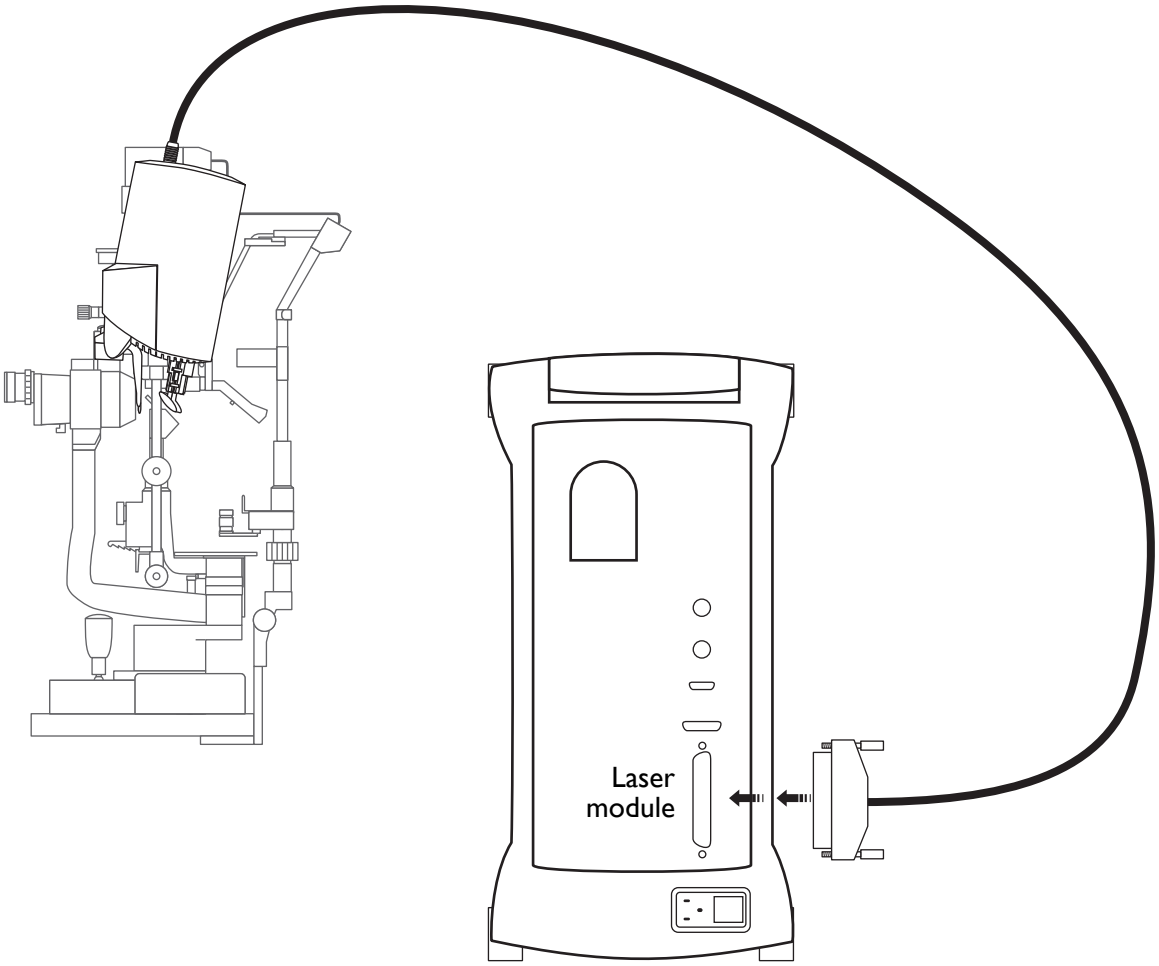
6 Carefully lower the laser module onto the tonometer support post and anchor pin. The laser module is properly mounted when the tonometer support post and anchor pin on the slit lamp connect firmly into the corresponding receptacles on the laser module, as shown.




Position and mount the laser module onto the slit lamp tonometer support post

## Connect the laser module power cable to the laser console

Plug the laser module power cable into the laser console, as shown.

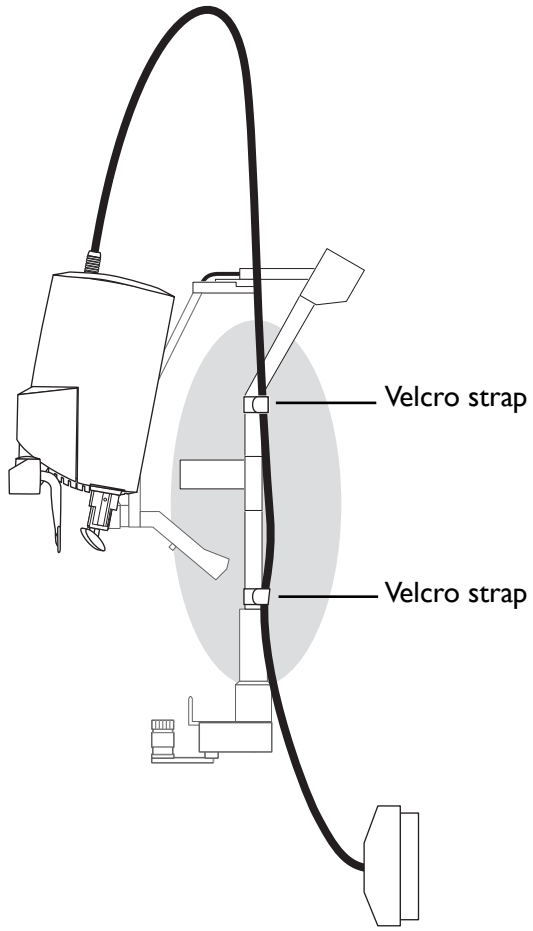



Laser console
(back panel)

Connect the laser module power cable to the laser console

## Secure the laser module cable

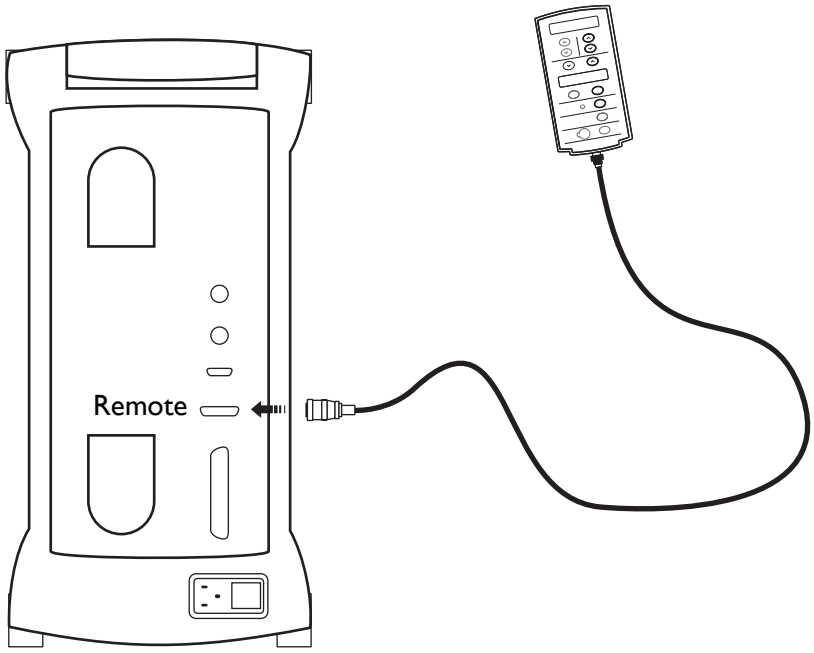
Secure the laser module power cable to the slit lamp headrest using the Velcro® straps.




Secure the laser module cable to the slit lamp headrest

## Connect the remote control

Plug the remote control cable into the remote control receptacle. Finger-tighten the screws to secure.

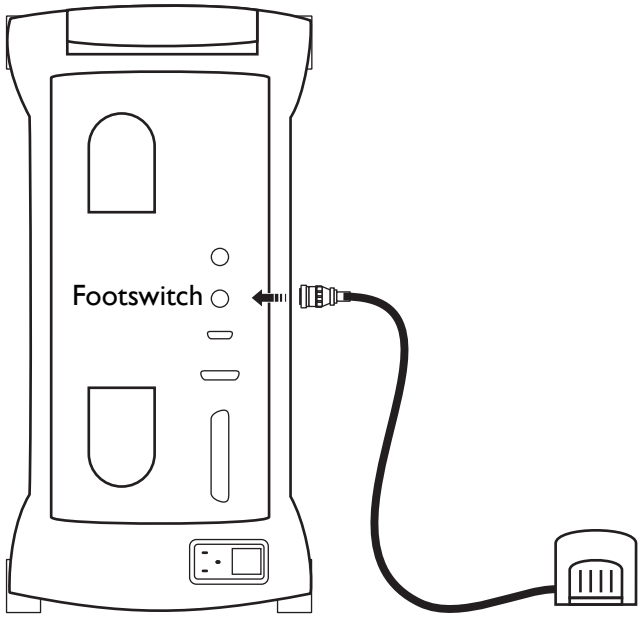



Laser console
(back panel)

Connect the remote control

## Connect the footswitch

Plug the footswitch cable into the footswitch receptacle. If the footswitch is not properly connected when the laser is turned on, *FS2* displays on the remote control display and the laser cannot be placed in ready mode.

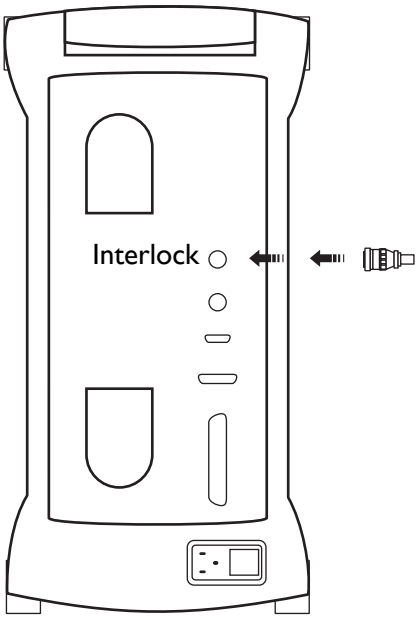



Laser console
(back panel)

Connect the footswitch

## Connect the interlock plug

Regardless of whether a door interlock is used, the interlock plug must be inserted into the interlock receptacle to operate the laser. If a door interlock will be used with the laser, plug the interlock plug and its associated door interlock cable into the interlock receptacle. When a door interlock is used, the laser can only be placed in ready mode when the interlocked door is closed. If the interlocked door is subsequently opened, or the plug is removed, the laser is disabled and *F3* illuminates on the remote control display.

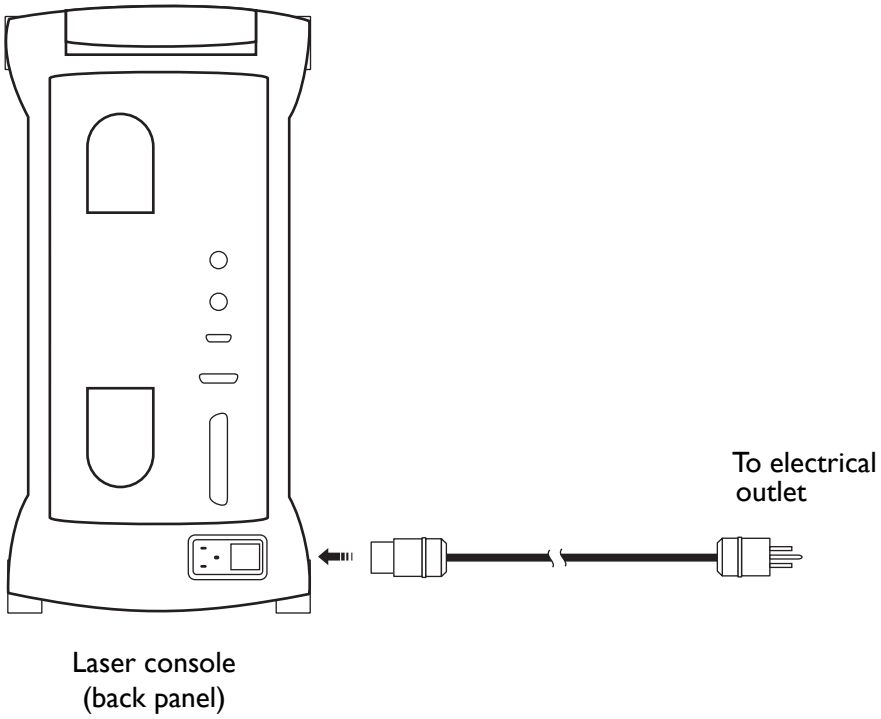



Laser console
(back panel)

Connect the interlock plug

## Plug in the main power cable

1. Ensure that the laser key switch is turned off.
2. Insert the main power plug into the main power receptacle, as shown.
3. Plug the other end into an electrical outlet.

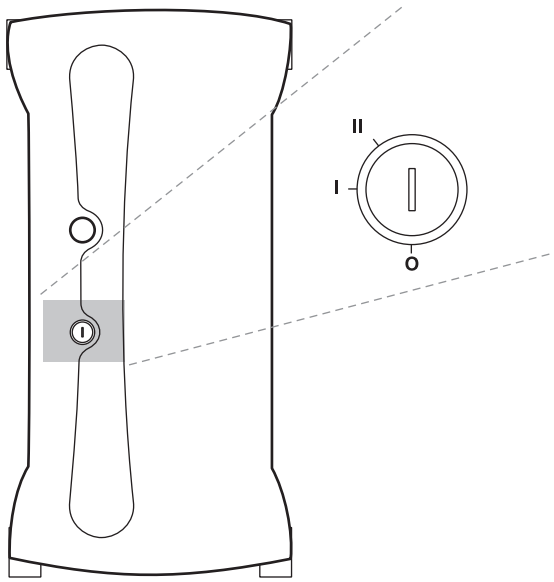



Plug in the main power cable

# Laser Basics

## Turning on the laser

Insert the key into the key switch, turn to the II (start) position, and release. Upon release, the key automatically springs back to the I (on) position.




Key switch

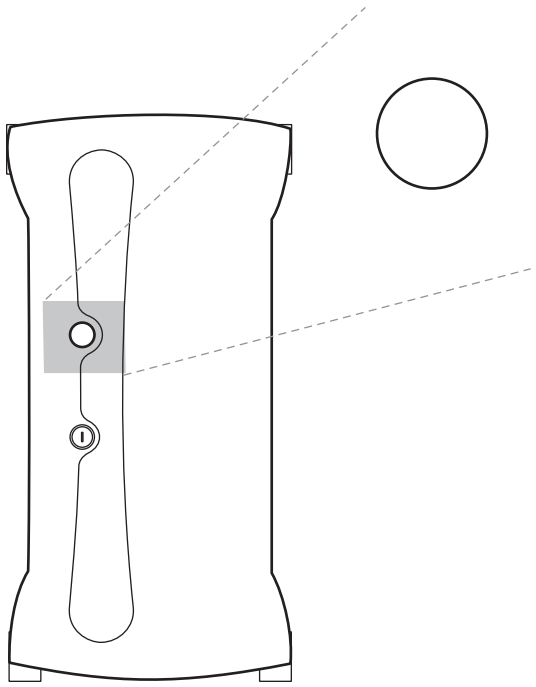
A system self-test and warm-up begins. During self-test and warm-up, the top remote control display illuminates a countdown. When the countdown finishes, the laser emission indicator illuminates, the system beeps, and the aiming beam appears. The standby icon on the remote control illuminates, and the laser is in standby mode. The laser defaults to the settings last used.

## Turning off the laser

Under normal operating conditions, turn the key switch to the o (off) position.

## Emergency off

In an emergency, press the red emergency off button to immediately de-energize the laser.



Emergency off

## Disconnecting the laser

1. Turn the key switch to the o (off) position.
2. Remove the laser power plug from the electrical outlet.
3. Place the remote control into its storage area on top of the laser console.
4. Unplug all of the cables from the laser console, and store them in their case.
5. Remove the laser module from the slit lamp, and store it in its case.

## Moving the laser

After disconnecting the laser, move the laser console and accessories to the desired site. Position the laser console a minimum of 4 inches (10 centimeters) from walls, furniture, or other equipment. Adequate space around the laser console ensures proper air circulation.

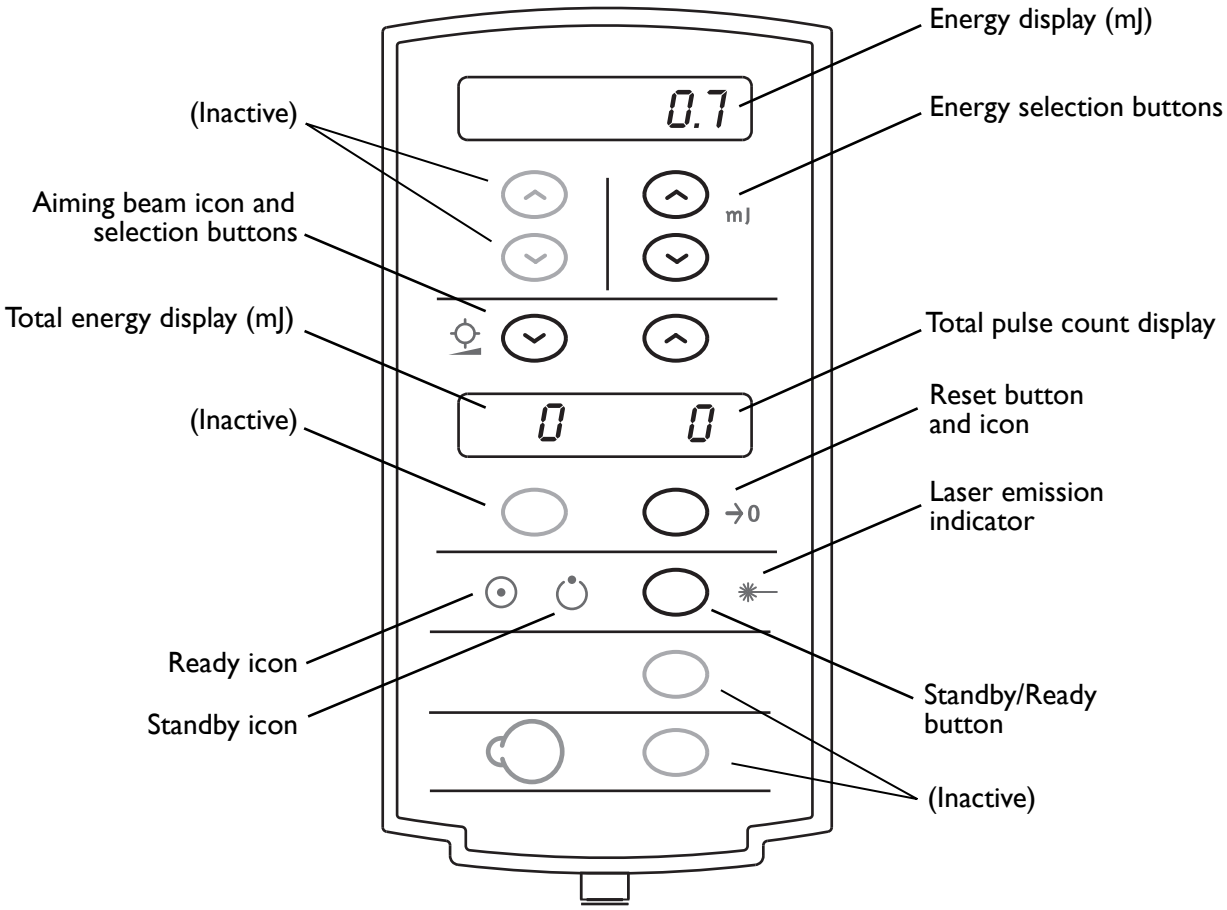
## System beeps

The system emits a higher-toned beep when it is able to perform the requested selection. The system emits a lower-toned beep when the laser is not ready, when the maximum or minimum treatment setting is reached, or when an error has occurred.

# General Remote Control Functions

## Selection buttons, icons, and displays

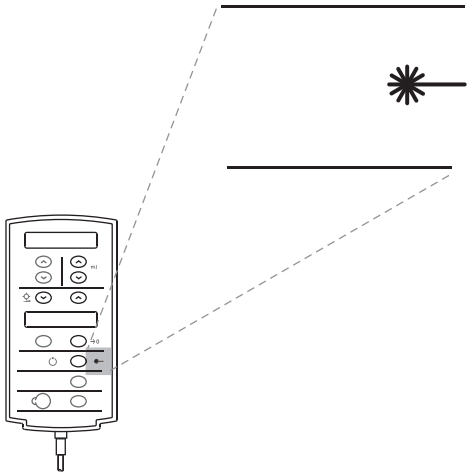
Use the selection buttons, icons, and displays on the remote control to change and monitor system information. The active buttons, icons, and displays illuminate when the remote control is connected and the laser is turned on.




Remote control functions

## Laser emission

When the laser is turned on and has finished warming up, the laser emission indicator ✷— illuminates. This indicates that the laser is fully powered and that radiation is accessible.



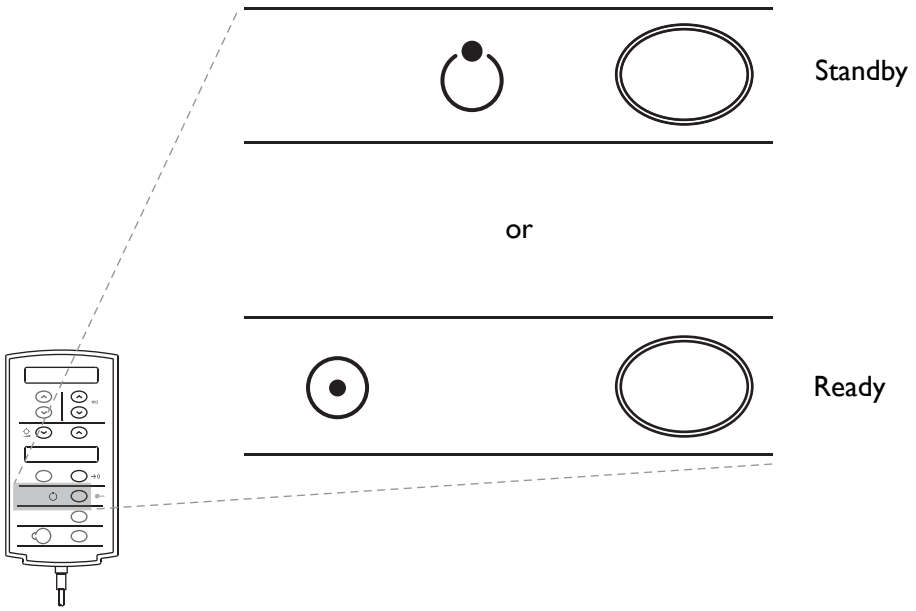
Laser emission

## Standby/Ready

Use the standby/ready toggle button to select the laser system status mode. In standby mode ◯, the footswitch is disabled and the safety shutter is closed; no treatment beam is available. In ready mode ⊙ , the footswitch is enabled and the treatment beam is available.

When the laser is turned on and has finished warming up, the laser goes into standby mode and the standby icon and toggle button illuminate. To place the laser in ready mode, press the toggle button. The system beeps, and the ready icon displays.

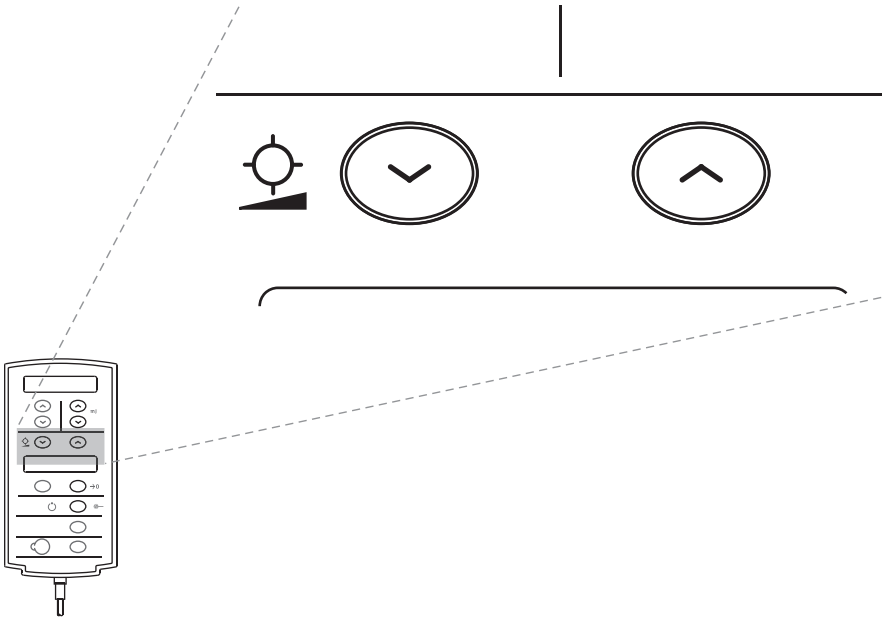
If the laser cannot be placed in ready mode, the system beeps, and an error message displays in the top display.




Standby/Ready

## Aiming beam

Use the aiming beam selection buttons to change the aiming beam intensity. When the laser is turned on and has finished warming up, the aiming beam icon and buttons illuminate. To decrease the intensity, press the down arrow button. To increase the intensity, press the up arrow button. To quickly increase or decrease the intensity, press and hold the down or up button until you hear a lower-toned beep.



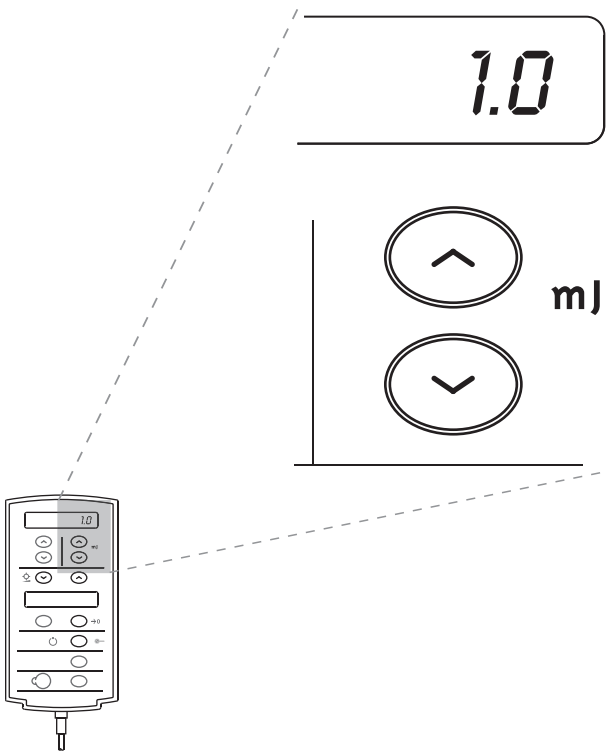
Aiming beam

# Remote Control Treatment Settings

## Energy

Use the up and down energy selection buttons to change the energy per pulse. Laser energy is displayed in millijoules. The available energy range is from 0.3 to 2 millijoules.

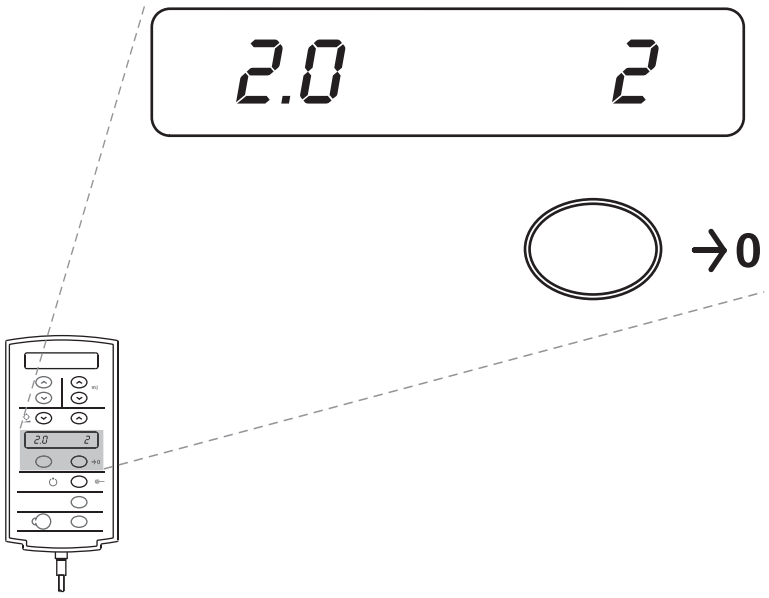
The energy display shows the currently selected energy per pulse.




Energy buttons, icon, and display

## Total energy and pulse count displays

The total energy (mJ) delivered since the reset button was pressed is shown on the left side of the display. The total pulse count since the reset button was pressed is shown on the right side of the display. Use the reset button to reset the total pulse count and energy displays to zero.




Total energy and total pulse count displays and reset button

# Slit Lamp Setup

To ensure that there is no focal shift between magnifications and to provide maximum working distance with the contact lens:

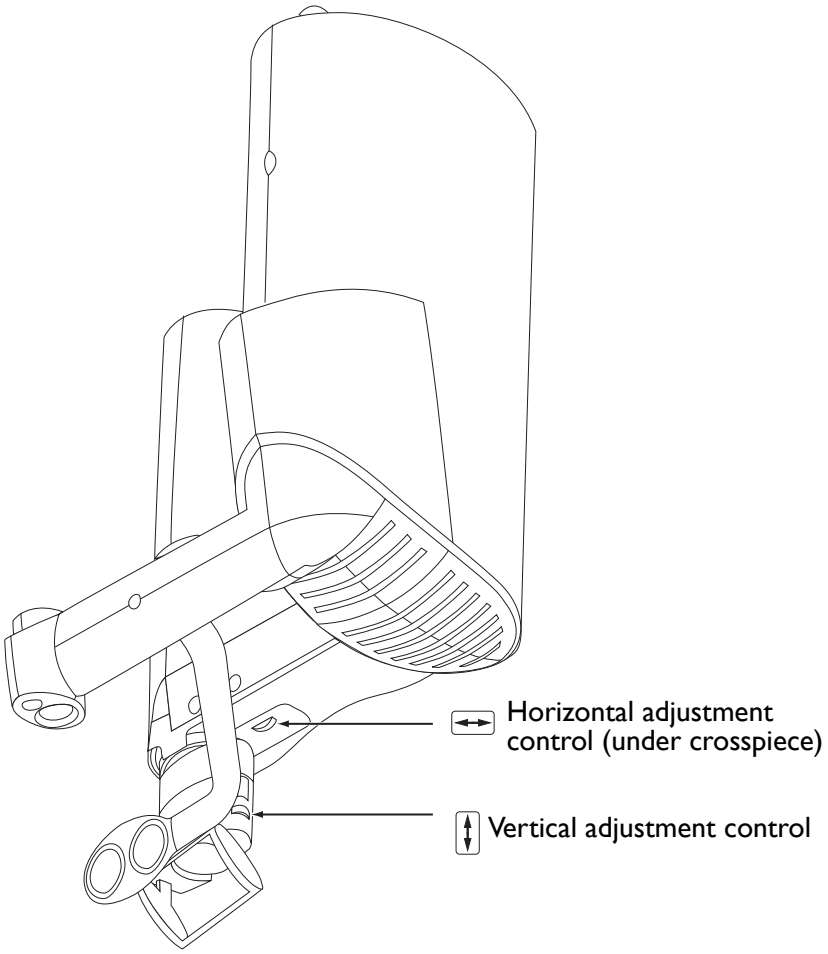
1. Turn on the Selecta II laser.
2. Position and affix a paper target on the headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.

   Use detail on the paper within the field of view as a focusing target. Decrease the aiming beam intensity until the aiming beam is not visible (lowest setting).
3. Set the eye pieces to 0.
4. Set the magnification to the highest setting, and focus the slit lamp on the target. Lock the slit lamp base.
5. Set the magnification to the lowest setting. Adjust eyepieces, alternating from + to - to achieve the best focus on the target. Repeat the procedure for each eye. This step eliminates accommodation.
6. Set the magnification to the highest setting. Unlock the slit lamp base, focus the slit lamp on the target, then relock the slit lamp base.
7. Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to - to achieve the best focus on the target. Repeat the procedure for each eye.
8. Note the index number of the slit lamp eyepieces relative to the index marks as a future starting point for this procedure.

# Laser Setup on the Slit Lamp

The beam delivery mirror has a special transparent coating that allows the laser beam to be reflected at a 90° angle relative to the target tissue. The transparent coating allows you to coaxially view the target tissue through the slit lamp optics. The beam delivery mirror is linked to the horizontal and vertical adjustment controls. When you manipulate these controls, they move the mirror, which, in turn, positions the laser beam.

The laser setup procedure on the slit lamp ensures that the laser beam is focused at the same focal point as the slit lamp binoculars. To the observer, the laser aiming beam spot appears focused when the surrounding tissue is in focus.




Laser beam position controls

1. Turn on the laser.
2. Tape a piece of laser alignment thermal-sensitive paper (Kentek Zap-It® or equivalent) onto the slit lamp forehead rest.

> **WARNING -** Ensure that there are no reflective surfaces behind the paper mounted on the forehead assembly.

3. Set up the slit lamp as described in the Slit Lamp Setup section of this manual.
4. Place the laser in ready mode.
5. Set the energy on the remote control to 2 millijoules.
6. Set the slit lamp magnification to the highest setting.
7. Focus the slit lamp on the laser alignment paper target.
8. Press the footswitch to make a laser exposure on the paper. A large, consistent exposure should be produced. The size of the exposure diminishes with anterior movement of the slit lamp.
9. Verify that the red aiming beam lies in the center of the exposed area.

> If the aiming beam is not coincident with the exposed area, contact your local Lumenis representative.

# Preoperative Instructions

1. Ensure that the laser is properly connected, as described in the Connection Instructions section of this manual.
2. Verify that your slit lamp is set up, as described in the Slit Lamp Setup section of this manual.
3. Verify that the laser is set up on the slit lamp, as described in the Laser Setup on the Slit Lamp section of this manual.
4. If used, post a Laser in Use warning sign outside of the treatment room door.
5. Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear. Refer to the Safety and Regulatory section of this manual for additional information.

# Intraoperative Instructions

1. Turn on the laser.
2. Position the patient.
3. Place the contact lens on the patient's eye.
4. Adjust the slit lamp, if necessary.
5. Select the treatment parameters on the remote control, as described in the Remote Control Treatment Settings section of this manual.
6. Position the aiming beam on the target tissue.
7. Place the laser in ready mode.
8. Press the footswitch to deliver the treatment beam.

# Postoperative Instructions

1. Place the laser in standby mode.
2. If desired, record in the patient's record the total energy and pulse count values shown in the remote control displays.
3. Turn off the laser.
4. If used, remove the Laser in Use sign from the treatment room door.
5. If desired, disconnect the laser, as described in the Laser Basics section of this manual.
6. Clean the laser module and laser console, as described in the Maintenance section of this manual.
7. Clean the contact lens as described by the manufacturer.

# Maintenance

## Overview

# Troubleshooting Guide

If the instrument fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction. First, please check for the following items:

### Electrical power source

Verify that the electrical disconnect switch, the circuit breaker, is turned on.

### Laser console electrical

Verify that the laser is on and properly connected to an electrical service outlet.

### Delivery system connection

Verify that the delivery system is properly connected.

### External door interlock

If the external door interlock is used in conjunction with a remote switch, verify that the external door interlock plug is inserted in the external door interlock receptacle. Close the interlocked door.

| Symptom | Probable Cause | Suggestion |
|---|---|---|
| **Laser does not turn on, and the remote control will not illuminate** | The laser is not plugged in. | ⇨ Place the electrical service disconnect switch in the off position, plug the laser power cord into the appropriate outlet, and turn the electrical service disconnect switch to the on position. |
| | The building power (main electrical service) is turned off. | ⇨ Turn on the building power. |
| | The remote interlock has been activated. | ⇨ Close the operating room door. |
| | The keyswitch was not held long enough. | ⇨ Try to start the laser again, ensuring that the key is held in the start position for at least 2 seconds. |
| | The remote control is not properly connected. | ⇨ Refer to the Operation section of this manual, and check the remote control connections. |
| **Inadequate or no aiming beam** | The aiming beam is set to the lowest intensity. | ⇨ Refer to the General Remote Control Functions section of this manual, and adjust the laser's aiming beam intensity. |
| | The Selecta II components are not properly connected. | ⇨ Refer to the Operation section of this manual, and check the Selecta II connections. |
| | Slit lamp binocular eyepieces are not properly adjusted. | ⇨ Refer to your slit lamp operator manual. |

| Symptom | Probable Cause | Suggestion |
|---|---|---|
| **No treatment beam is delivered when the footswitch is pressed, or the beam is of poor quality** | The laser is in standby mode. | ⇨ Place the laser in ready mode. |
| | The Selecta II components are not properly connected. | ⇨ Refer to the Operation section of this manual, and check the Selecta II connections. |
| | The laser module optics are dirty. | ⇨ Refer to the Inspect and Clean the Selecta II Components section of this manual, and clean the optics as described. |
| | The laser module optics are misaligned. | ⇨ Contact your local Lumenis representative. |
| **Inadequate laser power** | The laser module optics are dirty. | ⇨ Refer to the User Maintenance section of this manual, and clean the optics as described. |
| | The laser module optics are misaligned. | ⇨ Contact your local Lumenis representative. |
| **Illumination mirror interferes with laser module safety filter** | The Lumenis laserized illumination mirror is not installed. | ⇨ Refer to the Operation section of this manual, and install the mirror. |
| **Inadequate slit lamp illumination** | The illumination intensity control is not in the proper position, or the illumination bulb is burned out. | ⇨ Refer to your slit lamp operator manual. |
| | Slit adjustments are needed. | ⇨ Refer to your slit lamp operator manual. |

| Symptom | Probable Cause | Suggestion |
|---|---|---|
| **F3 advisory message displays on the remote control** | The remote interlock has been activated. | ⇨ Close the interlocked door, or connect the remote interlock plug. |
| **F4 advisory message displays on the remote control** | The detected energy level was more than 20% higher than the level selected. | ⇨ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative. |
| **F5 advisory message displays on the remote control** | The detected energy level was at least 20% lower than the level selected. | ⇨ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative. |
| **F6 advisory message displays on the remote control** | The detected energy level was at least 100% higher than the level selected. | ⇨ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative. |
| **F7 advisory message displays on the remote control** | The detected energy level was at least 50% lower than the level selected. | ⇨ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative. |
| **F47 advisory message displays on the remote control** | The laser temperature is too high. | ⇨ Place the laser in standby mode. Allow the laser to cool down. Place the laser in ready mode to continue treatment. If the condition continues, contact your local Lumenis representative. |
| **F52 advisory message displays on the remote control** | The footswitch is not properly connected to the laser. | ⇨ Refer to the Operation section of this manual, and connect the footswitch as instructed. If the condition continues, restart the laser, ensuring that the footswitch is not pressed. If the condition persists, the footswitch may be defective; contact your local Lumenis representative. |

# User Maintenance

## Annual laser maintenance

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

## Laser repair

All laser repairs should be performed by a Lumenis-certified service engineer. For training and information, contact your local Lumenis service representative.

## Inspect the Selecta II components

Before and after each use, inspect the Selecta II components for evidence of dirt, debris, or damage.

## Clean the laser module

Periodically inspect the eye safety filter and beam delivery mirror. If necessary, clean the surfaces as follows:

1. Turn off the power to the slit lamp and the laser.
2. Wrap a piece of lens tissue (Kodak® or equivalent) around one end of a cotton-tipped applicator (Puritan® or equivalent non-glued tip applicator).
3. Place several drops of reagent or 100% ethanol or methanol on the tissue.
4. Wipe the optic gently in one direction with lens tissue to remove all dust and debris. Do not wipe in more than one direction, as loose particles might be dragged across the surface and scratch the optical coating.

The laser module optics have delicate coatings. When cleaning, wipe them gently, and avoid getting fingerprints on them. If an optic appears to be damaged, contact your local Lumenis representative.

## Clean the external surfaces of the laser console

Use a cloth dampened with a noncaustic cleaning solution, such as soap and water, isopropyl alcohol, or a “hospital-grade” disinfectant, to wipe the external surfaces of the laser console. Dry with a clean cloth, or allow to air dry.

⚠ **CAUTION -** Do not spray or pour cleaning agents directly on the laser console. You may damage the console and laser system electronics.

## Water utilities

No water utilities are required for this laser. It has a self-contained cooling system.

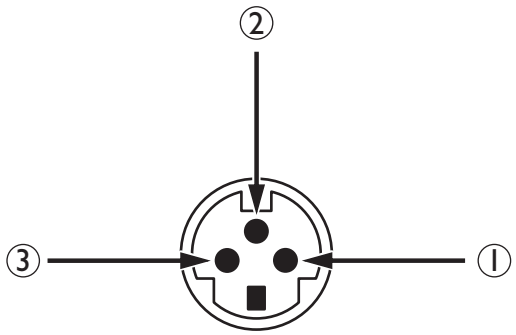
# External Door Interlock Pin Assignments

The external door interlock is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed while the laser is in ready mode.

The interlock can be set up with a remote switch, or an external switch can be wired to the interlock plug. Plug wiring shall only be performed by a qualified electrical professional. Total length of cable shall not exceed five meters (16 feet).

Pin assignments are as follows:

| Pin | Signal Name | Signal Description |
|---|---|---|
| **1** | Remote Interlock | Connect to switch, normally open |
| **2** | Return | Connect to switch common |
| **3** | None | No connection |

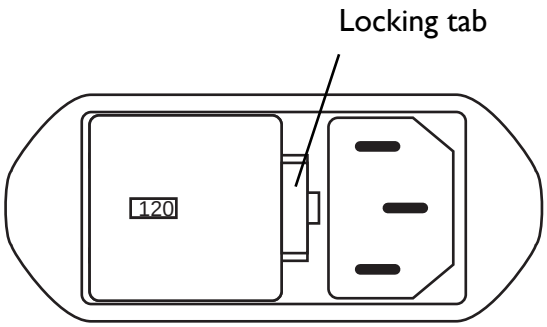



Remote door interlock pin assignments
(mating face shown)

# Voltage Selection

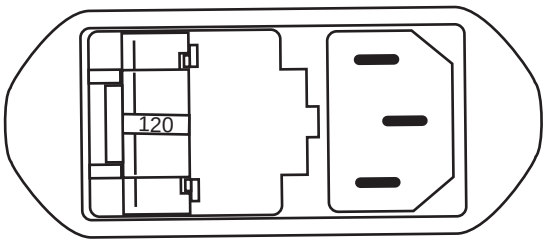
1. Turn off the laser.
2. Remove the power plug from the wall receptacle.
3. Remove the power plug from the laser's main power receptacle.

   Locate the electrical input module, which is adjacent to the main power receptacle.
4. Unlock the electrical input module cover by inserting a small flathead screwdriver into the slot. Gently push against the locking tab until the lock releases.
5. Remove the cover from the module.




Electrical input module

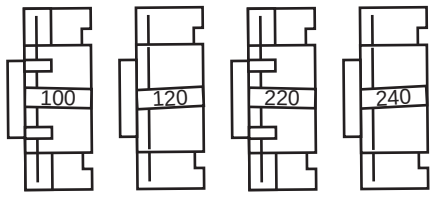
6. Extract the voltage selector from the electrical input module.




Voltage selector

**7** Rotate the voltage selector until the desired voltage is upright:

- 100
- 120
- 220
- 240



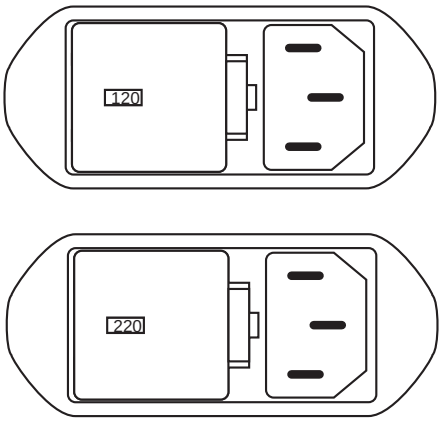

Examine and orient the voltage selector

**8** Put the voltage selector back into the electrical input module. If the voltage selector does not fit, it is upside down; invert and reinsert.

If the voltage has been changed, the fuses must also be changed. See the Changing the Fuses section of this manual.

**9** After the desired voltage is selected and correct fuses installed, place the cover back onto the module. Gently push against the cover until the locking tab latches.

**10** Confirm that the desired voltage is displayed in the voltage selector window.

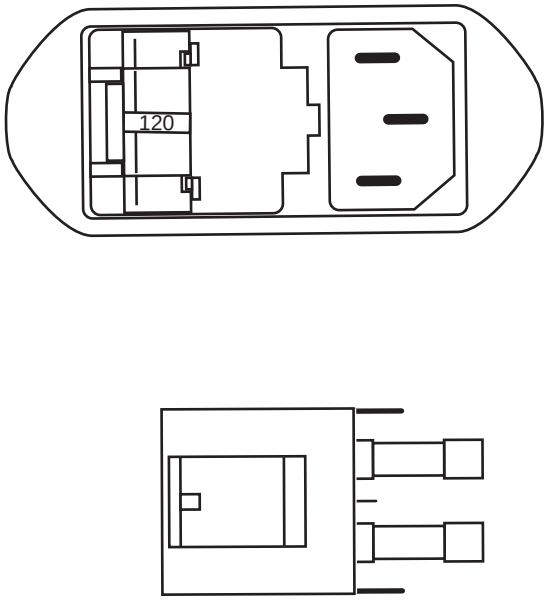



Confirm selected voltage

# Changing the Fuses

1. Turn off the laser.
2. Remove the power plug from the wall receptacle.
3. Remove the power plug from the laser's main power receptacle.

   Locate the electrical input module, which is adjacent to the main power receptacle.
4. Unlock the electrical input module cover by inserting a small flathead screwdriver into the slot. Gently push against the locking tab until the lock releases.




Changing the fuses

5 Remove the cover from the module. Replace the two 5 millimeter by 20 millimeter fuses with the appropriate replacement fuses as indicated below:

| Voltage Configuration | Fuse Rating |
|---|---|
| 100/120 | 2 A T* |
| 220/240 | 1 A T* |
| *timed fuse | |

Fuse table

6 Place the cover back onto the module. Gently push against the cover until the locking tab latches.

# Energy Calibration

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and European EN 60825 Class 3 and 4 medical lasers supply their customers with power calibration instructions.

Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Calibration questions should be referred to your local Lumenis representative.

## Disclaimer warning

Calibration is a service procedure to be done only by Lumenis-certified service engineers or customers who have taken and passed a Lumenis Service Certification Training course. Adjustment by anyone other than a trained Lumenis service engineer or a certified customer voids any existing manufacturer's warranty on the instrument. A service manual for the laser may be purchased from Lumenis. 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.

## Calibration setup

1. Put on the appropriate laser safety eyewear.
2. Remove the side cover from the laser console.
3. Flip the service switch (SW2) on the laser console to access service mode. *STEPSIZE* displays on the remote control top display.
4. Attach the oscilloscope leads to TP31 (main 532 nm) and TP23 (ground).

> When the Selecta II is in service mode, you cannot see any of the icons on the remote control display.

5. Install an energy detector at the treatment site.

> Ensure that the detector head is not placed at the treatment beam's focal point, otherwise damage to the energy detector head will occur.

6. Toggle either of the upper left buttons on the remote control until *BURST CAL* displays on the bottom display.
7. Press the left button below the lower display (*BURST CAL* display) to start the burst calibration routine. This procedure may take a few minutes. Once the burst calibration procedure is finished, *DONE* displays.
8. Toggle either of the upper left buttons on the remote until *MOTOR POS* displays on the top display.

## Calibration instructions

1. Toggle either of the upper right buttons on the remote control until 532 CAL displays in the lower display.
2. Press the left button below the lower display (532 CAL display) to go into 532 nm mode.
3. Toggle either of upper left buttons on the remote control until MOTOR 2 displays in the top display.
4. Select the ready mode.
5. Repeatedly press the footswitch, adjusting the upper right buttons (incrementing/decrementing steps) on the remote control until 1 mJ displays on the energy detector.
6. Verify that the signal on the TP31 is a positive going signal from 0 to 2VDC ± .1VDC@ 1 mJ. If the signal is not at the proper amplitude, adjust R71 on the controller PCB for 2VDC ± .1VDC.
7. Move the positive lead of the oscilloscope to TP24 (safety 532 nm) and press the footswitch again.
8. Verify that a 2VDC ±.1VDC positive going signal displays on the oscilloscope at 1 mJ. If not, adjust R55 on the Controller PCB until a 2VDC positive going signal displays.
9. Toggle the upper left buttons on the remote control until ENERGY CAL displays in the top display.
10. Press the two upper right buttons on the remote control until 532 CAL displays in the lower display.
11. Press the button below the lower display (532 CAL display) to start the energy calibration routine. During the auto calibration routine, which can take up to 10 minutes, the laser discharges every three seconds at different energy levels.
12. Turn the laser off and then on.
13. Verify that the laser was properly calibrated by discharging the laser at different energy levels, comparing the energy reading on the remote control display to the reading on the energy detector.

# Specifications

*Specifications subject to change without notice.*

| Selecta II Laser | |
|---|---|
| **Treatment beam** | |
| Type | Q-switched Nd:YAG |
| Principal output | 532 nm wavelength |
| Operating mode | Fundamental |
| Pulse duration | 3 nanoseconds |
| Energy | 0.3 to 2.0 mJ |
| Laser beam spot size | 400 µm |
| CDRH classification | Class IIIb |
| EN 60825 classification | Class 3B |
| **Aiming beam** | |
| Type | Diode laser |
| Power | 0 to <1 mW |
| Principal output | 635 nm wavelength |
| CDRH Classification | Class II |
| EN 60825 classification | Class 2 |
| **Electrical requirements** | |
| 100/120 VAC | 50/60 Hz, 2 Amps |
| 220/240 VAC | 50/60 Hz, 1 Amp |
| **Cooling** | Air-cooled |

| Selecta II Laser, continued | |
|---|---|
| **Physical characteristics** | |
| Laser module | 28 cm x 18 cm x 13 cm<br>(11 inches x 7 inches x 5 inches) |
| Laser console | 43 cm x 22 cm x 30 cm<br>(17 inches x 8.5 inches x 12 inches) |
| Total system weight | 11 kilograms (25 pounds) |
| **Environmental operating conditions of laser** | |
| Temperature range | 10°C to 25°C (50°F to 77°F) |
| Humidity | 90% Relative |
| **Compatible slit lamps** | Haag-Streit 900 BM and equivalents<br>Topcon SL-1E<br>Topcon SL-3E<br>Topcon SL-7E<br>Marco III<br>Mentor SH-12 |
| **Laser safety eyewear** | Refer to the Laser Safety Eyewear section of this manual for information. |

# 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."

# Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment shipped to Lumenis US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant." To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided at the back of this manual) must be enclosed in the package, or Lumenis will assume that the product is contaminated and will assess the customer with cleaning costs.

Any decontamination inquiries should be directed to the Lumenis US service offices.

# Safety and Regulatory

## Overview

# Introduction

The Selecta II is classified as a Class IIIb laser by the Center for Devices and Radiological Health of the Food and Drug Administration and as a Class 3b by the European Standard EN 60825.

Users 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.

See 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.

This package conforms to the conditions and limitations specified in US federal regulations, title 49 CFR 173.426 for radioactive material, excepted package-articles manufactured from natural thorium, UN 2910.

# Laser Safety Eyewear

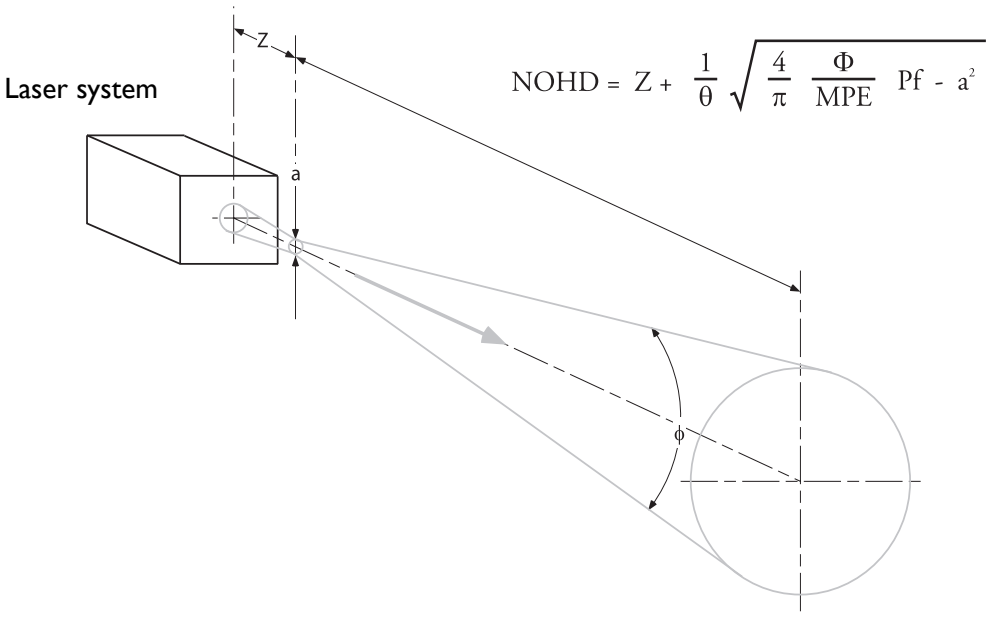
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (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, ANSI Z136.3, or International Standard IEC 60825-1:2007.

The following formula was used to calculate the worst case NOHD for Lumenis Selecta II 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 profile); |
| 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:

| Laser System | θ | Φ | MPE | Pf | a | Z |
|---|---|---|---|---|---|---|
| Selecta II | 0.058 | 0.002 J | 0.50 ($10^{-6}$) J/cm$^2$ | 2 | 0.0046 cm | 5.7 cm |

which results in a *worst case* NOHD of :

| Laser System | NOHD |
|---|---|
| Selecta II | 17.46 meters |

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:

| Laser System | OD |
|---|---|
| Selecta II | 4.02 |

Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1, section 4.6.2 and Appendix C. For users who must comply with EN 207, the safety eyewear must have a protection class of L5.

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.

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.

# 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.

**WARNING -** 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.

**WARNING -** 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.

**WARNING -** 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.

# Additional Safety Considerations

## Electrical hazards

**WARNING -** Never remove the laser protective covers. Removing the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the laser console.

**WARNING -** The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

## Fire hazard

**WARNING -** Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and similar substances. An explosion and/or fire could occur.

## Protecting nontarget tissues

**WARNING -** Except during actual treatment, the system must always be in the standby mode. Maintaining the system in the standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

**WARNING -** Never place hands or other objects in the path of the laser beam. Severe burns could occur.

**WARNING -** Only the person directing the laser beam should have access to the laser footswitch. Use caution depressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch depressed is the correct one to avoid accidental laser exposure.

**WARNING -** To avoid accidental exposure to laser radiation, always move the patient out of the beam path before restarting the system.

**CAUTION -** U.S. federal law restricts this device to sale by or on the order of a physician.

**CAUTION -** Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

**CAUTION -** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

# Regulatory Compliance

Lumenis lasers systems comply with 21 CFR 1040.10 & 1040.11, except for deviations pursuant to Laser Notice 50, Dated June 24, 2007, 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 Medical Device Directive MDD 93/42/EEC.

## Key lock switch

To prevent unauthorized use, the laser can only be turned on with the master key, the key can only be removed when the laser is turned off, and the laser only operates when the key is inserted into the keyswitch. When the key-switch is turned to the start position, the laser power-up sequence is initiated.

## Emergency off pushbutton

The laser has an emergency off pushbutton which immediately turns off the laser.

## Laser emission indicator

Illumination of the laser emission indicators on the remote control and the laser module provide a visible warning to the operator that after approximately 5 seconds laser radiation is accessible. The time delay is incorporated to allow appropriate action by the operator to avoid unintentional laser radiation exposure.

## External door interlock

An external door interlock receptacle and plug are provided to disable the laser if the treatment room doors are opened while the laser is in ready mode. Refer to the Laser Safety Eyewear section of this manual for additional information.

## Manual reset

If laser emission is externally interrupted during treatment by remote interlock activation, the laser will automatically go into standby and the safety shutter will revert to a closed position. To resume treatment, manually reset the laser by placing the laser in ready mode. If laser emission is interrupted during treatment by main electrical power loss, the laser system will automatically turn off. To resume treatment after an electrical power loss, the system must be manually restarted by rotating the keyswitch to the start position.

## Protective housing

The laser has a protective housing that prevents unintended human access to laser radiation above Class I limits. The housing must only be opened by a Lumenis-certified technician.

## Safety interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the laser does not have, and is not required to have, any safety interlocks within the meaning of US FDA 21 CFR, Section 1040 or European EN 60825-1. However, the protective housing cannot be easily opened without special tools.

## Location of controls

Operation and adjustment controls are located so that the user need not be exposed to laser radiation during laser operation or adjustment.

## Eye filter

The laser module has specially designed eye filters which guard the operator from exposure to laser radiation. The protective filter ensures that all laser radiation returned to the operator's eyes is below the Class I limit.

## Safety shutter

The laser includes an electronic safety shutter that prevents unintentional laser emission. The safety shutter opens only when the user places the system in ready mode and depresses the footswitch. 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.

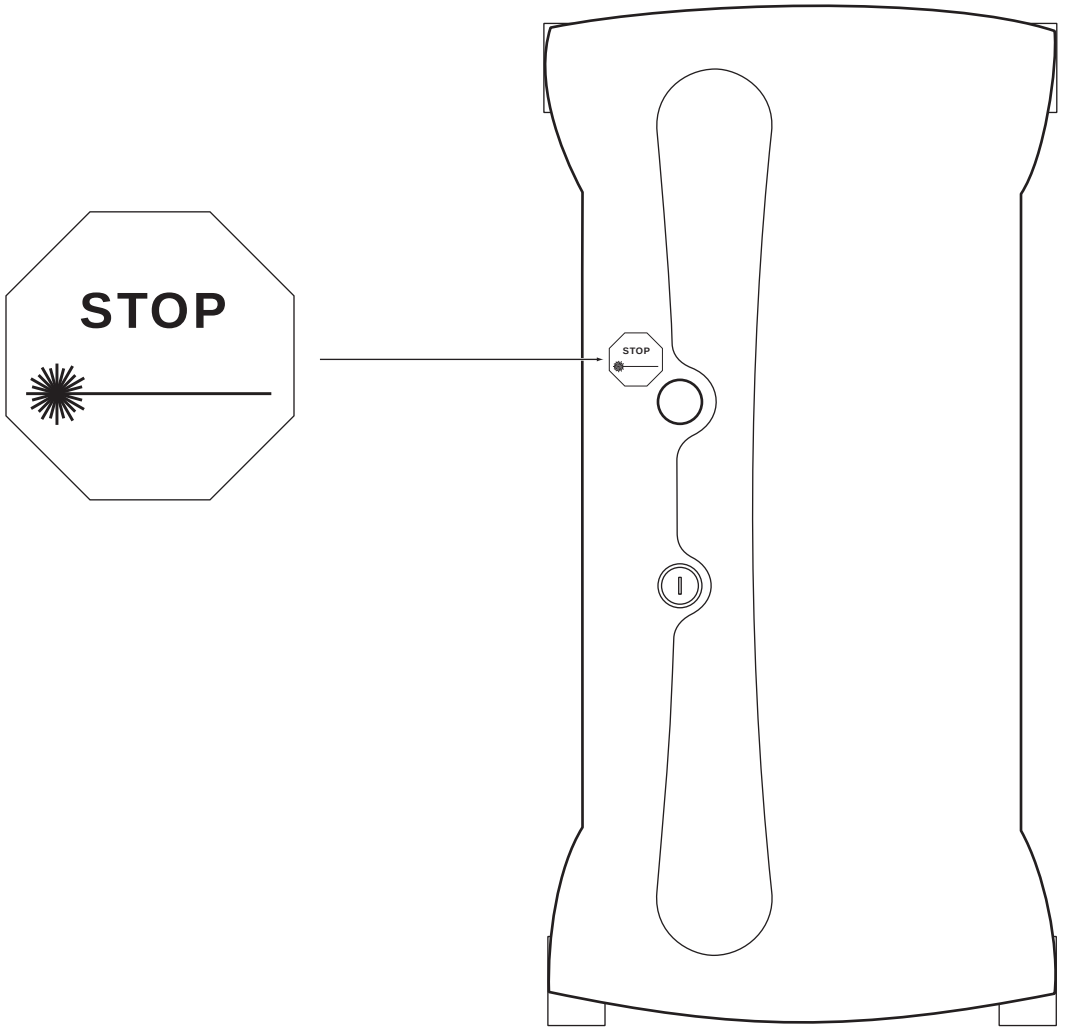
## Electronic fault detection circuitry

If the electronic system detects a fault condition, laser exposure cannot occur. The high voltage power supply is turned off, the high voltage capacitor is discharged, the safety shutter is closed, and the footswitch is disabled.

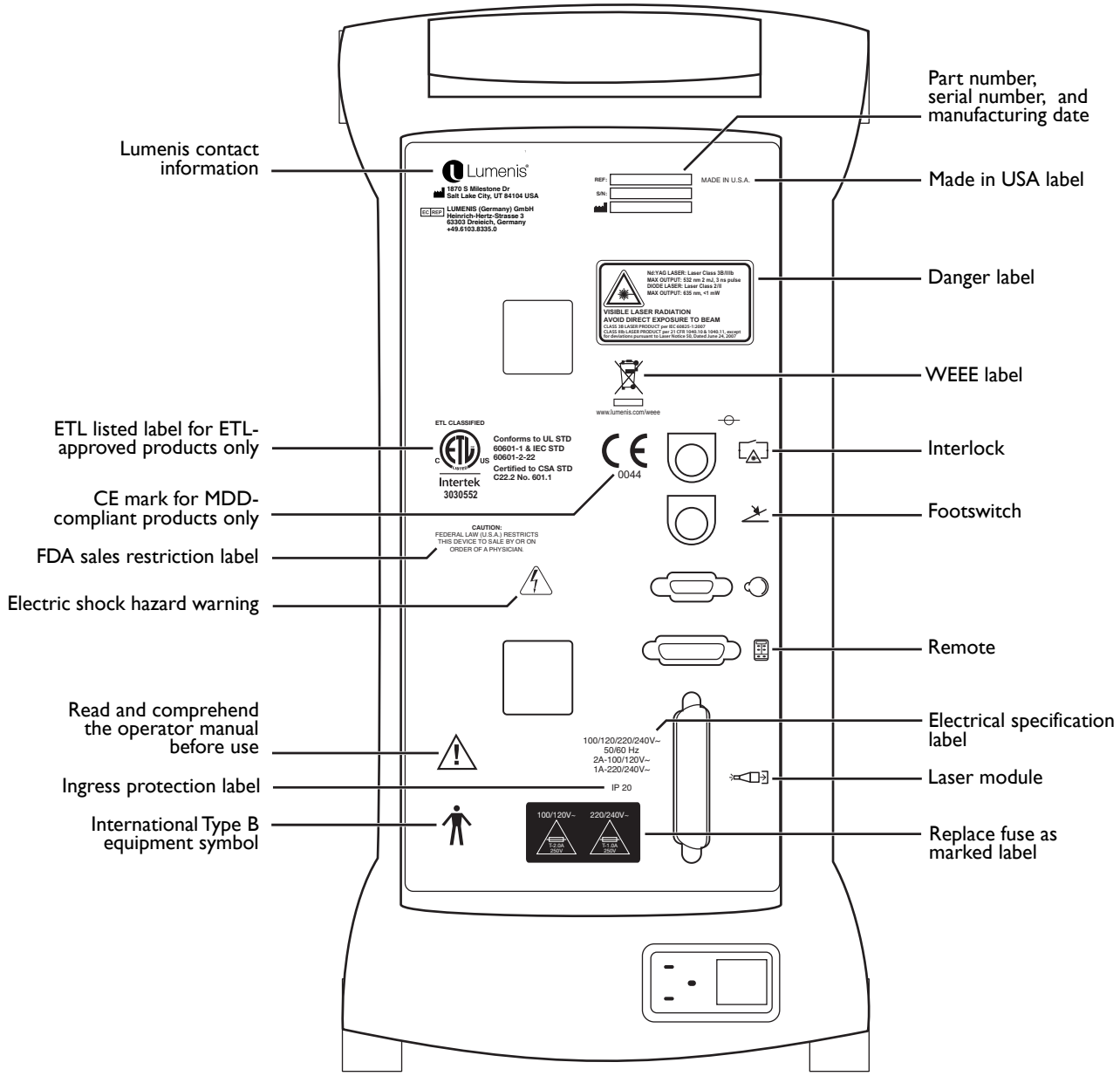
Some fault conditions may be cleared by the operator. Refer to the Troubleshooting Guide in this manual for additional information.

# Location of Regulatory and Other System Labels

As required by national and international regulatory agencies, appropriate warning labels have been mounted in specified locations.




Location of regulatory compliance labels




Location of regulatory compliance labels

Lumenis®
1870 S Milestone Dr
Salt Lake City, UT 84104 USA
EC REP LUMENIS (Germany) GmbH
Heinrich-Hertz-Strasse 3
63303 Dreieich, Germany
+49.6103.8335.0

Lumenis contact information

100/120/220/240V~
50/60 Hz
2A-100/120V~
1A-220/240V~

Electrical specification label

IP 20

Ingress protection label

CE
0044

CE mark

ETL CLASSIFIED
C ETL US LISTED
Intertek
3030552

**Conforms to UL STD 60601-1 & IEC STD 60601-2-22**
**Certified to CSA STD C22.2 No. 601.1**

ETL listed label for ETL-approved products only

**CAUTION:**
FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.

FDA sales restriction label

Electric shock hazard warning

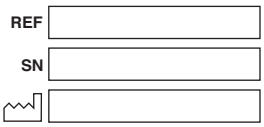
Read and comprehend the operator manual before use

International Type B equipment symbol


(Instructions for proper disposal of the system, as required by the Waste in Electrical and Electronic Equipment Directive 2002/96/EC, are provided by Lumenis at the following website: http://www.lumenis.com/weee)

WEEE label

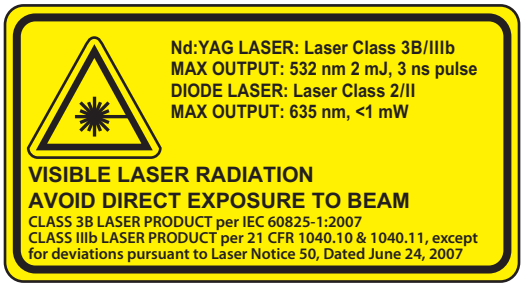
Location of regulatory compliance labels



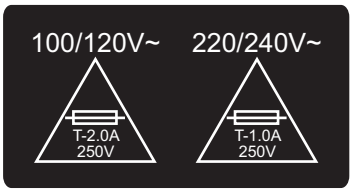

Part number, serial number, and manufacturing date

MADE IN THE U.S.A.

Made in the U.S.A.




Danger label




Replace fuse as marked label

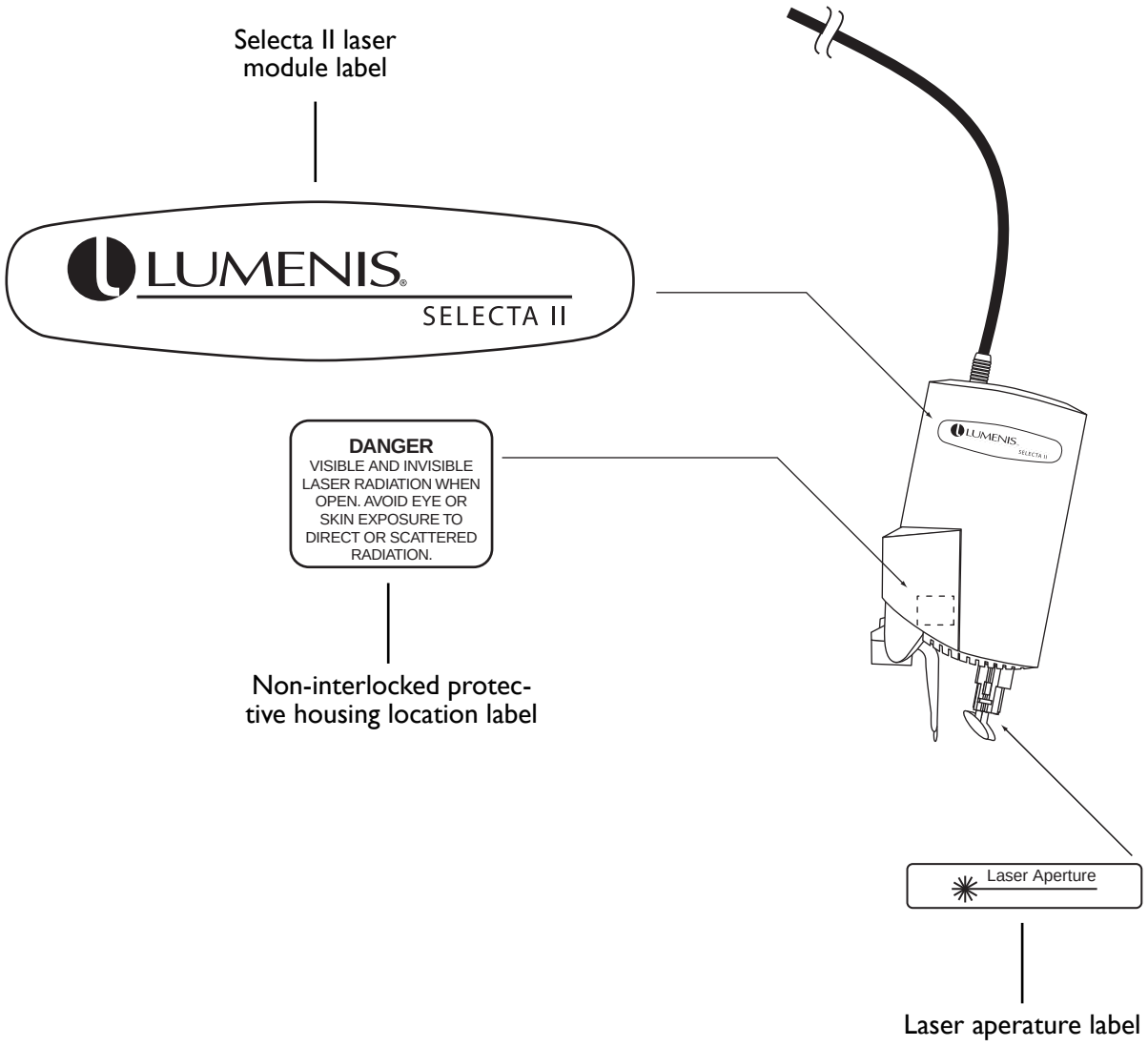
Interlock

Footswitch

Remote

Laser module

Location of regulatory compliance labels




Location of regulatory compliance labels

# Professional Use Instructions

## Overview

# Description of System

The Selecta II is a frequency-doubled, Q-switched Nd:YAG ophthalmic laser intended for use in selective laser trabeculoplasty. The Selecta II delivers single, visible pulses of light (532 nm wavelength), 3 nanoseconds in duration, with a 400 µm spot size and pulse energies ranging from 0.1 to 2.0 millijoules per pulse. A diode laser provides a visible aiming beam. A compatible slit lamp is used to deliver the laser light. The physician is able to control the delivery of laser pulses using a footswitch.

# Clinical Procedure and Parameters

Prior to treatment, a topical anesthetic is administered to the eye to be treated. A standard gonioscopy lens without magnifying optics is placed on the eye to be treated. The pigmented trabecular meshwork is brought into focus using the slit lamp.

Treatment consists of delivering 50 (±10) single, non-overlapping laser pulses of a determined optimum energy level to 180 degrees of the trabecular meshwork. The optimum energy level for treatment is defined as the maximum energy that can be delivered without causing photodisruption/optical breakdown of the trabecular meshwork. The optimum energy level for treatment will vary from patient to patient because the threshold for thermal injury, evidenced by bubble formation, is determined primarily by the level of pigmentation in cells of the trabecular meshwork.

To determine the optimum energy level for treatment, the laser energy should initially be set to 0.8 mJ. The aiming beam can be used to target the area to be treated. Pulse delivery is controlled by means of a footswitch. A single laser pulse is delivered to either the six o'clock or twelve o'clock position of the trabecular meshwork. The energy level should be increased or decreased by 0.1 mJ until bubble formation is observed; the energy level at which bubble formation occurs is known as the "threshold energy". After the threshold energy has been identified, the laser energy level should be decreased by 0.1 mJ; this lower energy level is known as the "treatment energy". Treatment should continue at the treatment energy level until 50 (±10) single, non-overlapping laser spots have been created along 180 degrees of either the nasal or temporal segment of the trabecular meshwork.

*Immediately following the laser treatment, prednisolone acetate 1% drops should be administered to the treated eye and continued four times daily for four to seven days.*

# Selecta II Mechanism of Action

The mechanism of action of the Lumenis Selecta II Frequency-doubled, Q-Switched Nd:YAG Ophthalmic Laser is the selective targeting of pigmented trabecular meshwork cells. The Selecta II achieves its intended effect through the use of single laser pulses of short duration and low fluence (energy/area). The short duration of the laser pulses minimizes the amount of heat that is dissipated from pigmented cells and absorbed by surrounding, non-pigmented tissues. When the Selecta II is operated within a defined energy range, the fluence of the resulting laser pulses is below the level where optical breakdown occurs. Higher energy levels may cause photoacoustic and/or photomechanical damage to adjacent non-pigmented cells or the trabecular support architecture.

# Indications for Use

The Selecta II is indicated for use in laser trabeculoplasty.

# Contraindications for Use

The Selecta II is contraindicated in patients with neovascular glaucoma and angle closure glaucoma.

# Complications and Adverse Events

In a clinical study sponsored by Lumenis (formerly Coherent Medical Group), patients who received selective laser trabeculoplasty treatment experienced some complications and adverse events which were considered to be related to the treatment, including mild transient anterior chamber inflammation in many patients, IOP increase ≥ 10mmHg, conjunctivitis, and eye pain. A number of other complications occurred at an incidence of less than 1%, including blurred vision, iritis, corneal edema, corneal lesion, and headache. Although not considered treatment-related, another potential complication of laser trabeculoplasty is the formation of peripheral anterior synechiae.

# Precautions

The following precautions are suggested when using the Selecta II:

- To reduce the risk of damage to non-targeted tissues, the treatment energy setting should be the minimum energy necessary to perform the treatment. Caution should be exercised when using pulse energies exceeding 1.4 mJ.
- Caution should be exercised during treatment if blood vessels are present in the angle.
- Treatment of blood vessels in the vicinity of the trabecular meshwork should be avoided due to the risk of hemorrhage.
- Caution should be exercised when treating patients with pre-existing anterior chamber inflammation including uveitis, since the procedure itself may induce a mild anterior chamber inflammatory response.
- Ocular surgery should be performed only when the structures to be treated can be visualized clearly.

# Decontamination Certificate

Under the provisions of Postal Law, Title 18, United States Code, Section 1716, and Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, "etiologic agents, diagnostic specimens and biological products…are nonmailable…"

The undersigned therefore certifies that the Lumenis equipment being returned herein by

| | |
|---|---|
| Individual/Institution | City, State, Country |

has undergone decontamination with a commercially available germicide cleared for use as a "Hospital Disinfectant" and is clean and free from biohazards, including—but not limited to—human or animal blood, tissue or tissue fluids or components thereof.

The undersigned also agrees to reimburse Lumenis for any costs incurred in cleaning the enclosed equipment, in the event said item(s) is/are received by Lumenis in a contaminated condition.

| | |
|---|---|
| Model | Model |
| Serial Number (if applicable) | Serial Number (if applicable) |
| Lumenis RMR Number | Lumenis RMR Number |
| Typed/Printed Name | Position/Title |
| Signature | Date |