Novus® Spectra™ Family of Lasers

Solid-State 532-nm Green Laser

Operator Manual

LUMENIS®

Enhancing Life. Advancing Technology.

Manufactured by:

LUMENIS®

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Safety and Regulatory

Introduction

The Novus Spectra ophthalmic laser systems are classified as Class IV lasers by the Center for Devices and Radiological Health of the Food and Drug Administration and as Class 4 by the International Standard IEC 60825.

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

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

See the American National Standard (ANSI) publications Z136.3-2005, ANSI Z136.1-2007, and EN 207 for recommendations on the safe use of lasers in health care facilities.

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

Laser Safety Eyewear

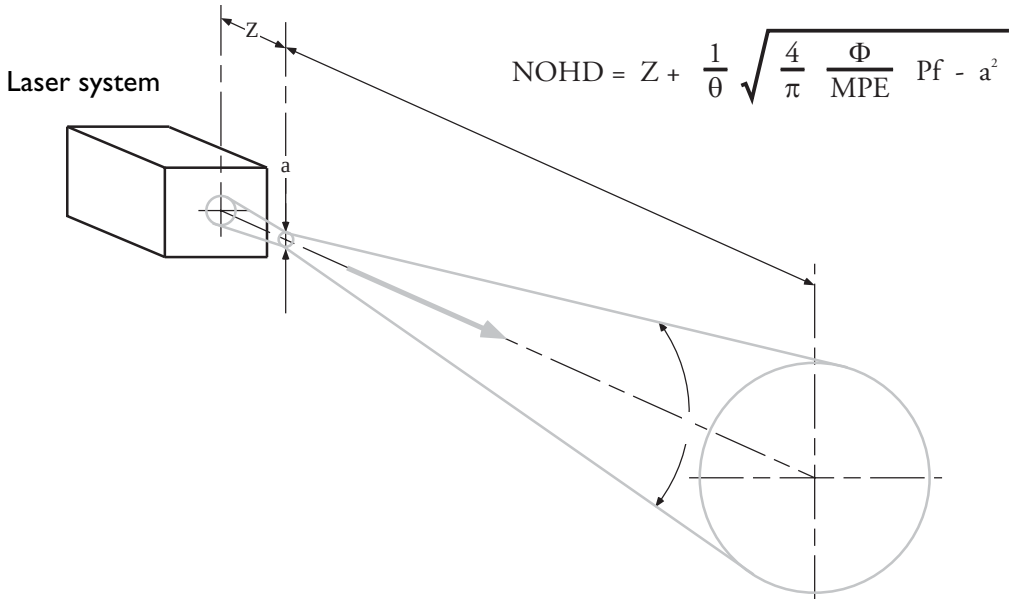
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1-2007, ANSI Z136.3-2005, or International Standard IEC 60825-1: 2007.

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

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

where,

Z	=	the distance of the beam waist from the laser system;
a	=	the beam waist diameter ($1/e^2$ of axial irradiance for gaussian beam);
θ	=	minimum full angle beam divergence ($1/e^2$ of axial irradiance for gaussian beam);
e	≈	2.7182818285, the base of natural logarithms;
Φ	=	maximum energy of one laser pulse or maximum CW laser power;
Pf	=	the profile correction factor (1 for uniform profile or 2 for gaussian irradiance profile);
MPE	=	Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);
NOHD	=	the Nominal Ocular Hazard Distance (measured from laser aperture);
	=	the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

	θ (rad)	Φ (W)	**MPE** (W/cm^2)	**Pf**	**a** (cm)	**Z** (cm)
LaserLink HS	0.020	2.5	0.00255	1	0.050	5.7
LaserLink Z	0.010	2.5	0.00255	1	0.100	9.8
Novus Spectra	0.041	2.5	0.00255	1	0.025	9.8
LIO Keeler	0.024	2.5	0.00255	2	0.096	36.6
LIO Heine	0.022	2.5	0.00255	2	0.107	37.08
LIO Tri Color	0.022	2.5	0.00255	2	0.107	37.08
Acculite	0.014	2.5	0.00255	2	0.02	0
Lumenis 1000	0.010	2.5	0.00255	1	0.100	9.8

which results in a *worst case* NOHD of:

	NOHD (m)
LaserLink HS	17.74
LaserLink Z	34.60
Novus Spectra	8.72
LIO Keeler	21.19
LIO Heine	23.08
LIO Tri Color	23.08
Acculite	3.57
Lumenis 1000	34.60

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:

	OD
LaserLink HS	3.41
LaserLink Z	3.41
Novus Spectra	3.41
LIO Keeler	3.41
LIO Heine	3.41
LIO Tri Color	3.41
Acculite	3.57
Lumenis 1000	3.41

Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1-2007, 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.

Depending on the procedure, the physician must protect the patient's eyes with either laser safety eyewear or one of the following items moistened with a nonflammable solution: thick cloth, eye pads, or gauze 4 x 4's. For periorbital treatment, the physician must protect the patient with dulled, metal eye shields.

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

Protecting nontarget tissues

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

WARNING - Never deliver the treatment beam to the target tissue if the aiming beam is not visible; the fiber optic cable or the delivery device may be damaged. A damaged cable or device may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

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

WARNING - -Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, and power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.

WARNING - Laser beam integrity checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; contact your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.

WARNING - To prevent accidental laser discharge, always place the laser in standby mode before connecting the delivery system.

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

WARNING - Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.

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

CAUTION - Laser equipment not in use should be protected against unqualified use by removal of key from keyswitch.

Fire hazards

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

WARNING - The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher and water should be readily available.

Electrical hazards

WARNING - Never open the laser console protective covers. Opening the covers will expose personnel to high voltage components and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.

WARNING - To avoid electrical shock, 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.

Regulatory Compliance

Lumenis lasers and delivery systems comply with 21 CFR Chapter I, 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 European Medical Device Directive MDD 93/42/EEC.

⚠ **CAUTION -** US law restricts this device to sale by or on the order of a physician.

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

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

Emergency stop button

The laser has an emergency stop button that immediately turns off the laser.

> The emergency stop button turns off all power to the laser off, but does not turn off the CPU board or the laser console display. When the button is pressed, an EOFF code will appear in the laser console display, and the system will be in standby. To clear the EOFF, release the emergency stop button. The system will return to standby mode with all of the user settings retained.

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 on position | , the laser power-up sequence is initiated.

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.

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.

External door interlock

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

Safety interlocks

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

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, 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 OFF ◯ then ON ❙ .

Electronic fault detection circuitry

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

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

Safety shutter

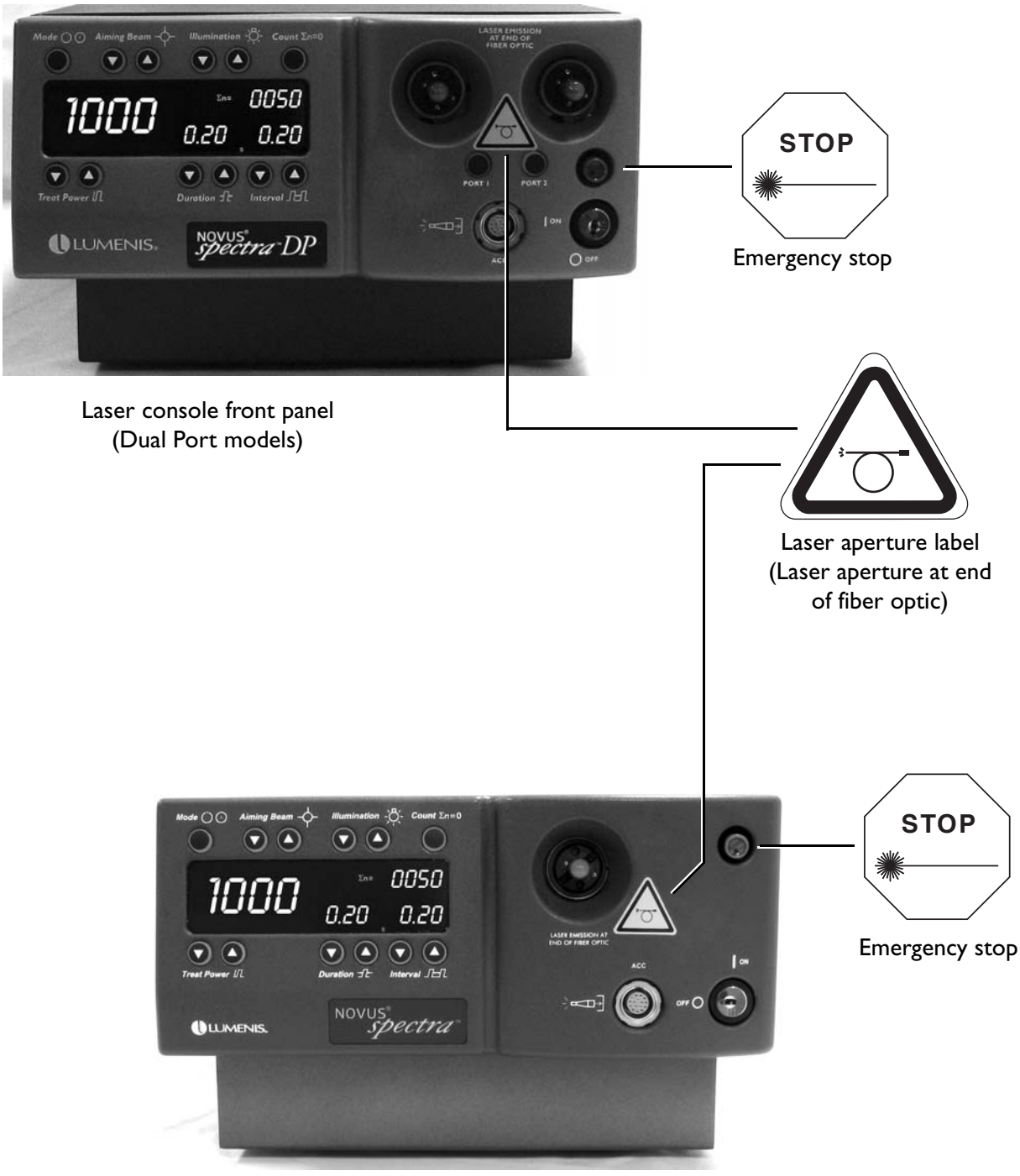
The laser includes an electronic safety shutter that prevents unintentional laser emission. The safety shutter opens only when the laser is in ready mode. The safety shutter remains closed when the system is turned off, during self-test at system turn on, when the system is placed in standby mode, or when the safety monitor detects a fault.

Laser emission indicators

The Ready mode illuminates on the laser console and the Ready icon ⊙ illuminates on the remote control screen when the system is in ready mode. These indicators alert the user that the system is able to emit laser radiation. Before treatment beam delivery, the system emits a low-pitched tone to indicate the beginning of a two-second delay until laser radiation is accessible. An audible tone occurs during treatment beam delivery, and the laser emission indicator ✳— on the remote control screen illuminates. The indicators continue the duration of treatment beam emission.

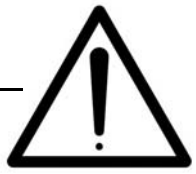
Location of regulatory and system labels

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



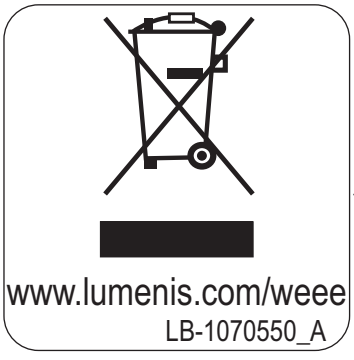
Locations of regulatory compliance labels

Laser console rear panel



Attention, read manual

Fuse rating label
(replace fuse as marked)



WEEE label

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

Locations of regulatory compliance labels

CE 0044

LUMENIS®

COMPLIANT WITH
IEC 60601-1
IEC 60601-1-2
IEC 60601-2-22
IEC 60825-1

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

Lumenis (Germany) GmbH
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D-63303 Dreieich, Germany
+49.6103.8335.0

PL-158 REV C

CE mark, IEC certifications, order of physician label, and European authorized distributor

INTERTEK ETL LISTED c US
3030552

ETL CLASSIFIED
CONFORMS TO UL STD 60601-1
CERTIFIED TO CAN/CSA STD C22.2 NO. 601.1

ETL label

Laser console bottom

REF

SN

Rev

100-240 V~ 50/60 Hz 6.3 A 1φ

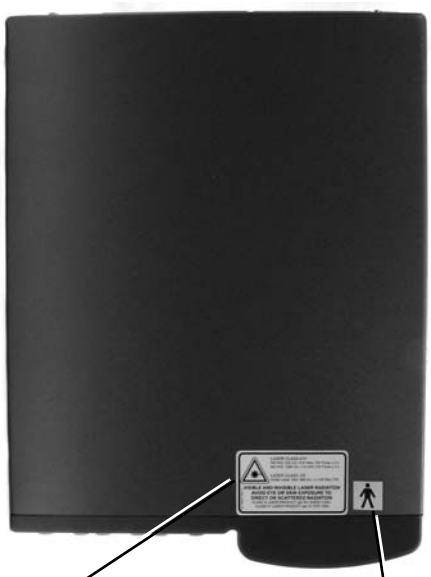
THIS PRODUCT COMPLIES WITH 21 CFR, CHAPTER 1, SUBCHAPTER J

MANUFACTURED IN THE U.S.A BY:

LUMENIS®
3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104 U.S.A.

PK-971 REV. E

Part number, serial number, and manufacture date; power requirements; made in USA; Lumenis address



Laser console top

VISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
CLASS 4/IV LASER PRODUCT
Nd:YAG: 532 nm, 8 W Max, CW Pulse ≤ 3 s

VISIBLE LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2/II LASER PRODUCT
Diode Laser: 630–680 nm, <1 mW Max, CW

CLASS 4 LASER PRODUCT per IEC 60825-1:2007
CLASS IV LASER PRODUCT per 21 CFR 1040.10 & 1040.11, except for deviations pursuant to Laser Notice 50, Dated June 24, 2007

PL-156-01 English Rev. F

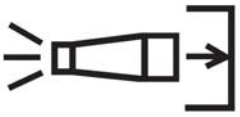
Danger label

Type B electric shock protection

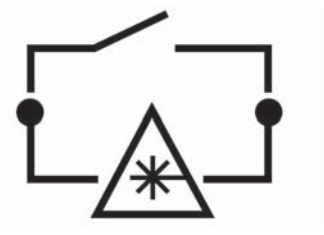
Locations of regulatory compliance labels

Protected earth plug

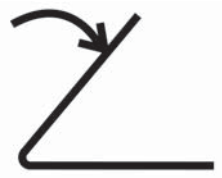
Attention, read manual



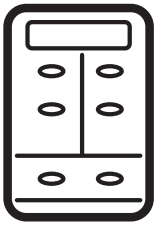
Delivery device receptacle



Remote interlock



Footswitch



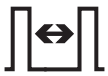
– Remote control

Rear panel regulatory labels

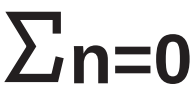
Treat Power

Pulse Duration

Aiming beam



Pulse interval



Count reset

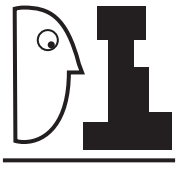
Illumination

Ready

Standby

Laser emission indicator

LIO



Slit lamp icon

Probe icon

Remote control icons

General Operation

Introduction: The Novus Spectra Laser

The Novus® Spectra™ 532-nm green laser is the benchmark for ease, speed, and intricate treatment in ophthalmic surgery, integrating the reliability of 532-nm green light with the convenience of a small, portable laser package.

The adaptability of the Novus Spectra is ideal for ophthalmic procedures such as angle-closure glaucoma, open-angle glaucoma, diabetic retinopathy, retinal detachments, and age-related macular degeneration. It also is ideal for otologic procedures such as stapedotomy, stapedectomy, tympanoplasty, myringotomy, bleeding control, lysis of adhesions, and treatment of soft tissue adhessions. Our complete line of delivery systems and accessories further extends the versatility of the Novus Spectra laser.

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

Characteristics of the 532-nm green laser beam

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

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

Laser Preparation

The laser is shipped directly from the factory to your site. Your local Lumenis representative initially unpacks, inspects, sets up, and installs the laser to ensure that it is ready for use. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced with the operation and safety considerations of the laser.

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

Novus Spectra Components

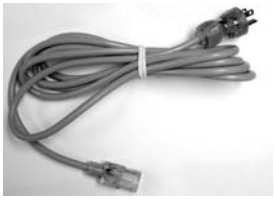
The Novus Spectra laser system comprises:

- a laser console with display—single or dual port systems are available with either 1.5 or 2.5 Watts maximum output power
- an optional remote control
- a footswitch
- all electrical cables necessary for proper connection

Delivery devices, including integrated slit lamps and slit lamp tables, if ordered, may also be shipped with your laser system.

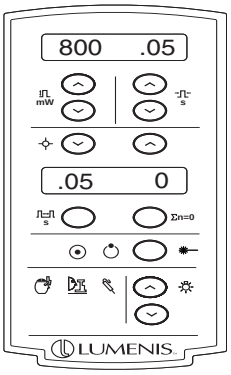
Single port system

Dual port system



Power Cord

Footswitch



Remote control (optional)

Novus Spectra laser console and components

Laser console

The laser console houses the display, main power keyswitch, emergency stop button, control electronics, laser source and associated optics, and power supply. The laser console is the central unit to which the laser components and delivery devices attach.

Remote control (optional)

The optional remote control provides all of the necessary controls for setting treatment parameters. It can be used in place of, or in addition to, the laser console controls.

External door interlock plug

The external door interlock plug must be inserted into the external interlock receptacle on the rear of the laser console for the laser to operate. The plug comes pre-installed from the factory. The plug may be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

Footswitch

The footswitch activates the laser treatment beam when you depress it while the laser is in ready mode. If you are using the Smart footswitch, the footswitch engages the automatic eye safety filter when you place your foot inside of the footswitch housing while the laser is in ready mode. If you are using the PowerEase footswitch, you can adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.

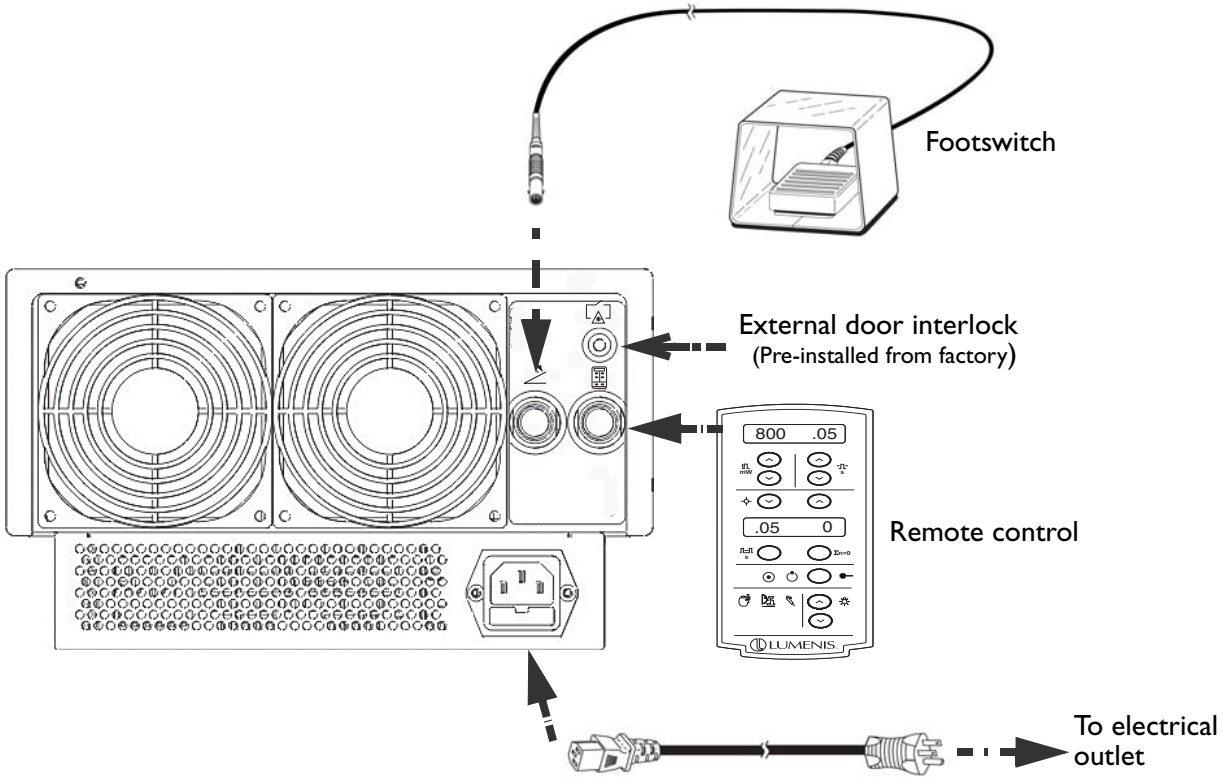
Delivery devices

Delivery devices for a variety of applications may have been shipped with your Novus Spectra laser. Refer to the operator manuals included with those delivery devices for specific descriptions and operating instructions. Compatible delivery devices include probes, fibers, laser indirect ophthalmoscopes (LIO), LaserLinks and integrated slit lamps.

Connection Instructions

CAUTION - Do not touch any optical lens; finger oils may damage the delicate coatings.

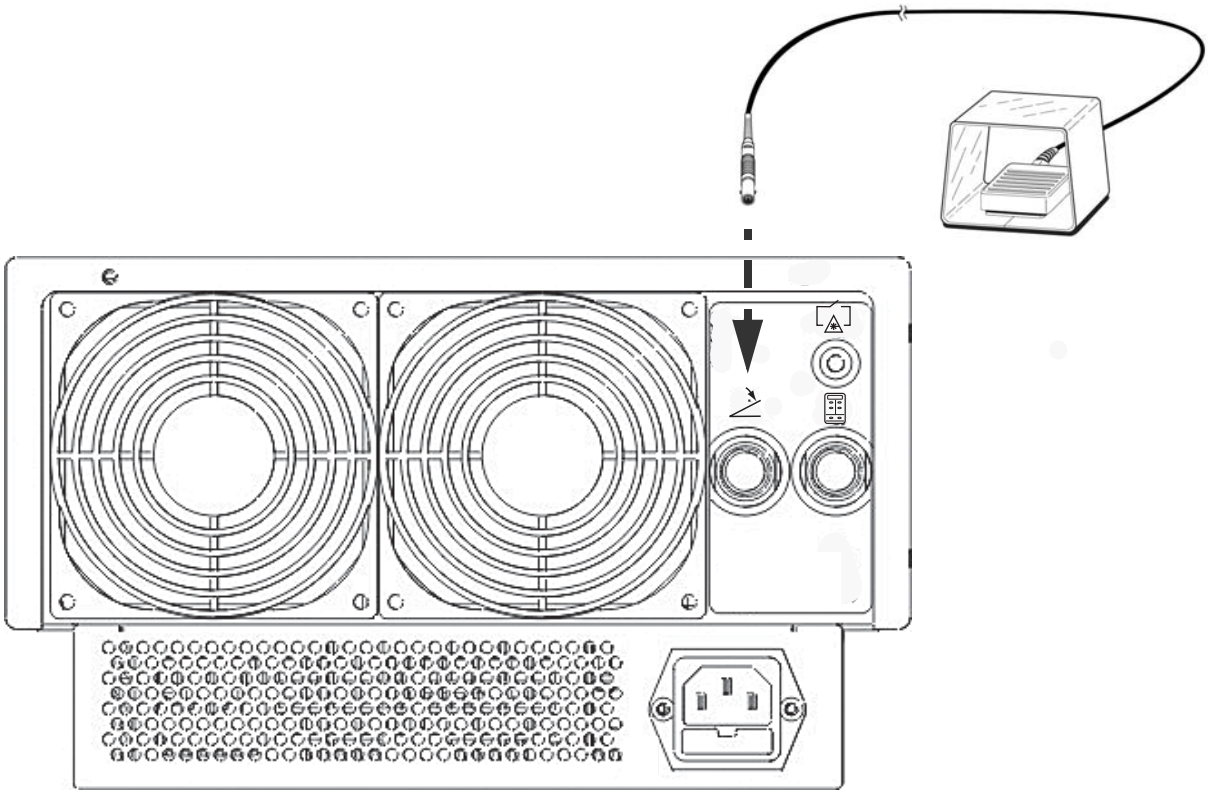
Before connecting the laser components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Ensure that the electrical cables are not frayed or split. Inspect all delivery devices, as instructed in the appropriate delivery device operator manual. Contact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



Novus Spectra Connections

Connecting the footswitch

Insert the footswitch plug into the (footswitch) receptacle on the rear of the laser console. If the footswitch is not properly connected when the laser is turned on, "E200" displays on the laser console until the footswitch is properly connected.



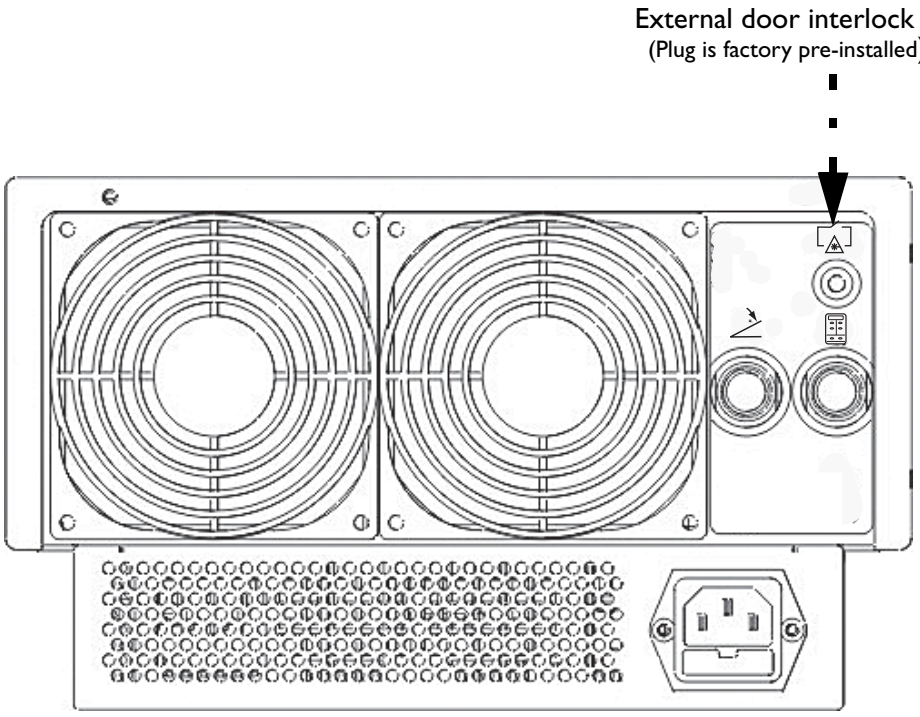
Connecting the footswitch

Using the external door interlock

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, an interlock plug must be inserted into the external door interlock receptacle whether or not you are using an external door interlock. The laser will be inoperative unless a plug is inserted into the receptacle. For your convience, the Novus Spectra comes from the factory with an interlock plug pre-installed.

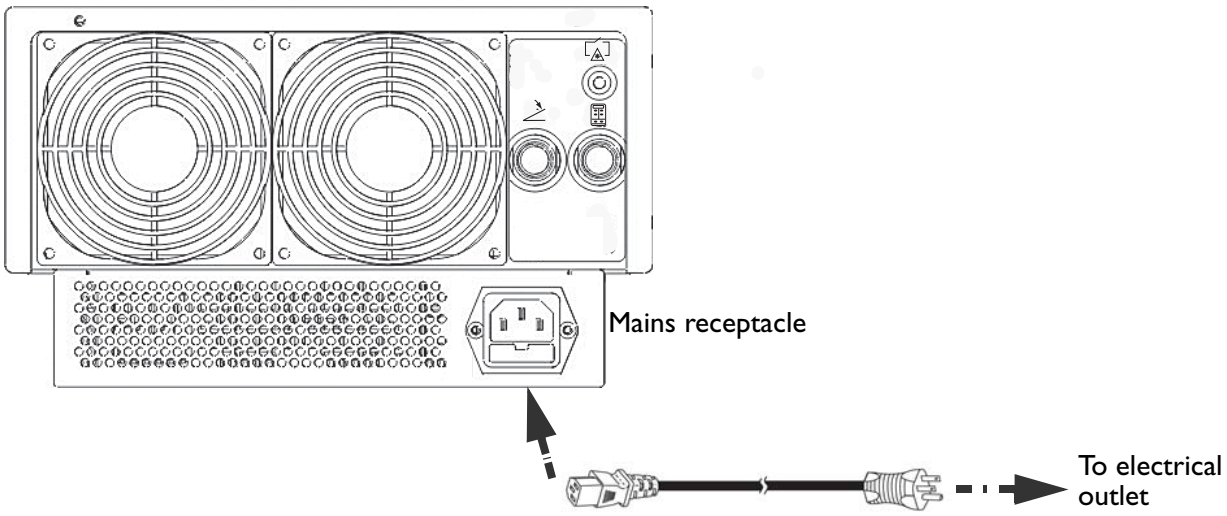
An external door interlock rated at 12 VDC is required for this system. When using an external door interlock, the laser automatically disables and returns to standby mode if the treatment door is opened or the interlock plug is removed. The code "ILOC" will appear on the laser console display. To resume treatment, close the treatment room door or reinsert the interlock plug, and press the Mode selector to return the system to ready mode.



Inserting the external door interlock plug

Plugging in the main power cable

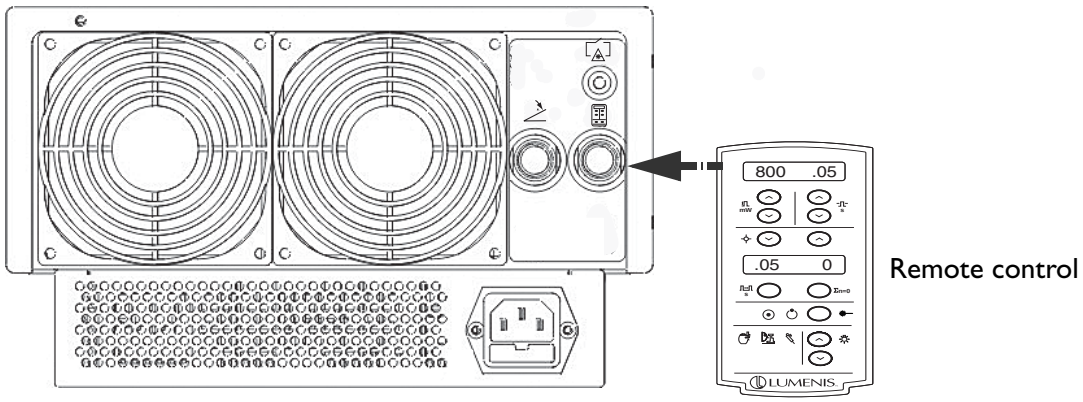
1. Ensure that the keyswitch is in the ◯ (off) position.
2. Insert the mains power plug into the mains receptacle on the rear of the laser console.
3. Insert the other end of the main power plug into the wall socket and ensure that the plug is secure.



Plugging in the main power cable

Connecting the remote control

If desired, connect the remote control at any time by inserting the remote control plug into the (remote control) receptacle on the rear of the laser console.



Connecting the remote control

Connecting the delivery device(s)

WARNING - EndoOto probes must only be used with 2.5 Watt units; 1.5 Watt units cannot provide adequate energy for EndoOto procedures.

WARNING - To avoid possible damage to the laser, use only qualified, compatible Lumenis delivery devices. Using other than Lumenis delivery devices may jeopardize safe operation or damage the laser and will void your Lumenis warranty or service contract.

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

WARNING - Carefully inspect any delivery system sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system

WARNING - If an emulation plug is used, the operator shall assume all responsibility for ensuring that the proper eye safety filters are used.

A variety of delivery devices are compatible with this laser. To connect a delivery device, attach the delivery device laser connector to an available fiber port on the front of the laser console. Attach any additional connectors to the ACC (accessory) receptacle, as appropriate for your delivery device. Refer to the appropriate delivery device operator manual for detailed connection and operating instructions.

When a delivery device is properly connected, the corresponding icon displays on the remote control.

 represents a LaserLink™ or slit lamp

 represents a probe or handpiece

 represents an LIO

If the delivery device is not properly connected, an E300 error code will display on the laser console, and the delivery device icon willnot illuminate on the remote control.Verify that the device is properly connected to the appropriate receptacles before turning the laser on. If the delivery device is not compatible with the Novus Spectra laser system, an E301 error code will display.

Connecting eye safety filters (LaserLink, slit lamp, and Acculite only)

Installing the eye safety filter(s)

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

If the eye safety filter is not properly connected to the laser, an E400 error code will display on the laser console. If the eye safety filter is not compatible, an E401 error code will display.

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

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

Connecting an automatic eye safety filter to the laser

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

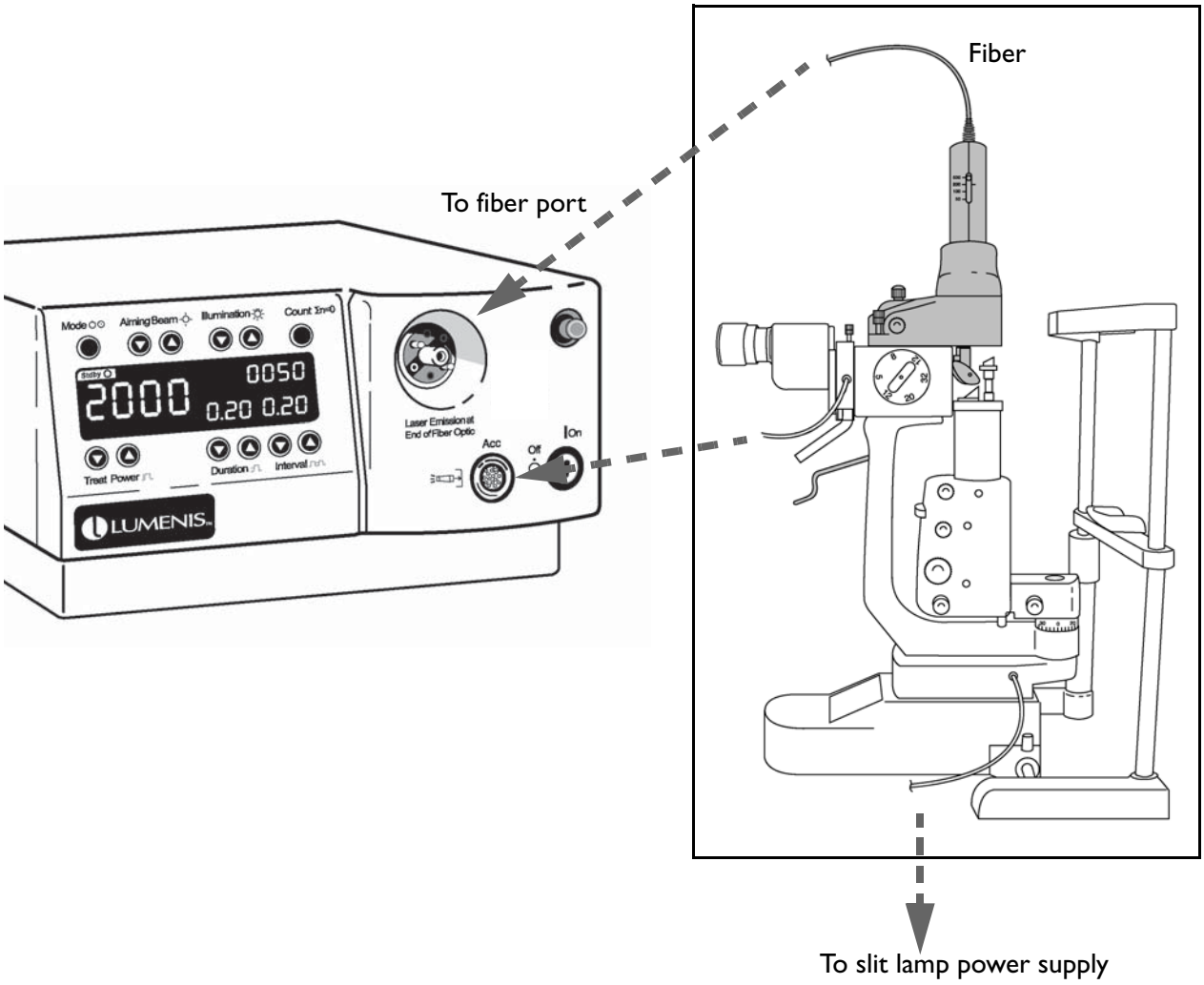
To connect the eye safety filter to the laser:

1. Insert the eye safety filter plug into the eye safety filter extension cable, as instructed in the appropriate delivery device operator manual.
2. Insert the extension cable plug into the ACC receptacle on the front of the laser console.

Connecting a fixed eye safety filter to the laser

If you are using a fixed eye safety filter, then you must insert an emulation plug into the ACC receptacle.

The LIO (laser indirect ophthalmoscope) delivery device has an integrated eye safety filter. If you are using an LIO, you do not need to insert an emulation plug into the ACC receptacle.



Example of delivery device and eye safety filter connections (slit lamp, LaserLink, and single port Spectra is shown)

Laser Console Basics

Turning on the laser

1. Insert the key into the keyswitch.
2. Turn the key to the | (on) position.
3. A laser self-test and warmup begin and the display screen will show a line of dashes. The self-test and warmup take approximately one minute. When the warm-up is successfully completed, the display screen will show Stdby ⏲ to indicate that the laser is in standby mode.

> Depressing the footswitch during warmup will disable the footswitch.
>
> If any fault conditions are encountered during the laser self-test and warmup, refer to the "Troubleshooting Guide" in the Maintenance chapter.

Restarting the laser

In most cases you will not need to restart the laser. If a condition occurs that requires you to restart the laser:

1. Turn the keyswitch to the (off) position; wait 5 seconds.
2. Turn the keyswitch to the (on) position. The laser begins the routine start-up sequence.

Keyswitch

Turning off the laser

Under normal operating conditions, turn the keyswitch to the ◯ (off) position to turn off the laser. Remove the key to prevent unauthorized use of the laser.

Emergency stop

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

When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, unplug the main power plug from the wall socket, or turn off the main electrical service (wall circuit breaker).

The emergency stop button turns all power to the laser off, but does not turn off the CPU board or the laser console display. When the button is pressed, an EOFF code will appear in the laser console display, and the system will be in standby. To clear the EOFF, press the emergency stop button. The system will return to standby mode with all of the user settings retained.

Disconnecting the laser

1. Place the laser in standby mode.
2. Turn the keyswitch to the ○ (off) position.
3. Remove the main power plug from the wall socket.
4. Disconnect the delivery device(s) from the laser. If the delivery device is single-use, dispose of it properly. Otherwise, inspect and clean the delivery device(s), as instructed in the appropriate delivery device operator manual(s).
5. Remove the footswitch from the laser.
6. Disconnect the automatic eye safety filter(s), if used, and remove the eye safety filter extension cable or emulation plug from the laser.
7. Disconnect the external door interlock, if used.
8. Clean the exterior surfaces of the laser, as instructed in the Maintenance chapter.

Moving the laser console

This is a portable laser, so it can be simply picked up and moved from place to place. For transporting long distances, place the laser in the carrying case.

Laser beam integrity check

WARNING - Refer to the appropriate delivery device manual for important, additional information on laser beam integrity specific to that device.

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

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

1. Ensure that the delivery device is properly fastened to the laser as described in the Connection Instructions section of this manual.
2. Turn on the laser.
3. Verify that E300 (fiber not connected) or E301 (fiber not compatible) IS NOT displayed on the laser console or remote control. If E300 displays, make sure the connector is fastened properly in the fiber port. If E301 displays, connect a compatible delivery device.
4. Set the aiming beam to the highest intensity, as instructed in "Adjusting aiming beam intensity" in this chapter.
5. Hold a nonreflective surface, such as a tongue depressor, in front of the probe fiber tip or at the delivery device focal plane. A red spot, the aiming beam, should appear on the flat surface. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.

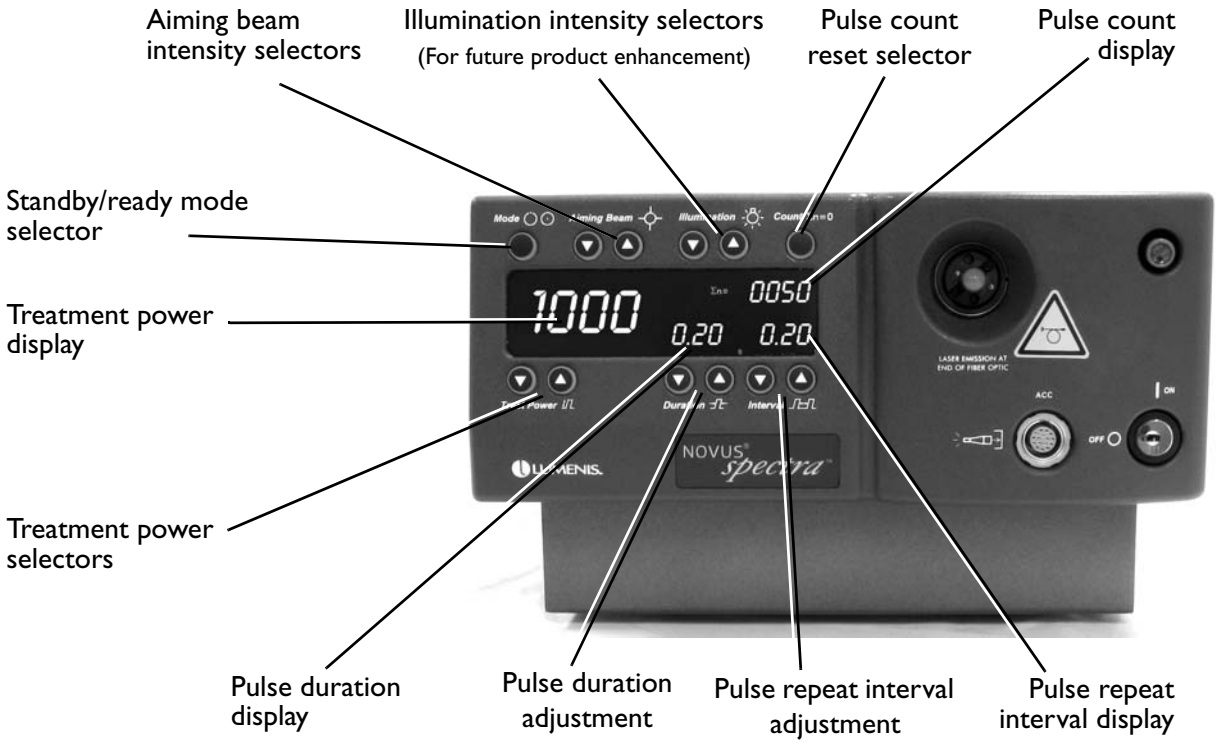
WARNING - Do not use the delivery device if the aiming beam is set to the highest intensity and is still weak or not visible; the fiber may be damaged. A damaged fiber may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

6. Set the laser treatment parameters, as instructed in the Setting Treatment Parameters of this chapter.

Laser Console and Remote Control Basics

Single port laser selectors, icons, and displays (1.5W and 2.5W units)

The laser console selectors are identified by English labels and icons.

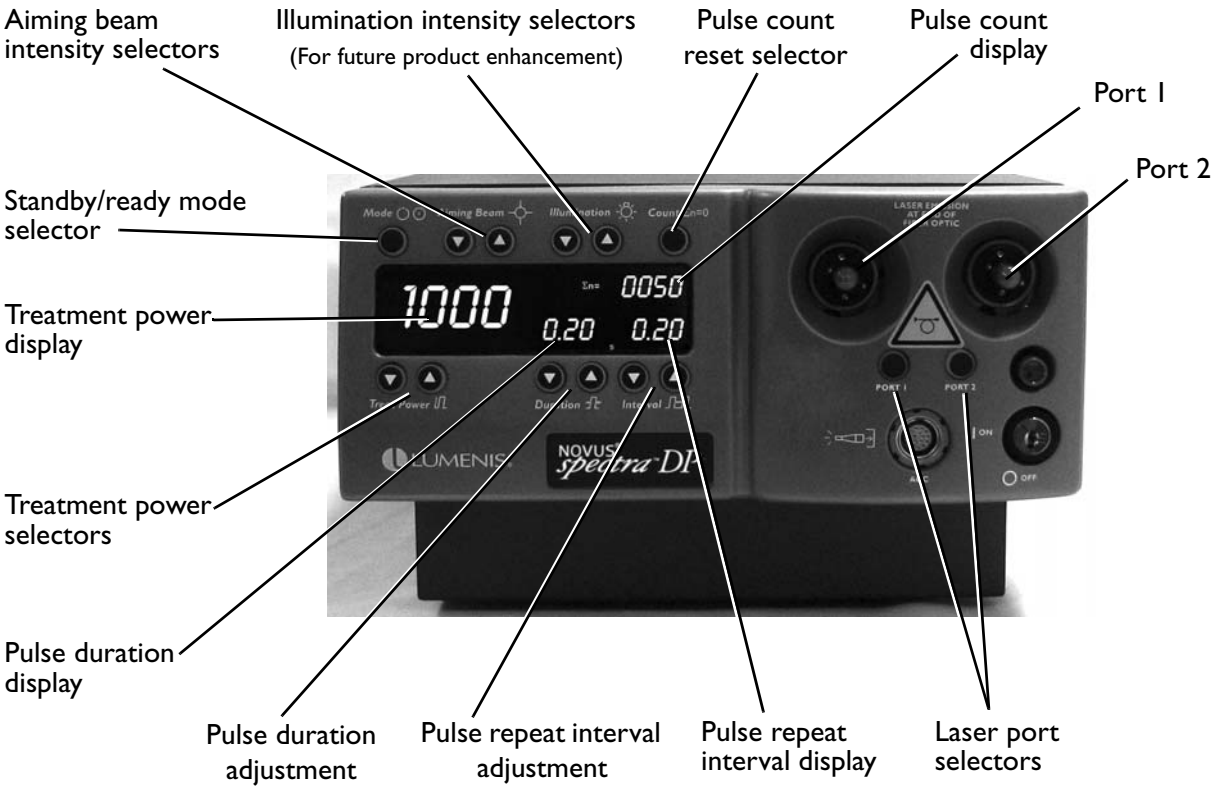


Single port system

Dual port laser selectors, icons, and displays (1.5W and 2.5W units)

The laser console selectors are identified by English labels and icons.

Press the **PORT 1** or **PORT 2** selector to activate the desired laser port. The selector will illuminate to indicate the active port.

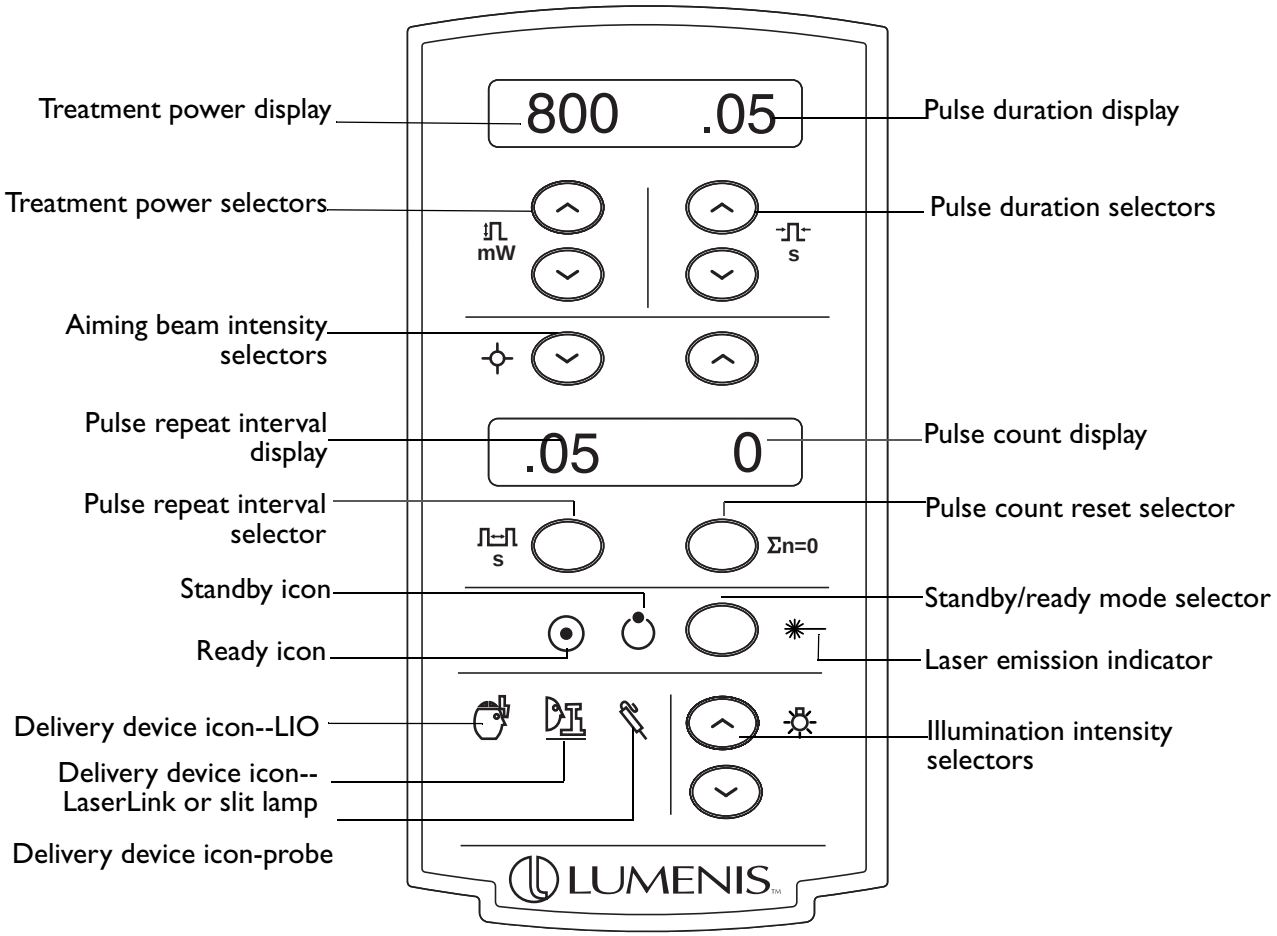


Dual port system

Remote control selectors, icons, and displays

The remote control is labeled with icons. The selectors, icons, and display illuminate when the remote control is connected and the laser is turned on.

Fiber ports cannot be changed from the Remote



Remote control buttons, icons and displays

Laser status and laser emission: ready and standby modes

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

WARNING - Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in ready mode.

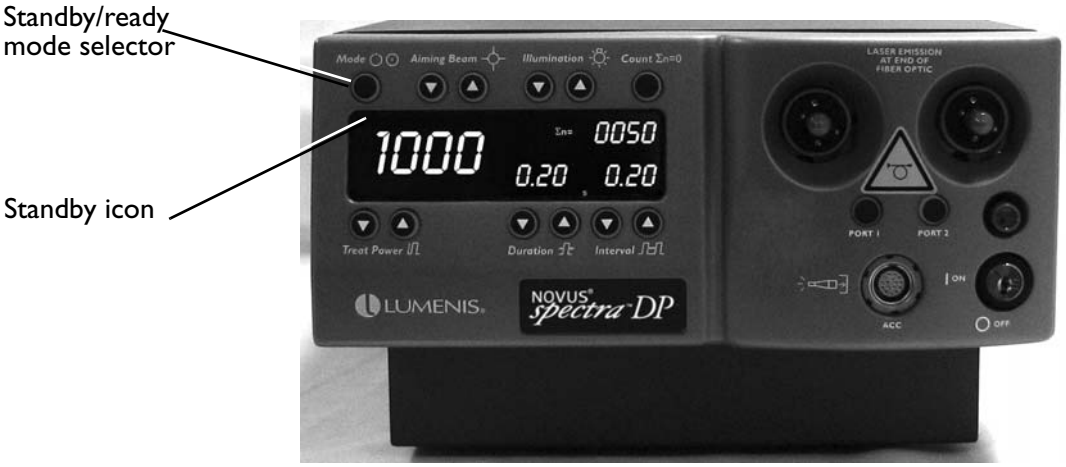
The display at the left of the laser console shows the laser status: standby or ready. On the remote control, either the ⏻ standby or ⊙ ready icons will illuminate.

When the laser is turned on and has finished warming up, it defaults to standby mode. "Stdby ⏻ " displays on the laser console as well as the power, duration, and interval default settings. On the remote control, the ⏻ icon is illuminated. In standby mode, the aiming beam is present but the footswitch is disabled and the treatment laser cannot be activated.

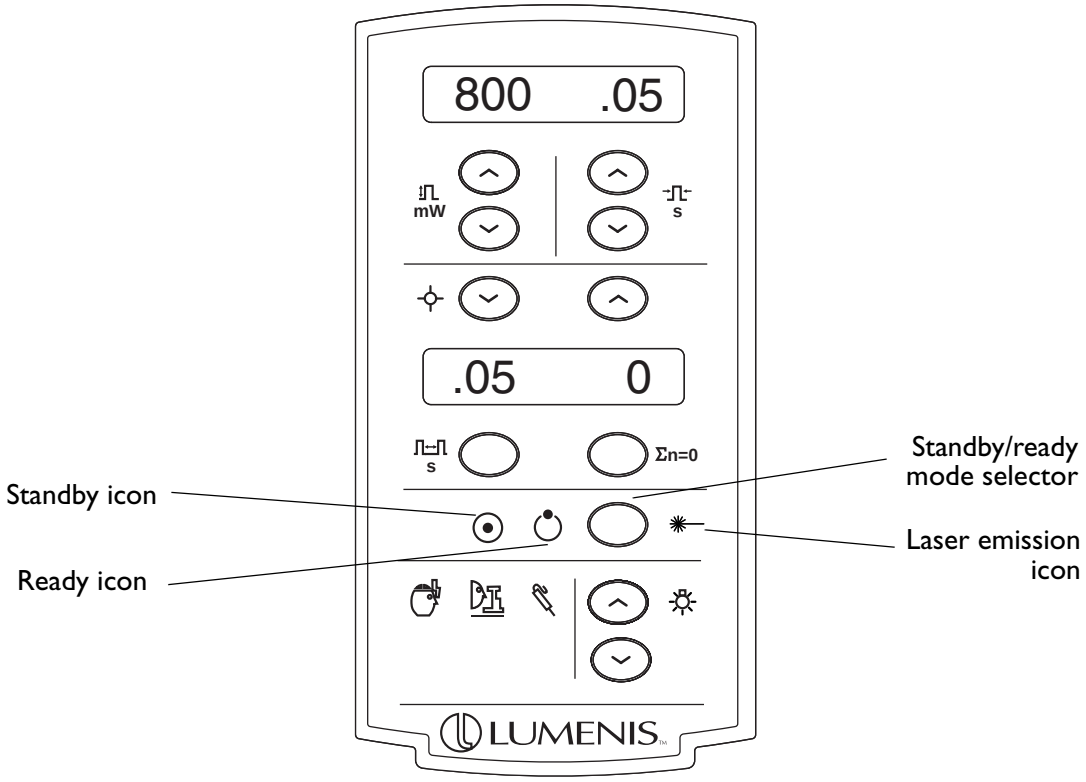
Pressing the Mode selector will switch the laser to ready mode. "Ready ⊙" displays on the laser console and the ready icon ⊙ illuminates on the remote control. The system beeps to indicate the start of a two-second delay, after which the treatment beam can be activated by depressing the footswitch. When the footswitch is depressed, the eye safety filter will engage (if using an automatic eye safety filter) and the treatment beam will be activated. While the treatment beam is being delivered, an audible tone is emitted and if the remote control is used, the laser emission indicator ✳— illuminates. The Count display will incrementally show the number of pulses delivered.

If the laser is not used for five minutes, the system automatically defaults to standby mode.

If the laser cannot be placed in ready mode, the system beeps, and an error message displays on the laser console display and remote control.



Standby/ready mode selector and Standby icon on laser console



Standby/ready mode selector and icons on remote control

Setting Treatment Parameters

You can set treatment parameters from either the laser console display or the remote control. The system beeps when a maximum available setting is selected.

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

Selecting and verifying the delivery device

Connect the desired delivery device, as described in "Connecting the delivery device." Verify that the appropriate delivery device icon illuminates on the remote control:

indicates a LaserLink or slit lamp is connected

indicates a probe is connected

indicates an LIO is connected

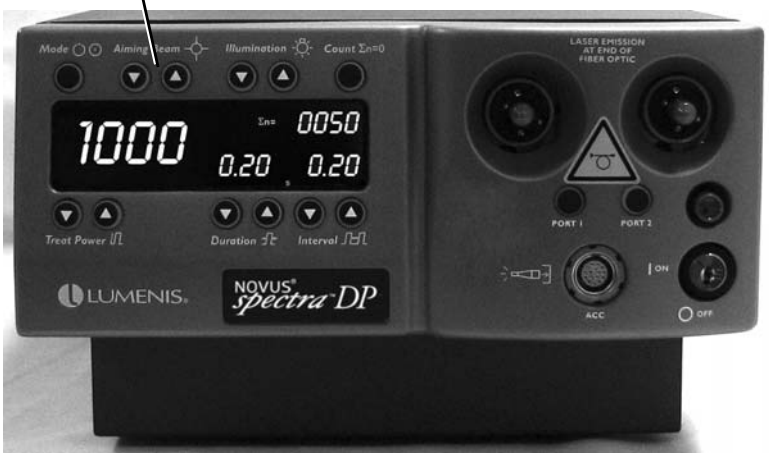
If using a dual port system, press the **PORT 1** or **PORT 2** selector to activate the desired laser port. The selector will illuminate to indicate the active port.

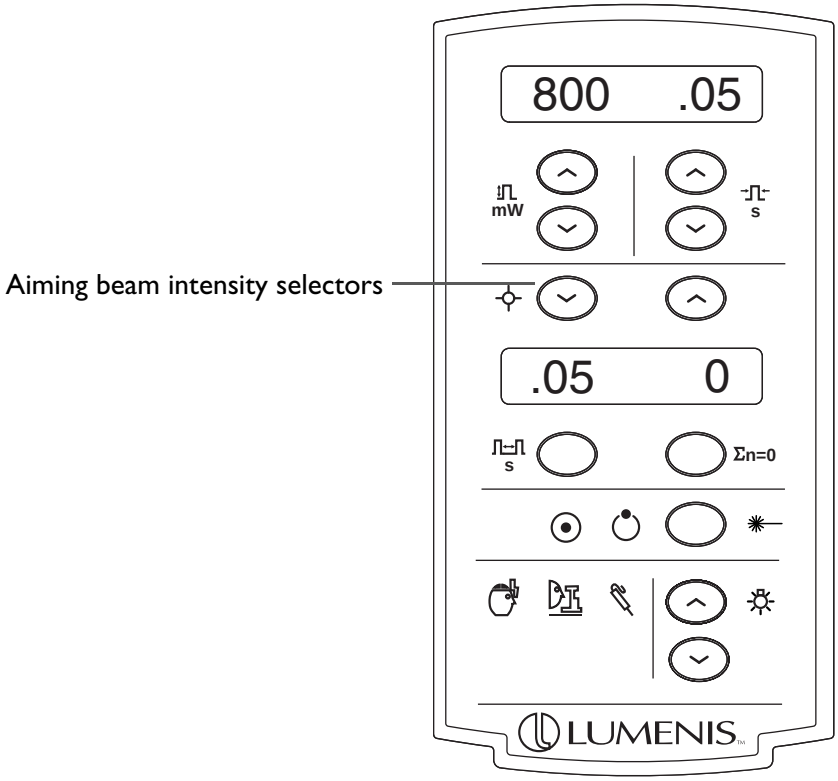
WARNING - Always ensure that a compatible eye safety filter is properly connected for the selected delivery device. Failure to properly use an eye safety filter for those delivery devices that require them can result in serious eye damage. Refer to the appropriate delivery device operator manual for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

Adjusting the aiming beam intensity

Adjust the aiming beam intensity to the desired level by pressing the aiming beam (increase) and (decrease) selectors. To adjust the aiming beam intensity from the remote control, press the (increase) and (decrease) selectors in the (aiming beam) field.

During some procedures, the aiming beam may obstruct the view of the treatment site while lasing. The aiming beam can be either on or off while lasing. To turn the aiming beam off, press the down selector to the "0" setting.





Adjusting the aiming beam

Setting the power

The maximum available treatment power varies depending on the system purchased (1.5 W or 2.5 W) and on the type of delivery device used with the 2.5 W unit. The range for the 2.5 Watt unit varies from 1800 mW, nominal for slit lamps, to 2500 mW, nominal for the Acculite endoprobes.

To set the power from the console, press the Treat Power ▲ (increase) and ▼ (decrease) selectors until the desired setting displays. To set the power from the remote control, press the ⌃ (increase) and ⌄ (decrease) selectors in the **mW** (power) field until the desired setting displays. The system will beep when the maximum available power is selected.

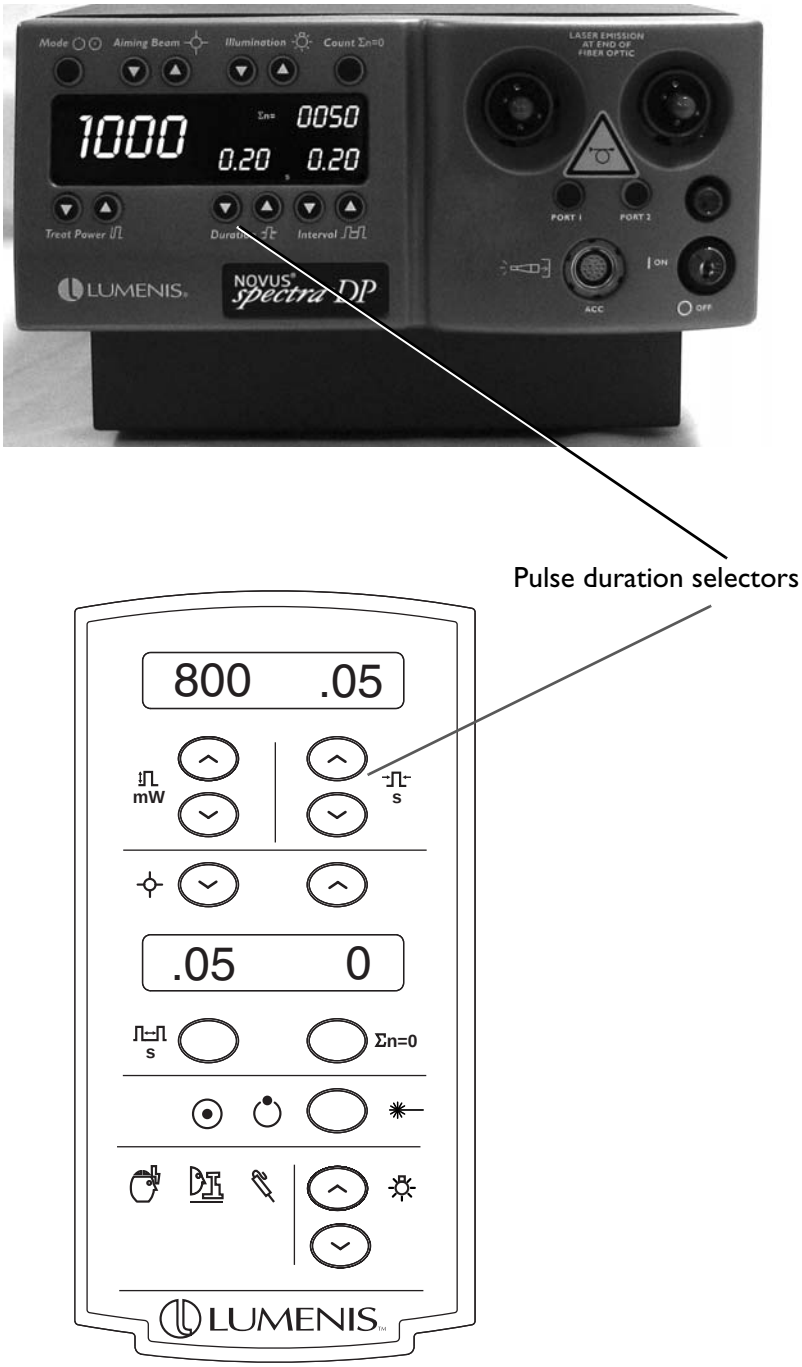
If you are using the PowerEase footswitch, you can also adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.

WARNING - Always inspect the optics and delivery device as describedin "Connection Instructions" to ensure that the device is clean and undamaged. Never use a device that appears damaged or dirty. Doing so may dangerously reduce the delivered power and result in unintended, adverse tissue effects.

Setting the exposure time (pulse duration)

The pulse duration setting determines the duration of each laser exposure. Exposure time settings range from 0.01 to 3.0 seconds. If you release the footswitch before the selected exposure time has elapsed, laser exposure is interrupted.

To set the pulse duration, press the up or down pulse duration selectors on either the laser console or remote control until the desired value displays.



Setting the pulse duration

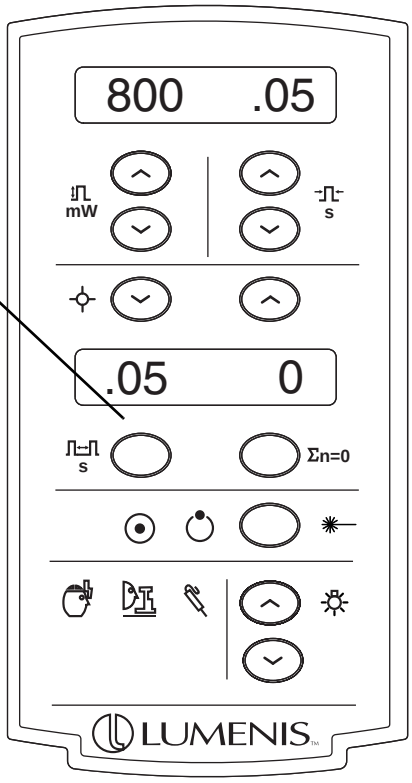
Setting the pulse interval

The pulse interval is the time between laser pulses. Single and repeat pulse modes are available. In single pulse mode, the laser delivers a single pulse each time you depress the footswitch. In repeat pulse mode, the laser delivers repeated pulses at a specified interval, from 0.05 s to 1.0 s, until you release the footswitch.

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

To set the pulse interval, press the up or down Interval selectors on the laser console display or the remote control until the desired value displays.

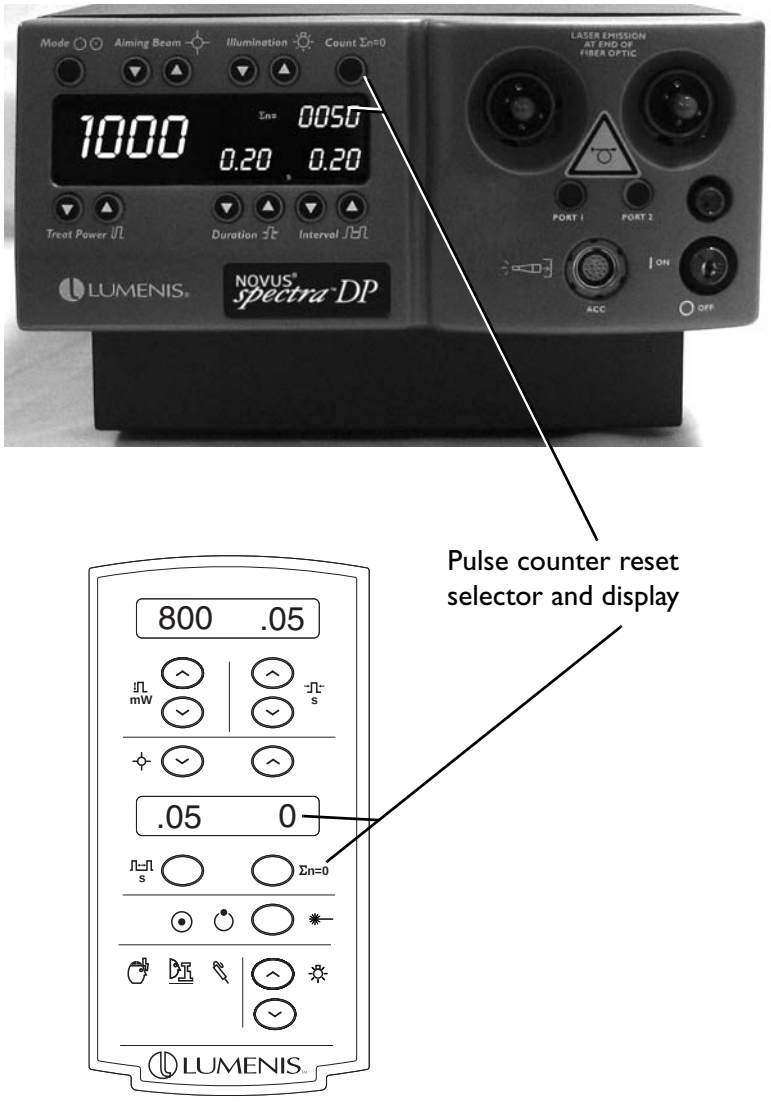
Pulse interval display and selectors



Setting the pulse interval

Resetting the pulse counter

The pulse counter displays the total number of treatment pulses delivered since the reset selector was last pressed. The range on the Novus Spectra display is 0-9999 pulses. It can be reset to zero by pressing the Count Reset selector located above the display on the laser console or by pressing the count reset selector underneath the display on the remote control. The pulse count will reset to “0” when the laser is shut down.



Resetting the pulse counter

Preoperative Instructions

1. Verify that the laser is properly connected, as instructed in "Connection Instructions" in this manual.
2. Verify that the delivery system is properly connected as instructed in the delivery system operator manual. If using an external door interlock, verify that it is also properly connected.
3. Post the "Laser in Use" warning sign outside the treatment room door.
4. Plug the laser main power into the wall socket.
5. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See "Laser Safety Eyewear" in this manual for detailed laser safety eyewear information.
6. Turn on the laser, as instructed in "Laser Console and Remote Control Basics" in this chapter.
7. Perform the aiming beam integrity check, as instructed in "Laser beam integrity check" in this chapter.

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

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

CAUTION - Before using the laser, always verify that the displays on both the laser console and the remote control are properly working and are consistent with each other.

Intraoperative Instructions

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

1. Set the treatment values, as instructed in this manual, and verify that the desired settings are displayed on the control panel.
2. If using a dual port system, press the **PORT 1** or **PORT 2** selector to activate the desired laser port. The selector will illuminate to indicate the active port.
3. Ensure that the aiming beam is visible and position it on the target tissue.
4. Place the laser in ready mode
5. Depress the footswitch to deliver the treatment beam to the tissue. The ✳— (laser emission) icon will illuminate on the remote control, and the system emits a beep.

   If surgery must be interrupted, place the laser in standby mode to disable the footswitch.

Postoperative Instructions

1. Place the laser in the standby mode.
2. Turn off the laser, as instructed in “Laser Console Basics” in this manual.
3. Unplug the laser and coil the power cable to prevent damaging it.
4. Unplug the footswitch and coil the cable to prevent damaging it.
5. If desired, disconnect the delivery device and store the laser and delivery device components, as instructed in “Laser Console Basics” in this chapter and in the delivery device operator manual. Refer to the delivery device operator manual for additional postoperative instructions specific to the delivery system.
6. Disconnect the external door interlock (if used).
7. Clean the exterior surfaces of the laser, as instructed in the Maintenance section of this manual.

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. If none of these solutions remedies the problem, consult the troubleshooting table that follows. Error codes appear on the laser console display or on the remote control display screen.

Laser console electrical

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

Delivery system connection

Verify that the delivery system is properly connected.

External door interlock

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

Problem or Error Code	Probable Cause	Suggestion
System does not turn on. Display does not illuminate.	The laser is not plugged in.	⇨ Plug the power cord into the laser and into an appropriate outlet.
	The building power (main electrical service) is turned off.	⇨ Turn on the building power.
	The electrical outlet is defective.	⇨ Use another outlet or have the outlet professionally tested and, if appropriate, repaired
	The fuse is blown.	⇨ Replace fuses.
No treatment beam output although the aiming beam operates properly.	There is an internal laser system failure.	⇨ Contact your local Lumenis representative.
	The footswitch may be defective.	⇨ With the laser in ready mode, verify that the laser emission icon ✳— appears (remote control) or that a tone (laser console) occurs when the footswitch is depressed. If either the tone or the icon does not appear, contact your local Lumenis representative.
No treatment beam output and no aiming beam. Displays and indicators are normal.	There is an internal laser system failure.	⇨ Contact your local Lumenis representative.
Treatment beam and aiming beam are out of alignment.	The laser system is internally misaligned.	⇨ Contact your local Lumenis representative.
Inadequate or no aiming beam.	The aiming beam is off or at a low setting.	⇨ Adjust the aiming beam intensity. If you are unable to fix the problem, contact your local Lumenis representative.
	The delivery device optics are dirty.	⇨ Verify that the delivery device optics are clean, as instructed in your delivery device operator manual.

Problem or Error Code	Probable Cause	Suggestion
Inadequate treatment beam or tissue effect.	The treatment or aiming beam is not properly aligned.	⇨ See "Treatment beam and aiming beam are out of alignment".
	The delivery device optics are dirty.	⇨ Verify that the delivery device optics are clean, as instructed in your delivery device operator manual.
	The delivery device is not properly connected.	⇨ Verify that the delivery device is properly connected, as instructed in your delivery device operator manual.
E200	The footswitch cable is not properly connected to the laser console, or the footswitch cable is defective.	⇨ Ensure that the footswitch is properly connected to the laser console and that the footswitch cable is not damaged. If the condition continues, restart the laser system. If the condition persists, contact your local Lumenis representative.
E300	The fiber is not properly connected.	⇨ Ensure that the fiber is properly connected.
E301	The fiber is not compatible.	⇨ Connect a compatible fiber.
E400	The delivery device is not properly connected.	⇨ Ensure that accessory cords are properly connected.
E401	The delivery device is not compatible.	⇨ Connect a compatible delivery device. Consult your delivery device and laser system manual for compatibility information.
EOFF	The emergency stop button  is depressed.	⇨ Depress the emergency stop button again; the system will return to standby mode.
ILOC	The remote interlock has been activated by the opening of an interlocked door or an improperly connected interlock plug.	⇨ Close the interlocked door or connect the interlock plug. Press the Mode button to select ready mode.
F100	There is an internal shutter failure	⇨ Contact your local Lumenis representative
F101 or 102	There is an internal shutter failure	⇨ Contact your local Lumenis representative
F201 or 202	The footswitch is not functioning properly.	⇨ Replace or repair footswitch.

Problem or Error Code	Probable Cause	Suggestion
F203	The footswitch has been depressed while trying to enter ready mode.	⇨ Release the footswitch. Press the mode selector again to continue, ensuring that the footswitch is not depressed.
F204	Footswitch error	⇨ There is a three second delay from the time the Ready button is pressed and the time the footswitch can be pressed. Wait for the Ready indicator on the console to illuminate before pressing the footswitch. ⇨ Check footswitch connections and cord. If the condition persists, contact your local Lumenis representative.
F402	Delivery device error	⇨ First, remove and inspect the delivery device as instructed in your delivery device operator manual; then, verify that the device is properly connected as instructed. If the condition persists, contact your local Lumenis representative.
E501	The laser detected a lower level of energy than the level selected by the user.	⇨ Turn off the system for five seconds, then restart. If the condition persists, contact your local Lumenis representative.
E502	The laser detected a higher level of energy than the level selected by the user.	⇨ Turn off the system for five seconds, then restart. If the condition persists, contact your local Lumenis representative.
E701	The laser detected an over temperature condition.	⇨ Let the system remain in standby for five minutes. If the error does not clear, turn off the system and wait for 1 minute, then restart. If the condition persists, contact your local Lumenis representative.
F803	Power interlock error	⇨ Turn the laser on and off. If the condition persists, contact your local Lumenis representative.
F503-F505, F601-F604, F702-F704, F901-F909, CA01	Internal system operating errors	⇨ Contact your local Lumenis representative.

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 representative.

Clean the external surfaces of the laser console

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

Clean the laser display

Use a soft cloth to apply antistatic glass or plastic cleaner to the laser display.

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

Water utilities

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

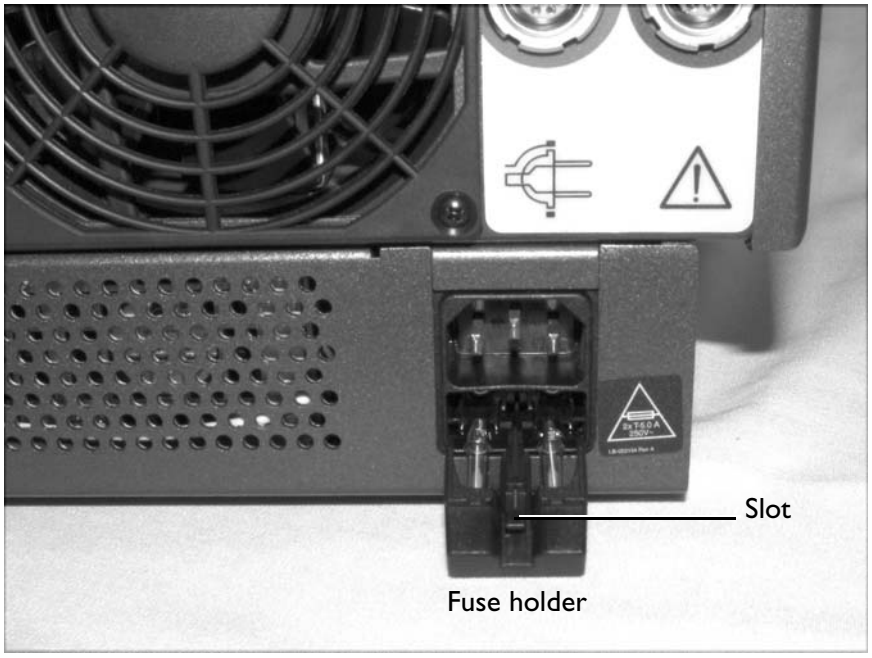
Electrical Requirements

The Novus Spectra laser is designed to meet UL2601-1, IEC 60601-1-1, 60601-1-2, 60601-1-4, 60601-2-22, and 60825-1, and CSA 22.2 No. 601 requirements. The laser is available in one electrical configuration with a universal, 100–240 V~, 50/60Hz, 6.3 A 1ϕ power input.

The supplied hospital-grade power cord should be used with a standard 15-A wall outlet. The power cord shipped with the system will vary according to local electrical requirements.

Replacing the Fuses

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



Specifications

Specifications are subject to change without notice.

Novus Spectra Laser	
Treatment beam	
Type	Frequency-doubled Nd:YAG, diode-pumped solid-state
Wavelength	Green: 532 nm
Power output	50–1500 mW (1.5 Watt unit) 50–2500 mW (2.5 Watt unit)
Duty cycle	50 mW = power setting ≤ 500 mW: all settings are available 500 mW < power setting ≤ 1000 mW: duty cycle limited to 75% 1000 mW < power setting: duty cycle limited to 50%
Pulse duration	Factory pre-sets starting at 0.01 s up to 3.00 s (for durations greater than 1.00 s, power is limited to 500 mW)
Pulse interval	Factory pre-sets starting at 0.05 s up to 1.00 s and single pulse
Pulse counter	Counts pulses delivered; range = 0–9999
Laser beam spot size	Controlled by delivery system
Illumination	The accessory port provides from 0–20 W of electrical power to an external bulb. Adjustable by pressing the illumination up/down buttons.
Beam divergence (Delivery device convergence)	**Accessory** — **Convergence (in radians)** Probes — 0.05–0.14 LaserLink S — 0.05 LaserLink HS — 0.05 LaserLink Z — 0.05 LaserLink Z 25SL — 0.05 LaserLink 30SL — 0.05 LaserLink 20SL — 0.05 Keeler LIO — 0.024 Heine LIO — 0.022 Lumenis 1000 — 0.041
CDRH classification	Class IV
European MDD Laser Classification	Class 4
Aiming beam	
Type	Diode
Power	Adjustable up to <1.0 mW
CDRH classification	Class II
European MDD laser classification	2
Principal output	630–680 nm (red)
Cooling	Air cooled

Novus Spectra Laser	
Electrical requirements	
Voltage Frequency Wall outlet	100–240 VAC ±10% 50/60 Hz, single phase 15 A, Dedicated service
Environmental requirements (operating)	
Maximum altitude	3,900 meters (13,000 feet)
Operating temperature	10 °C to 37 °C (50 °F to 99 °F)
Maximum humidity	up to 90% at 37 °C (99°F) noncondensing
Environmental requirements (nonoperating)	
Maximum altitude	Standard commercial shipping altitude
Operating temperature	-10 °C to 55 °C (14 °F to 131 °F)
Maximum humidity	90% at 55 °C (131°F) noncondensing
Physical characteristics	
Height Width Depth (Single port system) Depth (Dual port system) Weight	15.2 cm (6 in.) 25.4 cm (10 in.) 37.5 cm (14.5 in.) 37.5 cm (14.5 in.) 8 kg (17 lb)
Power cable length	4.1 m (13.5 ft) U.S. 2.4 m (8 ft) International
Footswitch cable length	4.6 m (15 ft)
Latex	This product is latex free
Laser safety eyewear	Refer to “Laser Safety Eyewear” in the Safety and Regulatory section of this manual for detailed laser safety eyewear information.
Compatible delivery systems	Slit lamp delivery systems for Zeiss and Haag Streit style slit lamps Laser indirect ophthalmoscopes (LIO) for Keeler and Heine Acculite Endoprobes EndoOto probes (only used with 2.5 Watt units) Integrated slit lamps

Calibration Procedure

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

Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Questions regarding this procedure 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. Contact your local Lumenis representative for information on service training courses or to purchase a service manual for the laser. It is company policy not to distribute service tools outside of the Lumenis Service Organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

Calibration instructions

The following equipment is required for calibration:

- Power meter (Ophir or equivalent)
- Potentiometer adjustment tool
- Digital voltmeter (Fluke 77 or equivalent)

> ⚠ **WARNING -** As a precaution against accidental exposure to the output beam or its reflection, personnel checking or adjusting calibration should wear specially tinted laser safety eyewear. For further information on laser safety eyewear, see the Laser Safety Eyewear section of this manual.

To calibrate the laser:

1. Ensure that the keyswitch is in the ○ (off) position.
2. Open the top protective cover of the laser console.

> ⚠ **WARNING -** Opening the laser console protective covers will expose the user to the laser resonator and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.

3. On the CPU board (bottom PCB), slide switches 1 and 2 of SW2 to the open position.
4. Turn the keyswitch to the | (on) position, slide SW2 switches 1 and 2 to the closed position. The laser is now in calibration mode. The display flashes an upper case “C”.
5. Select 1000 mW power, 50 ms exposure time, and a 50 ms interval time.
6. Attach a digital voltmeter across Main and Safe test points. Select DC volts, auto-ranging.
7. Remove the CPU board and place a power meter in front of the fiber port.
8. Select ready mode, then depress the footswitch. Adjust the Main_Gain pot on the Analog Board (top PCB) until the power meter reads 500 mW average or 1000 mW peak. Adjust the Safe_Gain pot until the voltmeter reads 0 V ±5 mV.
9. Turn the laser off then back on. Allow the laser to perform its self-test. The laser should go into standby mode without any error codes displayed on the laser display or remote control.

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 U.S. 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 U.S. service offices.

Indications for Use

General Information

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

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

Laser light is preferentially absorbed by pigments within tissue and causes an increase in tissue temperature. Laser light is also absorbed by nonpigmented tissues, but the absorption coefficient is less than that of pigmented tissue. The wavelength typically penetrates pigmented tissue to a depth of approximately 0.8 to 1.1 mm (around 1000 µm). Light from the laser is also scattered in tissue. This scattered light causes a lateral spread of the laser energy. The following equation describes the intensity of laser light in tissue, at a depth x into the tissue, along the incident ray.

$$I = I_0 e^{-\sqrt{\alpha^2 + 2\alpha\beta}\, x} = I_0 e^{-\mu x} \quad \textbf{\textit{Equation 1}}$$

where α is the absorption coefficient [cm^{-1}], β is the scatter coefficient [cm^{-1}], I is the intensity at a distance x into the tissue, I_0 is the intensity at the tissue surface, and e is the base of the Napierian log. The term

$$\sqrt{\alpha^2 + 2\alpha\beta} = \mu \quad \textbf{\textit{Equation 2}}$$

is the wavelength-dependent attenuation coefficient [cm^{-1}].

Some values of α, β, and μm for several tissue types are shown in the following table:

Tissue	Absorption Coefficient α [cm^{-1}]	Scatter Coefficient β [cm^{-1}]	Attenuation Coefficient μm [cm^{-1}]	Depth of Penetration [μm]
Human Dermis (In Vitro)	8	83	37.4	267
Blood Thrombus	110	13	122.3	82
Fibrous Plaque	18	19	31.7	315
Vessel Wall	11	11	19	526

Table 1: Absorption coefficient, scatter coefficient, attenuation coefficient, and depth of penetration for some representative tissue types.

Tissue effects

Tissue effects are caused by the absorption of electromagnetic laser radiation and its conversion to heat. Diffusion of heat through the tissue depends on the thermal properties of the irradiated material. The pulse train may also be optimized for the desired tissue effect.

Determining the irradiance required to elicit a specific response at tissue is extremely complex and depends on several factors. Among these factors are the following:

- The reflection coefficient at the air or water interface with target tissue
- Pigmentation of the target tissue
- Laser wavelength
- Laser pulse duration
- Blood flow
- Other factors that may influence the heat equation

This list is not intended to be all inclusive. A "cookbook" approach to surgery and tissue effects is not recommended. General guidelines can, however, be suggested. The guidelines suggested are intended to be conservative. Before setting out guidelines for each of the tissue effects of interest, we must define these effects:

Definitions

Coagulation	Heating of tissue sufficient to cause denaturation of proteins
Vaporization	Rapid heating sufficient to cause boiling of intracellular water or combustion of cellular components, resulting in bulk tissue loss
Cutting	Fine line, localized vaporization of tissue

The approximate irradiance required for each of these effects is given in the following Table:

Desired Effect	Approximate Required Irradiance
Heating	> 10 W/cm^2
Coagulation	100-500 W/cm^2
Vaporization	> 1000 W/cm^2
Cutting	> 1000 W/cm^2
Rapid Cutting	> 5000 W/cm^2

Table 2: Approximate irradiance required for specific tissue effects

Increasing the irradiance will limit lateral thermal damage, but not without a trade-off. Hemostasis will not be as effective at higher irradiance, because lateral thermal damage and, therefore, coagulation around the laser impact site are reduced.

For vaporization of soft tissue, irradiance of more than 1000 W/cm^2 is recommended. For applications where more finely controlled removal of tissue is desired, single pulse mode or repetitive pulse mode with a time interval is preferable to continuous wave laser energy. Refer to the Operation section of this manual for detailed information on how to adjust settings on your laser. The surgeon may optimize tissue absorption by controlling the power setting, pulse duration, spot size, and pulse interval. Tissue changes occur along a predictable continuum as the temperature increases.

Each phase of tissue change has a visual endpoint, enabling the surgeon to stop treatment at the desired level. Each phase serves different therapeutic goals. These phases of tissue change are described and summarized in Table 3.

Phase 1	Heating of the tissue from 43° to 50°C may allow for the uncoiling and annealing of collagen helices so that opposed edge tissues may be fused by reforming covalent bonds. Below 45°C, there is little cell damage. Above 45°C, enzymes degrade. These changes may or may not be reversible. A faint whitening signals the start of the next phase.
Phase 2	As heating proceeds above 50°C, protein denaturation begins. As temperatures rise above 60°C, extracellular proteins and collagen fibers begin to denature. Such loss of structure is seen histologically as coagulation injury or hypereosinophilia of the tissue. Beyond 60°C, immediate or eventual cell death is inevitable. Tissue coagulation should be complete when the surgeon notes a uniformly white (or grey) tissue color, blood and lymph coagulation, or necrosis. Phase 2 is complete when the surgeon observes the start of shrinkage.
Phase 3	The tissue slowly drys out and shrinks. As the temperature reaches 90° to 100°C, the underlying collagen and elastin structures begin to degrade. Caution should be exercised not to damage deeper or hidden structures (e.g. perforation). This phase is useful for shrinking tumors away from vital structures.
Phase 4	As heating proceeds beyond 100°C, water begins to boil, leaving behind vacuoles within the remaining proteinaceous structure of the coagulated tissue. Vacuoles are a definite indication of temperatures in excess of 100°C. As temperatures rise above 125°C, complete oxidation of protein and lipids occurs, leaving behind carbon particles. As

tissue turns black, temperatures rise fast because scattering stops and absorption proceeds rapidly (black absorbs all visible wavelengths). Charring is the visual signal that the final phase, tissue ablation, is about to begin.

Phase 5 — Carbonization or charring of the tissue surface indicates high-temperature processes. The surgeon can see the tissue being vaporized as a plume of gas and smoke. Ablation temperatures for calcified tissues may exceed 500°C.

Phase	Tissue Temperature	Tissue Effect	Surgeon's Observation
1	43-50°C	Temperature Increase	No visible change
2	50-60°C	Protein Denaturation	Blanching (whitening)
3	90-100°C	Water Evaporates	Shrinkage
4	100-150°C	Tissue Carbonizes	Blackening (Charring)
5	> 175 °C	All Vaporize	Smokey Plume, Reduction in volume

Table 3: The effect of temperature increase on tissue

Operators should be aware that laser light is transmitted through transparent and translucent tissue with relatively little absorption. Particular care should be exercised so that the laser light is not transmitted through such tissue or fluids, with attendant thermal damage to more highly pigmented tissue in underlying or surrounding regions. The wavelength will be transmitted through water or other clear irrigating solutions, such as Ringer's, without absorption.

Analysis of clinical and laboratory experience to date indicates that irradiance of roughly 100 W/cm^2 to 500 W/cm^2 is required for the adequate photocoagulation of tissues. Incisional and excisional vaporization (debulking) occurs with irradiance greater than 1000 W/cm^2. Irradiance greater than 5,000 W/cm^2 results in rapid incision. (See Table 2).

General warnings and precautions

WARNING - Lumenis and/or related entities assume no responsibility for parameters, techniques, methods or results. Physicians must use their own clinical judgement and professionalism in determining all aspects of treatment, i.e. technique, proper power settings, intervals, durations, etc.

WARNING - The physician should seek formal training from established courses on the use of the laser and its accessories. Any information given in this text is not intended to pro-vide such instruction, and is not to be considered a substitute. Because words can not rival actual experience, it is imperative that physicians using this equipment experience its tissue effects before ever attempting to use it on patients.

CAUTION - The laser may be expected to coagulate vessels up to 1.5 mm in diameter. In larger diameter vessels, coagulation may prove difficult, and the use of means other than the laser, such as electrocautery, may be needed.

CAUTION - Thermal damage caused by laser light substantially diminishes beyond the focal point of the beam or the tip of the fiber optic. Nevertheless, unfocused laser emissions travel in a straight line until obstructed or reflected, and care should be taken concerning what materials are present beyond or behind the target tissue. This is necessary to protect surgical personnel and tissues other than those intended for treatment from accidental exposure to the treatment beam.

CAUTION - The laser unit should be handled carefully and moved slowly to avoid jarring. Maintenance and service should be performed only by appropriately trained personnel.

CAUTION - To avoid electrical hazards from the operation of this laser unit, floors must be kept dry. In a wet-field environment, the laser should be protected from splashing and standing in pooled liquid. Personnel should avoid casual contact with the laser in a wet field. The optional watertight footswitch is strongly recommended for use in a wet-field environment.

CAUTION - The footswitch should be cleaned and inspected once each day prior to use. It is recommended that someone be stationed at the laser console during surgery to control the laser. The doctor should verify all treatment parameters before firing the laser.

CAUTION - In using any delivery devices or accessories, attention must be paid to the specific instructions and precautions applicable to those devices. This manual and the appropriate delivery device operator manual should be carefully read and comprehended before use.

Laser plume precautions

CAUTION - For the majority of ophthalmic procedures, there is no laser plume generated. However, the user should be aware that laser plumes do present a potential hazard. Plumes may be potentially hazardous, both in terms of particulate matter and infectivity. Special care must be taken to limit the exposure of both patient and surgical staff to any laser plume smoke or vapor.

CAUTION - Surgical staff should wear surgical masks that remove particles as small as 0.3 um. Latex surgical gloves should also be worn, as current evidence suggests that the hands are the most likely site of infective viral transmission during laser surgery. Gowns, caps, and eyewear that protect against splatter and laser light should all be worn.

CAUTION - Although it is highly unlikely that viable tumor cells occur in the laser plume, it has been reported that intact viral DNA is liberated into the air with the vapor of CO_2 laser-treated verrucae. In addition, exposure to CO_2 laser smoke has been shown to have harmful effects on the airway in animal models. The solid-state 532-nm laser plume may have similar characteristics to the CO_2 laser plume.

CAUTION - Laser plume may contain viable particulates.

CAUTION - If used, a smoke evacuation system should remove particles as small as 0.3 um with 80% efficiency. The filter should be changed regularly in accordance with the manufacturer's instructions in order to maintain full air flow and prevent possible accumulation of infectious material.

Irradiance, fluence, and power

Refer to “Delivery Devices and Accessories” in this section, as well as to the appropriate delivery device operator manual for additional details regarding power and duration settings to achieve the desired irradiance or fluence.

Adverse effects

⚠ **CAUTION -** Adequate suction must be maintained when using the laser to treat any pathology suspected to be of viral origin. This is to limit the possibility of spread of any virus that may exist in the laser plume.

⚠ **CAUTION -** Complications of laser therapy are the same as complications for any other procedure. Some of these complications may be serious and could result in death.

Pain

The extent and duration of pain following laser therapy is usually minimal but is dependent upon the surgical procedure.

Sepsis

The possibility of infection must be considered and treated accordingly in any surgical procedure. Laser interaction with tissue sterilizes only the treated area.

Bleeding

Coagulation is the primary tissue effect of the Novus Spectra laser. The possibility of postoperative bleeding must be considered following the sloughing of tissue. Observation for bleeding by postoperative hematocrit evaluation and dressing evaluations should be considered.

Fluid overload

Mild edema and minimal electrolyte changes may occur from prolonged procedures and absorption of the distention media.

Guidelines for use

The patient should be prepared for surgery in the routine fashion for the procedure being done. This includes preoperative medications, anesthesia, surgical positioning, preparation, and draping.

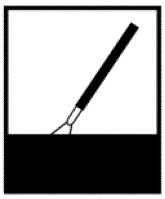
The appropriate laser delivery device should be selected based upon the desired tissue effect. The choice of contact versus noncontact devices should be based upon personal preference gained from experience and training.

Noncontact and free-beam devices

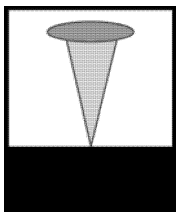
See "General Information" at the beginning of this section for a description of the physics of laser light interaction. Tissue effect may be controlled by altering the distance between hand-held fiber optic delivery devices and the target tissue.

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

All recommendations for safe use of your laser system should be followed. Users should be aware of the recommended practices for the safe use of lasers in health care facilities, as described in ANSI Z136.3[1] and ANSI Z136.1[2]. Laser applications done with noncontact devices are indicated throughout this manual by the following icon:



Laser applications using free-beam devices, such as slit lamps, are indicated by the following icon:



1. Reference 2, "General references"
2. Reference 3, "General references"

General references

1. Boulnois JL. “Photophysical Processes in Recent Medical Laser Developments” Lasers in Medical Sciences. Vol. 8 pp 47-66, 1986.
2. American National Standards Institute. “Safe Use of Lasers in Health Care Facilities” ANSI Standard Z-136.3. New York: ANSI, 1430 Broadway, 1996.
3. American National Standards Institute. “Safe Use of Lasers” ANSI Standard Z-136.1. New York: ANSI, 1430 Broadway, 1993.

Ophthalmic Applications of the Laser

The laser is used to treat several ocular diseases in both the anterior and posterior chambers of the eye. The laser is particularly well suited for treating the eye because it has minimal effect on transparent tissues and materials. This means that the laser can be efficiently delivered to opaque structures of the eye through the transparent cornea, aqueous humor, lens, and vitreous humor. This allows many conditions to be treated by noninvasive techniques.

Laser energy is delivered to opaque structures within the eye by means of a slit lamp that has been specially adapted for use as a laser delivery system.

The delivery system includes a lens system to focus the laser energy and vary the size of the laser spot in the plane of observation of the slit lamp. It usually includes some kind of mechanism to manipulate the position of the laser beam without moving the slit lamp. The laser energy is delivered to the slit lamp by means of a flexible fiber optic.

For most procedures, a laser contact lens is used to direct the laser energy to the part of the eye being treated. The contact lens may have mirrors so that laser energy can be delivered to areas of the retina behind the iris, or into the angle so that the trabecular meshwork can be treated. The contact lens also helps to hold the eye open and still so that laser energy can be delivered effectively.

The laser may be used for procedures done in the hospital or in a physician's office, and for in-patient or out-patient procedures. The use of the laser is not a contributing factor in deciding whether a procedure is done on an in- or an out-patient basis.

Posterior Segment Laser Procedures

⚠ **CAUTION -** Users should be aware of general laser warnings, precautions, and adverse effects listed in "General Information" in this chapter.

⚠ **CAUTION -** Please see "Ophthalmology References" in this chapter for literature regarding the use of the laser in retinal laser procedures.

Indications

The laser is indicated for posterior chamber procedures involving the retina.

The Conditions of the retina for which the laser is useful include diabetic retinopathy, retinal detachments, and senile macular degeneration, among others.

Contraindications

Contraindications for using the laser include opacities in the cornea or lens, or blood in the vitreous humor that may interfere with the delivery of laser energy to the desired structure.

The following are additional contraindications for panretinal photocoagulation[1]:

- Grade IV or greater glial proliferation exists throughout the posterior pole of the eye.
- Grade IV or greater vitreoretinal traction exists.
- Excessive areas of capillary closure are present by fluorescein angiography. When more than 60% of the macular and paramacular areas have been occluded by microinfarction and macroinfarction, photocoagulation has not been beneficial and has exacerbated some cases of macular edema, resulting in immediate visual loss in the treated eye.
- Florid surface neovascularization extends over most of the posterior pole in a vine-like arborization. In these cases, pituitary ablation has proved to be the method of choice for the control of these drastically afflicted eyes.
- The posterior polar regions have been replaced by surface glial proliferation, and a network of cord-like vitreous membranes exists between the various vascular components that cannot be satisfactorily attacked by any vitrectomy, vitreo-retinal, or membranectomy procedure. In these cases, photocoagulation can shrink the closely adherent vitreous strands, causing an increase in the vitreo-retinal tractional and possibly a detachment of the retina. However, laser endophotocoagulation at the time of vitreoretinal

1. Reference 7, "Ophthalmology References"

surgery, when tractional membranes have been excised or lysed, can prove to be very useful when properly applied.

- The retina is grossly edematous on the basis of massive leakage of capillary structures in the posterior regions of the retina. In these eyes, photocoagulation is usually ineffective in cauterizing the smaller vessels, and high powers are necessary to obtain any type of response, most of which is ineffectual.
- The eye is afflicted with severe renal retinopathy with edema, intraretinal yellowish serum accumulations, attenuation and tortuosity of the vascular elements, and general deterioration of the retina. In these cases, photocoagulation accomplishes little, and only rarely can decrease the leakage from the small vessels or alleviate the underlying process.
- The eye is characterized by diabetic and hypertensive retinopathy changes that produce massive edema, exudates, areas of capillary closure, and other components similar to those seen with diabetic renal retinopathy. In clinical experience, photocoagulation has not helped posterior polar edema and exudation where the underlying problem has been advanced hypertension.

Adverse effects and complications

WARNING - The most common complication of panretinal photocoagulation is increased macular edema secondary to panretinal photocoagulation, usually with a concurrent decrease in visual acuity. Visual acuity loss is the result of redirection of the blood flow from the shunting vessels in the midperiphery toward the macular region. In addition, blowout hemorrhages from the areas of neovascularization, particularly on the optic nerve, have been observed, and may be caused by an increase in peripheral resistance secondary to photocoagulation, or by an inadvertent Valsalva maneuver by the patient.

WARNING - Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician.

Macular striae and increases in vitreoretinal traction have occurred, particularly in more advanced cases of proliferative diabetic retinopathy. These areas, as well as zones along the vitreous base, should be observed closely so that pars plana vitrectomy can be used, if necessary, to alleviate excessive vitreoretinal traction caused by the panretinal photocoagulation process.

An increase in lenticular opacities has occurred, although it is doubtful that the photocoagulation procedure contributed to the process.[1]

Precautions

CAUTION - Following photocoagulation, patients should be cautioned against any activity that could increase the venous pressure in the head, neck, or eyes, such as straining, lifting, or holding their breath. Patients should be advised to sleep with the head of their bed elevated 15° to 20°.

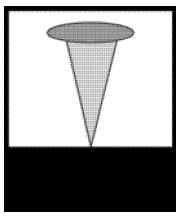
CAUTION - Patients should be cautioned against stifling a sneeze, because this raises the blood pressure within the eyes to a high level. Vigorous nose blowing should also be discouraged. Rubbing the eyes following photocoagulation may disrupt blood vessels inside the eyes. Sneezing and coughing should be controlled with cough syrup or other medications.

CAUTION - Patients should be cautioned, however, against the use of medications such as nose drops, sprays, inhalators, or other medications that contain ephedrine or epinephrine, because these drugs tend to elevate systemic pressure.

CAUTION - Immediately following treatment, patients should avoid altitudes over 8000 ft. (Commercial aircraft cabins are pressurized below this altitude.)

1. Reference 8, “Ophthalmology References”

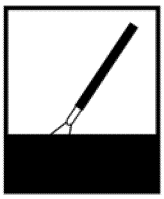
Guidelines for use



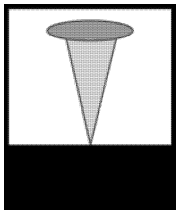
- For retinal laser treatments, the pupil is dilated and topical anesthetic is applied. A laser contact lens is then placed on the eye. Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician. The contact lens used is usually a Goldmann 3-mirror lens, a Karickhoff 4-mirror lens or a Rodenstock pan-fundus lens. These contact lenses allow the doctor to treat areas of the retina which cannot otherwise be reached by the laser. The topical anesthetic is normally adequate, but occasionally a retrobulbar injection is needed to further anesthetize the eye.
- The laser parameters for retinal procedures vary, depending on the desired results. Often the laser emission is filtered so that only the green light is used to treat the retina. This is because the longer wavelength is scattered less, and is absorbed more selectively in the layers of the retina that produce the best therapeutic result. The normal procedure is to start with a low power density that produces no visible reaction on the retina. The power density is then increased until a blanching occurs in the area being treated by the laser. The power density (power per unit area) is a function of the power being delivered by the laser and the spot size of the laser. The tissue reaction is also dependent on the total energy delivered, so the pulse duration is an important parameter. For procedures performed on the slit lamp, the pulse duration is usually kept at 0.5 s or less, so that the patient cannot move during the treatment pulse. Because the laser affects tissue by turning the optical energy of the laser light into thermal energy, a longer pulse duration means that more total thermal energy is delivered into the eye.
- The spot sizes used for retinal procedures are usually 200 to 1000 µm, although for some procedures the 100 or even the 50 µm spot will be used in the macula or around a retinal detachment. The power setting for retinal procedures is usually about 400 to 800 mW. The power setting will vary widely, however, depending on the area of the retina being treated, the spot size, the pulse duration, the pigmentation of the retina, and the turbidity of the vitreous.

The following is a list of some of the retinal conditions that can be treated with the laser, and a method of laser treatment.

Diabetic neovascular retinopathy



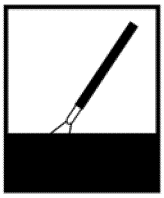
Laser photocoagulation is often used to control diabetic neovascularization. This condition is the proliferation of blood vessels in the retina. These newly formed blood vessels often have aneurysms that will, if left untreated, result in vitreous hemorrhage.



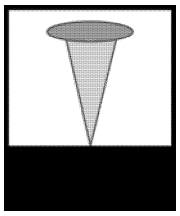
The laser treatment for this condition is called pan-retinal photocoagulation (PRP). During PRP, approximately 30% of the area of the retina is treated by the laser. A large spot size (100 to 400 µm) and approximately 400 to 800 mW of laser power are normally used. The laser burns are applied in a checker-board pattern with a space of untreated retina between the laser burns approximately equal to the diameter of the laser spot size. It may take as many as 1500 burns to treat an eye. Therefore, the treatment is often given in more than one session. As a result of the treatment, the treated retina dies in the region of the laser burn, and the remaining untreated retinal tissues can be supplied with sufficient nutrients by the existing blood supply, so the new blood vessels stop growing. The laser can also be used to coagulate a blood vessel that is hemorrhaging.

The macula is usually avoided whenever possible while applying laser treatment to the retina. However, if there is some condition of the macula that requires laser therapy, yellow or red wavelengths are recommended.

Retinal detachments

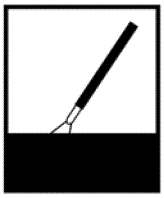


The laser can sometimes be used to help control retinal detachments. The desired effect is to form a chorioretinal scar by making laser burns around the detached portion of the retina. A row of burns approximately 200 to 500 µm in diameter is made around the edges of the detachment. The power used is usually about 250 to 450 mW, and the pulse duration is 0.1 to 1.0 s. After the periphery of the detachment has been secured, additional laser burns are made over the detached portion of the retina.



Complications can occur because of traction caused by the shrinkage or shortening of the vitreous strands. This traction can cause the detachment to spread. Also, as in any retinal laser treatment, if too much power is used a vitreal hemorrhage can result.

Endophotocoagulation



The preceding retinal procedures are usually done through the slit lamp delivery system. For intraoperative use, the laser energy is delivered through an endoprobe via a parsplana incision in the sclera. The size of the laser burn is controlled by changing the distance of the probe from the retina. Because the laser light exiting the probe has a fixed angle of divergence, the farther the probe is from the target, the larger the spot on the retina will be. Also, because no lens system is needed to focus the beam on the target, less power from the laser is needed to produce a whitening of the retina, which is what the surgeon looks for while photocoagulating, whether through the slit lamp or through an endoprobe. This result can usually be obtained with about 200 to 500 mW of power, depending on the size of the laser spot.

The procedures done with endoprobes include photocoagulation of retinal detachments and pan-retinal photocoagulation.

Anterior Segment Laser Procedures

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

Please see "Ophthalmology References" in this chapter for sources of literature regarding anterior chamber laser procedures.

Indications

The laser is indicated to ablate tissues of the iris or trabeculum.

Uses

Other uses of the laser in ophthalmology involve the anterior segment of the eye. The two most common procedures are performed to control glaucoma. These procedures are the peripheral iridectomy for angle-closure glaucoma and trabeculoplasty for open-angle glaucoma.

Laser trabeculoplasty is not a cure for glaucoma, but another means by which operative surgery may be postponed in many patients.

Contraindications

The following conditions are contraindicated to laser trabeculoplasty:

- Aphakic eye with vitreous fluid in the anterior chamber
- Neovascular glaucoma
- Glaucoma caused by congenital abnormalities of the angle
- Less than 90° of open angle or extensive low-lying peripheral anterior synechiae present circumferentially around the angle
- Significant corneal edema or a diminished aqueous clarity obscuring visualization of the angle detail
- Glaucoma secondary to active uveitis

The following conditions are relative contraindications to laser iridectomy:

- Marked corneal edema that may preclude the surgeon's ability to achieve a patient iridectomy. Scattering of the laser beam by corneal edema diffuses the laser power, and precise focusing on the iris may be impossible. Use of higher powers of laser energy may cause irreparable corneal deterioration.
- Corneal endothelial burns may be generated when treating patients with an extremely shallow or flat anterior chamber. Laser applications should be timed sufficiently apart so that heat generated in the aqueous can dissipate without heating the corneal endothelium. When the anterior chamber is extremely shallow, the power should be reduced to avoid endothelial corneal burns. This

reduction of power may require additional applications of laser energy in order to penetrate the iris.

- Contraindications to laser iridectomy include a flat anterior chamber, a completely sealed angle, and angle-closure glaucoma due to primary synechial closure of the angle. This may occur in uveitis, neovascular glaucoma, or the iridocorneal-endothelial syndrome. In these cases, pupillary block is not a contributing mechanism.

Warnings

⚠ **WARNING -** Intraocular pressure should be closely monitored following laser iridotomy or trabeculoplasty.

⚠ **WARNING -** Hemorrhage from the trabecular meshwork occasionally occurs and is manifested as an ooze of blood from Schlemm's canal to the site of laser impact. This is easily stopped by increasing the pressure of the gonioprism to the cornea, or by applying a 200 µm spot size, low power coagulation at the bleeding site.

⚠ **WARNING -** Pupillary distortion may be encountered if the iris root or peripheral iris has been treated. This distortion may or may not be permanent, depending on the severity of the accidental damage.

⚠ **WARNING -** Angle-closure glaucoma has been reported following laser trabeculoplasty when miotics were discontinued. Medical therapy should be continued following laser trabeculoplasty.[1]

Precautions

⚠ **CAUTION -** Intraocular pressure elevations have been reported to occur in up to 53% of eyes when 360° of the trabecular meshwork has been treated with 100 spots at the initial session. Intraocular pressure rises occur most frequently from 1 to 2 hours following laser treatment, although they may occur several hours afterward. [2] For this reason, it is imperative to monitor patients with severe damage, particularly when visual field loss involves fixation, and it is not unreasonable to admit such patients for 24-hour monitoring of intraocular pressure following laser trabeculoplasty.

⚠ **CAUTION -** Peripheral anterior synechiae may occur when the posterior portion of the trabecular meshwork or other structures posterior to the meshwork are treated. These are best avoided by meticulous delivery of a well-focused laser beam.

⚠ **CAUTION -** Transient comeal epithelial burns have reportedly resolved within 1 week without scarring. Endothelial burns are rarely encountered when careful focusing is employed.

1. Reference 11, “Ophthalmology References”
2. Reference 9, “Ophthalmology References”

Adverse effects

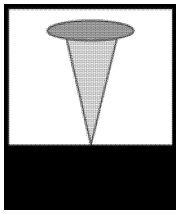
⚠ **CAUTION -** A "snuff out" of the central visual acuity has been reported as a complication of an intraocular pressure spike. Patients with advanced field loss should be carefully treated and monitored. Progressive field loss following laser trabeculoplasty is possible, even in the presence of seemingly adequately controlled intraocular pressure.[1]

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

Guidelines for use

Peripheral iridectomy

The peripheral iridectomy is performed for angle-closure glaucoma. The desired result is a hole approximately 150 to 200 µm in diameter. The aqueous humor can then flow through this hole and the ocular pressure will be relieved.



There are several effective variations of the procedure for a peripheral iridectomy. A frequently used method is described.

1. The contact lens used to perform an iridectomy is the Abraham lens. This lens has a button on it which focuses the laser beam down to one half of its size in air. This means that the 50 µm spot is focused down to a 25 µm spot on the iris, and so the power density is raised by a factor of four. At this spot size, a laser power setting of 1 W gives a power density of about 200,000 W/cm^2. This is enough power to vaporize tissue. A topical anesthetic is usually sufficient to deaden the surface of the eye.

2. A rosette of four to five burns, approximately 500 µm in diameter, are made on the iris about two-thirds of the distance from the pupillary border to the iris root at about the 2:30 position. These burns are made with about 500 mW of power and a pulse duration of 0.2 to 0.5 s. The purpose of these burns is to soften the iris and find a good site to make the smaller, penetrating burns used to finish the iridectomy. If a suitable site is not found, another rosette of burns can be made at another location. A major factor in the success rate of iridectomies is the choice of a site where the hole will be made.

3. The iris is penetrated by using a 50 µm spot with a power setting of 1200 to 1500 mW (1.2 to 1.5W) and a pulse duration of 0.2 to 1.0 s. It is important that the penetrating burns be superimposed on top of each other with the laser being refocused into the bottom of the crater each time to minimize the charred tissue and the size of the hole. After the laser has burned through the

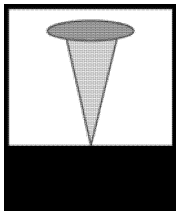
1. Reference 10, "Ophthalmology References"

iris, the iridectomy is completed by working around the edges of the hole to increase the size of the hole to approximately 150 to 200 µm.

> ⚠ **CAUTION -** All glaucoma medications should be continued postoperatively. Sometimes, one of the effects of the iridectomy is a short term rise in the ocular pressure. Because the iridectomy is performed in an effort to reduce ocular pressure, this can be a serious problem. For this reason, the patient should be closely monitored after the procedure, and glaucoma medications should be continued.

Trabeculoplasty

Trabeculoplasty is a procedure used to control open-angle glaucoma. The mechanism by which trabeculoplasty reduces the ocular pressure is unclear. It is believed that the laser burn creates scar tissue which shrinks part of the trabecular meshwork so that the aqueous can again flow through the stretched meshwork and relieve the pressure.



1. Again, a topical anesthetic is used. The contact lens used is the Goldmann lens. This lens has a mirror with an angle of 62°. This allows the surgeon to see into the angle of the eye, providing a good view of the trabecular meshwork. When the mirror is in the 6 o'clock position, the 12 o'clock portion of the meshwork is viewed. The inferior half of the meshwork is usually treated first, so the lens is placed with the mirror in the 12 o'clock position.

2. The laser burns are placed at the border of the pigmented and the nonpigmented meshwork. It is important that the laser beam be focused down to a well-defined 50 um spot, so that the laser aiming beam is distinct and the burns can be precisely placed. Approximately 1.0 W of power and a 0.1-s pulse duration are used. The immediate result of the laser burn should be a depigmentation of the trabecular meshwork and minimal bubble formation at the site of the laser burn.

3. Usually 180° of the trabecular meshwork is treated, with about 50 burns equally spaced over the circumference of the inferior meshwork. Generally, the inferior meshwork is treated first because it tends to be more pigmented and laser energy is more readily absorbed. Some physicians advocate doing the other 180° about 2 weeks later, but others find that treating only 180° gives satisfactory results.

> ⚠ **CAUTION -** The ocular pressure should fall for about six weeks after the treatment is performed. After this time, the pressure usually remains constant for several years. However, if the pressure begins to rise again, repeated trabeculoplasty appears to be much less successful in controlling the pressure spike than the first time the procedure is performed.

Ophthalmology References

1. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy Clinical application of diabetic retinopathy -study (DRS) findings, DRS report number 8. Ophthalmology 1981; 88:583-600.
2. Quigley HA. Long Term Follow-up of Laser Iridotomy. Ophthalmology 1981; 88:218-114.
3. Fleischman JA, Swartz Ma, Dixon JA. Krypton Laser Endophoto-coagulation An Intraoperative Trans-Pars Plana Technique Archives of Ophthalmology, 99: 1610-1612, 1981
4. Ritch R, Podos SM. Krypton Laser Treatment of Angle Closure Glaucoma Perspectives in Ophthalmology. Vol. 4, No. 2, June, 1980.
5. Schwartz AL, et. al. Krypton Laser Trabecular Surgery in Uncontrolled Phakic Open Angle Glaucoma Ophthalmology Vol. 88 No. 3, March 1981.
6. Bradbury, M. J., ed. 1987. Posterior Segment Laser Section, Current Techniques: Proliferative Diabetic Retinopathy. *Ophthalmic laser surgery.* Vol. 1, No.2: 121-129.
7. L'Esperance, FA. Ophthalmic Lasers Third Edition Photocoagulation of Ocular Disease: Application and Technique. pp 382.
8. L'Esperance, FA. Ophthalmic Lasers Third Edition Photocoagulation of Ocular Disease: Application and Technique. pp 396.
9. Kurata F, et al. Intraocular pressure the day of Krypton Laser Trabeculoplasty in Primary Open-angle Glaucoma Ophthalmology 89:338, 1980.
10. Thomas JV, Simmons Ri, and Belcher CD III. Complications of Argon Laser Trabeculoplasty. *Glaucoma* 4:50,1982.
11. Wise JB. Errors in Laser Spot Size in Laser Trabeculoplasty Ophthalmology, 91:186, 1984.

Otologic Applications of the Laser

WARNING - EndoOto probes must only be used with 2.5 Watt units; 1.5 Watt units cannot provide adequate energy for EndoOto procedures.

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

Indications

- The laser is indicated in procedures where color-specific absorption, small spot size, and high power densities are required. The laser beam may be used to photocoagulate, vaporize, or cut tissue by utilizing the appropriate beam delivery accessory and varying spot size, output power, and pulse duration.
- The laser has been shown to achieve satisfactory results in stapedotomy, stapedectomy, tympanoplasty with fascia graft[1], myringotomies[2], control of bleeding, lysis of adhesions, and soft tissue adhesion ("spot welding").[3]

Uses

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

Contraindications

- One investigator reported that the laser was not indicated in the removal or vaporization of cortical bone or dense bone as found in obliterative otosclerosis.[4]
- Uninflamed mastoid cases, such as endolymphatic sac surgery and cochlear implants do not benefit from the laser.

1. Reference 18, "Otology references"
2. Reference16, "Otology references"
3. References 16 and 18, "Otology references"
4. Reference 4, "Otology references"

Warnings

WARNING - The physician should be well acquainted with standard operating procedures and the use of the operating microscope. Formal instruction in these areas is available through established programs.

WARNING - Although hemostasis is to be expected from use of the laser, coagulation may prove difficult in highly vascular lesions and the use of means other than the laser may be needed.

Precautions

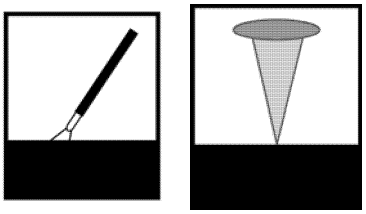
CAUTION - In clinical experience, the laser has not been found to be effective for obtaining hemostasis in cortical bone.

CAUTION - Blood should not be allowed to contaminate or color the perilymph surface. A bloodless field will help prevent absorption of the laser energy by the clear perilymph.[1]

CAUTION - The usual precautions observed for general anesthesia for any purpose, and for otological procedures specifically, are to be followed.

Guidelines for use

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



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

1. Reference 17, “Otology References”

Otology references

1. Dixon, JA. Surgical Application of Lasers Current Problems in Surgery Yearbook Medical Publishers, 1984.
2. Apfelberg DB, (Ed.). Evaluation and Installation of Surgical Laser Systems 1987 Springer-Verlag, New York.
3. Simpson TS, Shapshay SM, (Eds). Lasers in Otolaryngologic Surgery The Otolaryngologic Clinics off. Am. 16(4):737-894, 1983.
4. McGee TM. The Argon Laser in Surgery for Chronic Ear Disease and Otosclerosis Laryngoscope 93(9):1177-1182, 1983.
5. Perkins RC. Laser Stapedotomy for Otosclerosis Laryngoscope 90:228-240, 1980.
6. Gillis TM, Strong MS. Surgical Lasers and Soft Tissue Interactions Otolaryngol ClinNorth Am 16(4):775-784, 1983.
7. McGee TM. A Versatile Argon Microsurgical Laser. Otolaryngol Head Neck Surg90:139-141, 1982.
8. Vollrath M, Schreiner C. Influence of Argon Laser Stapedotomy on Cochlear Potentials Acta Otolaryngol 94(Suppl 385): 1-31,1982.
9. Vollrath M, Schreiner C. Effect of Argon Laser Stapedotomy on Cochlear Potentials Acta Otolaryngol 95:47-53, 1983.
10. Vollrath M, Schreiner C. Influence of Argon Laser Stapedotomy on Cochlear Potentials III Extracochlear recorded DC potential Acta Otolaryngol 96:49-55, 1983.
11. Vollrath M, Schreiner C. Influence of Argon Laser Stapedotomy on Inner Ear Function and Temperature Otolaryngol Head Neck Surg 91:521-526, 1983.
12. Gardner G, Robertson JH, Tomoda K, Clark WC. CO_2 Laser Stapedotomy: Is It Practical Am J Otolaryngol 5:108-117,1984.
13. Tolhurst KD. Uses of Surgical Laser in Otolaryngology and Head and Neck Surgery The Guthrie Bulletin 54(2):63-66,1984.
14. Coker NJ, Ator GA, Jenkins HA, Neblett CR, Morris JR. Carbon Dioxide Laser Stapedotomy Thermal Effects in the Vestibule Arch Otolaryngol 111(8):601-605,1985.
15. Glasscock ME, et al. The Argon Laser in Acoustic Tumor Surgery Laryngoscope 91(9):Part 1.
16. DiBartolomeo JR, Ellis M. The Argon Laser in Otology Laryngoscope 90:1980.
17. DiBartolomeo JR. The Argon and CO_2 Lasers in Otolaryngology: Which One and Why? Laryngoscope 91(9):Suppl 26:1-16, 1981.

18. Escudero L, et.al. Argon Laser in Human Tympanoplasty Arch Otolaryngol 105(5):252-253,1979.

19. Miyazaki M. Changes of Electrocochleography in Regional Difference of Labyrinthine Lesion by Argon Laser Irradiation J Otolaryngol Jpn: 87(2):149-159, 1984.

20. Clark WC, Robertson JH, Gardner G. Selective Absorption and Control of Thermal Effects A Comparison of the Laser Systems Used in Otology and Neurotology. Otolaryngol Head Neck Surg 92(l):73 -79,1984.

21. Gillis TM, Strong MS, Shapshay, et al. Argon Laser and Soft Tissue Interaction Otolaryngol Head Neck Surg 92(1):7-12,1984.

22. Carruth JA. The Role of Lasers in Otolaryngology World JSurg 7(6):719-724,1983.

23. Apfelberg DB, Mittelman H, Chadi B. Carcinogenic Potential of in vitro Carbon Dioxide Laser Exposure to Fibroblast Obstet Gynecol 61:493,1983.

Delivery Devices and Accessories

Filters

Lumenis offers fixed and moving physician's filters for integrated slit lamps, indirect ophthalmoscope attachments, and microscopes. These filters shield the physician's or observer's eyes from laser light and allow a normal field of view when the laser is in the Ready mode. The filters contain high quality optical elements for high visibility and easily attach to operating room microscopes. For a list of available filters, contact your local Lumenis representative. Lumenis eye safety filters may be sterilized using activated dialdehyde solutions formulated for plastic and rubber equipment. These solutions may be obtained from most medical supply companies.

Acculite Endoprobe or fiber optic devices 

Fiber optic endoprobes, such as the Lumenis Acculite endoprobe, when used to deliver laser energy, are effective tools for both anterior and posterior segment photocoagulation. Anterior segment treatment of the iris or ciliary body is effective in the surgical management of glaucoma. Endophotocoagulation is a useful adjunct to vitreoretinal surgery, including panretinal photocoagulation, retinopexy, and treatment of neovascularization.

Spot sizes delivered through the Acculite endoprobes vary, depending on the distance of the Acculite endoprobe tip from the treatment site. Power requirements vary from 300 milliwatts to 1 watt, depending on the type of treatment and the desired tissue effect.

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

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

- Ensure that the fiber is fully inserted into the laser aperture. This will allow the best efficiency through the laser fiber.
- Care must be taken when handling the optical fiber not to bend or kink it excessively since this could fracture the fiber allowing laser light to emerge from the fracture site.
- Identify all tissues that lie in the potential path of the laser beam to avoid laser exposure to tissues other than those undergoing treatment.
- Carefully identify and protect all relevant anatomic structures from possible undesired exposure.

- Ensure that the probe tip does not come into direct contact with tissue when treating; if it does, the optical efficiency of the fiber will be compromised.
- Use a suction tip in the treatment area to evacuate the laser plume.

Fluence

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

$$F = \frac{E}{A} \quad \textit{Equation 3}$$

$$I = \frac{P}{A} \quad \textit{Equation 4}$$

$$E = P \times T_S \quad \textit{Equation 5}$$

$$A = \pi r^2 = \pi\left(\frac{d}{2}\right)^2 = 0.7854d^2 \quad \textit{Equation 6}$$

where

F = Fluence (J/cm^2)	T_s = Time duration in seconds (s)
I = Irradiance (W/cm^2)	A = Spot size area in cm^2
E = Energy (J)	d = Spot diameter
J = Joules	r = Spot diameter ÷ 2
P = Power out of fiber in watts (W)	

Table 4 lists resulting spot sizes using approximate irradiance and fluence for 1 W of delivered power, durations of 0.5 s and 1.0 s, and a fiber diameter of 300 or 600 um.

Fiber Diameter (µm)	Spot Size (mm)	Spot Size Area (cm2)	Irradiance (W/cm2)	Fluence at 1 s (J/cm2)	Fluence at 0.5 s (J/cm2)
300 (0.3 mm)	0.3	0.000707	1415	1415	707
	3.0	0.0707	14	14	7
600 (0.6 mm)	0.6	0.00283	354	354	177
	3.0	0.0707	14	14	7

Table 4: Irradiance and Fluence at 1 W and 0.5 s and 1.0 s Delivered

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

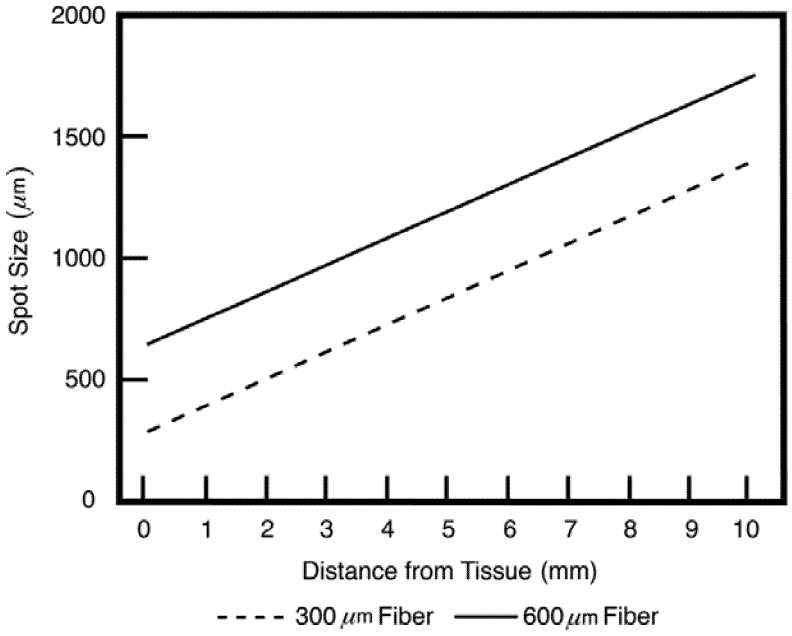


Figure 1. Spot size as a function of distance from fiber tip

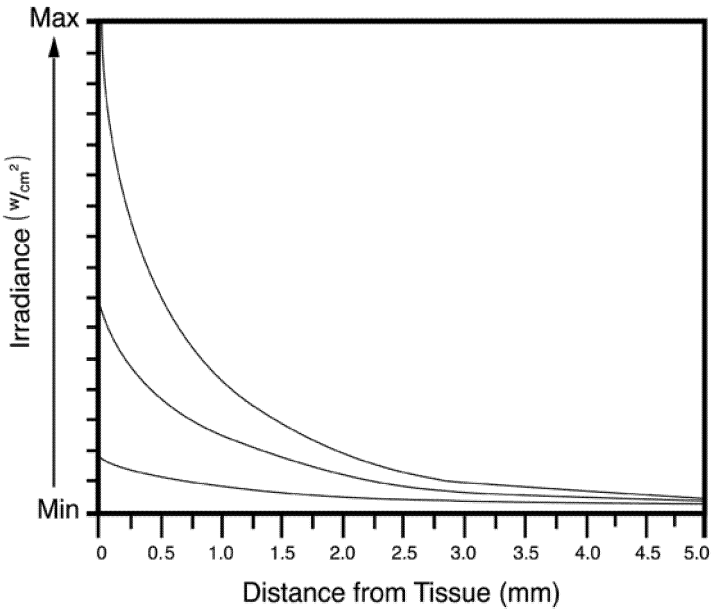


Figure 2: Irradiance as a function of distance from fiber tip

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

Fiber Optic	Distance from tissue (mm)	Spot Size (mm)	Irradiance (W/cm^2)
200 µm	0	0.20	3183
	1	0.45	641
	2	0.69	267
	3	0.94	145
	4	1.18	91
	5	1.43	62
300 µm	0	0.30	1415
	1	0.55	428
	2	0.79	203
	3	1.04	118
	4	1.20	77
	5	1.53	55
600 µm	0	0.60	354
	1	0.85	178
	2	1.09	107
	3	1.34	71
	4	1.58	51
	5	1.83	38

Table 5: Spot Size and Irradiance at 1 W Delivered

Laser Indirect ophthalmoscope (LIO) 

Users should be aware of the general laser warnings, precautions, and adverse effects outlined in "General Information" in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

Indications

The indirect ophthalmoscope is indicated for the delivery of laser energy in eyes harboring peripheral retinal pathology such as retinal breaks, lattice degeneration, or peripheral neovascularization.

The following are indications for the use of the LIO:

- Any eye requiring laser treatment out to the ora serrata
- Treating eyes with rubeosis iridis from central vein occlusion
- Treating eyes during pneumatic retinopexy retinal reattachment procedures
- Delivering laser energy through small pupils or to eyes with lens opacities
- diabetic retinopathy (pan-retinal photocoagulation)
- segmental peripheral photocoagulation
- segmental photocoagulation
- cloudy vitreous cavities
- pediatric retinal repairs (under general anesthesia)

Uses

- The LIO is used in the treatment of retinal detachments in the peripheral fundus, anterior to the equator. Other potential uses include extending a PRP further anterior than can conveniently be reached with a conventional slit lamp laser photocoagulator.
- Retinal photocoagulation may be done in patients with media opacities which make conventional photocoagulation at a slit lamp difficult or impossible.
- Treatment of patients in the supine position is also possible with the LIO.

Contraindications

- The LIO should not be used in or near the macula, or in other areas of the eye where accuracy more precise than 300 um is required. The instabilities inherent in the aiming of the LIO preclude its use in these areas.
- The doctor should always hold the viewing lens so that his view of the target is free of aberrations when the laser is fired. Aberrations

can affect the size of the laser spot and will change the power density delivered to the retina. Aberrations can also produce a non-uniform power density (or “hot spots”) in the laser spot.

- It is recommended that the condensing aspheric lens used to image the retina have a power of 20 diopters. Lenses with powers other than 20 diopters may be used but the physician should understand the relationship between hand-held lens power, the sensitivity of position of the optical elements involved, and the final retinal spot size. Refer to your LIO operator manual for additional detailed information concerning spot size, working distance and power.
- The condensing lens used with the L1O should be clear and should have an anti-reflective coating. Although condensing lenses are available with yellow tints to reduce the amount of short-wavelength light which reaches the retina, these tinted lenses should not be used with the LIO because a large percentage of the laser energy is absorbed by this type of lens.
- The LIO should not be used if there is blood in the vitreous that obstructs the view of the retina. The high absorption of laser wavelengths by blood may preclude the use of the LIO if blood is present in the vitreous.

Warnings

⚠ **WARNING -** All normal precautions pertaining to laser safety should be carefully observed. These include everyone present in the room (other than the doctor and the patient) wearing laser safety goggles, warning signs posted at all entrances to the area where the laser is being used, and only nonflammable drapes and anesthetics being used.

⚠ **WARNING -** The LIO should be carefully inspected before each use to be sure that it is not damaged.

Guidelines for use

- The LIO can be configured at the factory for use with a Lumenis argon laser, krypton laser, or diode-green (Novus Spectra) laser. Only the filter material and electrical characteristics differ.
- The LIO consists of an indirect ophthalmoscope that has been modified with a fixed laser safety filter and a lens system to focus the laser beam.
- Like an unmodified indirect ophthalmoscope, the LIO is mounted on a headband. The LIO is connected to the laser by a fiber optic which is plugged into the laser in the same way that any Lumenis fiber optic is connected to the laser.
- The LIO is designed to conveniently deliver laser energy to the far periphery of the fundus. With the indirect ophthalmoscope, the doctor has a clearer view of the areas of the fundus which are anterior to the equator of the eye than can be obtained using a slit lamp.
- Another advantage is the ability to position the patient to take advantage of gas bubbles that are injected into the eye during pneumatic retinopexy to force the retina into the proper position (so that it is resting against the choroid). If the laser treatment can be performed when the retina is in this position, the retina can be attached using the laser and may be less likely to detach again. If the patient can be positioned so that the retina can be treated without the laser beam having to pass through the gas bubble, it makes the laser treatment easier.
- A third potential advantage over conventional slit lamp delivery systems is the fact that the LIO does not employ a contact lens to direct the laser beam. Because there is no contact with the eye, it may be possible to treat eyes that are injured and cannot have any force exerted on them.
- The LIO can also be used with scleral depression in place of, or as an adjunct to cryotherapy. It has been theorized that the use of cryotherapy scatters cells from the retinal pigment epithelium, which may lead to proliferative vitreoretinopathy. There is no evidence that laser treatment scatters these cells, and so it may be an improved treatment modality for retinal reattachment procedures.
- The laser spot size can be changed by varying the distance between the LIO and the condensing lens, and by varying the distance from the condensing lens to the retina. Both of these distances are limited if a clear view of the fundus is to be obtained. However, the ability of the user's eyes to accommodate changing focal length can have an effect on the laser spot size if the user is not aware of this phenomenon while adjusting the image of the retina.

- Because this condensing lens is the last optical element that the laser beam passes through, the power and position of this lens will have an effect on the laser beam in terms of spot size and the focus of the image of the laser beam on the retina.
- For most eyes, the image of the retina formed by the hand-held lens is real, inverted, and located a few centimeters above the hand-held lens.

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

$$M = \frac{60 \text{ diopter}}{\text{power of hand-held lens}}$$

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

- Because the laser beam is a converging beam, the size of the laser beam in the retinal image plane can be varied by moving the point of focus of the laser beam out of the laser beam's object plane (retinal image plane). Figure 2 shows how altering working distance affects retinal spot size. Note that because the laser beam divergence angle of small spot sizes is greater than the laser beam divergence angle of large spot sizes, working distance has a greater effect on the small spot sizes.

References–Indirect ophthalmoscope

1. Friberg T. Clinical Experience with a Binocular Indirect Retina 7:28-31, 1987.
2. Friberg T. Principles of Photocoagulation Using Binocular Indirect Ophthalmoscope Laser Delivery Systems International Ophthalmology Clinics 30(2):89-94, 1990.
3. Friberg T, Eller A. Pneumatic Repair of Primary and Secondary Retinal Detachments Using a Binocular Indirect Ophthalmoscope Laser Delivery System Ophthalmology 95:187-193, 1988.
4. Campochario P, Gaskin H, Vinores S. Retinal cryopexy Stimulates Traction Retinal Detachments in the Presence of an Ocular Wound Archives of Ophthalmology 105:1567-1570, 1987.

Slit lamps and LaserLinks for slit lamps

> Users should be aware of the general laser warnings, precautions, and adverse effects outlined in "General Information" in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

Description

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

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

Indications

Slit lamp delivery systems and LaserLinks are indicated for the delivery of laser energy to the eye. They can be used in conjunction with contact lenses designed for the delivery of laser energy. Lumenis slit lamp attachments and integrated slit lamps are indicated for the delivery of laser energy in posterior chamber procedures involving the retina.

Conditions of the retina for which the slit lamp is useful include:

- Diabetic neovascular retinopathy
- Retinal detachments
- Senile macular degeneration

The slit lamp can also be useful for indications involving the anterior segment of the eye. The two most common procedures used to control glaucoma are:

- Peripheral iridectomy for angle-closure glaucoma
- Trabeculoplasty for open-angle glaucoma

Contraindications

There are no contraindications specific to the use of the slit lamp.

Guidelines for use

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

Appendix 1

EMC Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
Novus Spectra is intended for use in the electromagnetic environment specified below. The customer or the user of Novus Spectra should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	Novus Spectra uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Novus Spectra 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: **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.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Novus Spectra is intended for use in the electromagnetic environment specified below. The customer or the user of Novus Spectra should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	Class A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>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 <5% U_T (>95% dip in U_T) for 5 sec.	Class A Class A	Mains power quality should be that of a typical commercial or hospital environment. If the user of Novus Spectra requires continued operation during power mains interruptions, it is recommended that Novus Spectra be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Novus Spectra is intended for use in the electromagnetic environment specified below. The customer or the user of Novus Spectra should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Novus Spectra system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (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 Novus Spectra system is used exceeds the applicable RF compliance level above, the Novus Spectra system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Novus Spectra 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 Novus Spectra System

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

Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.368	0.368	0.737
1	1.16	1.16	2.33
10	3.66	3.66	7.37
100	11.16	11.16	23.33

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