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Safety and Regulatory
Introduction

The Selecta ophthalmic laser systems are classified as Class IIIb lasers by the Center for Devices and Radiological Health of the Food and Drug Administration and as Class 3b by the International Standard IEC 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.

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 Z136.1-2000, ANSI Z136.3-2005, or International Standard IEC 60825-1: 2001.

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

\[
\text{NOHD} = Z + \frac{1}{\theta} \sqrt{\frac{4}{\pi} \frac{\phi}{\text{MPE}} \text{Pf} - a^2 Z + \theta^4}
\]

where,

- \(Z\) = the distance of the beam waist from the laser system;
- \(a\) = the beam waist diameter (1/e² of axial irradiance for gaussian beam);
- \(\theta\) = minimum full angle beam divergence (1/e² of axial irradiance for gaussian beam);
- \(e \approx 2.7182818285\), the base of natural logarithms;
- \(\phi\) = maximum energy of one laser pulse or maximum CW laser power;
- \(\text{Pf}\) = the profile correction factor (1 for uniform profile or 2 for gaussian irradiance profile);
- \(\text{MPE}\) = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);
- \(\text{NOHD}\) = 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:

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

<table>
<thead>
<tr>
<th>Laser System</th>
<th>(\theta)</th>
<th>(\Phi)</th>
<th>MPE</th>
<th>Pf</th>
<th>a</th>
<th>Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selecta Duet 1064 nm laser</td>
<td>0.262</td>
<td>0.03 J</td>
<td>(1.67 \times 10^{-6}) J/cm(^2)</td>
<td>2</td>
<td>0.0007 cm</td>
<td>9.3 cm</td>
</tr>
<tr>
<td>Selecta Duet 532 nm laser</td>
<td>0.016</td>
<td>0.002 J</td>
<td>(0.50 \times 10^{-6}) J/cm(^2)</td>
<td>2</td>
<td>0.004 cm</td>
<td>9.3 cm</td>
</tr>
</tbody>
</table>

which results in a *worst case* NOHD of:

<table>
<thead>
<tr>
<th>Laser System</th>
<th>NOHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selecta Duet 1064 nm laser</td>
<td>8.4 meters</td>
</tr>
<tr>
<td>Selecta Duet 532 nm laser</td>
<td>63.0 meters</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Laser System</th>
<th>OD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selecta (all models)</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1-2000,
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 or joystick laser activation pushbutton 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 or joystick pushbutton. 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.

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

- **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.
Regulatory Compliance

Lumenis lasers and delivery systems comply with 21 CFR Chapter 1, Subchapter J, 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 keyswitch 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 indicator on the remote control provides a visible warning to the operator that after approximately 2 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. 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. The laser will automatically go into standby when electrical power is resumed. To resume treatment, manually reset the laser by placing the laser in ready mode.
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 International Standard IEC 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 slit lamp 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 or joystick laser activation pushbutton. 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 and joystick laser activation pushbutton 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—Illumination Tower

- Slit lamp slit width selector wheel
- Slit lamp illumination aperture selector wheel
- Slit lamp color filter selector wheel
Location of regulatory compliance labels—Illumination Tower
Location of regulatory compliance labels—Wheelchair-accessible table

- Emergency stop
- Table up-down control
- Footswitch receptacle
- Remote receptacle and external door interlock receptacle
- Danger Label
- Electrical specification, fuse rating, and mains receptacle

Visible and Invisible Laser Radiation
Avoid exposure to beam
CLASS 3B LASER PRODUCT
Nd:YAG: 532 nm, 2 mJ Max / 3 ns pulse
Nd:YAG: 1064 nm, 10 mJ Max / 3 ns pulse
Visible Laser Radiation
Do not stare into beam
CLASS 2 LASER PRODUCT
Diode Laser: 635 nm, <1 mW Max, CW

Selecta
PBL200051, Rev J
Location of regulatory compliance labels—small office table

Emergency stop

Table up-down control

Remote receptacle and external door interlock receptacle

Footswitch receptacle

Danger Label

Electrical specification, fuse rating, and mains receptacle
Lumenis contact information

CE mark

Model name, serial number, and manufacturing date

Danger label

ETL label

Electrical specification

Patents pending

DHHS certification

FDA sales restriction

Regulatory compliance labels
Emergency Stop

**Type B electric shock protection**

Electrical hazard (outside housing)

Non-Interlock housing danger (outside housing)

Flammable anesthetics and gases warning

**External door interlock receptacle**

Mains receptacle

Footswitch receptacle

Remote receptacle

**Attention, read manual**

(Laser aperture)

(Fuse rating)

532 nm / 1064 nm
OD = 5+

(Nonoperating environmental specifications (on shipping box))

Temperature
-10°C – 55°C
14°F – 131°F

Humidity
90% @ +55°C
NON-CONDENSING

Regulatory compliance labels
Safety and Regulatory

- **Ingress protection**
- **Table up-down control**
- **Illumination bulb specification**

**Regulatory compliance labels**

- **IP 20 Protection**
- **Laser energy adjustment control**
- **Posterior Offset**
- **Slit lamp slit width selector wheel**
- **Slit lamp illumination intensity control**
- **Aiming beam intensity control**
- **Slit lamp color filter selector wheel**
- **Slit lamp illumination aperture selector wheel**
Operation
Introduction

The Lumenis® Selecta® ophthalmic laser system is a fully integrated, high-performance diagnostic slit lamp and therapeutic laser delivery system. The Selecta laser family is capable of delivering 1064 nm Nd:YAG and/or 532 nm SLT laser light. In addition, a Lumenis LaserLink™ S can be attached to provide 532 nm photocoagulation when connected to a Lumenis Novus Spectra™ laser system.

The Selecta ophthalmic laser family includes the:

- Selecta® Duet™ — a combined 1064 nm photodisruptor and 532 nm SLT laser
- LaserLink S — a slit lamp laser delivery adapter
- Selecta® Trio — a Selecta Duet and a LaserLink S with compatible Lumenis 532 nm photocoagulator

Selecta has all of the standard controls and functions of a diagnostic slit lamp and is intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule.

The Lumenis Selecta is also an ophthalmic surgical laser designed for performing:

- photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser, including
  - discission of the posterior capsule of the eye (posterior capsulotomy),
  - discission of pupillary membranes (pupillary membranectomy),
  - and iridotomy/iridectomy;
- photocoagulation
- selective laser trabeculoplasty

The Selecta produces short, individual pulses of focused laser light with wavelengths of either 1064 nm or 532 nm, depending on the selected operational mode. Using a slit lamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient’s eye.

When the photodisruptor mode is selected, the treatment wavelength is 1064 nm. A twin-aiming beam targets the area of tissue disruption.

When the SLT mode is selected, the treatment wavelength is 532 nm. A coaxial aiming beam targets the trabecular meshwork via a contact lens. The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork.

If an optional LaserLink S delivery device is attached to the Selecta system and a Lumenis Novus Spectra 532 nm photocoagulator, the Selecta works strictly as a standard diagnostic slit lamp—all photodisruptor and SLT laser functions
are disabled. The LaserLink S laser delivery adaptor is used for treatments specifically cleared for the compatible laser photocoagulator.

Selecta is shipped directly from the factory to your site. Your local Lumenis representative initially unpacks, inspects, sets up, and installs the Selecta 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 device.

⚠️ **CAUTION** - Do not attempt to operate the laser system until a qualified Lumenis representative has installed and checked it for proper operation.

Thereafter, you, or the nursing staff at your facility, will perform the daily maintenance routines associated with this device, including inspecting and cleaning the components; focusing; and verifying the aiming beam. These procedures are detailed in this manual.

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 your delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
Selecta System Components

Selecta is comprised of the following major components:

- a diagnostic slit lamp with parallel binocular optics and five-position magnification
- an integrated Nd:YAG laser module that delivers 1064 nm and/or 532 nm wavelengths, depending on the laser model
- a remote control with an integrated liquid crystal display (LCD) for operating the device
- a fixed, internal laser eye safety filter
- an electrically adjustable table with slit lamp power supply. The table is available in two sizes: a medium-sized, wheelchair-accessible table or a smaller, non-wheelchair-accessible version that is specifically suited to small offices.
- an optional footswitch, door interlock plug, and all the necessary cables for proper connection and operation of the system
- A focus post for verifying the alignment of the illumination and aiming beams at the focal plane.

The system connections and controls are described in the following pages.
Laser module

The integrated laser module houses the treatment and aiming beams, laser source, and associated optics, enabling an otherwise diagnostic slit lamp to be used as a therapeutic laser instrument.

Remote control

The remote control is the control panel for the Selecta laser. The remote control allows you to select laser treatment settings, such as laser mode, energy, and aiming beam intensity. The remote control can be placed on the table so that the operator can verify the laser treatment parameters without moving back from the slit lamp binoculars.

Slit lamp table and console

The slit lamp table and console houses the main power keyswitch, emergency off button, control electronics, and power supply. The integrated slit lamp is mounted on the slit lamp table. The table height is electronically adjustable. The table also includes the mains receptacle, a fused IEC socket for 100-120 V or 220–240 V AC.

Footswitch and joystick pushbutton

The laser treatment beam can be activated either by a pushbutton on the slit lamp joystick or by an optional footswitch. The method of activation is user-selectable via the laser options screen. For safety reasons, when the user selects either footswitch or joystick, the system automatically disables the other.

Main power cable

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

External door interlock plug

The external door interlock is a safety feature that disables the laser if someone opens the treatment room door or removes the interlock plug.
Connection Instructions

⚠️ CAUTION - Do not use device if slit lamp seems unstable or inadequately secured.

Inspect the Selecta components

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

Connect the remote control

Plug the remote control cord into the remote control receptacle on the slit lamp console, as shown.
Connecting the remote control to the slit lamp console
Connect the footswitch (optional)

The Selecta provides a choice of laser activation. By default, the laser is activated by the joystick laser pushbutton. However, many physicians prefer footswitch activation, and Lumenis provides a footswitch that may be used with the system. If the footswitch is used, plug the footswitch cable into the footswitch receptacle, as shown.

If a footswitch is connected, the Footswitch laser activation mode must also be selected on the options screen of the laser remote control, as described in the “Laser Basics—Remote Control” section of this manual.

If the footswitch is selected on the options screen remote control, but is not properly connected when the laser is turned on, (footswitch not connected) displays on the remote control display and the laser cannot be placed in ready mode.
Connecting the footswitch
**Connect the external door interlock plug**

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.

Use of an external door interlock is optional; however, if you do not use a door interlock, you must insert the external door interlock plug into the [external interlock] receptacle, as shown.

If you use an external door interlock, 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 [external interlock not connected] illuminates on the remote control display. To resume treatment, close the treatment room door or reinsert the interlock plug, and press the [ready] button on the remote control.

---

*External door interlock receptacle (on back of system)*

*External door interlock plug*
Plug in the main power cable

1. Ensure that the system keyswitch 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.

Plugging in the main power cable
Installing optional accessories

**CAUTION** - Disconnect or stabilize all accessories during transportation.

A variety of optional viewing accessories is available for the Selecta, such as camera and video adaptors, and a co-observation tube. Compatible Selecta accessories are listed in the “Specifications” section of this manual. You may also contact your local Lumenis representative for additional product information.

**CAUTION** - Ensure all attachments are attached and fastened securely.

**WARNING** - Ensure all eye safety filters for attachments are properly placed. Ensure the correct optical density for the desired wavelengths is clearly marked. Refer to Laser Safety Eyewear in the Safety and Regulatory section of this manual for more information.

The installation instructions provided here show the installation of a co-observation tube; however, installation is essentially the same for all accessories. When using observation equipment, you must first install a beam splitter onto the slit lamp. To ensure that the observer is protected by the eye safety filter, you will mount optional viewing accessories between the binoculars and the magnification changer.

Remove the slit lamp binocular assembly

1. Grasp the slit lamp binocular assembly with one hand; with the other hand, loosen the slit lamp binocular screw.

2. Slightly tilt and lift the binocular assembly to remove it from the magnification changer.
Install the beam splitter

3 Install the beam splitter by inserting the beam splitter dovetail mount into the magnification changer dovetail receptacle and lining up the guide pin with the guide pin slot. Tighten the magnification changer screw to secure the connection.

Remount the binocular assembly onto the slit lamp

4 Insert the binocular assembly dovetail mount into the beam splitter dovetail receptacle, lining up the guide pin with the guide pin slot.

5 Seat the guide pin into the guide pin slot, and tighten the binocular screw to secure the connection.

Secure the beam splitter between the binocular assembly and magnification changer
Attach a compatible viewing device to the beam splitter
(co-observation tube shown)

1 Verify that the beam splitter is properly installed, as instructed earlier in this section.

2 Guide the centering groove on the co-observation tube into the beam splitter side port.

3 Rotate the beam splitter attachment ring clockwise to secure the connection.

*Attach the compatible viewing device to the beam splitter (co-observation tube shown)*
Attaching the LaserLink S delivery device

CAUTION - Before use, refer to the LaserLink S Operator Manual for detailed installation and operation instructions.

1. Position the illumination tower out of the way.
2. Place the LaserLink S on top of the Selecta Slit Lamp.
3. Secure the LaserLink S with the attached thumb screw.
4. Verify that the Remote Control shows the LaserLink icon and does not allow the system to display YAG or SLT functions.
5. Replace the Selecta Slit Lamp’s single illumination mirror with the dual illumination mirror.
6. Attach the LaserLink S fiber optic to the photocoagulator, as described in the LaserLink S operator manual.
7. Disconnect the external door interlock plug from the Selecta and connect the plug to the photocoagulator when the LaserLink S is connected and in use. Re-connect the external door interlock plug to the Selecta when the LaserLink S and photocoagulator are no longer in use.
System Basics

Main system controls

The integrated slit lamp is mounted on an electronically adjustable table. Located on the slit lamp table are the main system controls: the system keyswitch, the laser emergency off pushbutton, and the table height control button. Locking wheels enable the table to be easily and safely moved from one treatment room to another. The power supply provides power to the illumination tower and fixation light. The main power receptacle, fuse module, and the remote control, external door interlock, and footswitch receptacles are located on the table.

Laser settings are selected from the remote control. The laser activation mode is user-selectable: either a footswitch or joystick pushbutton may be used.
Emergency laser stop button

Table top

Remote control

Table height control

Joystick laser pushbutton

Slit Lamp

Power on indicator light

Keyswitch

Main power receptacle (near right rear wheel)

Laser footswitch

Locking wheels

Selecta
PBL200051, Rev J
Turning on the system

Insert the key into the keyswitch and turn it to the 1 (on) position.

The power on indicator lights up and the system initiates a self-test. During self-test, the initialization screen on the remote control displays progress and status messages. Upon successful completion of the self-test, the system beeps, and the remote control changes to the laser mode screen. The standby icon on the remote control illuminates, and the laser is in standby mode. The system will default to minimum settings.

Turning off the system

Under normal operating conditions, turn the keyswitch to the 0 (off) position.
Standby, Ready, and Laser Emission mode

When the laser is turned on and has completed initialization, the laser defaults to standby mode. The standby indicator illuminates on the remote control.

In standby mode (◉), the joystick pushbutton and footswitch are disabled and the safety shutter is closed; no treatment beam is available. In ready mode (◉), the joystick pushbutton or footswitch is enabled and the treatment beam is available.

To commence treatment, the clinician depresses the Standby/Ready toggle button, placing the laser in ready mode. There is a two-second transition between standby and ready mode, during which the ready icon on the remote control flashes. When the system beeps and the ready icon (◉) illuminates on the remote control, it indicates that the laser is fully powered and that laser radiation (the treatment beam) is accessible via the user-selectable footswitch or joystick pushbutton. When the clinician depresses the footswitch or joystick pushbutton, the laser emission symbol (●) illuminates on the remote control, indicating that the system is emitting laser light to the treatment site.

Standby, Ready, and Laser Emission mode (photodisruptor screen shown)
Emergency off

In an emergency, press the red emergency off button to immediately de-energize the system.
System beeps

The system emits unique beeps to distinguish certain types of events. For example, the system beeps when the standby or ready laser status mode is changed, when the system is not ready to accept input, when the maximum or minimum treatment setting is reached, when the energy delivered was less than requested, or when an error has occurred.

Disconnecting the system

1. Turn the keyswitch to the **O** (off) position.
2. Remove the system power plug from the electrical outlet.

Moving the system

After disconnecting the system, move the slit lamp table and accessories to the desired site. Step on the wheel brake to lock the wheel, as shown. To unlock the wheel, place your foot under the brake and lift the lever up.
Slit Lamp Basics

Slit lamp positioning and joystick control

The slit lamp is mounted to the table and allows for gross positioning of the slit lamp. Loosen or tighten the instrument base locking screw, as shown in the following illustration, to move the slit lamp and to adjust the friction between the base and the table top. The slit lamp position can be locked by tightening the instrument base locking screw.

The joystick controls lateral, longitudinal, and vertical positioning of the slit lamp. Moving the joystick moves the instrument in the corresponding direction. Turning the joystick clockwise raises the slit lamp microscope; turning it counter-clockwise lowers it.

The position of the laser aiming and treatment beams is fixed in the system. Therefore, moving the joystick to position the slit lamp, correspondingly adjusts the position of the laser aiming and treatment beams. The joystick also has a laser pushbutton which can be used to activate the laser treatment beam.

The laser may be activated by either a footswitch or by the joystick laser pushbutton. The method of laser activation is user selectable via the footswitch/joystick mode button on the remote control options screen. For safety, the laser enables only the selected mode, and automatically disables the other.

Forcing the joystick to move after the slit lamp base has been locked may damage the instrument.

Slit lamp controls

CAUTION - During use, beware of hot surfaces on the slit lamp illumination tower.

As shown in the following illustration and described in the following section, the Selecta slit lamp has all of the standard diagnostic slit lamp controls such as illumination intensity, illumination aperture, slit width adjustment and rotation, as well as the typical diagnostic slit lamp adjustments, such as diopter eyepiece adjustments, magnification, binocular focus, and interpupillary distance adjustment. In addition, as an integrated laser slit lamp, the Selecta also has controls that are specific to operation of the laser. The laser controls that are located on the slit lamp itself are: the joystick laser activation button, the energy adjustment knob, the posterior YAG offset control, and the aiming beam intensity control. All other laser functions are located on the remote control module.
Slit lamp controls

Eyepieces, diopter adjustment, and interpupillary distance

The Selecta slit lamp microscope eyepieces have a 12.5x magnification, with diopter adjustments on both eyepieces of ±5. One eyepiece has crosshairs to aid focusing. The eyepiece positions can be manually adjusted to suit the operator's interpupillary distance. Eyecups can be pushed back if the operator wears spectacles.

Microscope magnification changer

The magnification changer is used to select the slit lamp viewing magnification. The magnification is adjusted using the large rotary control knob behind the binocular assembly.

Illumination tower rotation

The illumination tower incorporates the illumination mirror which directs the slit lamp illumination to the treatment area. The tower can be rotated approximately 90° either side of center. To rotate the tower, loosen the illumination tower locking screw and manually rotate the tower as desired. Tighten the tower locking screw to lock the tower into position. An angle scale, located below the illumination tower locking screw, indicates the rotation angle of the tower.

Slit width control

Slit width ( ) is adjusted using a rotary control knob on each side of the illumination tower. Rotate the knob clockwise to widen the slit width, counter-clockwise to narrow the slit, as shown on the control icon.

Slit rotation control

The slit can be rotated up to 90° either side of vertical. The slit rotation control is a knurled section of the illumination tower. Rotate the control in the direction of the desired rotation. A slit rotation angle scale is located directly above the slit rotation control.

Illumination aperture and color filter selector wheels

The illumination aperture ( ) and color filter ( ) selector wheels are located on the front of the illumination tower beneath the slit width control. The top wheel selects the illumination aperture. The bottom wheel selects the colored viewing filters. The filter selections are: green, cobalt blue, neutral density (ND at 28% attenuation), and none.

Microscope arm rotation

The microscope arm can be rotated approximately 30° either side of center. To rotate the microscope arm, loosen the microscope arm locking screw and
manually rotate the microscope arm to the desired position. An arm position angle scale, located directly beneath the microscope arm locking screw, indicates the rotation angle of the microscope arm.

**Slit lamp illumination intensity control**

A rotary control on the right hand side of the slit lamp base adjusts the slit lamp illumination intensity ( ). Rotate the control clockwise to increase intensity, counter-clockwise to decrease intensity, as shown on the control icon.

**Chin rest height adjustment**

The patient chin rest may be adjusted up and down using the chin rest height adjustment knob, located on the chin rest assembly. Rotate the knob to adjust the chin rest up or down.

**Laser controls on the slit lamp**

**Laser eye safety filter**

The microscope contains an integrated, fixed eye safety filter that protects the operator’s eyes from exposure to laser radiation.

**Laser aiming beam intensity control**

A rotary control on the right side of the slit lamp base adjusts the laser aiming beam intensity ( ). To increase the laser aiming beam intensity rotate the control clockwise, to decrease intensity rotate the control counter-clockwise, as shown on the control icon.

**Energy Adjustment control**

Laser energy is adjusted using a rotary control ( ) located on each side of the microscope column. As indicated on the icon next to the control, rotate the control clockwise to increase laser energy, counter-clockwise to decrease laser energy.

**Posterior YAG offset control**

The posterior YAG offset control ( ) is located on each side of the microscope column. The YAG offset control adjusts the focal plane of the treatment laser energy posteriorly. 100 µm is the nominal setting, as indicated on the control knob. The posterior YAG offset is continuously adjustable from 0 to 350 µm posterior, with detents at 0, 100, 250, and 350 µm.
Laser Basics

Remote Control

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

⚠️ **WARNING** - Do not use the device if the remote display is blank, unresponsive, or incorrect.

⚠️ **WARNING** - Do not use the device if the remote displays error messages; refer to maintenance section of this manual.

Photodisruptor Mode—remote control screen

Remote control (Photodisruptor-1064 nm screen shown)
SLT Mode—remote control screen

Remote control
(SLT-532nm screen shown)
PC (external photocoagulator) Mode—remote control screen

Remote control
(PC mode shown)
Options Screen Mode—remote control screen

Remote control
(Options screen shown)
Standby, Ready, and Laser Emission mode

Use the standby/ready toggle button to select the laser standby/ready mode. When the laser is turned on and has completed initialization, the laser defaults to standby mode. The standby indicator illuminates on the remote control.

In standby mode (●), the joystick pushbutton and footswitch are disabled and the safety shutter is closed; no treatment beam is available. In ready mode (○), the joystick pushbutton or footswitch is enabled and the treatment beam is available.

To commence treatment, the clinician depresses the standby/ready toggle button, placing the laser in ready mode. There is a two-second transition between standby and ready mode, during which the ready icon on the remote control flashes. When the system beeps and the ready icon (○) illuminates on the remote control, it indicates that the laser is fully powered and that laser radiation (the treatment beam) is accessible via the user-selectable footswitch or joystick pushbutton. When the clinician depresses the footswitch or joystick pushbutton, the laser emission symbol (●) illuminates on the remote control, indicating that the system is emitting laser light to the treatment site.

The Selecta provides a choice of laser activation. By default, the laser is activated by the laser pushbutton on the slit lamp joystick. However, many physicians prefer footswitch activation, and Lumenis provides a Selecta footswitch that may be used with the system. If a footswitch is connected, the Footswitch laser activation mode must also be selected on the options screen of the remote control, as described in the “Laser Basics—Remote Control” section of this manual.
Selecting Standby or Ready mode
(Photodisruptor screen shown)
Laser mode

If you've purchased the Selecta Duo, the laser mode pushbutton lets you select either the YAG or SLT laser mode. The remote control screen will change to reflect all of the treatment settings available in the selected laser mode.

PC mode is used in the Selecta Trio configuration, which utilizes a LaserLink S delivery device and a Novus Spectra 532 nm photocoagulator. In PC mode, laser standby/ready, aiming beam intensity, treatment settings, and treatment delivery are all controlled by the Novus Spectra laser.
Aiming beam

The aiming beam intensity can be adjusted with the aiming beam intensity control knobs located on the slit lamp (shown on the “Slit Lamp Controls” illustration), or by using the remote control aiming beam pushbutton. To decrease the intensity, press the lower portion of the button. To increase the intensity, press the upper portion of the button.
Remote Control System Options

Select the options screen

The Selecta remote control options screen is where you can set system preferences such as the volume of system beeps, the interface language, and whether the treatment laser is activated by the joystick pushbutton or a footswitch. To enter the options screen, press the options toggle on the top right of the remote control. To return to the laser treatment screens, press the options toggle again.
Language

The Selecta system interface can be displayed in either English or icon mode. The language interface button is located on the options screen. In English mode, any informational or error messages are displayed in English and with an error code, such as “E109”. In icon mode, any informational or error messages are displayed only with an error code. To toggle between the two modes, press the language interface button on the remote control options screen.

Choosing the system interface language
(Options screen shown)
**LCD screen brightness**

The brightness of the remote control LCD screen can be adjusted to suit treatment room light conditions by using the remote control LCD brightness pushbutton. The LCD screen brightness pushbutton is located on the remote control options screen. To decrease the brightness of the LCD screen, press the lower portion of the button. To increase the brightness, press the upper portion of the button.

*Adjusting the remote control screen brightness (Options screen shown)*
Laser activation mode—Joystick or Footswitch

The Selecta provides a choice of laser activation. By default, the laser is activated by the laser pushbutton on the slit lamp joystick. However, the laser can be activated either by a pushbutton on the slit lamp joystick or by a footswitch. The currently active mode is highlighted on the options screen, as shown below. To change the laser activation mode, press the Joystick/Footswitch toggle button.

For safety, when the user selects either footswitch or joystick, the system automatically disabled the other. If the footswitch is selected on the options screen remote control, but is not properly connected when the laser is turned on, (footswitch not connected) displays on the remote control display and the laser cannot be placed in ready mode.
Volume

The preferred volume of the system beeps can be adjusted using the volume controls. The volume control is located on the remote control options screen. To lower the beep volume, press the lower portion of the button. To increase the volume, press the upper portion of the button.
Remote Control Treatment Settings

Energy—photodisruptor and SLT mode

Use the energy control to adjust the energy per pulse or energy per burst, depending on the laser mode. Rotate the control clockwise or counterclockwise to respectively increase or decrease the laser energy. Laser energy is displayed in millijoules. Refer to the “Specifications” section of this manual for available energy settings. The energy display shows the currently selected energy.

Selecting the energy per burst
(Photodisruptor mode shown)
Total energy and pulse count displays—Photodisruptor and SLT mode

The total energy (mJ) delivered since the reset button was pressed is shown in the total energy display. The total pulse count since the reset button was pressed is shown in the total pulse count 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
(Photodisruptor mode shown)
Burst mode—Photodisruptor laser mode

There are three burst modes available in photodisruptor laser mode: single, double, and triple burst. For example, if triple burst is selected, when the treatment laser is activated, the selected energy will be delivered in a “pulse train” of three pulses. Refer to the “Specifications” section of this manual for additional detailed information.

Set the burst mode using the burst mode selector. The currently selected burst mode is shown in the burst mode display.
Preoperative Setup of the Slit Lamp and Laser

**WARNING** - Do not use the device if the illumination is not present or cannot be made to appear after adjusting slit knobs.

**WARNING** - Use caution when adjusting the table up and down to prevent patient injury or discomfort.

Focusing the Slit Lamp

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

1. Turn on the system as instructed in “Turn on the system” section of this manual.

2. 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.

3. Use detail on the paper within the field of view as a focusing target, and adjust the aiming beam intensity to the lowest setting, until it is not visible.

4. Set the binocular eye piece diopter setting to 0.

5. Set the magnification to the highest setting, and focus the slit lamp on the target. Lock the slit lamp base.

6. Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to - to achieve the best focus on the target; complete the procedure for each eye.

7. Set the magnification to the highest setting. Unlock the slit lamp base, and focus the slit lamp on the target. Lock the slit lamp base.

8. Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to - to achieve the best focus on the target; complete the procedure for each eye.

9. Note the index number of the slit lamp eyepieces relative to the index marks as a future starting point for this procedure.

10. View the target through the eyepieces, and adjust the focus to obtain the smallest spot on the target.

11. Remove the paper target from the headrest.
Verify that the slit spot is centered

1. Verify that the laser system is in standby mode.

2. Set the slit spot to 5 mm.

3. Set the microscope magnification to the maximum setting.

4. Visually verify that the slit spot is centered in the field of view. If the spot is not centered, contact your Lumenis service representative.

Verify that the slit spot is centered
Verify the laser aiming beam accuracy—YAG

⚠️ **WARNING** - Verifying the aiming beam is extremely important for the safe operation of your laser equipment. Do not use the laser if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to nontarget tissue and possible injury.

⚠️ **WARNING** - Correct optical alignment is critical for accurate aiming of the equipment. This pre-operative procedure should be performed daily.

1. Tape a piece of laser alignment thermal-sensitive paper (Kentek Zap-It® or equivalent) onto the slit lamp headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.

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

Follow the original manufacturer’s instructions regarding the proper use of thermal paper.

2. Turn on the system as instructed in “Turn on the system” section of this manual. Verify that the laser is in standby mode.

3. Set the aiming beam to the highest intensity.

4. Look through the slit lamp eyepieces at the paper target. A red spot, the aiming beam, should appear on the paper target. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.

⚠️ **WARNING** - Do not use the device if the aiming beam is set to the highest intensity and is still weak or not visible. Doing so may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

5. Reduce the aiming beam to a comfortable intensity.

6. Adjust the eyepieces to the desired accommodations.

7. Adjust the slit width to full circle illumination and low intensity.

8. Swing the illumination tower to one side, if necessary, so that it does not obstruct the aiming beam.

9. Position the slit lamp so that the aiming beams converge to form one spot on the paper target.
WARNING - If the aiming beams cannot be made coincident, do not use the laser on patients. Doing so may cause inadvertent damage to nontarget tissue and injury to the patient. Contact your local Lumenis representative.

10 Lock the slit lamp in this position.

11 Select minimum energy settings.

12 Select the Ready mode.

13 Verify that the aiming beams are still converged into a single spot.

14 Depress the joystick pushbutton or the footswitch to activate the laser.

15 Inspect the burn mark through the binoculars. Verify that the burn mark on the target photographic paper is coincident with the aiming beam spot.

16 Repeat the test as necessary.

WARNING - If the laser burn mark and the aiming beams are not coincident, do not use the laser on patients as it may cause serious injury. Contact your local Lumenis representative.

Verify the laser aiming beam accuracy—SLT

WARNING - Verifying the aiming beam is extremely important for the safe operation of your laser equipment. Do not use the laser if the aiming beam is not visible. Ensure that it is a clear circular shape, with no part of the beam missing. Operating the laser without the aiming beam or with a poor aiming beam may result in laser exposure to nontarget tissue and possible injury.

WARNING - Correct optical alignment is critical for accurate aiming of the equipment. This pre-operative procedure should be performed daily.

1 Swing the illumination tower to the center position.

2 Tape a piece of laser alignment thermal-sensitive paper (Kentek Zap-It® or equivalent) onto the slit lamp headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.

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

3 Turn on the system as instructed in “Turn on the system” section of this manual.
4 Verify that the laser is in standby mode.

5 Turn on the slit lamp illumination.

6 Look through the slit lamp eyepieces at the paper target.

7 Set the slit to vertical.

8 Focus each eyepiece until the target is seen clearly.

9 With the illumination set to the narrowest slit, swing the illumination tower from side to side and verify that the slit does not move on the target.

10 Open the slit and set the illumination to the smallest round aperture.

11 Set the magnification to the middle setting and view the target through the binoculars. The aiming beam should be centered in the field of view and in the center of the illumination aperture.

At high magnification settings, the spot may not appear exactly in the center of the field of view, but this will not affect the beam positioning accuracy.

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

12 Select SLT mode.

13 Select an energy of approximately 1 to 2 mJ.

14 Select the Ready mode.

15 Depress the joystick pushbutton or the footswitch to activate the laser.

16 Inspect the burn mark through the binoculars. Verify that the burn mark on the target photographic paper is coincident with the aiming beam spot. A round, 400 µm burn spot should be visible if the microscope is properly focused on the target.

⚠️ **WARNING** - If the laser burn mark and the aiming beams are not coincident, do not use the laser on patients as it may cause serious injury. Contact your local Lumenis representative.

17 Repeat the test as necessary.
Operation Instructions

Preoperative Instructions

1. Ensure that the Selecta system is properly connected, as described in the “Connection instructions” section of this manual.

2. Post the “Laser in Use” warning sign outside the treatment room door.

3. Verify that the pre-operative system set up, as described in this manual, was properly performed.

4. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear, as described in the “Laser Safety Eyewear” section of this manual.

5. Turn on the laser, as instructed in this manual.

Intraoperative Instructions

1. As detailed in this manual, prepare the treatment room and verify that the laser is turned on and in standby mode.

2. Position the patient.

3. Turn on the slit lamp illumination.

4. If used, place the contact lens in the patient’s eye.

5. Adjust the slit lamp, if necessary. Verify a clear view of the target tissue.

6. Select the desired treatment parameters.

WARNING - Verify energy settings before, during, and after treatment.

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.

7. Place the laser in ready mode.

8. Depress the joystick laser pushbutton or footswitch to deliver the treatment beam to the target site.
Postoperative Instructions

1. Place the laser in standby mode.

2. Turn the system keyswitch to the O (off) position. Remove the key to prevent unauthorized use of the laser.

3. Clean the Selecta, as instructed in the “Maintenance” section of this manual.

4. Cover the Selecta with its dust cover to protect it and ensure that the optical components remain free of dust and other contaminants.
Maintenance
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.

**System console electrical**

Verify that the system 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.
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Suggestion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System does not turn on, and the remote control will not illuminate</strong></td>
<td>The system 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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The building power (main electrical service) is turned off.                      ⇒ Turn on the building power.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The remote interlock has been activated.                                        ⇒ Close the operating room door.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The system is not turned on.                                                    ⇒ Verify that the system key is turned to the (on) position.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The remote control is not properly connected.                                   ⇒ Refer to the Operation section of this manual, and check the remote control connections.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The emergency stop switch is depressed.                                         ⇒ Ensure that the emergency stop switch is not depressed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>System fuses are blown.                                                        ⇒ Check that the fuses are not blown. Disconnect the power cord before removing or changing the fuses. Refer to “Changing the Fuses” in the Maintenance section of this manual for additional information.</td>
<td></td>
</tr>
<tr>
<td><strong>The remote control does not function.</strong></td>
<td>The remote control is not properly connected.                                   ⇒ Refer to “Connect the Remote Control” in the Operation section of this manual, and verify that the remote is properly connected.</td>
<td></td>
</tr>
<tr>
<td><strong>Inadequate or no aiming beam</strong></td>
<td>The aiming beam is set to the lowest intensity.                                 ⇒ Increase the aiming beam intensity, as described in “Laser Basics” in the Operation section of this manual.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The system components are not properly connected.                              ⇒ Refer to the Operation section of this manual, and check the system connections.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Slit lamp binocular eyepieces are not properly adjusted.                        ⇒ Refer to the Focusing the Slit Lamp section of this manual for additional information for properly adjusting the Slit lamp binocular eyepieces.</td>
<td></td>
</tr>
<tr>
<td>Symptom</td>
<td>Probable Cause</td>
<td>Suggestion</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Slit lamp optics are dirty.</td>
<td></td>
<td>➞ Inspect and clean the slit lamp optics, as detailed in “User Maintenance” in this chapter.</td>
</tr>
<tr>
<td><strong>No treatment beam is delivered when the footswitch or joystick pushbutton is pressed, or the beam is of poor quality</strong></td>
<td>The laser is in standby mode.</td>
<td>➞ Place the laser in ready mode.</td>
</tr>
<tr>
<td></td>
<td>The laser activation mode is not properly selected on the remote control options screen.</td>
<td>➞ As detailed in the “Laser activation mode” section of this manual, verify that the correct laser activation mode is selected on the remote control options screen. For example, if you are using the footswitch to activate the treatment beam, ensure that the footswitch mode is selected.</td>
</tr>
<tr>
<td></td>
<td>The laser components are not properly connected.</td>
<td>➞ Refer to the Operation section of this manual, and check the laser system connections.</td>
</tr>
<tr>
<td></td>
<td>The laser module optics are dirty or misaligned.</td>
<td>➞ Contact your local Lumenis representative.</td>
</tr>
<tr>
<td><strong>Inadequate laser power</strong></td>
<td>The laser module optics are dirty or misaligned.</td>
<td>➞ Contact your local Lumenis representative.</td>
</tr>
<tr>
<td><strong>Cannot select the Ready mode</strong></td>
<td>The LaserLink S is attached and the Selecta system is in YAG or SLT laser mode.</td>
<td>➞ Remove the LaserLink S.</td>
</tr>
<tr>
<td></td>
<td>The slit lamp table is in motion.</td>
<td>➞ Adjust the table to the desired height and position, and then select the Ready mode.</td>
</tr>
<tr>
<td></td>
<td>The incorrect illumination mirror is installed.</td>
<td>➞ Install the single illumination mirror, as described in the LaserLink S operator manual.</td>
</tr>
<tr>
<td><strong>No or inadequate slit lamp illumination</strong></td>
<td>The illumination intensity control is not in the proper position.</td>
<td>➞ Refer to the Operation section of this manual and adjust the illumination intensity control.</td>
</tr>
<tr>
<td></td>
<td>The illumination bulb is burned out.</td>
<td>➞ Refer to “Changing the Slit Lamp Illumination Bulb” in the Maintenance section of this manual for information on replacing the halogen illumination lamp.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Probable Cause</td>
<td>Suggestion</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
<td>------------</td>
</tr>
<tr>
<td>Slit adjustments are needed.</td>
<td>⇒ Refer to the Operation section of this manual for information on adjusting the slit width.</td>
<td></td>
</tr>
<tr>
<td>Slit Lamp table power cord not plugged in.</td>
<td>⇒ Plug in power cable and ensure that the power switch is turned on.</td>
<td></td>
</tr>
<tr>
<td>Fuse is blown.</td>
<td>⇒ Check that the fuses are not blown. Disconnect the power cord before removing or changing the fuses. Refer to “Changing the Fuses” in the Maintenance section of this manual for additional information.</td>
<td></td>
</tr>
<tr>
<td>Microscope does not focus</td>
<td>The eyepieces are incorrectly fitted into the binoculars.</td>
<td>⇒ Ensure that the eyepieces are fully inserted into the binoculars.</td>
</tr>
<tr>
<td></td>
<td>The illumination bulb is faulty.</td>
<td>⇒ Refer to “Changing the Slit Lamp Illumination Bulb” in the Maintenance section of this manual for information on replacing the illumination bulb.</td>
</tr>
<tr>
<td>Illumination is blurred</td>
<td>The illumination bulb is incorrectly fitted or faulty.</td>
<td>⇒ Refer to “Changing the Slit Lamp Illumination Bulb” in the Maintenance section of this manual for information on replacing the illumination bulb.</td>
</tr>
<tr>
<td>“External room interlock” or “W104” displays on the remote control</td>
<td>The external room interlocked door has been opened or the external door interlock plug has been pulled out of the system.</td>
<td>⇒ Close the interlocked door, or connect the remote interlock plug, as described in the Operation section of this manual.</td>
</tr>
<tr>
<td>“Energy High &gt;20%” or “I109” displays on the remote control</td>
<td>The detected energy level was more than 20% higher than the level selected.</td>
<td>⇒ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.</td>
</tr>
<tr>
<td>“Energy Low &lt;20%” or “I110” displays on the remote control</td>
<td>The detected energy level was at least 20% lower than the level selected.</td>
<td>⇒ Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Probable Cause</td>
<td>Suggestion</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>“Energy High &gt; 50%” or “C101” displays on the remote control</td>
<td>The detected energy level was at least 50% higher than the level selected.</td>
<td>Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.</td>
</tr>
<tr>
<td>“Energy Low &lt; 50%” or “C102” displays on the remote control</td>
<td>The detected energy level was at least 50% lower than the level selected.</td>
<td>Place the laser in ready mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.</td>
</tr>
<tr>
<td>“Over Temperature” or “W106” displays on the remote control</td>
<td>The laser temperature is too high.</td>
<td>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.</td>
</tr>
<tr>
<td>“Footswitch Not Present” or “W108” displays on the remote control</td>
<td>The footswitch is not properly connected to the laser.</td>
<td>Refer to the Operation section of this manual, and connect the footswitch as instructed. If the condition continues, restart the system, ensuring that the footswitch is not pressed during start up. If the condition persists, the footswitch may be defective; contact your local Lumenis representative.</td>
</tr>
<tr>
<td></td>
<td>The footswitch is properly connected, but the footswitch laser activation mode is not selected on the remote control options screen.</td>
<td>Refer to the Remote Control Options Screen in the Operation section of this manual for instructions on selecting the footswitch laser activation mode.</td>
</tr>
<tr>
<td>“No LaserLink” or “W110” displays on the remote control.</td>
<td>The LaserLink S delivery device is not properly connected.</td>
<td>Refer to the LaserLink connection instructions in the LaserLink S operation manual, and connect the LaserLink S S as instructed.</td>
</tr>
<tr>
<td>If any other code displays that is not explained here...</td>
<td>The error condition is not user correctable.</td>
<td>Contact your local Lumenis representative.</td>
</tr>
</tbody>
</table>
User Maintenance

Annual laser maintenance

Preventative maintenance, safety, power, and calibration checks should be performed annually by 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.

Inspecting the laser system components

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

Cleaning the slit lamp and laser module optics

Before each use, inspect the slit lamp oculars and objective lens for dirt, debris, or damage. If necessary, clean the surfaces as follows:

1. Turn off the system power.

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.

   Do not use ethanol or methanol to clean the external surfaces of the console or slit lamp. Doing so may harm the surface.

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 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.

   Never use dry swabs or tissues to clean optics. They may damage the optical coatings or scratch the surface.
Cleaning the external surfaces of the laser console and slit lamp

Clean the external surfaces of the laser console and slit lamp before every patient. 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 and slit lamp. 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.

Cleaning and disinfecting areas of patient contact

Selecta laser treatment involves only brief skin contact with the patient, but attention should be given to the possibility of cross-contamination between patients. The areas of skin contact include the slit lamp table, chin rest, headrest and handles.

Responsibilities of the health facility

Follow your institution's standard procedures and guidelines for cleaning and disinfecting areas of patient contact, such as:

- determining the level of cleaning and disinfection required between patients
- developing appropriate education and training for proper cleaning and disinfection
- ensuring that routine cleaning and disinfection methods used in the facility are compatible with the device
- scheduling and performing a routine cleaning and disinfection regimen

Guidelines for cleaning and disinfecting patient contact areas

The following is provided as a general guideline:

- thorough cleaning of all patient contact areas is recommended before every new patient
- disposable chin rest papers can also be used (chin rest papers are supplied with the Selecta and can be ordered separately)
- the system may be cleaned by wiping all contact areas using a suitable, hospital-grade liquid cleaning agent that is non-corrosive, non-toxic and low in residue
Clean the gonioscopy contact lens

The Lumenis Selecta contact lenses have a special low-reflectivity coating bonded to the lens, and so must, therefore, be handled carefully. As soon as a lens is removed from a patient’s eye, thoroughly rinse it in cold or warm water to remove salts, mucous and gonioprism solution. Wash in warm water with a few drops of clear dishwashing liquid, then rinse with cool water and blot dry. Dry completely before storing it in the case.

Disinfect the gonioscopy contact lens

To effectively disinfect the lens:

1. Soak the lens in a solution of 2% glutaraldehyde (aqueous solution) for a recommended exposure time of 20 minutes. Household bleach (sodium hypochlorite) solution may be used instead, diluted 1 part bleach to 10 parts water, with a recommended exposure of 10 minutes.

2. Rinse the lens thoroughly with cool water and blot dry.

3. Allow the lens to dry completely before storing in the case.

Sterilize the gonioscopy contact lens

To sterilize the gonioscopy contact lens:

1. Remove the lens from its case before sterilizing.

2. To sterilize, use ethylene oxide gas with aeration not to exceed 52°C (125°F), following the sterilizer manufacturer’s recommendation.

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:

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal Name</th>
<th>Signal Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote Interlock</td>
<td>Connect to switch, normally open</td>
</tr>
<tr>
<td>2</td>
<td>Return</td>
<td>Connect to switch common</td>
</tr>
<tr>
<td>3</td>
<td>None</td>
<td>No connection</td>
</tr>
</tbody>
</table>

Remote door interlock pin assignments
(mating face shown)
Changing the Fuses

1. Turn off the system.

2. Remove the power plug from the wall receptacle and unplug the cord from the system’s main power receptacle.

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

<table>
<thead>
<tr>
<th>Voltage Configuration</th>
<th>Fuse Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-240VAC</td>
<td>3.15A</td>
</tr>
</tbody>
</table>

*Fuse table*

6 Place the cover back onto the module. Gently push against the cover until the locking tab latches.
Changing the Slit Lamp Illumination Bulb

It is prudent to always have spare bulbs on hand so that patients do not have to be rescheduled should a bulb burn out during a procedure.

1. Turn off the system.

2. Remove the power plug from the wall receptacle.

   **CAUTION** - The bulb is likely to be hot immediately after turning the system off. Wait until the lamp cools before replacing it. Do not directly touch the new bulb; finger oils may substantially shorten the life of the bulb.

3. If the replacement bulb is dirty with oil or dust, clean it with ethanol, using a cotton swab or tissue, before use. Be careful not to directly touch the bulb.

4. On the right side of the illumination tower, loosen the bulb housing cover by turning the thumbscrew counter-clockwise.
5 Once the housing door is open, slide the clip spring away from the base of the bulb receptacle. To remove the old bulb, grasp the bulb base and pull it out.

Slide the clip spring and remove the bulb

6 Holding a new bulb by its base, and being careful not to touch the glass with your fingers, insert the prongs securely into the bulb receptacle. Close the cover door and tighten the thumbscrew.

Place a new illumination bulb in the receptacle
Energy Calibration

Energy calibration should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance. 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.
Electromagnetic Compatibility

Like other electrical medical equipment, the Selecta requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the Selecta must be installed and operated according to the EMC information provided in this manual. See Appendix 1, EMC Guidance and Manufacturer’s Declarations.

The Selecta has been designed and tested to comply with IEC60601-1-2:2001+A1:2004 (Edition 2.1) requirements for EMC with other devices.

⚠️ **WARNING** - This system is intended for the use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.

⚠️ **CAUTION** - Portable and mobile RF communications equipment may affect the normal function of the Selecta Laser System.

⚠️ **WARNING** - Do not use cables or accessories other than those provided with the Selecta Laser System, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

⚠️ **WARNING** - If the Selecta Laser System is used adjacent to or stacked with other equipment, observe and verify normal operation of the laser system in the configuration in which it will be used prior to using it in a surgical procedure.
Specifications

The Selecta Ophthalmic laser system delivers both a 1064 nm and 532 nm treatment beam; therefore, the laser specifications outlined below for each wavelength are applicable to the Selecta Duet model.

<table>
<thead>
<tr>
<th>Laser Specifications</th>
<th>Selecta Duet 532 nm laser</th>
<th>Selecta Duet 1064 nm laser</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Frequency-doubled, Q-switched Nd:YAG</td>
<td>Q-switched Nd:YAG</td>
</tr>
<tr>
<td><strong>Principal output—wavelength</strong></td>
<td>532 nm wavelength</td>
<td>1064 nm wavelength</td>
</tr>
<tr>
<td><strong>Operating mode</strong></td>
<td>Frequency doubled, pulsed</td>
<td>Fundamental, pulsed</td>
</tr>
<tr>
<td><strong>Pulse duration</strong></td>
<td>3 nanoseconds</td>
<td>3 nanoseconds</td>
</tr>
<tr>
<td><strong>Pulse mode</strong></td>
<td>single pulse</td>
<td>single, double, or triple pulse</td>
</tr>
<tr>
<td><strong>Energy</strong></td>
<td>0.3 to 2 mJ</td>
<td>0.3 to 30 mJ</td>
</tr>
<tr>
<td><strong>Maximum Rep Rate</strong></td>
<td>3.0 Hz</td>
<td>3.0 Hz</td>
</tr>
<tr>
<td><strong>Laser beam spot size</strong></td>
<td>400 µm at visual focal plane</td>
<td>8 µm</td>
</tr>
<tr>
<td><strong>Cone angle</strong></td>
<td>&lt;3°</td>
<td>14° to 16°</td>
</tr>
<tr>
<td><strong>Posterior Offset</strong></td>
<td>N/A</td>
<td>100 µm nominal, continuously adjustable from 0 to 350 µm posterior, with detents at 0, 100, 250, and 350 µm.</td>
</tr>
<tr>
<td><strong>CDRH classification</strong></td>
<td>Class IIIb</td>
<td>Class IIIb</td>
</tr>
<tr>
<td><strong>IEC 60825 classification</strong></td>
<td>Class 3B</td>
<td>Class 3B</td>
</tr>
</tbody>
</table>

| Aiming Beam Specifications | | |
|-----------------------------|---------------------------|
| **Type**                    | CW Diode laser            | CW Diode laser |
| **Power**                   | 300 µW maximum            | 150 µW maximum |
| **Principal output**        | 635 nm wavelength         | 635 nm wavelength |
| **CDRH Classification**     | Class II                  | Class II |
| **IEC 60825 classification** | Class 2                  | Class 2 |
### Specifications

#### Laser Safety Eyewear

<table>
<thead>
<tr>
<th></th>
<th>Selecta Duet 532 nm laser</th>
<th>Selecta Duet 1064 nm laser</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Laser safety glasses with an OD5 @532 nm. Refer to the Laser Safety Eyewear section of this manual for information.</td>
<td>Laser safety glasses with an OD5 @1064 nm. Refer to the Laser Safety Eyewear section of this manual for information.</td>
</tr>
</tbody>
</table>

#### Electrical Requirements

<table>
<thead>
<tr>
<th></th>
<th>100 - 240 VAC, 50/60 Hz, 3.15 Amps</th>
<th>100 - 240 VAC, 50/60 Hz, 3.15 Amps</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Cooling

<table>
<thead>
<tr>
<th></th>
<th>Air-cooled</th>
<th>Air-cooled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Physical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Selecta Duet 532 nm laser</th>
<th>Selecta Duet 1064 nm laser</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Table height</strong></td>
<td>Wheelchair accessible, 945 mm max, 695 mm min, travel -250 mm (37.8 in max, 27.4 in min, travel -10.4 in)</td>
<td></td>
</tr>
<tr>
<td><strong>Table width</strong></td>
<td>Small: 630 mm (24.8 in)</td>
<td>Medium: 880 mm (34.5 in)</td>
</tr>
<tr>
<td><strong>Table depth</strong></td>
<td>Small: 400 mm (15.7 in)</td>
<td>Medium: 450 mm (17.8 in)</td>
</tr>
<tr>
<td><strong>Table wheel base</strong></td>
<td>Small: 520 mm x 440 mm (20.4 in x 17.2 in)</td>
<td>Medium: 460 mm x 830 mm (18.1 in x 32.7 in)</td>
</tr>
<tr>
<td><strong>Total system weight</strong></td>
<td>&lt;60 kg</td>
<td>&lt;60 kg</td>
</tr>
</tbody>
</table>

#### Environmental requirements (operating)

<table>
<thead>
<tr>
<th></th>
<th>15°C to 40°C (59°F to 104°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature range</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Humidity</strong></td>
<td>0 to 75% at 40°C, non-condensing</td>
</tr>
<tr>
<td><strong>Altitude</strong></td>
<td>up to 3,900 m</td>
</tr>
</tbody>
</table>

#### Environmental requirements (non-operating)

<table>
<thead>
<tr>
<th></th>
<th>-10°C to 55°C (14°F to 131°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature range</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>0 to 90% at 55°C, non-condensing</td>
</tr>
<tr>
<td><strong>Altitude</strong></td>
<td>Standard commercial shipping altitude</td>
</tr>
<tr>
<td><strong>Vibration</strong></td>
<td>Capable of surviving transport by normal commercial recognized air, sea, and land carriers</td>
</tr>
<tr>
<td><strong>Shock</strong></td>
<td>Lumenis shock requirements, based on size and weight</td>
</tr>
</tbody>
</table>

---

Selecta
PBL200051, Rev J
## Accessories, delivery devices, and compatible lasers

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD0200037</td>
<td>Beam Splitter (2-port)</td>
</tr>
<tr>
<td>OD0200038</td>
<td>35 mm camera adaptor w/ 52 mm objective</td>
</tr>
<tr>
<td>OD0200039</td>
<td>35 mm camera adaptor w/ 49 mm objective</td>
</tr>
<tr>
<td>OD0200041</td>
<td>Video camera adaptor</td>
</tr>
<tr>
<td>OD0200042</td>
<td>Co-observation tube</td>
</tr>
<tr>
<td>OD0200043</td>
<td>Digital camera</td>
</tr>
<tr>
<td>0642-507-01</td>
<td>Basic footswitch</td>
</tr>
<tr>
<td>0642-508-01</td>
<td>Smart Footswitch</td>
</tr>
<tr>
<td>0642-509-01</td>
<td>PowerEase Footswitch</td>
</tr>
<tr>
<td>SA-0028940</td>
<td>Dual illumination mirror</td>
</tr>
<tr>
<td>0642-510-01</td>
<td>Novus Spectra Laser</td>
</tr>
<tr>
<td>GA-0020310</td>
<td>LaserLink S delivery system</td>
</tr>
</tbody>
</table>

## Slit Lamp

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Galilean stereoscopic microscope with converging optics</td>
</tr>
<tr>
<td><strong>Lamp</strong></td>
<td>Halogen, 12 V, 30 W, precentered</td>
</tr>
<tr>
<td><strong>Objective lens</strong></td>
<td>1.25 x, antireflection coating (AR) for visible and laser wavelengths</td>
</tr>
<tr>
<td><strong>Eyepiece lens</strong></td>
<td>12.5 x, diopter adjustable in range ±5 D</td>
</tr>
<tr>
<td><strong>Total magnification</strong></td>
<td>42 x (12.5 x eyepiece)</td>
</tr>
<tr>
<td><strong>Magnification changer</strong></td>
<td>5 position—6 x, 9 x, 16 x, 28 x, 42 x</td>
</tr>
<tr>
<td><strong>Interpupillary distance adjustment</strong></td>
<td>55 - 88 mm</td>
</tr>
<tr>
<td><strong>Field of view</strong></td>
<td>11.3 mm diameter at 16 x magnification</td>
</tr>
<tr>
<td><strong>Illumination tower working distance</strong></td>
<td>60 mm from center of illumination prism optical axis to focal point</td>
</tr>
<tr>
<td><strong>Focal length</strong></td>
<td>93 mm</td>
</tr>
<tr>
<td><strong>Slit width</strong></td>
<td>0.01 to 12 mm, continuously adjustable</td>
</tr>
<tr>
<td><strong>Slit rotation</strong></td>
<td>-90° (horizontal) to 0° (vertical) to +90° (horizontal), continuously variable. Detent at 0° and stops at ±90°</td>
</tr>
<tr>
<td><strong>Illumination apertures</strong></td>
<td>0.2, 5, 8.9, 13.3 mm and tear drop (variable 1.7 to 12.2 mm)</td>
</tr>
<tr>
<td><strong>Illumination filters</strong></td>
<td>Green, cobalt blue, Neutral Density (ND) 28% attenuation, and none</td>
</tr>
<tr>
<td><strong>Fixation lamp</strong></td>
<td>Green or red, 12 V</td>
</tr>
<tr>
<td><strong>Chin rest</strong></td>
<td>Adjustable, vertical travel 50 mm (2 in), with fixation lamp</td>
</tr>
</tbody>
</table>
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.
Professional Use Instructions
The Selecta Family Indications for Use

The Selecta family of ophthalmic lasers include the following:

- **Selecta Duet**: photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy; and selective laser trabeculoplasty.

- **LaserLink S**: laser delivery system for use by an ophthalmologist in the treatment of ocular tissue; laser delivery system indicated for use for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, Indications for Use section.

- **Selecta Trio**: same indications for use as a Selecta Duet and LaserLink S slit lamp delivery device with a currently cleared Lumenis 532nm photocoagulator.
General Intended Use

The Lumenis Selecta is a fully integrated, high-performance diagnostic slit lamp and therapeutic laser delivery system. Selecta has all of the standard controls and functions of a diagnostic slit lamp and is intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior segment.

The Lumenis Selecta is also an ophthalmic surgical laser designed for performing:

- photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser, including
  - discission of the posterior capsule of the eye (posterior capsulotomy),
  - discission of pupillary membranes (pupillary membranectomy),
  - and iridotomy/iridectomy;
- selective laser trabeculoplasty

The Selecta produces short, individual pulses of focused laser light with wavelengths of either 1064 nm or 532 nm, depending on the selected operational mode. Using a slit lamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient's eye.

When the photodisruptor mode is selected, the treatment wavelength is 1064 nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave that disrupts nearby tissue.

When the SLT mode is selected, the treatment wavelength is 532 nm. A coaxial aiming beam targets the trabecular meshwork via a contact lens. The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork.

If an optional LaserLink S delivery device is attached to the Selecta system and a compatible Lumenis 532 nm photocoagulator laser, such as the Novus Spectra, the Selecta works strictly as a standard diagnostic slit lamp— all photodisruptor and SLT laser functions are disabled. The LaserLink S laser delivery adaptor is used for treatments specifically cleared for the compatible laser photocoagulator.

Practitioners 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.

The physician is advised to consult medical journals for information on laser treatment in a particular specialty.

The use of a laser is at the physician's discretion except in cases where the application is contraindicated.
SLT Clinical Procedure and Parameters

Selective Laser Trabeculoplasty (SLT)—532nm Nd:YAG

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 or activation button on the slit lamp joystick. 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° of either the nasal or temporal segment of the trabecular meshwork.

SLT Mechanism of Action

The mechanism of action of the Lumenis Selecta 532nm frequency-doubled, Q-Switched Nd:YAG ophthalmic laser is the selective targeting of pigmented trabecular meshwork cells. The Selecta 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 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.
SLT Contraindications for Use

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

SLT 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 of 10 mm Hg, 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.

SLT Precautions

The following precautions are suggested when using the Selecta for SLT:

- 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.
Photodisruptor Clinical Procedure and Parameters

Photodisruption—1064 nm Nd:YAG

The Selecta Nd:YAG 1064 nm treatment laser is intended for posterior capsulotomy, posterior membranectomy, and other ophthalmic surgical procedures such as iridotomy.

As in all surgery, there are risks involved and use of the laser may be contraindicated for patients with certain pre-existing ocular pathologies. Objective assessment of potential patients for these procedures must be done in light of the risks.

General description of treatments

For optimal treatment, the objective is to use the minimum number of laser shots to achieve the desired tissue effect or to obtain an adequate opening, depending on the procedure. The initial energy should be set to the lowest possible effective level. If the capsule is tough or scarred, higher energy levels may be required, but the energy should be increased in small increments until the optimum energy level is obtained. Once an opening has been established, it is enlarged, as necessary, to the desired size.

Tissue effects

Unlike some commonly used ophthalmic lasers, such as argon, krypton or ruby laser photocoagulators, which principally act on the chromophore of the target tissue and which produce a primarily thermal effect, by contrast, the Selecta 1064 nm wavelength acts principally on water in tissue and produces a cutting or disrupting tissue effect. Therefore, the Selecta 1064 nm laser will damage any tissue or structure on which the beam is focused. Care should be taken to avoid inadvertently damaging nontarget tissue.

⚠️ CAUTION - Care should be taken to focus the laser only on intended target tissue. In addition, the surgeon should be aware of nontarget tissue that may be beyond or near the target treatment area. Do not focus the laser on or near iris blood vessels because the shock wave may produce bleeding and induce astigmatism. The beam should never enter the eye at greater than 30° from the visual axis.
Posterior Capsulotomy—1064 nm Nd:YAG

The Selecta 1064 nm laser is indicated for disruption of the posterior capsule of the eye (posterior capsulotomy).

Contraindications

The following represent contraindications for posterior capsulotomy or pupillary membranectomy:

- pre-existing ocular pathologies including:
  - corneal edema that interferes with visualization of the capsule
  - diffuse haze of the aqueous humor
  - extensive corneal dystrophy
- chronically elevated intraocular pressure (IOP), especially when uncontrollable under medication
- eyes with no potential visual function
- subjects with glass posterior chamber intraocular lenses (IOL), except those subjects whose medical condition precludes invasive surgery
- Variations in IOL material and geometry may affect YAG procedural parameters and clinical success. Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

Warnings

Risks

As with any surgical procedure, there are risks involved in Nd:YAG laser posterior capsulotomy or pupillary membranectomy, including:

- significant transient elevation of intraocular pressure (IOP),
- persistent elevation of IOP,
- cystoid macular edema,
- rupture of the anterior hyaloid face and anterior displacement of the vitreous,
- retinal detachment

The potential impact of using of high energy levels and a high number of laser pulses (i.e., at the upper limits of the available ranges) to disrupt some pupillary membranes must be considered. The anterior shift of the plane of optical breakdown from the focal point and elongation of the breakdown region that occurs as power increases become significant at high energy levels. These effects may result in increased risk of injury to the corneal endothelium, the iris, and, if present, an intraocular lens (IOL). Corneal, iris, and IOL...
status should be evaluated prior to, and monitored closely during and after, procedures in which high pulse energies are used. In addition, the transient rise in IOP that follows Nd:YAG laser posterior capsulotomy in many patients should also be monitored following pupillary membranectomy. The release of debris due to disruption of pupillary membranes should be recognized for potential impact on IOP.

**Poor candidates for posterior capsulotomy**

Patients with any of the following conditions may not be suitable candidates for posterior capsulotomy or pupillary membranectomy because the procedure may not improve visual acuity or visualization of the posterior segment, or may pose a special risk to the patient’s eyesight:

- active ocular disease
- nystagmus, blepharospasm, or other neurological conditions that make ocular fixation impossible
- slight or moderate haze of the aqueous humor or cornea
- inability to cooperate in positioning and immobilization
- poor vision (20/40 or worse) and clear optical media including the capsule
- 20/30 or better preoperative vision and no other serious vision disability, such as glare or poor reading vision, associated with the posterior capsule condition. (Several clinical studies have shown that 2-7% of these subjects experience a decrease in postoperative vision.)

**Intraocular pressure rise**

Significantly increased IOP has been reported in a substantial number of laser-treated patients, particularly those presenting with preoperative glaucoma or preoperative IOP of greater than 20 mm Hg, and those with other evidence of deranged aqueous dynamics or poor outflow facility. Other risk factors for elevations of IOP include:

- use of high amounts of energy during the procedure,
- absence of an IOL, and
- use of cycloplegic drugs

Physicians should carefully monitor all subjects for IOP rise in the 2-5 hours after treatment with the laser. Patients who exhibit a pressure rise generally return to pretreatment levels within 24 hours but should be carefully followed throughout this period. Persistent IOP elevation occurs in some patients. Clinical estimates are that 2-3% of patients may be treated for secondary glaucoma.
Medical therapy should be instituted as circumstances and medical judgment dictate. Persistent administration of an oral hyperosmotic agent in the first several hours after treatment may be warranted.

**Damage to intraocular lens**

Pitting or marking of IOLs occurs in Nd:YAG laser posterior capsulotomy with several clinical studies reporting a 25% or greater incidence. The potential of IOL damage is a function of lens type, proximity to the posterior capsule, the level of laser energy used, and physician experience. Risk of damage increases if the patient has a posterior chamber IOL, if the posterior capsule lies close to the IOL, and as the total amount of energy employed to effect capsule opening increases.

Posterior chamber lenses, particularly those close to the posterior capsule, have the greatest potential for damage. This potential can be minimized by carefully focusing behind the lens in pseudophakic subjects, by optimizing the view of the posterior capsule with the use of a contact lens, by avoiding repetitive shots to the same area, and by using the lowest energy setting necessary to open or sever the membrane.

Numerous pits on the IOL may result in glare, which can affect the visual outcome. Physicians who experience problems with continued pitting should consider ending the treatment.

The Selecta aiming beam is offset longitudinally up to 0.1 mm in front of the Nd:YAG beam. Physicians who experience continued focusing problems, which can lead to IOL pitting, should first check the ocular setting of each eye on the slit lamp. If this does not correct the problem, contact your local Lumenis representative for assistance.

Use extreme caution in assessing patients with glass IOLs for Nd:YAG treatment. Instances of shattered glass IOLs have been reported. In such cases, explantation of the IOL may be necessary. If the Nd:YAG treatment is selected, it should be conducted on low energy and with extreme care.

An increase in IOL pitting is possible when silicon IOLs are used. We advise caution when using silicon IOLs and recommend using +250 offset position. If pitting persists, manually position the lamp to increase the posterior offset.

**Inadvertent patient movement**

Misaiming the laser or movement of the patient may result in damage to non-target ocular tissue or the area surrounding the target tissue. If the patient cannot fixate, use of a contact lens or retrobulbar anesthesia injection is recommended.

**Bleeding**

Bleeding may occur if the iris or vascular tissue is inadvertently lased. The bleeding generally stops spontaneously, but if it does not subside, this
condition may require treatment or may interfere with, or be aggravated by, continuation of the Nd:YAG procedure.

Pupillary block

Extra-capsular cataract extraction (ECCE) patients who did not have a concurrent iridectomy are at increased risk of pupillary block. Although the incidence is low, the patients should be advised that if symptoms of pupillary block occur (such as pain), they should immediately contact the treating surgeon.

Rupture of the anterior hyaloid face

A proportion of subjects (about 25% in clinical studies) may experience rupture of the anterior hyaloid face. This potential is greater for aphakic subjects (no IOL present). Such patients are at increased risk of anterior vitreous movement from the normal plane. In the event of vitreous movement to the cornea, an increased incidence of corneal edema may result.

Focusing of the laser is recommended, posterior to the target treatment plane (particularly in pseudophakic subjects), then moved anteriorly as required. In aphakic subjects, the alternative technique of focusing anterior to the target treatment plane and moving posteriorly can be used.

Retinal damage

Retinal damage, such as retinal detachment, tears, holes, and cystoid macular edema, has been reported in several clinical studies. The incidence of such retinal problems remains low. Clinical estimates of these problems indicate an incidence of less than 2%.

Patients at risk

The following patients are at special risk when undergoing Nd:YAG posterior capsulotomy or pupillary membranectomy:

- extra-capsular cataract extraction patients without a patent iridectomy are at an increased risk of pupillary block
- aphakic patients are at increased risk of immediate postoperative IOP elevation
- patients with preoperative glaucoma, prior filtering surgery or preoperative IOP of greater than 20 mm Hg, or other evidence of deranged aqueous dynamics or poor facility outflow, are at a significantly higher risk of postoperative IOP rise to levels of clinical concern
- patients with IOLs, particularly posterior chamber lenses close to the posterior capsule, are at risk of IOL pitting or cracking
- patients with pre-existing ocular conditions have a greater chance of experiencing postoperative complications
• patients with vascularization of any target membrane are at increased risk of bleeding

Precautions

Targeting

Focus the unit in accordance with the description provided in the Operation section of this manual. In dual aiming beam systems such as Selecta, the Nd:YAG beam extends beyond the diode beams, so there is an increased probability of Nd:YAG beam impingement of the iris. The diode aiming beam focus spot is longitudinally offset up to a maximum of 350 microns in front of the Nd:YAG beam. Therefore, the operator should not activate the laser without verifying that the aiming and treatment beams are appropriately coincident and properly targeted. Verify that the treatment beam path is not obstructed by other nontarget tissues. Care should be taken when working at the iris margin or at a wide angle to the patient’s visual axis.

The aiming/treatment beam offset can be adjusted using the Selecta posterior offset control. With the offset control set at 100 microns, Selecta delivers a preset offset equal to 100 microns in air.

Energy use

To reduce risk of damage to nontarget tissues, the lowest possible energy level should be used, beginning with 1-2 mJ and increasing the energy as required. The burst-mode capability should not be used initially for capsule dissection. Burst mode should be used only when increasing levels of single shot energy have not been successful in opening the capsule. If the capsule is tough or scarred, higher energy shots may be required. It is recommended that the increase be in 1-2 mJ steps. The clinical experience indicates that the mean power level used is 2.7 mJ, and 97% of the subjects were treated at less than 5 mJ.

The minimum number of shots required to obtain an adequate opening should be used. The mean is 40 shots, although greater than 100 shots may be required for membranous tissue. The risk of IOL damage increases with increasing energy level and number of shots used. Once an opening has been established, it is enlarged, as necessary, until the capsulotomy is adequate.

In the presence of edematous, clouded, scarred or irregular astigmatic corneas, the laser beam may be less effective, necessitating higher energy settings to obtain optical breakdown. Medical judgment must be used to determine whether the corneal condition in such circumstances contraindicates laser posterior capsulotomy.
Patient considerations

A thin fluid layer on the cornea is desirable. The patient is asked to blink regularly to avoid corneal drying. Topical steroids should be used for any significant postoperative inflammation.

Adverse effects

Adverse effects include:

- IOP rise to 50 mm Hg or greater, regardless of duration. (Hospitalization may be required for the institution of IOP-reducing therapy. Pain and nausea may accompany such a significant IOP rise.)
- IOP rise to 30 mm Hg or greater persisting for one week or more
- secondary glaucoma
- hyphema
- inflammatory reactions, such as iritis, vitritis, or uveitis
- retinal complications, such as retinal hemorrhage, retinal tears or holes, retinal detachment, and cystoid macular edema
- pupillary block
- anterior hyaloid face rupture
- anterior displacement of the vitreous
- vitreous movement with corneal touch
- corneal injury (including damage to the endothelium, stroma, or epithelium)
- anterior chamber injury (including loose cortex, or capsular fragments, flare, cells, or debris)
- intraocular lens damage (including pits, fractures, or dislocations)
- intraocular bleeding
- vitreal chamber injury (including loose cortex or capsular fragments)
- generalized endophthalmitis with vitreous involvement
- corneal edema
- neovascularization of the iris
- iris damage
- vitreous hemorrhage
Iridotomy—1064 nm Nd:YAG

The Selecta 1064 nm wavelength is indicated for performing an iridotomy (hole in the iris).

Contraindications

The following represent contraindications for iridotomy. Pre-existing ocular pathologies including:

• eyes with opacities of the media such that the iris cannot be adequately visualized
• eyes without a pupillary block component to their glaucoma
• eyes with a glass IOL

Variations in IOL material and geometry may affect YAG procedural parameters and clinical success. Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

Warnings

Risks

As with any surgical procedure, there are risks in Nd:YAG laser iridotomy, including:

• significant transient elevation of IOP
• damage to the lens
• transient bleeding from the iridotomy margin, and hyphema
• localized corneal damage
• anterior chamber reaction (including flare, cells and debris)
• closure of the iridotomy with time
• inability to control glaucoma adequately (despite a successful iridotomy), necessitating chronic medical therapy or further invasive intraocular surgery
• damage to the retina or choroid

In addition, there are risks that have not been reported but which are theoretically possible in Nd:YAG laser iridotomy, including:

• persistent elevation of the IOP
• rupture of the anterior hyaloid face and anterior displacement of the vitreous in an aphakic eye

Accordingly, the physician should make an objective assessment of the potential benefits of Nd:YAG laser iridotomy in light of these risks.
Poor candidates for Nd:YAG laser iridotomy

Patients with any of the following conditions may not be suitable candidates for Nd:YAG laser iridotomy because of the risks of bleeding, or inability to create an iridotomy or iridotomy closure:

- slight or moderate haze of the cornea or aqueous humor
- chronic uveitis
- pupillary block associated with neovascular glaucoma or with any condition causing engorged iris blood vessels
- tendency to bleed (as with hemophilia or patients receiving anticoagulant therapy)
- inability to cooperate in the procedure
- nystagmus
- blepharospasm

Intraocular pressure rise

Significant rises in the IOP occur following both argon laser and Nd:YAG laser iridotomy in a substantial proportion of treated eyes. The risks of IOP elevation do not appear to differ between Nd:YAG laser and argon laser treatment. Patients should therefore be carefully monitored during the post-operative period. Clinical data suggest that if a pressure rise will develop, it is almost always detectable within the first two to three post-operative hours. No risk factors are yet known to be positively associated with this IOP rise after iridotomy. However, eyes with acute pupillary block glaucoma tend not to have this problem.

The decision to use additional medical treatment in the event of a rise of IOP should be based on the status of the individual patient. Most elevations resolve without intervention within 24 hours of Nd:YAG laser surgery. The treating physician should take into consideration the pre-existing condition of the optic nerve and other ocular structures when deciding whether to treat the eyes with IOP-lowering medication.

Damage to the lens

Clinically visible evidence of crystalline lens damage has been reported following Nd:YAG laser iridotomies in humans, and has been noted in animal studies and in human histologic studies. The risk of lens damage during Nd:YAG laser iridotomy will increase if:

- laser focusing is inaccurate
- laser energy is applied through an already patent iridotomy
- laser energy is applied through the pupil directly to the lens
energy levels greater than 10 mJ are used
there is apposition of the peripheral iris to the lens as might occur with extensive posterior synechiae

To reduce the risk of lens damage when an iridotomy is performed, the following actions are recommended:

- ensure good patient fixation
- use an appropriate contact lens
- select an iris treatment site as far in the periphery as is practical (as with all iridotomies, the site should be located under the upper lid whenever possible)
- focus the aiming beam on the surface of the treatment site
- use the minimum number of pulses per burst
- use the lowest possible amount of energy per pulse
- avoid treatment through a site that is already totally or partially patent

Inadvertent patient movement

Inadvertent or uncontrolled eye movement by the patient may result in hitting tissues adjacent to the target. If a patient cannot fixate with the untreated eye to assure stabilization of the treated eye, retrobulbar anesthesia injection is recommended.

Bleeding

Mild, localized bleeding occurs in 20% to 50% of eyes undergoing Nd:YAG laser iridotomy. Mild hyphema is rare (less than 2%) and severe hyphema is very uncommon (less than one in 200). Unlike an argon laser, an Nd:YAG laser creates minimal heat at the treatment site and, therefore, does not cauterize vessels. Eyes with engorged iris blood vessels (active uveitic, neovascular, or angle closure glaucoma) are at an increased risk of bleeding. Patients who are otherwise at risk of bleeding (as with hemophilia or those receiving anticoagulant therapy) are also at an increased risk of bleeding and hyphema.

In otherwise normal patients with pupillary block glaucoma, bleeding usually stops spontaneously and can be controlled by digital pressure upon the contact lens. All eyes should be observed with a biomicroscope for bleeding. If bleeding occurs, additional Nd:YAG laser treatment may aggravate it. Further, if bleeding does not stop spontaneously or after applying digital pressure, argon laser photocoagulation of the bleeding site may be necessary.
Corneal damage

Localized corneal endothelial lesions have been produced above the iridotomy site in 10%-20% of eyes treated with Nd:YAG laser. These opacities may interfere with visualization of the iridotomy. In most eyes these opacities clear within a few days, but occasionally there is a permanent non-progressive small diameter opacity. The changes do not interfere with visual function. Careful laser focusing and the lower energy settings may decrease the likelihood of this problem.

Retinal damage

Nonrhegmatogenous retinal detachment in nanophthalmic eyes and microperforations of the retina have been reported following Nd:YAG iridotomy.

Closure of the iridotomy with time

Closure of iridotomy has been reported in a small percentage of cases weeks or months after Nd:YAG laser treatments. This closure occurs most frequently in eyes with chronic uveitis. The closure rate for Nd:YAG laser iridotomies is much lower than for argon laser iridotomies. In a randomized study reported in the literature in bilateral primary chronic angle-closure glaucoma, each patient received treatment in one eye with a Nd:YAG laser and with an argon laser in the other eye. Within the first postoperative month, 9 of 50 argon laser treated eyes experienced iridotomy closure, compared to none of the Nd:YAG laser-treated eyes.

Failure to control glaucoma

Successful iridotomies are not necessarily accompanied by long-term control of glaucoma, for several possible reasons:

- the eye may have developed peripheral anterior synechiae (PAS)
- the angle may be open but the eye may have residual open angle glaucoma
- a combination of the above

Patients should be monitored for persistent glaucoma.

Patients at special risk

The following categories of patients are at special risk when undergoing Nd:YAG laser iridotomy:

- patients with chronic uveitis have an increased tendency towards both early and late iridotomy closure
- patients with vascularization of the iris or engorgement of iris vessels are at increased risk of bleeding
patients with a bleeding tendency (as with hemophilia or those receiving anticoagulant therapy) are at increased risk of bleeding

Precautions

Targeting

Focus the unit in accordance with the description provided in the Operation section of this manual. Unlike other lasers commonly used in ophthalmology (argon, krypton, and dye lasers) which rely on thermal effects, the 1064 nm Nd:YAG laser is a cutting or disrupting instrument capable of damaging any tissue or structure on which the beam is focused. Therefore, the Nd:YAG laser should only be focused on target tissues and care should be used to avoid exposure of all adjacent tissues and structures.

The diode aiming beam focus spot is longitudinally offset up to a maximum of 350 microns in front of the Nd:YAG beam. This offset is adjusted on the laser using the posterior offset control. With the offset control set at 100 microns, Selecta delivers a preset offset equal to 100 microns in air.

Energy

Minimal effective energy and minimal pulses per burst should be used to reduce risk of damage to nontarget areas. In animal studies, the use of higher total energy, larger numbers of pulses, and more pulses per burst have been associated with an increased risk of damage to the lens. Lens damage has been reported clinically in human eyes that have undergone Nd:YAG iridotomy.

Adverse effects

The following adverse effects and complications have been observed in patients who have undergone Nd:YAG iridotomy:

- transient elevated IOP
- hyphema
- corneal injury (including damage to the endothelium, stroma or epithelium)
- anterior chamber reaction (including flare, cells, and debris)
- transient blurred vision immediate postoperative
- minor, transient, pupillary distortion
- corneal edema
- transient bleeding from the iridotomy margin
- closure of iridotomy over time
- damage to the lens (perforation, rupture)
Appendix 1
Guidance and Manufacturer’s Declaration Electromagnetic Emissions

Selecta ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of Selecta ophthalmic laser family should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group I</td>
<td>Selecta ophthalmic laser family 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>Selecta ophthalmic laser family is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning statement is heeded:</td>
</tr>
<tr>
<td>Harmonic emissions IEC61000-3-2</td>
<td>Class A</td>
<td>Warning: This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.</td>
</tr>
<tr>
<td>Voltage Fluctuations/ flicker emissions IEC61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Selecta ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of Selecta ophthalmic laser family should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±6kV contact, ±8kV air</td>
<td>Class A</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2kV for power supply lines, ±1kV for input/output lines</td>
<td>Class A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1kV line(s) to line(s), ±2kV line(s) to earth</td>
<td>Class A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 0.5 cycle, 40% $U_T$ (60% dip in $U_T$) for 5 cycles, 70% $U_T$ (30% dip in $U_T$) for 25 cycles, &lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 sec.</td>
<td>Class A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of Selecta ophthalmic laser family requires continued operation during power mains interruptions, it is recommended that Selecta ophthalmic laser family be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>N/A</td>
<td>Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.
Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Selecta ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of Selecta ophthalmic laser family should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

$$ d = \left[ \frac{3.5}{V_1} \right] \sqrt{P} $$

$$ d = \left[ \frac{7}{E_1} \right] \sqrt{P} $$

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 (a), should be less than the compliance level in each frequency range (b).

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 Selecta ophthalmic laser family system is used exceeds the applicable RF compliance level above, the Selecta ophthalmic laser family system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Selecta ophthalmic laser family unit.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Selecta ophthalmic laser family System

The Selecta ophthalmic laser family system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Selecta ophthalmic laser family system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Selecta ophthalmic laser family system as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power (W) of transmitter</th>
<th>Separation distance (m) according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = \left(\frac{3.5}{V_1}\right)\sqrt{P})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.116</td>
</tr>
<tr>
<td>0.1</td>
<td>0.368</td>
</tr>
<tr>
<td>1</td>
<td>1.16</td>
</tr>
<tr>
<td>10</td>
<td>3.66</td>
</tr>
<tr>
<td>100</td>
<td>11.16</td>
</tr>
</tbody>
</table>

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.
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