

LaserLink™ HS

Operator Manual

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Operation

Introduction

The Lumenis LaserLink™ HS adapts a standard Goldman-style examination slit lamp for use as a therapeutic laser delivery system.

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

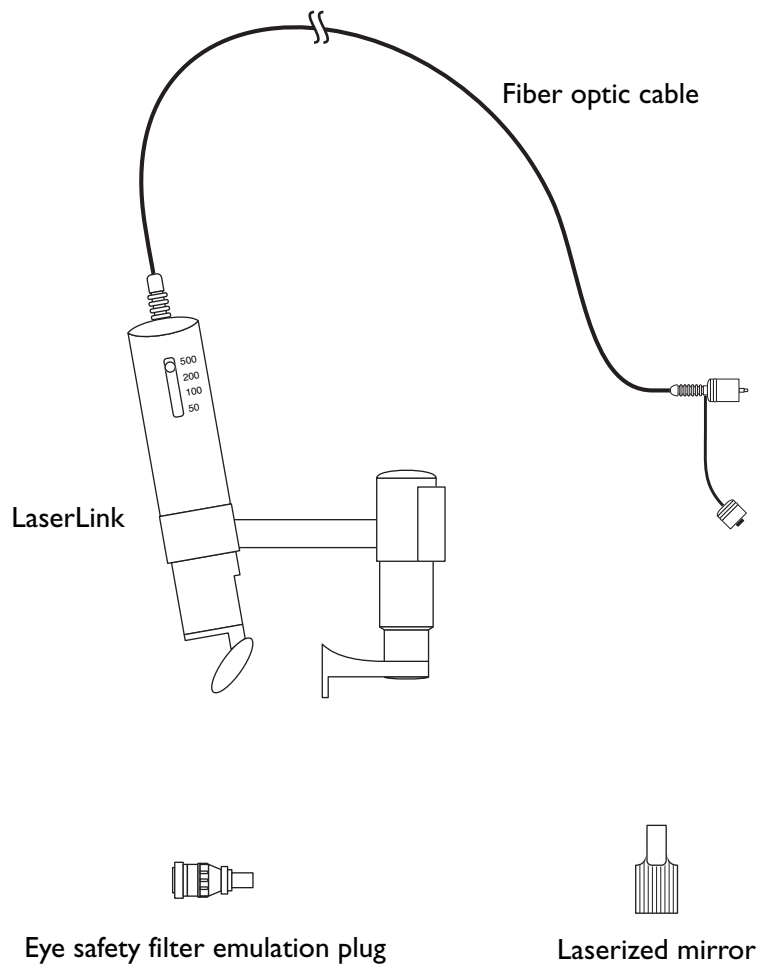


WARNING - Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended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

Inspecting the LaserLink HS Components

The LaserLink HS consists of a LaserLink with fiber optic cable, an eye safety filter emulation plug, and a laserized mirror.

Before connecting the LaserLink HS components, inspect the individual components for dirt, debris, or damage. Check the fiber optic cable to ensure that it is not punctured, fractured, or sharply bent.



LaserLink HS components

Connecting the LaserLink

LaserLink connections are essentially equivalent for all compatible slit lamps.



CAUTION - To prevent accidental laser exposure, always turn off the laser, as instructed in your laser operator manual, before installing the LaserLink.

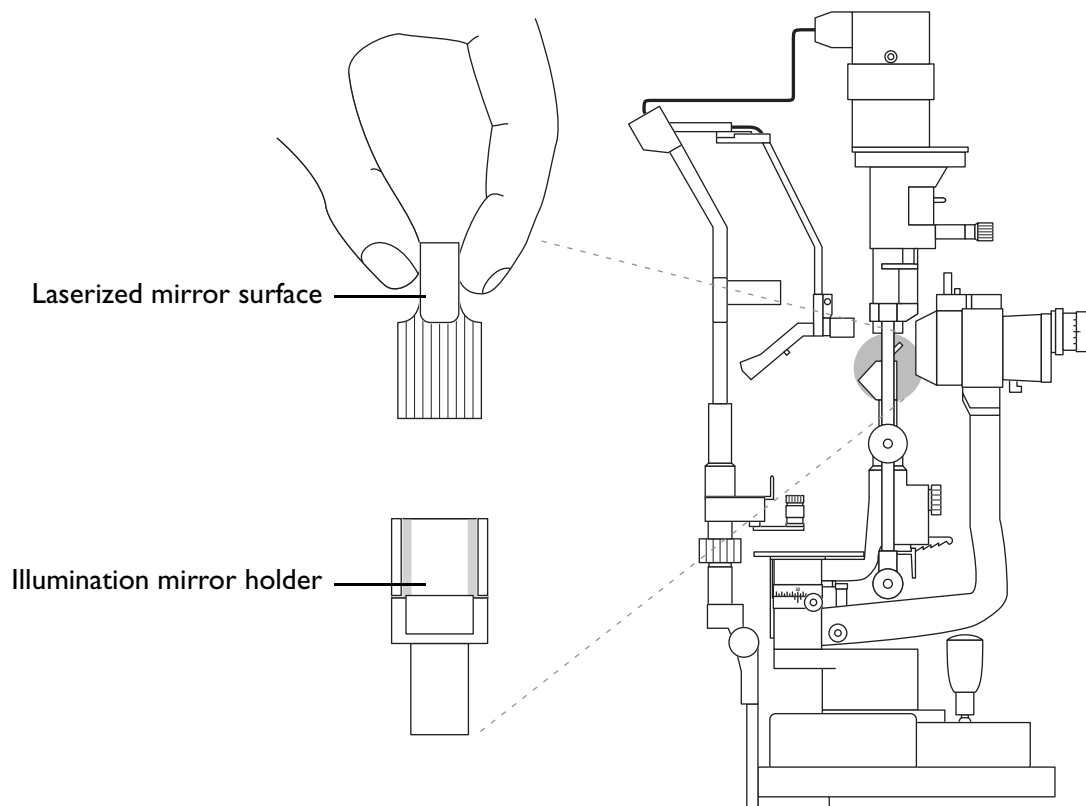


Refer to the Connection Instructions section of your laser operator manual, and perform the laser operating instructions in sequence with the instructions outlined in this manual.

- 1 If the laser is on, rotate the keyswitch to the off position, as instructed in your laser operator manual.
- 2 Ensure that the footswitch and interlock plugs are properly connected, as instructed in your laser operator manual.

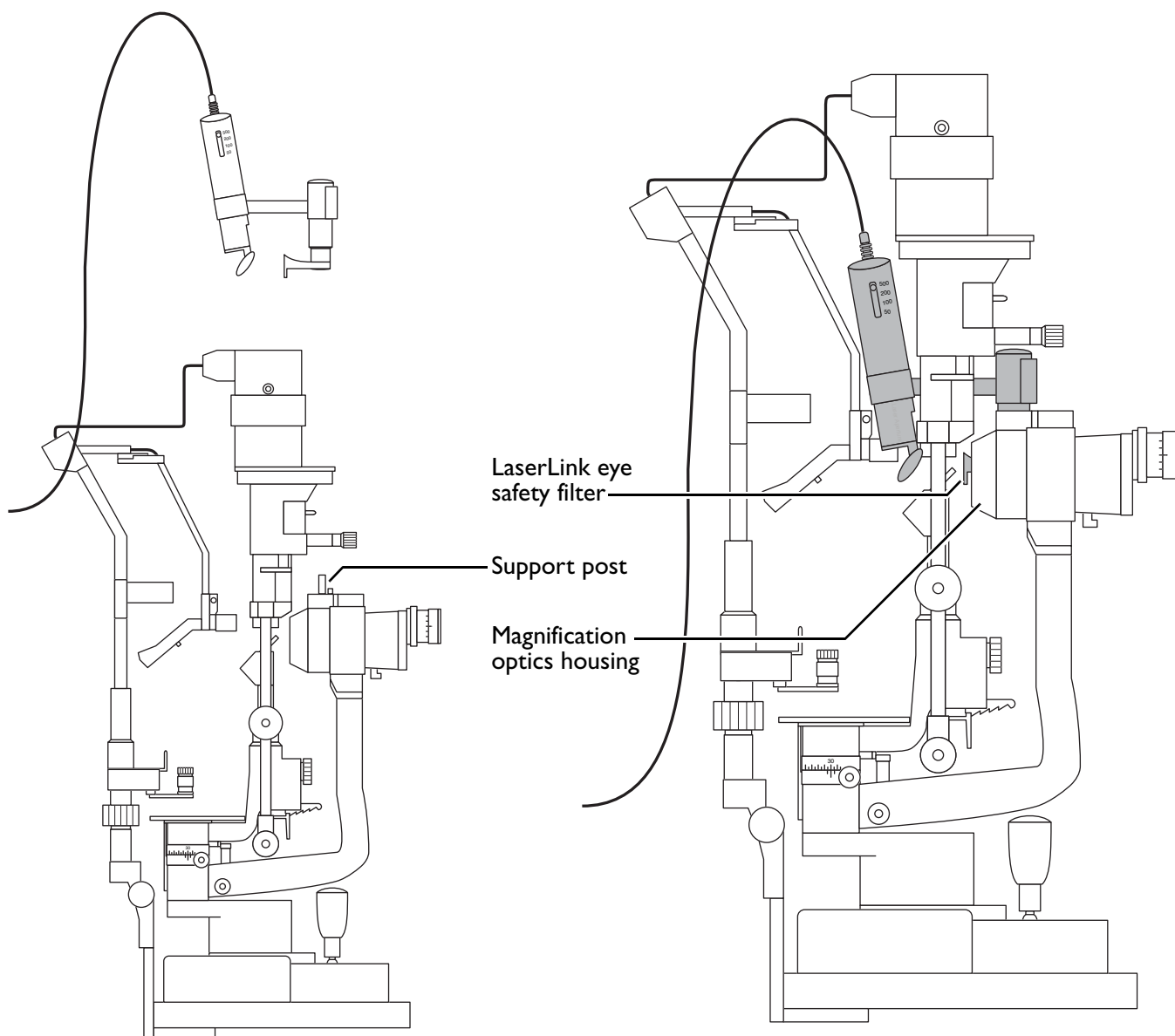
Attach the LaserLink HS to your slit lamp

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



Insert the Lumenis laserized mirror into the mirror holder

- 5 Position the LaserLink so that the eye safety filter is parallel to the slit lamp magnification optics housing.
- 6 Carefully lower the LaserLink onto the tonometer support post and anchor pin. The LaserLink is properly mounted when the tonometer support post and anchor pin on the slit lamp connect firmly into the corresponding receptacles on the LaserLink, as shown.



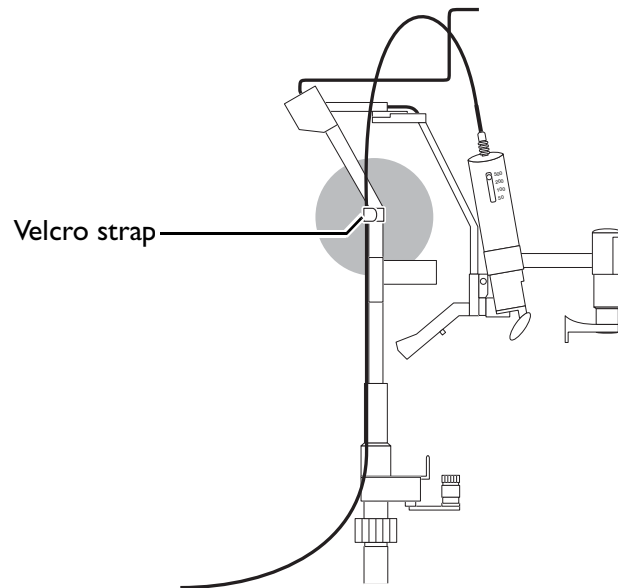
Position and mount the LaserLink onto the slit lamp tonometer support post

Secure the fiber optic cable

Secure the fiber optic cable to the slit lamp headrest using the Velcro® strap.



For optimal optical transmission, ensure that the optical fiber is not sharply bent.



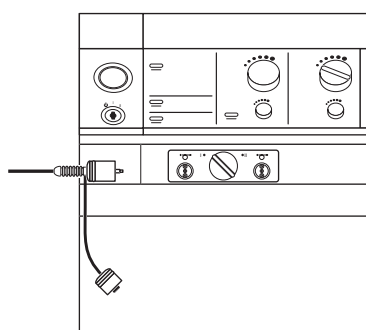
Secure the fiber optic cable to the slit lamp headrest

Connect the LaserLink cable to the laser

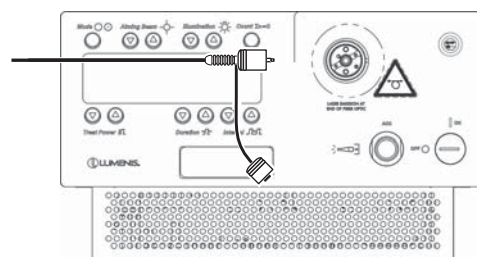
- 1 Remove the dust caps from the LaserLink laser connector and the laser console fiber receptacle.
- 2 Insert and carefully screw the laser connector into the fiber receptacle until secure.



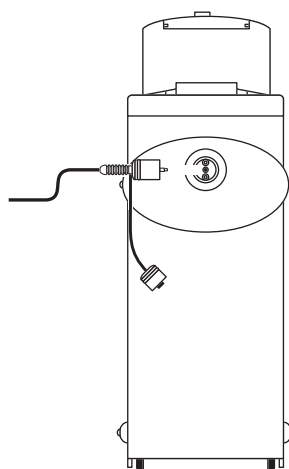
If the LaserLink cable is not properly connected when the laser is turned on, the fiber error message, as defined in your laser operator manual, displays on the control panel or remote control and the laser cannot be enabled. Tighten the laser connector to clear the message. The fiber error message also displays on lasers with dual fiber options if you select a fiber receptacle that has no delivery device attached. Select the fiber receptacle with the LaserLink attached to clear the message.



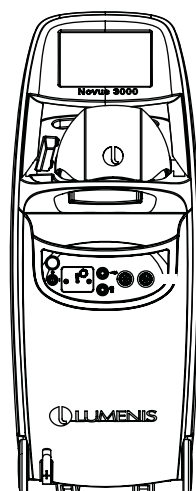
Novus 2000



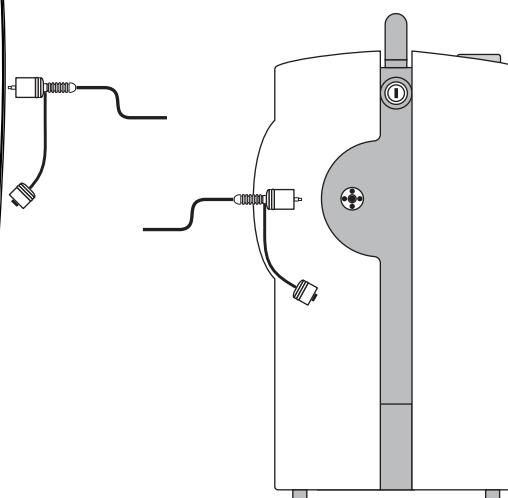
Novus Spectra



Ultima 2000 and 2000 SE



Novus 3000



Novus Verdi

Connect the LaserLink connector to the laser

If necessary, insert the eye safety filter emulation plug

Novus 3000

Insert an eye safety emulation plug into the  (eye safety filter) receptacle on the front of the laser console.

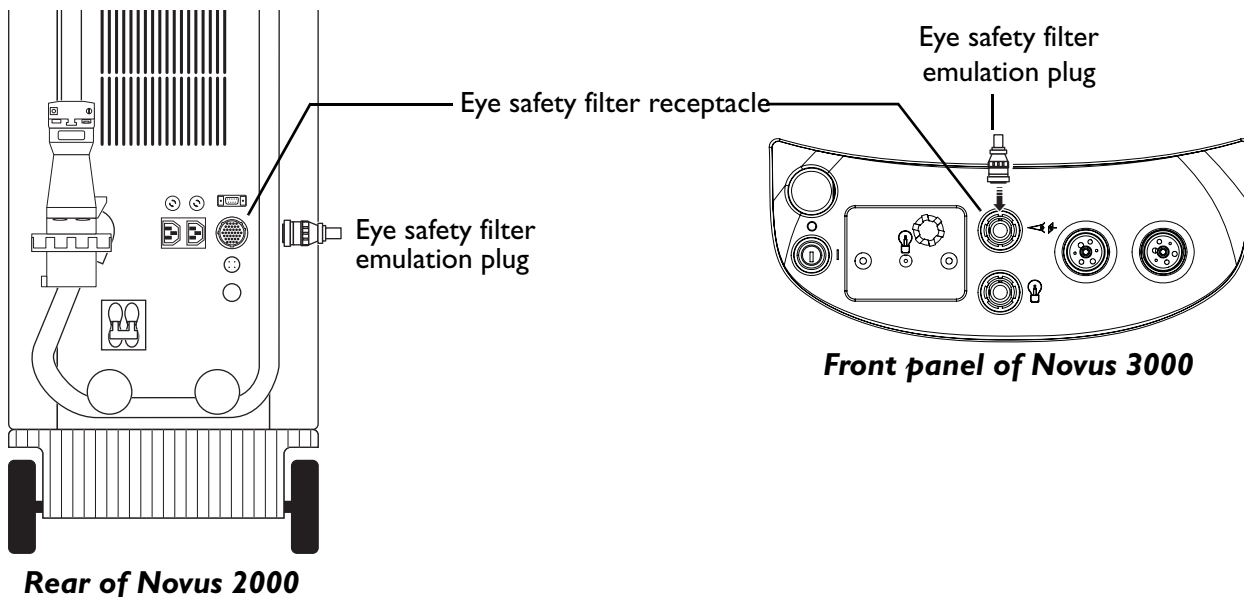
Novus 2000

If you are using the Novus 2000 single fiber configuration, or if you are using the Novus 2000 dual fiber configuration with only one delivery system, you must insert the eye safety filter emulation plug into the eye safety filter receptacle on the back of the laser console.



If the plug is not properly inserted when the laser is turned on, **E2** and the lock status indicator  display on the laser control panel and the laser cannot be enabled.

If you are using the Novus 2000 dual fiber configuration with two compatible Lumenis delivery systems, it is not necessary to insert the eye safety filter emulation plug.



Insert the eye safety filter emulation plug into the eye safety filter receptacle

Focusing the Slit Lamp

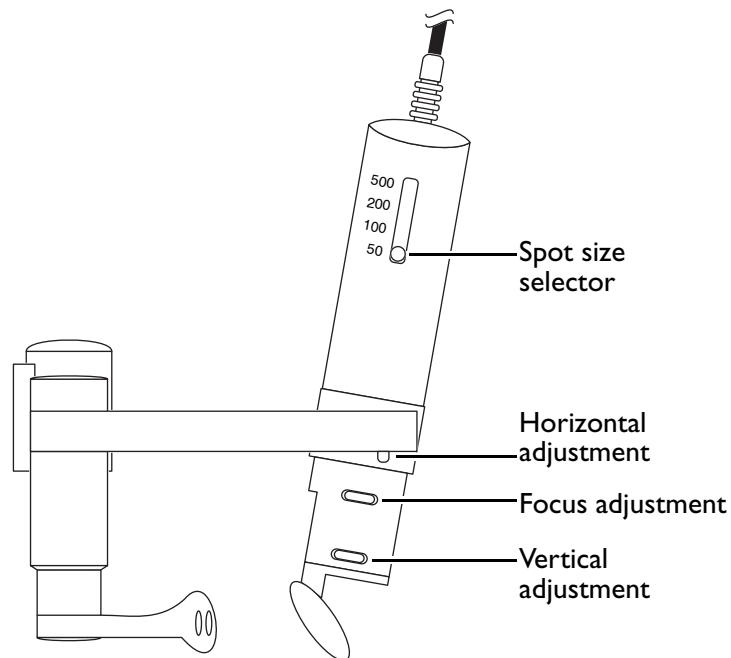
To ensure that there is no focal shift between magnifications and to provide maximum working distance with the contact lenses:

- 1** Ensure that your laser is off.
- 2** Turn on the slit lamp illumination and adjust the brightness intensity.
- 3** Affix a paper target on the headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.
- 4** Set the eyepieces to 0.
- 5** Set the magnification to the highest setting.
- 6** Focus the slit lamp on the target by moving the slit lamp with the joystick. Lock the slit lamp base.
- 7** Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to – to achieve the best focus on the target. Repeat the procedure for each eye. This step eliminates accommodation.
- 8** To fine tune the slit lamp focus, repeat steps 5-7.
- 9** Note the index number of the slit lamp eyepieces relative to the index marks as a future starting point for this procedure.

Focusing the Laser

To ensure that the laser beam is focused at the same focal point as the slit lamp binoculars:

- 1 Turn on the laser; leave it in standby.
 - 2 Position the spot size selector on the LaserLink to 50 μm .
-
-  **CAUTION** - Laser focus must only be obtained using the 50 micrometer spot size. If a spot size other than 50 micrometers is used, none of the spot sizes will be parfocal.
-
- 3 Adjust the aiming beam intensity until the red aiming beam is visible on the target.
 - 4 Adjust the slit width of the slit lamp to your customary slit width (narrow).
 - 5 Position the aiming beam on the center of the slit by adjusting the horizontal and vertical adjustment controls on the LaserLink.
 - 6 Focus the laser by adjusting the focus adjustment control on the LaserLink to obtain the smallest spot on the target.
 - 7 Unlock the slit lamp base, and remove the target.



LaserLink controls

Verifying the Aiming Beam



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



WARNING - 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 fire in the treatment room.

After focusing the laser and before beginning treatment, verify the aiming beam:

- 1 Affix a paper target on the headrest so that it is visible through the slit lamp eyepieces.
- 2 Set the aiming beam to the highest intensity, as instructed in your laser operator manual.
- 3 Look through the slit lamp eyepieces at the paper target. A red spot, the aiming beam, should appear on the paper target. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.



WARNING - Do not use the 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.

- 4 Reduce the aiming beam to a comfortable intensity.
- 5 Set the laser treatment parameters, as instructed in your laser operator manual.

Selecting the Laser Spot Size

The LaserLink spot size selector controls the laser spot size. The LaserLink HS features continuously variable spot sizes of 50 to 500 μm , with detents at 50, 100, 200, and 500 μm .

Spot size and power density

Power density at the treatment site largely determines the degree of interaction of the laser beam with tissue. Power density is defined as laser power divided by the area of the spot size. Power density can be increased by increasing the laser power or by decreasing the spot size.



WARNING - The relationship between spot size and power density is not linear. Reducing the spot size by 50% will quadruple the power density. The laser clinician must understand the relationships between spot size, laser power, power density, and thermal interaction of the laser beam with living tissue before using the laser and delivery device.



CAUTION - Power density may vary slightly from laser to laser. Laser power should initially be set at a low level and then increased gradually until the desired tissue effect is obtained.

The following table shows how the power density at the treatment site changes with increasing or decreasing laser beam spot sizes. The figures in this table should not be used to set treatment parameters; they are intended as a guide to the relationships between laser power, laser beam spot size, and laser beam power density at the treatment site.

Spot size	Laser power level (watts)			
	0.1	0.5	1.0	1.5
50 μm	5,000	25,000	50,000	75,000
100 μm	1,250	6,250	12,500	18,750
200 μm	320	1,600	3,200	4,800
500 μm	50	250	500	750

LaserLink laser power density table - watts/centimeter²

Preoperative Instructions

- 1 Ensure that the laser is properly connected, as instructed in your laser operator manual.
- 2 Turn off the laser, as instructed in your laser operator manual.
- 3 Attach the LaserLink HS to your slit lamp and secure the fiber optic cable, as described in *Connecting the LaserLink* in this manual.
- 4 Connect the fiber optic to the laser, as described in *Connecting the LaserLink* in this manual.
- 5 If using the Novus 2000 single fiber configuration, or if using the Novus 2000 dual fiber configuration with only one delivery system, insert the eye safety filter emulation plug into the eye safety filter receptacle on the back of the laser console.
- 6 Verify that the slit lamp is properly focused, as described in *Focusing the Slit Lamp* in this manual.
- 7 Post the “Laser in Use” warning sign outside the treatment room door.
- 8 Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See the *Laser Safety Eyewear* section of the laser operator manual for detailed information.
- 9 Verify that the laser beam is focused at the same focal point as the slit lamp binoculars, as instructed in *Focusing the Laser* in this manual.
- 10 Verify the aiming beam, as instructed in *Verifying the Aiming Beam* in this manual.

Intraoperative Instructions

- 1 As directed in your laser operator manual or Quick Reference Guide, prepare the treatment room and verify that the laser is turned on and in standby mode.
- 2 Position the patient.
- 3 If used, place the contact lens in the patient's eye.
- 4 Select the desired spot size; see *Selecting the Laser Spot Size* in this manual.
- 5 Select the desired treatment parameters, as instructed in your laser operator manual.



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.

- 6 Using the slit lamp joystick, position the aiming beam on the target tissue.
- 7 Place the laser in ready mode.
- 8 Depress the laser footswitch to deliver the treatment beam to the target site.

Postoperative Instructions

- 1** Place the laser in standby mode.
- 2** Turn the keyswitch to the off position. Remove the key to prevent unauthorized use of the laser.
- 3** Disconnect the LaserLink from the laser and slit lamp.
- 4** Place the dust caps on the LaserLink laser connector and the laser console fiber receptacle.
- 5** Clean the laser, as instructed in the Maintenance section of your laser operator manual.
- 6** Clean the LaserLink and eye safety filter, 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:

Electrical power source

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

Laser console electrical

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

Delivery system connections

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	Probable Cause	Solution
Inadequate slit lamp illumination.	The illuminator intensity is not in the proper position, or the illuminator bulb is burned out.	⇒ Refer to your slit lamp operator manual.
	Slit adjustments are needed.	⇒ Refer to your slit lamp operator manual.
Inadequate aiming beam or no aiming beam.	The aiming beam is set to the lowest intensity.	⇒ Refer to the Operation section of your laser operator manual, and adjust the laser's aiming beam intensity.
	The laser and delivery device components are not properly connected.	⇒ Refer to the Operation section of this manual and your laser operator manual, and check the connections.
	The laser is in standby mode.	⇒ Place the laser in ready mode.
	The wrong fiber is selected on lasers with dual fiber configurations.	⇒ Check, and if appropriate, select the correct fiber.
	The LaserLink laser connector is damaged.	⇒ Contact your local Lumenis representative.
	On the Novus Verdi laser, the aiming beam automatically shuts off after three minutes of inactivity.	⇒ Reactivate the aiming beam.
	On the Novus Verdi laser, the laser automatically shuts off after ten minutes of inactivity.	⇒ Restart the laser.

Problem	Probable Cause	Solution
No treatment beam is delivered when the footswitch is depressed, or the beam is of poor quality.	The laser is in standby mode.	⇒ Place the laser in ready mode.
	The laser and delivery device components are not properly connected.	⇒ Refer to the Operation section of this manual and your laser operator manual, and check the connections.
	The laser optics are dirty or out of alignment.	⇒ Contact your local Lumenis representative.
	The eye safety filter emulation plug is not connected to the Novus 2000 laser, or the plug is improperly connected.	⇒ Refer to the Operation section of this manual to verify that the eye safety emulation plug is properly connected to the laser console. If it is properly connected, contact your local Lumenis service representative. Do not use the delivery device unless advised to do so by the Lumenis representative.
	The wrong fiber is selected on lasers with dual fiber configurations.	⇒ Check, and if appropriate, select the correct fiber.
	The LaserLink laser connector is damaged.	⇒ Contact your local Lumenis representative.
Contact lens interferes with delivery device; LaserLink has limited working distance.	The LaserLink is not properly set up.	⇒ Refer to <i>Focusing the Slit Lamp</i> and <i>Focusing the Laser</i> in the Operation section of this manual.
The fiber error message, as defined in your laser operator manual, displays on the control panel or remote control.	The LaserLink is not connected or is improperly connected to the laser console.	⇒ Refer to the Operation section of this manual, and connect the LaserLink to the laser, as instructed.
	The wrong fiber is selected on lasers with dual fiber configurations.	⇒ Check, and if appropriate, select the correct fiber.
The eye safety filter error message, as defined in your laser operator manual, displays on the control panel or remote control.	No eye safety filter emulation plug is connected to the laser; the emulation plug is improperly connected; or the emulation plug is not operating.	⇒ Refer to the Operation section of this manual, and check the eye safety filter emulation plug connections. If properly connected, contact your local Lumenis representative. Do not use the delivery device unless advised to do so by the Lumenis representative.

Inspect and Clean the LaserLink

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



WARNING - Always disconnect the delivery system from the laser before inspection. Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage.



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

Clean the external surface of the delivery system

To clean the external surface, disconnect the delivery system from the laser and wipe using a cloth dampened with a noncaustic cleaning solution. Dry with a clean cloth.



Do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.

Clean the optical surfaces of the eye safety filter



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

- 1 Turn off the power to the slit lamp and the laser.
- 2 Wrap a piece of lens tissue (Kodak® or equivalent) around one end of a cotton-tipped swab.
- 3 Place several drops of reagent or pure grade ethanol or methanol on the tissue.
- 4 Wipe the optic gently in one direction with the lens tissue/swab to remove all dust and debris. Do not wipe in more than one direction, as loose particles may scratch the lens coating.
- 5 If the optic is still not clean, repeat the cleaning procedure beginning from step 2 using a clean lens tissue. Do not reuse the lens tissue; loose particles may scratch the optical coating.

Clean the laser connector

To clean the laser connector, use a cotton-tipped swab moistened with high-grade acetone or alcohol.

Specifications

Specifications are subject to change without notice.

Compatible Lumenis lasers and usable wavelengths (with appropriate eye safety filters)	
Novus 3000	532 nm (green)
Novus 2000	476-529 nm (blue-green); 514 and 529 (green)
Novus Spectra	532 nm (green)
Novus Verdi	532 nm (green)
Ultima 2000/2000 SE	476-529 nm (blue-green); 514 and 529 (green)
Laser beam spot size	50 to 500 μm , continuously variable
Eye safety filter optical density	> 5 (Refer to the Laser Safety Eyewear sections of this manual and your laser operator manual for detailed laser safety eyewear information.)
Compatible slit lamps	Haag-Streit 900 BQ, 900 BM, and 900 CN Topcon-3E Marco III Mentor SH-I2

Warranty Information

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

Decontamination of Returned Equipment

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

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

Safety and Regulatory

Introduction

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 Z136.1-2000, 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

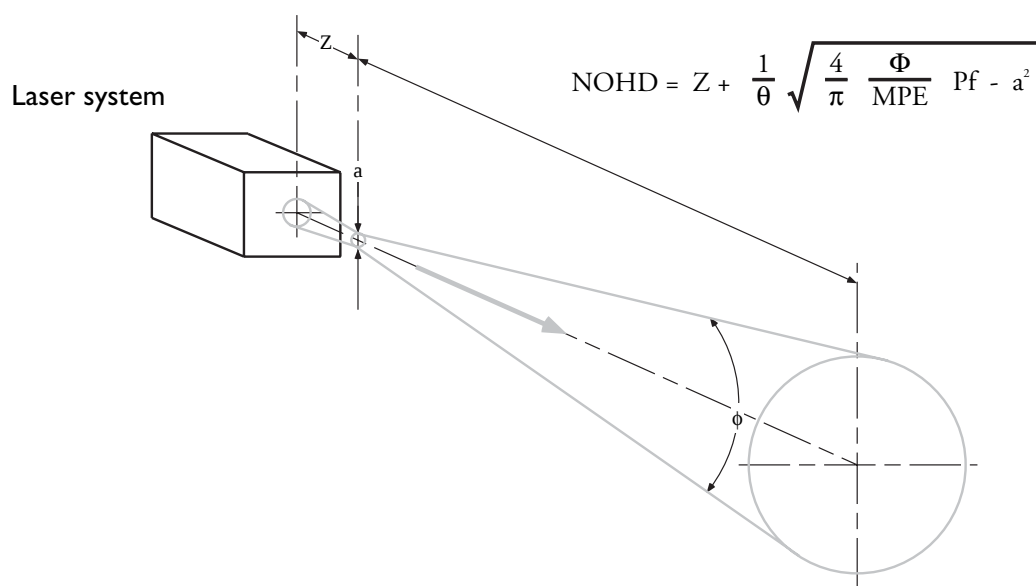
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (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 Z136.1-2000, ANSI Z136.3-2005, International Standard IEC 60825-1: 2001, Appendix A, or European Standard EN 60825-1:2001, Appendix A.

The following formula was used to calculate the *worst case* NOHD for Lumenis Novus 3000, Novus 2000, Novus Spectra, Novus Verdi, Ultima 2000 and Ultima 2000 SE lasers, and compatible delivery systems. Therefore, the values specified here meet or exceed the laser safety eyewear requirements for the LaserLink HS delivery system.

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

where,

- Z = the distance of the beam waist from the laser system;
- a = the beam waist diameter (1/e² of axial irradiance for gaussian beam);
- θ = minimum full angle beam divergence (1/e² of axial irradiance for gaussian beam);
- e ≈ 2.7182818285, the base of natural logarithms;
- Φ = maximum energy of one laser pulse or maximum CW laser power;
- Pf = the profile correction factor (1 for uniform profile or 2 for gaussian irradiance profile);
- MPE = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);
- NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture);
- = the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

Laser System	θ (rad)	Φ (W)	MPE (W/cm ²)	Pf	a (cm)	Z (cm)
Novus 3000	0.05	3.0	0.00255	I	0.02	5.7
Novus 2000	0.05	2.5	0.00255	I	0.02	5.7
Novus Spectra	0.05	2.5	0.00255	I	0.02	5.7
Novus Verdi	0.05	1.5	0.00255	I	0.02	5.7
Ultima 2000 /Ultima SE	0.05	1.5	0.00255	I	0.02	5.7

which results in a *worst case* NOHD of:

Laser System	NOHD
Novus 3000	7.81 m
Novus 2000	7.13 m
Novus Spectra	7.13 m
Novus Verdi	5.54 m
Ultima 2000 / Ultima SE	5.54 m

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

Laser System	OD
Novus 3000	3.49
Novus 2000	3.4
Novus Spectra	3.4
Novus Verdi	3.2
Ultima 2000/2000 SE	3.2

Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1-2000, section 4.6.2 and Appendix C. For users who must comply with EN 207, the safety eyewear must have a protection class of L5.

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

- 1 To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
- 2 Close the treatment room door before 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



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



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.



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.

Regulatory Compliance

Lumenis lasers and delivery systems comply with 21 CFR Chapter 1, Subchapter J, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

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

Eye safety filter

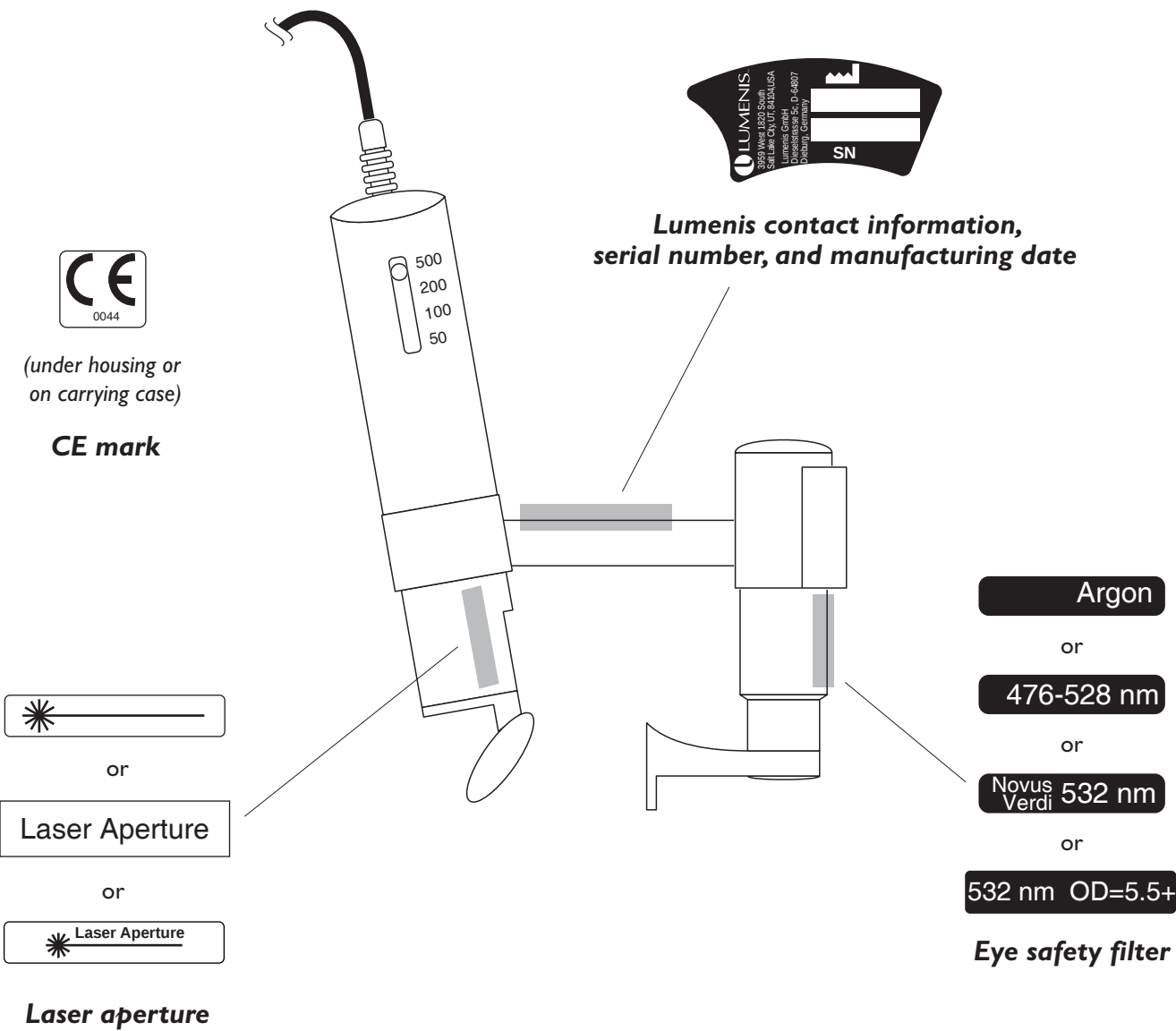
Lumenis delivery devices have specially designed eye safety filters that guard the operator from exposure to laser radiation. The protective filter ensures that all laser radiation returned to the operator's eyes is below the Class I limit.

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.

Location of regulatory and other system labels

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



Location of regulatory compliance labels

Indications for Use

Indications for Use

This delivery system is indicated for a variety of ophthalmic uses including, but not limited to, the indications specified in your laser operator manual. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator manual, Indications for Use section.

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

