Lumenis® PULSE™ 50H/100H

Holmium Surgical Lasers
Operator's Manual

Lumenis®
Energy to Healthcare

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

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

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

Lumenis provides web-based collection, recycling and reporting arrangements to the business end-user for equipment marked with the crossed-out wheelie bin.

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Chapter 1: Introduction

The Lumenis Pulse 50H and Lumenis Pulse 100H holmium laser systems provide utility in urology, orthopedics, ENT, gynecology and general surgery applications. Fiber delivery of holmium laser energy is ideal for minimally invasive surgery.

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 system and the appropriate optical fiber operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Lumenis medical lasers and laser optical fibers are intended solely for physicians trained in the use of these instruments.

In the USA:

CAUTION:

US federal law restricts this device to sale by or on the order of a physician.

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 system or optical fiber, contact Lumenis Customer Service.

NOTE:

All of the screen captures shown in this manual are for illustration only and may differ depending on the specific version of your system and the language selected.

Reference to the Lumenis Pulse Systems

This operator's manual discusses two laser systems: the **Lumenis Pulse 50H** system and the **Lumenis Pulse 100H** system.

- In many places the instructions in this manual are identical for both systems. In these instances the manual refers generically to the **System**.
- In instances where the instructions are explicit to one or the other system, the manual refers specifically to the **Pulse 50H** system or to the **Pulse 100H** system.

Manual Conventions

NOTE:

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

CAUTION:

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

WARNING:

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

System Description and Main Features

The Lumenis Pulse 50H or Pulse 100H laser system comprises the following main components and features:

- Laser system console
- Rotatable control panel with touch-screen technology
- Dual-pedal footswitch
- Security Identification System (SIS) technology
- Green aiming beam

Figure 1: Lumenis Pulse 50H / Pulse 100H Laser System Console

Laser System Console

The laser system console houses the control screen, the laser control keyswitch, emergency stop knob, main On/Off switch, control electronics, laser source and associated optics, and power supply. An optical fiber attaches to the fiber connection port on the front of the console, enabling laser energy to be delivered to the treatment site.

Touch-Screen Control Panel

The control panel is an LCD monitor with touch-screen technology that allows the operator to select treatment settings outside of the sterile field.

User Interface Language

To change the language displayed in the user interface screens consult with Lumenis Customer Service.

Footswitch

The dual-pedal footswitch activates the laser treatment beam when pressed, and offers the ability to select treatment from two sets of parameters by using the left or the right foot-pedal. It also incorporates a **Standby/Ready** foot-operated button.

Figure 2: Dual-Pedal Footswitch

Optical Fibers

A variety of optical fibers are available for use with the Lumenis Pulse 50H and Lumenis Pulse 100H laser systems. Lumenis fibers incorporate Security Identification System (SIS) technology. Refer to the appropriate optical fiber's instruction guide for specific operating instructions.

Component Checklist

- Lumenis Pulse 50H or Pulse 100H laser system console.
- Detachable dual-pedal footswitch.
- External door interlock connector.
- Keys
- Operator's manual.

Chapter 2: Theory of Operation

A laser, an acronym for **L**ight **A**mplification of **S**timulated **E**mission of **R**adiation, produces a highly concentrated beam of light of a given wavelength. Laser energy is generated by converting electrical energy to light energy using a flashlamp. The flashlamp energy is then used to excite the lasing medium, in this case a holmium YAG crystal rod. The laser energy is amplified in the laser resonator cavity and a small portion of the energy is allowed to leak out as the laser working beam.

The Pulse 50H or 100H holmium laser system emits a laser beam at a wavelength of 2100nm. This wavelength is strongly absorbed by water in tissue. Since soft tissue is comprised primarily of water, holmium laser energy can be used effectively for excision, incision, ablation, and vaporization when in direct contact with soft tissue and for coagulation when in near contact with soft tissue. Calculi (stones) also contain a sufficient amount of water that absorbs the laser energy leading to lithotripsy.

When working in liquid environment the holmium laser energy provides additional safety, since laser energy will be absorbed by the surrounding liquid, limiting its reach to non-target tissue.

The holmium laser wavelength falls in the near-infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye. Therefore, a low-power, visible aiming beam is used to verify the laser's target tissue.

Laser Power Parameters

Tissue laser interaction is primarily governed by the laser wavelength and the target tissue absorption coefficient at that wavelength, defining the effectiveness of the laser energy absorption in the target tissue. However additional characteristics of the specific laser system affect the laser tissue interaction.

Pulsed lasers (such as the holmium laser) deliver an average power (measured in Watts) that is achieved by multiplying the laser energy emitted during each pulse (measured in Joules) and the frequency at which these pulses are delivered (measured in Hertz).

The Lumenis Pulse 50H or Pulse 100H can deliver a maximum average power of 50W or 100W respectively obtained, i.e., by delivery of 2 x 25 Hz.

Holmium laser systems can deliver the same average power at different settings to achieve different laser tissue effect. Changing the energy of each pulse can be described as the “bite size” of the laser effect, whereas the frequency as the “bite rate”. For example, setting the system at 50W can be performed using the following sets of parameters: 2.5J at 20Hz or 2.0J at 25Hz.

When working with calculi, for example, these different settings may affect the stone by breaking the stone into particles versus disintegrating the stone into fine dust. The selection of the appropriate energy and frequency settings is dependent on the procedure and specific target tissue.

Each pulse is delivered at a specific time frame, leading to fast heating rise in temperature of the target tissue. By increasing the pulse duration, the time frame of energy delivery to the tissue changes and thereby changing the temperature profile of the tissue. A different temperature profile may lead to a heating rather than a vaporizing effect and is useful for example when blood vessel coagulation is desired.

The selection of appropriate power parameters and optical fiber is dependent on the procedure and the specific patient condition. It is recommended that you become familiar with laser characteristics and techniques by attending courses and consulting with colleagues in order to utilize the lasers capabilities in a safe manner.

Chapter 3: Safety

Introduction

This chapter contains important safety information related to the use of the laser system. All operating personnel should familiarize themselves with the contents of this chapter before operating the laser system.

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.

CAUTION:
Read this operator's manual carefully. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Optical Hazards

Laser Safety Eyewear

The following specifications were calculated for this systems:

System	Maximum Permissible Exposure	Nominal Ocular Hazard Distance
Lumenis Pulse 50H	2 mJ/cm^2	1.9 meters
Lumenis Pulse 100H	2 mJ/cm^2	1.9 meters

All personnel who are within the Nominal Ocular Hazard Distance are considered to be within the controlled area and must wear eye protection according to the following specifications:

System	Wavelength Used	Minimum Optical Density (OD)	Protection Level
Lumenis Pulse 50H	Ho:YAG (2.1 µm)	3.0	DI LB3
Lumenis Pulse 100H	Ho:YAG (2.1 µm)	3.0	DI LB3

WARNING:
Select the appropriate laser safety eyewear for the specific laser in use, by verifying that the above specifications are indicated on the laser safety eyewear that is at your disposal.

Laser safety eyewear must meet the requirements as per EN207 and ANSI Z136.1.

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.
4. 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 4s. For periorbital treatment, the physician must protect the patient with dulled, metal eye shields.

Additional Ocular Protection

WARNING:

- Always verify that the optical fiber is properly connected to the laser system. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical fiber, handpiece, probe or laser system aperture while the laser system is energized. Severe eye damage could occur. Turn off the laser system before inspecting any optical fiber or laser components.

Electrical Hazards

WARNING:

- Never open the laser system console protective covers. Opening the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians are qualified to work inside the console.
- Do not operate the laser system if any of the cords are faulty or frayed. The laser system should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Fire Hazards

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.
- The treatment beam can ignite most non-metallic 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.
- When performing procedures in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.

Additional Safety Considerations

CAUTION:

Smoke evacuation may be required if using the laser system in open-air procedures.

Protecting Non-Target Tissues

WARNING:

- When using an optical fiber, always inspect it to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The optical fiber may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the optical fiber with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the optical fiber. A damaged optical fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Never deliver the treatment beam to the target tissue if the aiming beam integrity has not been verified; the optical fiber may be damaged. A damaged optical fiber may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.
- Except during actual treatment, the laser system must always be in **Standby** mode. Maintaining the laser system in **Standby** mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

CAUTION:

- To prevent accidental laser discharge, always make sure that the footswitch is not being operated while connecting the optical fiber.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Only the person directing the aim of the laser beam should have access to the laser system footswitch. Use caution pressing the laser system footswitch when it is in proximity to footswitches for other equipment. Verify the footswitch pressed is the correct one in order to avoid accidental laser exposure.
- Never discharge the laser system without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.

Laser Emission Indicators

- An audible signal is emitted during lasing. A different audible sound is used for the left and right pedals.
- When lasing, a lasing emission indicator appears on the screen.

Warning, Certification and Identification Labels

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

Figure 3 displays the identification and certification labels affixed to the system and the symbols displayed in the labels:

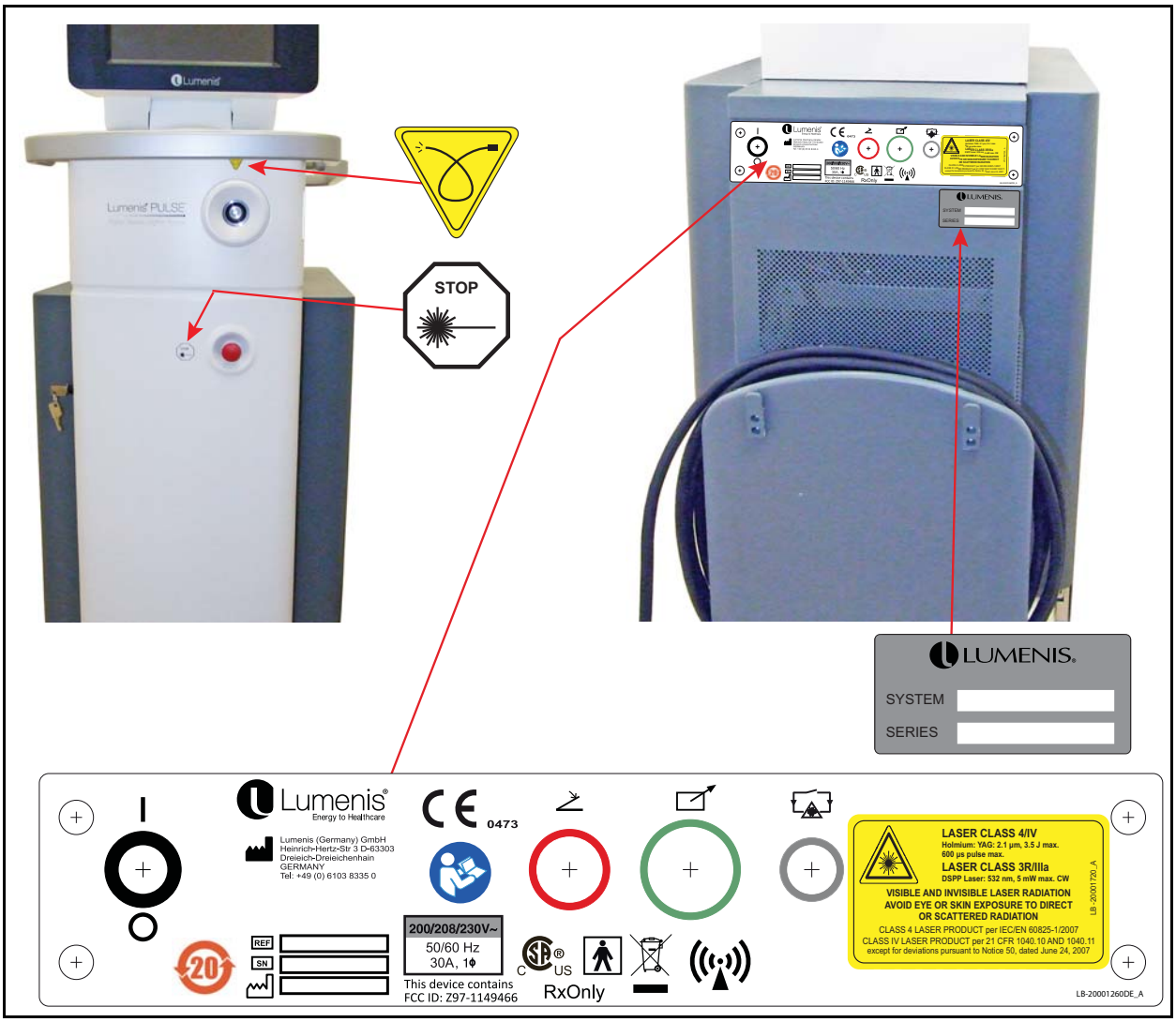
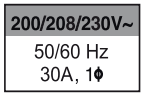


Figure 3: Location of Regulatory Compliance Labels

Explanation of the symbols used in the labels

The labels located on the system's front and rear panels contain the following information:

Symbol	Description
Lumenis Energy to Healthcare	Lumenis, Energy to Healthcare
CE 0473	CE Compliance

Symbol	*Description*
	Manufacturer
	Date of Manufacture
	Catalog Number
	Serial Number
Series	Series Number
System	Model Name
	Follow Instruction for Use
	Electrical Requirements
	Type BF Equipment
This device contains: FCC ID: Z97-1149466	This device contains: FCC ID: Z97-1149466
	Laser Class 4/IV Holmium:YAG Laser: 2.1µm, 3.5J max. 600 µs pulse max. Laser Class 4/IV DSSP Laser: 532nm, 5mW max. CW Visible and Invisible Laser Radiation Avoid eye or Skin Exposure to Direct or Scattered Radiation 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 Notice 50, Dated June 24, 2007
	Non-Ionizing Electromagnetic Radiation

Symbol	*Description*
	Emergency Laser Stop
	Fiber Connection Port (Aperture)
	External Interlock Connection
	Footswitch Connection
Rx ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	CSA Compliance
	Waste of Electrical and Electronic Equipment (WEEE) compliance
	RoHS Compliance (China)

Chapter 4: Clinical Guide

Lumenis recommends that physicians learn and gather additional knowledge related to the Lumenis Pulse 50H or 100H system. For details on courses available at Lumenis, contact your Lumenis representative.

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

WARNING:

Unauthorized use of this system may expose the operator/patient to potential electrical energy and laser radiation hazards.

The Ho:YAG wavelength has been shown to be a safe and effective tool for the ablation, vaporization, incision, excision, and coagulation of a variety of soft tissues. This has been demonstrated by both clinical and preclinical studies. The 2100nm wavelength of the holmium laser system is highly absorbed by water (absorption peak of water: 1940 nm). The absorption of the laser energy by water produces an energy density that heats the tissue to greater than 100°C thus vaporizing or ablating the tissue without deep coagulation, allowing for precise incision (cutting) and excision (dissection) when in direct contact with the tissue. When the laser system is not in direct contact with the tissue, the produced heat can dissipate, leading to coagulation of vessels to a depth of up to 3 mm.

The depth of the incision is determined by the amount of energy (in Joules) applied. The rate at which the incision is made is dependent upon the rate of energy pulses being delivered to the target tissue (in pulses per second, or Hertz). Optimum incision of tissue is accomplished by balancing the depth of the incision and the rate at which the incision is being formed. The physician may control both the energy setting and the repetition rate of the laser system, depending upon the specific type of soft tissue, the desired tissue effect (excision, ablation, or coagulation), and the speed at which this effect should be achieved.

The Ho:YAG wavelength provides effective hemostasis without damaging the surrounding or non-target tissues. Decreasing the laser

power density on vascularized tissue is an important tool in bleeding control. This may be achieved in 3 ways:

- Increasing the pulse width/duration.
- Reducing the energy per pulse and repetition rate.
- Defocusing the beam without changing the system controls by moving the tip of the optical fiber away from the target tissue approximately 2 to 5 millimeters.

The holmium wavelength's high absorption in water and ability to produce water vapor is also utilized for fragmenting stones. Urinary and biliary stones contain a sufficient amount of water needed to absorb the laser energy, heat and produce a vapor that causes enough pressure in the specific location that will lead to the fracturing of the stone. The power required to perform this application can be controlled by the pulse energy that is delivered to the tissue and the frequency at which the pulses are emitted. Both of these factors affect stone fragmentation.

The holmium wavelength's high absorption in water is advantageous when working in a water filled environment, as it enables safe delivery of energy without harming non-targeted tissue. Any water that interfaces between the laser and the tissue absorbs the laser energy, therefore distance between the laser and non-target tissue ensures its safety. Only laser energy that is delivered directly to the target tissue, in contact, will result in a significant tissue effect.

NOTE:

When treating calculi (e.g. urinary, biliary) migration of the stone may occur due to the mechanical effect of the laser energy (retropulsion). Migration may be avoided by several lasing techniques that are based on the laser interaction with the stone. First, decreasing the laser energy and increasing the pulse frequency to maintain the required power output. Second, maintaining the energy and frequency and increasing the pulse width.

Laser energy can be delivered to the tissue using various delivery devices. These include straight-firing and side-firing fibers. Refer to the specific delivery devices for detailed information.

NOTE:

Physicians are encouraged to continuously consult current literature and information provided in advanced workshops to keep abreast of the most effective and up-to-date practices.

Indications for Use

The Lumenis Pulse 50H and 100H system with delivery devices and accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; endo-nasal surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and general surgery.

Contraindications

The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.

- Inability to receive endoscopic or laparoscopic treatment.
- Intolerance to anesthesia.
- Resection or excision of large, highly vascularized organs.

Specific Contraindications in Urology

- Carcinoma of the prostate

Specific Contraindications in Gynecology

- Septic peritonitis
- Intestinal obstruction
- Septic shock
- Resection or excision of large, highly vascularized organs.

NOTE:

Lumenis has no clinical information concerning the safety of laser treatment on pregnant or nursing women.

Warnings and Precautions

This section contains warnings and precautions that are applicable to surgical procedures specifically related to the use of this system.

- Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength.
- Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings

until familiar with the instrument's capabilities. Use extreme caution until the biological interaction between the laser energy and tissue is thoroughly understood.

- Due to interaction between flammable gases in the operating field and the laser energy a flash fire may occur. Therefore, during laser procedures, measures to minimize this potential hazard should be practiced (e.g. avoid administration of inhaled general anesthetics; reduce oxygen levels during mechanical ventilation, use of laser resistance endotracheal tubes). The flammability of methane gas must also be considered when treating in or near the perianal area.
- The laser system should be used only on tissues that are fully observable. Do not use the laser system if the desired target is not visible. All available measures to visualize the target tissue (e.g. copious irrigation, hemostasis) should be taken.
- When using endoscopic equipment confirm that the tip of the optical fiber extends at least 12 mm beyond the end of the scope during laser treatment. Activating the laser system when the tip of the optical fiber is within the scope can result in penetration of holmium laser energy through the scope and destruction of the scope.
- Use of the laser system on anatomical structures in proximity to known critical structures, such as large arteries, veins, bowel, ureter, bladder, nerves, etc., should be performed carefully to avoid inadvertent or unintended damage of such structures. If applicable, maintain irrigation in the treatment area to reduce heat accumulation.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Highly vascularized anatomical structures should be approached with caution, taking into account the limited coagulative properties of the laser system. Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding vessel is larger than possible to control with the laser system. The risk of bleeding may be higher in patients taking anticoagulants/ platelet aggregates.
- Baskets, guide wires, and other surgical accessories may be damaged by direct contact with the laser treatment beam.

Complications

The following is a list of general complications that are related to surgery and within this context, laser surgery. The potential complications encountered in endoscopic laser surgery are the same as those normally

encountered in conventional endoscopic surgery. Refer to updated literature for specific procedure related complications.

- As with conventional surgery, the possibility of complications and adverse events, such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis, or infection may occur following treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or laser application.
- As with any surgical procedure there is a possibility of infection or scarring. Therefore, appropriate pre and post-surgical care should always be practiced.
- As with any conventional surgery discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- As with any conventional surgery, acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Remnants of destructed tissue may become necrotic or infected. If a question of infection exists, appropriate treatment should be carried out.
- Patients may experience bleeding at the site of laser therapy. Post treatment hematocrits are recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. If a question of sepsis exists, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.
- As with any conventional laparoscopic surgery, the use of gas to insufflate the abdomen may lead to a gas embolus. In the extreme case, death may result from an embolus. The use of carbon dioxide gas for insufflation will minimize patient risk, as it is highly soluble in blood. Insufflation pressure should be set to minimum settings for effective insufflation.

Detailed Indications for Use

The Lumenis Pulse 50H and 100H system with delivery devices and accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; endo-nasal surgery;

gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and general surgery.

The Lumenis Pulse 50H or 100H system with delivery devices and accessories are indicated for use in the performance of specific surgical applications as follows:

Urology

- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH).
- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
  - > Bladder
  - > Superficial and invasive bladder, urethral and ureteral tumors.
  - > Condylomas
  - > Lesions of external genitalia
  - > Ureteral and penile hemangioma
  - > Ureteral strictures
  - > Bladder neck obstructions
- Urinary Lithotripsy including:
  - > Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones.
  - > Treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
  - > Meniscectomy
  - > Plica removal
  - > Ligament and tendon release
  - > Contouring and sculpting of articular surfaces
  - > Debridement of inflamed synovial tissue (synovectomy)
  - > Loose body debridement
  - > Chondromalacia and tears
  - > Lateral retinecular release
  - > Capsulectomy in the knee
  - > Chondroplasty in the knee
  - > Chondrornalacia ablation
- Discectomy including:
  - > Percutaneous vaporization of the L4-5 and LS-Sl lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery

- Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
  - > Cholecystectomy
  - > Lysis of adhesions
  - > Appendectomy
  - > Biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon.
  - > Skin incision
  - > Tissue dissection
  - > Excision of external tumors and lesions
  - > Complete or partial resection of internal organs, tumors and lesions.
  - > Mastectomy
  - > Hepatectomy
  - > Pancreatectomy
  - > Splenectomy
  - > Thyroidectomy
  - > Parathyroidectomy
  - > herniorrhaphy
  - > Tonsillectomy
  - > Lymphadenectomy
  - > Partial nephrectomy
  - > Opilonidalcystectomy
  - > Resection of lipoma
  - > Debridement of decubitus ulcer
  - > Hemorrhoids
  - > Debridement of statis ulcer
  - > Biopsy

ENT Surgery

- Endoscopic endonasal/sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
  - > Partial turbinectomy
  - > Ethmoidectomy
  - > Polypectomy
  - > Maxillary antrostomy
  - > Fronta1 smusotomy
  - > Sphenoidotomy
  - > Dacryocystorhinostomy (DCR)
  - > Functional endoscopic sinus surgery (FESS)
- Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - > Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues.
  - > Tonsillectomy
  - > Adenoidectomy
- Open and laparoscopic gynecological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue).

Gynecological Surgery

- Open and laparoscopic gynecological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue).

Gastroenterology Surgery

- Open and endoscopic gastroenterology surgery (ablation, vaporization, incision, excision, resection, coagulation and hemostasis, including:
  - > Gall bladder calculi
  - > Biliary /bile duct calculi
  - > Benign and malignant neoplasm
  - > Polyps
  - > Colitis
  - > Ulcers
  - > Angiodysplasia
  - > Hemorrhoids
  - > Varices
  - > Esophagitis
  - > Esophageal ulcer
  - > Mallory-Weiss tear
  - > Gastric ulcer
  - > Duodenal ulcer
  - > Non-bleeding ulcer
  - > Gastric erosions
  - > Colorectal cancer
  - > Gastritis
  - > Bleeding tumors
  - > Pancreatitis
  - > Vascular malformations
  - > Telangiectasias
  - > Telangiectasias of the Osler-Weber-Renu disease

Pulmonary Surgery

- Open and endoscopic pulmonary surgery (cutting, ablation, vaporization, incision, excision and coagulation of soft tissue.

Dermatology and Plastic Surgery

- Incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in therapeutic plastic, dennatologic and aesthetic surgical procedures, including:
  - > Scars
  - > Vascular lesions
  - > Port wine stains
  - > Hemangioma
  - > Telangiectasia of the face and leg
  - > Rosacea
  - > Corns
  - > Papillomas
  - > Basal cell carcinomas
  - > Lesions of skin and subcutaneous tissue
  - > Plantar warts
  - > Periungual and subungual warts
  - > Debridement of decubitus ulcer
  - > Skin tag vaporization

Chapter 5: Preparing the System for Use

The laser system is shipped directly from the factory to your site. Your Lumenis service representative initially uncrates, inspects, sets up, and installs the laser system to ensure that it is working properly. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced with the performance and safety considerations of the laser system. Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser system and any optical fibers used during surgery, including inspecting and cleaning the laser and optical fibers; connecting, disconnecting, and sterilizing the delivery systems; and verifying the aiming beam integrity. These procedures are detailed in this manual and in the optical fiber instruction guide. If your scheduled surgical procedure requires disposable delivery devices or accessories, it is helpful to have extra items ready and available in the treatment room should they be needed to complete a procedure.

WARNING:

- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear. Refer to Laser Safety Eyewear.
- Before connecting the Lumenis Pulse 50H or 100H components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Verify that the electrical cables are not frayed or split. Contact your Lumenis Customer Service if any component appears damaged.

Moving the Laser System Console

1. Ensure that the laser system's power cable is properly disconnected.
2. Unlock the laser console wheels.
3. Using the laser console handle, move the laser system to the desired site.

CAUTION:

As with any heavy equipment, use caution when tilting the laser console or moving it up or down an incline. For optimum safety, use a second person when moving up or down a steep incline.

NOTE:

Do not move the laser console rapidly over uneven surfaces; doing so may damage the equipment

4. Position the laser console a minimum of 50 centimeters (20 inches) from walls, furniture, or other equipment.

NOTE:

Adequate space around the laser console ensures proper air circulation for system cooling.

5. Lock the laser console wheels.

Connecting the Footswitch

Insert the footswitch connector into the footswitch receptacle on the rear of the laser system console. Align the red dot on the footswitch connector on top, then press it in.

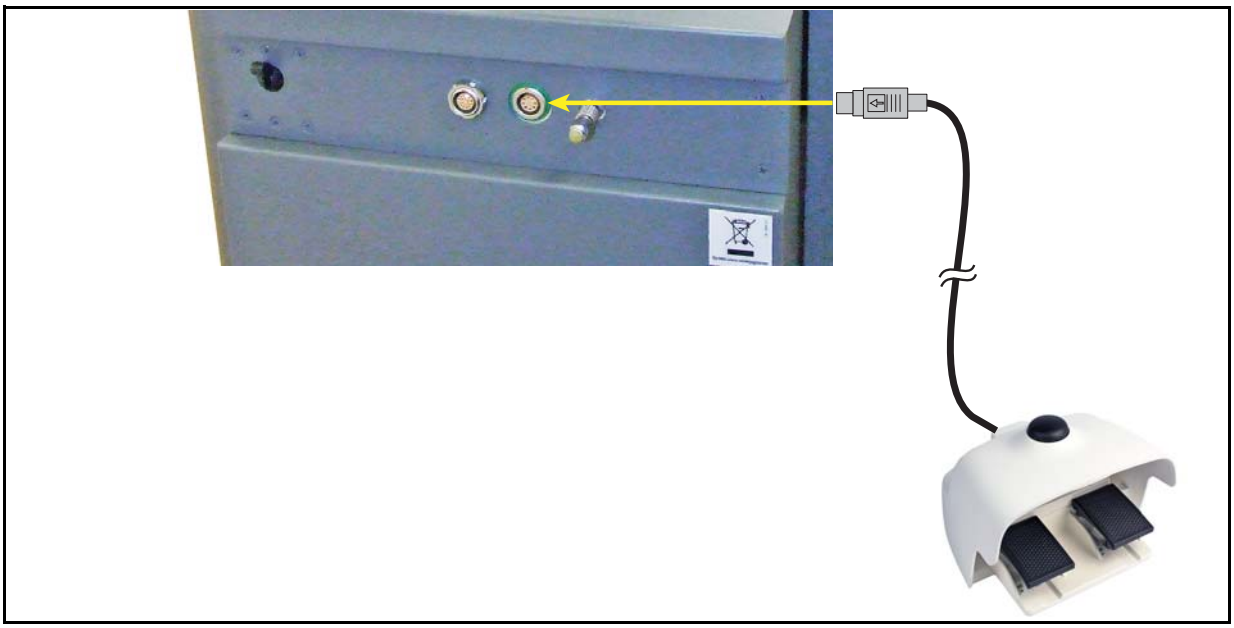


Figure 4: Connecting the Dual-Pedal Footswitch

NOTE:

If the footswitch is not properly connected when the laser system is turned on, the message **Attach Footswitch** appears in the notification bar until the footswitch is properly connected.

Connecting the External Door Interlock Connector

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

The laser system remains inoperative until the connector is inserted.

1. Align the pins of the external door interlock connector with the socket of the external interlock receptacle.
2. Insert the external interlock connector into the external interlock receptacle.
3. Turn the metal lock clockwise until it screws in.
4. If the treatment door is opened or if the external door interlock connector is removed, the laser system automatically disables and returns to **Standby** mode and a notification appears in the notification bar.
5. To resume treatment, close the treatment room door or reinsert the external door interlock connector, and press the **Ready** button.

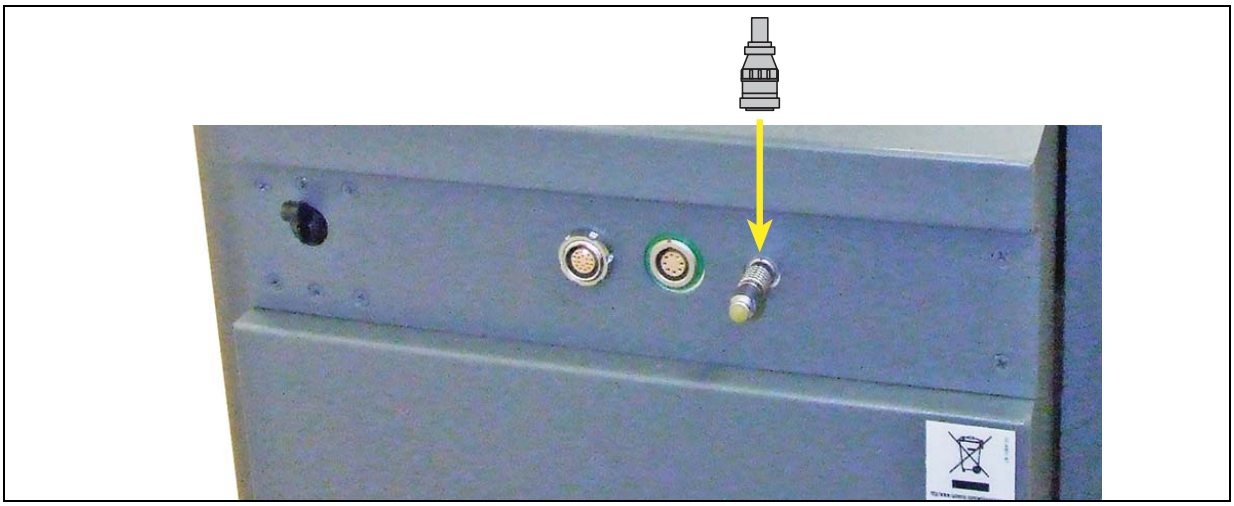


Figure 5: Connect the External Door Interlock Connector

Plugging in the Main Power Cable

1. Turn off the main electrical service (wall circuit breaker).
2. Ensure that the laser system's main power circuit breaker is in the off (down) position.
3. Insert the laser system's main power plug into the wall socket. If the laser system has a locking plug and socket, connect the plug collar to the socket so that the plug is secure from loosening.
4. Turn on the main electrical service (wall circuit breaker).

WARNING:

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

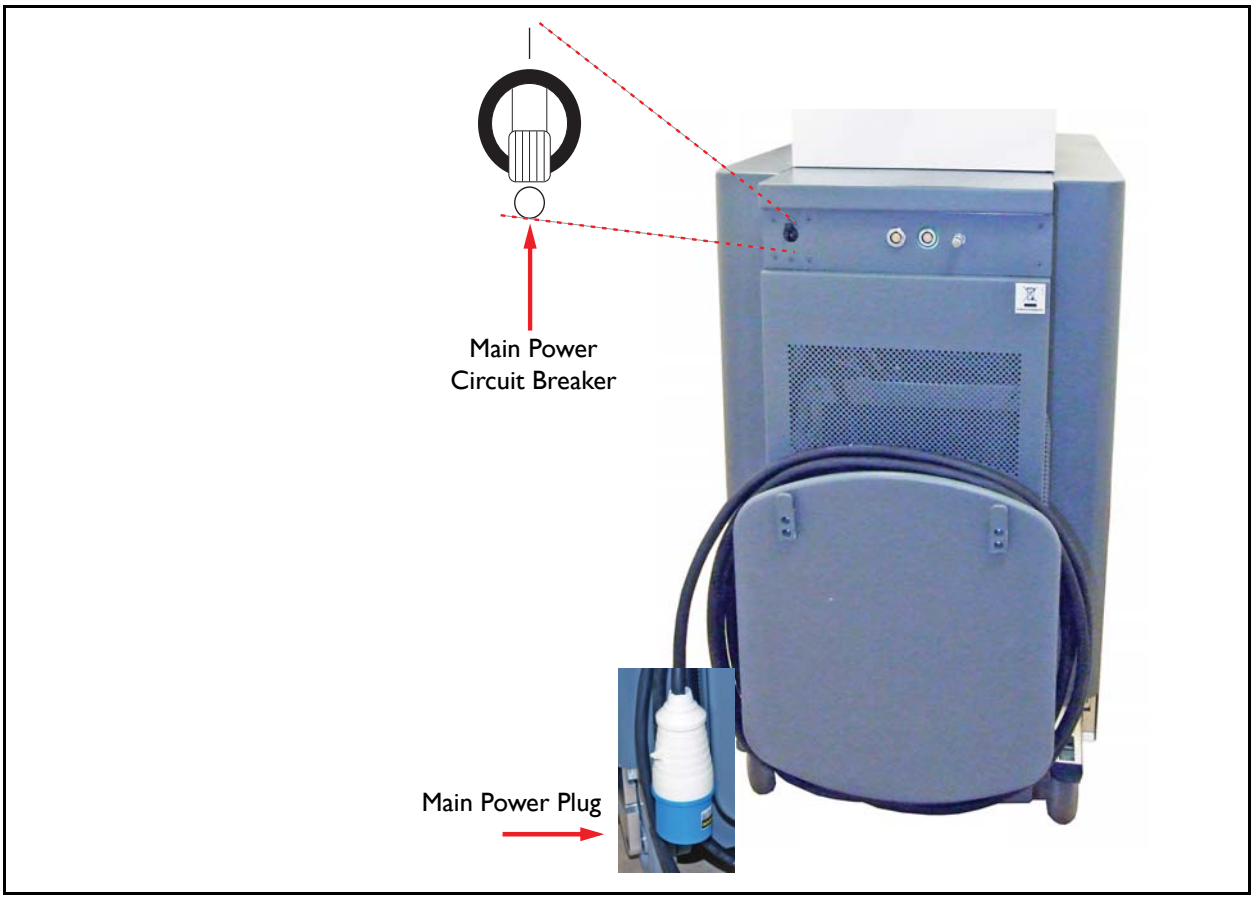


Figure 6: Main On/Off switch and Main Power Plug

Connecting the Optical Fiber

Before connecting the optical fiber to the laser system, refer to the appropriate optical fiber instruction guide for specific instructions, such as optical fiber inspection, sterilization, and assembly.

WARNING:

- Carefully inspect the optical fiber 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 optical fiber.
- When using an optical fiber, always inspect the optical fiber to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The optical fiber 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 optical

fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

- To avoid possible damage to the optical system, use only qualified Lumenis delivery systems. Using other than Lumenis delivery systems may jeopardize safe operation or damage the laser system and will void your Lumenis warranty or service contract.
- To prevent accidental laser discharge, always turn off the laser system before connecting the optical fiber.
- Always check the expiration date on the optical fiber packaging; do not use a optical fiber whose expiration date has passed.

NOTE:

SIS (Secure Identification System) enabled Lumenis Pulse 50H and Lumenis Pulse 100H laser systems will only operate with Lumenis-qualified SIS optical fibers. Attaching any other type of fiber will disable laser emission.

To ensure sterility of the optical fiber, the following aseptic technique must be used when you connect the optical fiber to the laser system:

1. Inspect the optical fiber as instructed in the appropriate optical fiber instruction guide.

WARNING:

Never inspect the optical fiber while it is connected to the laser system. Accidental laser exposure can cause severe eye damage.

2. The scrub nurse hands off the laser connector to the circulating nurse.
3. The circulating nurse removes the protective cap from the laser connector.

4. The circulating nurse secures the laser connector to the laser system by screwing the connector into the optical fiber receptacle on the front of the laser system.

   If the laser connector is not properly seated and securely screwed into the optical fiber connection port, the **attach fiber** message appears in the notification area on the control screen.

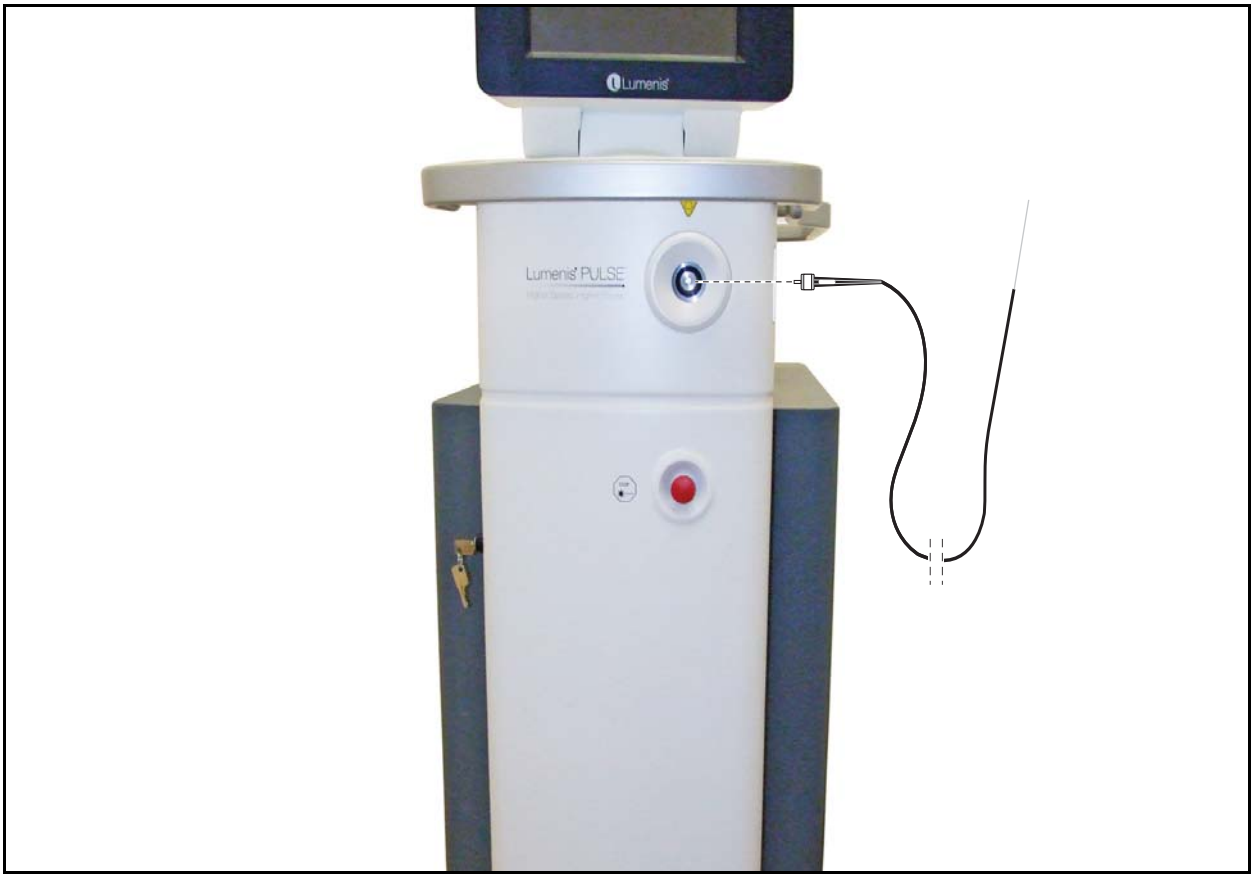


Figure 7: Connecting the Optical Fiber

WARNING:

When removing the protective cap, hold the laser connector, not the strain relief or optical fiber. Pulling on the strain relief or optical fiber may damage the optical fiber and result in unintended laser exposure.

CAUTION:

Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.

SIS (Secured Identification System) Technology

SIS enabled Lumenis Pulse 50H and Lumenis Pulse 100H laser systems will only operate with Lumenis-qualified SIS (Secure Identification System) optical fibers. Attaching any other type of fiber will disable laser emission.

Chapter 6: Operating Instructions

Emergency Stop Switch

In an emergency, press the laser emergency stop switch on the system's front panel, to immediately disable emission of the laser energy (Refer to figure 8.).

NOTE:

When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, set the laser system's main circuit breaker - located on the rear panel - to the **Off** position, and turn off the main electrical service (wall circuit breaker).

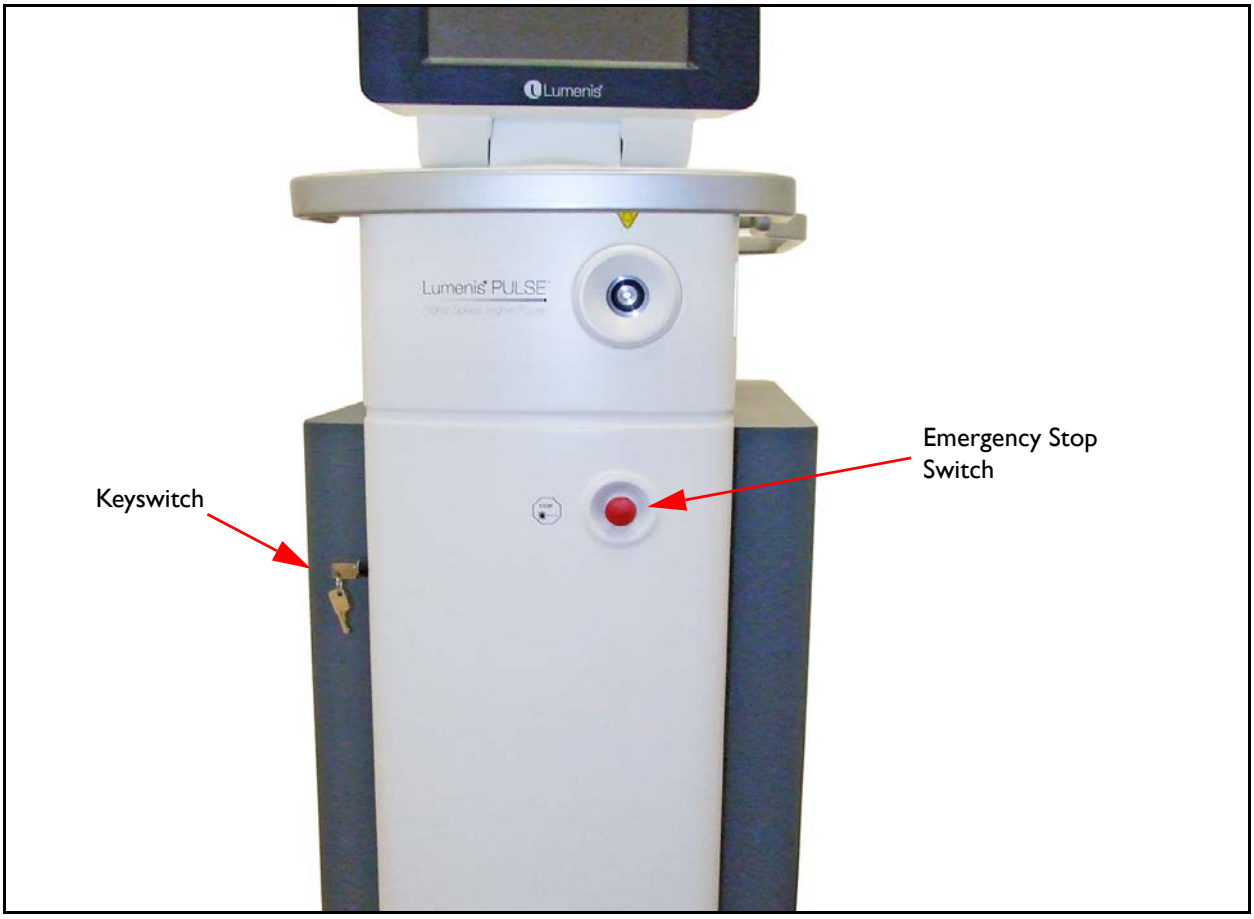


Figure 8: Controls for Turning Off the Laser System

Safety Eyewear

Verify that all persons in the operating room are equipped with appropriate laser safety eyewear.

Verification of Connections

1. Verify that the footswitch is properly connected.
2. Verify that the remote interlock connector is connected.

Powering on the System

1. Set the laser system's main power circuit breaker to the **On** (up) position.
2. Insert the key into the keyswitch (Refer to figure 8.) and rotate the key to the || (start) position; hold for one full second and release the key. Upon release, the spring-loaded key rotates to the |(on) position.

   A laser self-test and warm-up begin. The self-test and warm-up take approximately one minute. As internal tests are performed, self-test pass/fail messages display on the control screen. When the self-test is successfully completed, the main **Treatment** screen displays on the control panel.

NOTE:

If any fault conditions are encountered during laser system start-up and self-test, error messages can appear in the notification area on the control screen. Refer to the Troubleshooting section later in this manual.

Restarting the Laser System

If it becomes necessary to restart the system:

1. Turn the keyswitch to the (off) position.
2. Wait 5 seconds, then rotate the keyswitch to the || (start) position; hold for one full second, and release the key.

Treatment Screen Description

Once the laser self-test and warm-up have successfully completed, the main **Treatment** screen displays on the control panel.

The elements of the **Treatment** screen are detailed as follows (the numbered arrows in figure 9 correlate to the numbered steps below):

1. **Left Pedal Designation** – displays which footswitch pedal should be used for the group of output parameters in the box beneath the designator.

2. **Right Pedal Designation** – displays which footswitch pedal should be used for the group of output parameters in the box beneath the designator.

3. **Treatment Settings** for each pedal – each side of the screen defines the **Energy**, **Frequency** and **Pulse width** settings for lasing when the corresponding pedal is pressed. Press the ► or ◄ selectors to reach the desire settings; the derived power will be displayed

4. **Pulse Width** – the user may set the laser emission mode to short or long pulses. Toggle this button to select **Long** or **Short** pulses.

5. **Aiming Beam** – the **Aim Beam** display shows the selected aiming beam intensity: high, medium, low or off.
   - At laser system turn on the aiming beam setting retains the intensity setting from the last use of the laser system, or it will automatically select the minimum setting it the aiming beam was turned off at the last shut-down.
   - Press the **Aim Beam** ► or ◄ selectors to set the aiming beam intensity.
   - To turn off the aiming beam, press the ◄ selector until no bars are illuminated.

CAUTION:

If the aiming beam is turned off, ensure that the tip of the optical fiber and the targeted surgical site are both under direct visualization.

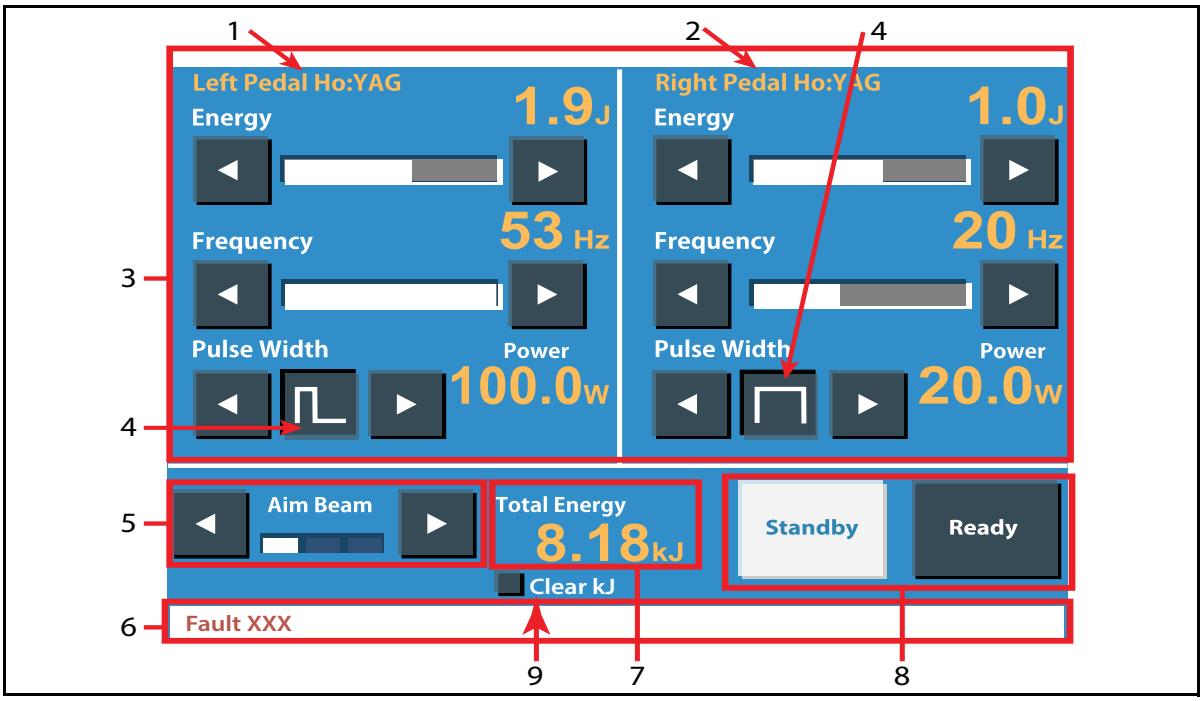


Figure 9: Treatment Beam Delivery via Right or Left Pedals

6. **Notification bar** - errors and notifications appear in the notification bar at the bottom of the screen, to alert you of a necessary action or a laser malfunction. Refer to Handling Error Messages and Notifications for a list of advisory indications, their probable causes, and solutions.

7. **Total Energy** – The Total Energy display shows the total holmium energy, in kilojoules, delivered since the last reset. The display automatically resets to zero the first time you press **Ready** after turning on the laser system, to allow reading of the total Energy of last treatment. To manually reset the display, press the **Clear kJ** selector.

8. **Standby/Ready** mode selection – **Standby/Ready** buttons determine whether pressing the footswitch will activate the laser system (**Ready** mode) or not (**Standby** mode).

WARNING:

Except during actual treatment, the laser system must always be in **Standby** mode. Maintaining the laser system in **Standby** mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

9. **Clear kJ** – clears the calculated total energy from the control panel; should always be cleared at the beginning of a new procedure.

Laser Emission Indicators

- The **Energy**, **Frequency** and **Pulse Width** parameter areas are highlighted by a yellow margin surrounding the applicable pedal on the screen (see figure 10) when the appropriate pedal is pressed, to alert the operator that laser energy is being emitted.
- An audible signal sounds during laser energy emission. The audible signal is different for the right and left pedals.

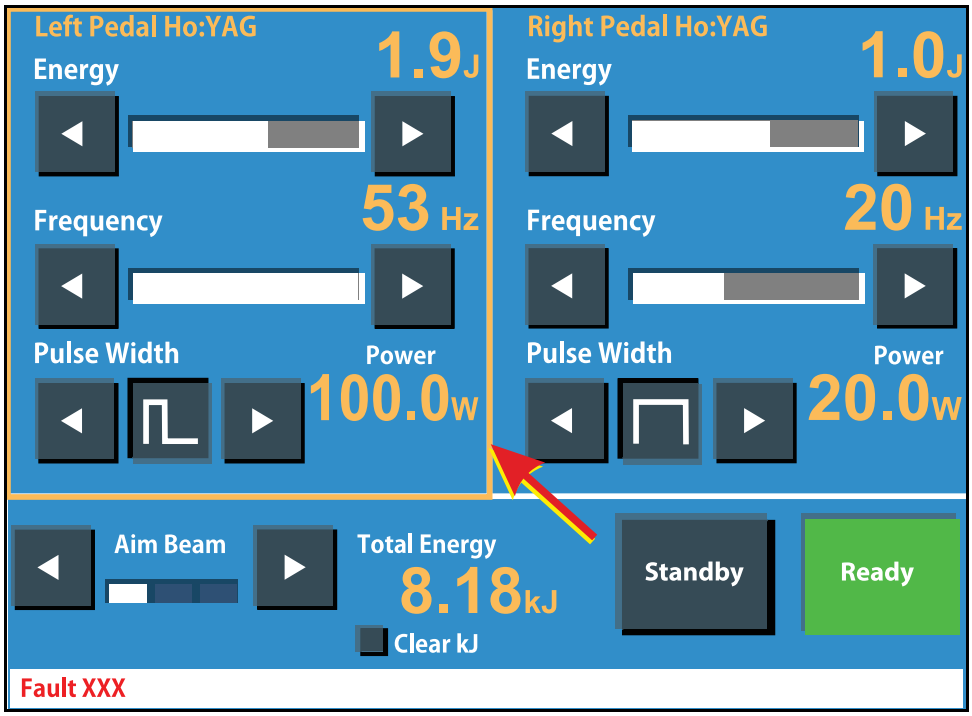


Figure 10: Laser Emission Indicator

Intra-Operative Instructions

1. Set the aiming beam to high intensity.
2. Test the integrity of the aiming beam.

   Hold a non-reflective surface, such as a tongue depressor, in front of the optical fiber tip. For side-emission delivery systems, hold the non-reflective surface in front of the side opening at the fiber tip.

   A green spot, the aiming beam, should appear on the surface. If the aiming beam is weak, check that it is set to high intensity. If the aiming beam is still weak, verify that the laser debris shield and optical fiber's connector are not damaged. Refer to Inspect the Debris Shield and the section in the appropriate optical fiber instruction guide (look under "Inspect the laser connector").

WARNING:

- Do not use the optical fiber if the aiming beam is set to high intensity and is still weak or not visible; the optical fiber may be damaged. A damaged optical fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Do not use the laser system or optical fiber if the aiming beam has not been verified. Verifying the aiming beam integrity is extremely important for the safe operation of your laser equipment.
- Do not use the laser system or optical fiber if the aiming beam is not visible. Operating the laser system without the aiming beam may result in laser exposure to non-target tissue and possible injury.

NOTE:

When using the optical fiber with an endoscopic camera, lower the intensity of the camera light if the aiming beam is weak or not visible. Doing so will not affect visibility at the treatment site, since the camera compensates for the lower level of light.

3. Enter the desired parameters into the **Energy**, **Frequency** and **Pulse Width** selectors on the control panel.
4. Position the aiming beam on the target tissue.

5. Press the **Ready** button to switch to **Ready** mode.

WARNING:
Always check your parameter settings on the screen before setting the system to **Ready** mode.

6. Verify that your foot is on the appropriate footswitch pedal for the left-side or right-side parameter settings on the screen.

7. Press the footswitch that corresponds to the desired set of parameters to deliver the treatment beam.

   As the laser delivers the treatment beam, the highlighted yellow margin appears around the appropriate footswitch settings area on the control screen and an audible signal sounds to alert you that laser energy is being emitted. The audible signal is different for the right and left pedals.

8. Press the **Ready** and **Standby** buttons on the screen or use the footpedal **Ready/Standby** button (on the top of the footswitch) to toggle between **Ready** and **Standby** modes.

9. If surgery is interrupted, set the laser system to **Standby** mode to disable the footswitch.

WARNING:
Always set the laser system to **Standby** mode when it is not in use to avoid unintended laser emission.

Post-Operative Instructions

1. Set the system to **Standby** mode.
2. Turn the keyswitch to the ⏻ (off) position.
3. Disconnect the optical fiber from the laser system.

   If the optical fiber is single-use, discard it. If it is multiple-use, prepare the optical fiber for reuse as instructed in the appropriate optical fiber instruction guide.
4. Set the laser system's main power circuit breaker to the Off (down) position
5. Turn off the mains circuit breaker.
6. Remove the main power plug from the wall receptacle and wrap the power cable around the cable rack (see figure 11).
7. Remove the footswitch connector from the laser system. and hang it from the footswitch storage mounts (see figure 11).
8. Disconnect the external door interlock.
9. Clean the exterior surfaces of the laser system.

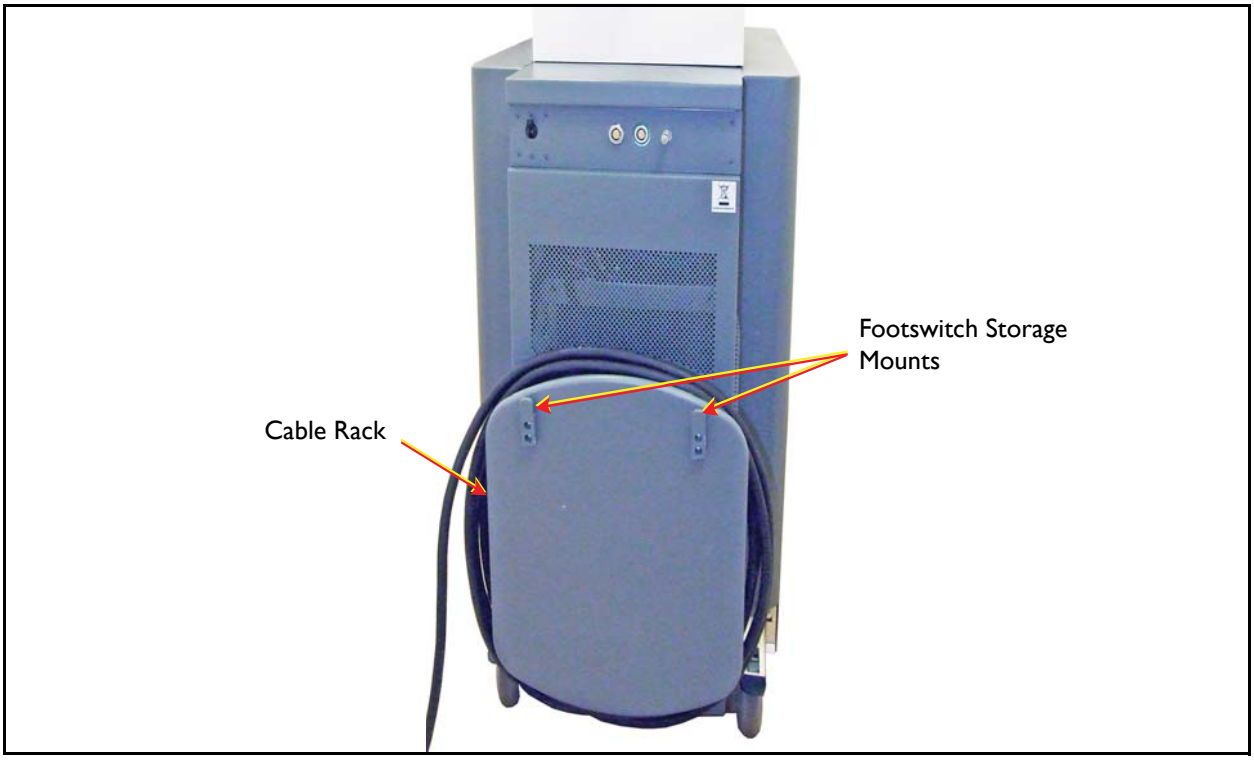


Figure 11: Laser Console Cable Rack and Footswitch Storage Mounts

Moving the Laser Console

Using the laser console's front and rear handles, move the laser system to the desired site.

CAUTION:

- As with any heavy equipment, use caution when tilting the laser console or moving it up or down an incline. For optimum safety, use a second person when moving up or down a steep incline.
- Do not move the laser console rapidly over uneven surfaces; doing so may damage the equipment.

Chapter 7 - Troubleshooting and Maintenance

Handling Error Messages and Notifications

Notifications and error messages appear in the **Notification bar** at the bottom of the screen.

1. Follow the instructions in the notification bar if any are given.
2. If instructions appear, perform the required task as detailed in the message. If the error is resolved, the message will fade and normal operation may be resumed.
3. Several types of errors will not fade - in a case like this press the **Standby** button to clear the notifications or error message; normal operation may be resumed.
4. Several types of errors will only appear with a number ("**Fault XXX**"); press the **Standby** button to clear the error and try to resume normal operation. If this does not resolve the problem restart the system.
5. If the problem does not resolve, contact Lumenis Customer Service.

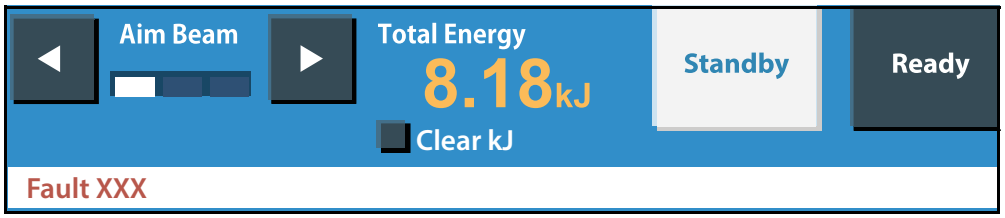


Figure 12: Notification Bar

Troubleshooting

If the system fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction.

Initialization Error Message Appears

1. Write down the error number.
2. Restart the system via the keyswitch.
3. If the problem re-occurs, contact Lumenis Customer Service.

System Does Not Turn On

The control screen does not illuminate.

1. Plug in the laser system.
2. Set the laser system's main circuit breaker to the **On** (up) position.
3. Turn on the main electrical circuit breaker.
4. Use another power outlet, or have the outlet professionally tested and repaired, if necessary.

Inadequate or No Aiming Beam

1. Adjust the aiming beam intensity.
2. Replace the optical fiber.
3. Lower the intensity of the endoscopic camera light.
4. Inspect and, if necessary, replace the debris shield.
5. Contact Lumenis Customer Service.

No Laser Energy Emission

1. Replace the optical fiber.
2. Inspect and, if necessary, replace the debris shield.
3. Contact Lumenis Customer Service.

"Popping" or "Tapping" Coming Sound from the Fiber Port

This is probably due to a malfunction of the optical fiber connector.

- Replace both the optical fiber and the debris shield.

Fiber Burn Back

Optical fiber burn back may occur during prolonged procedures, especially when using higher power.

- Renew the optical fiber tip by stripping and cleaving the fiber.

Unrecognized Fiber

1. Replace the optical fiber with a Lumenis compatible one and resume normal operation.
2. If problem persists, contact Lumenis Service.

A Notification or Error Message Appears on the Control Panel

There are three types of clearable errors:

- An error message that clears automatically (i.e., "Attach an Authorized Fiber") when an authorized fiber is attached.
- An error message that clears when the stated problem is resolved (i.e., "High temperature" will clear when the temperature of the system goes down).
- An error that requires user acknowledgement after resolving the problem (i.e., "Energy High"); press the Standby button on the screen to clear the message.

System Overheats

The laser system may overheat if it is used at a high power for an extended amount of time.

- Verify that the treatment room temperature is between 10 and 30°C (50 and 86°F).
- Verify that the laser system is at least 50 centimeters (20 inches) from walls, furniture, or other equipment.

NOTE:

If the laser system overheats, do not turn it off. Leaving the laser system on allows the internal cooling system to quickly cool the system's internal components. Allow the system to cool for several minutes and resume normal operation.

Message Appears: Attach an Authorized Fiber

SIS enabled Lumenis Pulse 50H and Lumenis Pulse 100H laser systems will only operate with Lumenis-qualified SIS (Secure Identification System) optical fibers. Attaching any other type of fiber will disable laser emission.

- Attach an authorized fiber or Contact Lumenis Customer Service to obtain the correct fibers.
- Refer to the optical fiber's Directions for Use document for specific instructions on how to work with the fiber.

Message Appears: Attach fiber

The optical fiber's connector is not properly connected to the laser system.

- Connect the optical fiber as instructed earlier in this manual.

Message Appears: Attach footswitch

The footswitch is not properly connected to the laser system.

- Connect the footswitch as instructed earlier in this manual.

Message Appears: Check footswitch

You are pressing either one both footswitch pedals in **Standby** mode.

- Release the footswitch, switch to **Ready** and press one of the footswitch pedals.

Message Appears: Check interlock

The interlock door is open, or the interlock plug is not properly inserted.

- Close the interlock door, or insert the interlock plug.

Message Appears: Insert debris shield

The debris shield is missing or is not properly inserted.

- Insert the debris shield.

Message Appears: No lasers

The system is experiencing a laser malfunction.

- Contact Lumenis Customer Service.

Message Appears: Energy high

The energy delivered is more than 50% higher than the selected level.

- Press the **Standby** button to clear the message, then press the **Ready** button and resume normal operation. If the condition continues, turn off the laser system for five seconds, then turn it back on. If the condition persists, contact Lumenis Customer Service.

Message Appears: Energy low

The energy delivered is less than 50% of the selected level.

- Press the **Standby** button to clear the message, then press the **Ready** button and resume normal operation. If the condition continues, turn off the laser system for five seconds, then turn it back on. If the condition persists, contact Lumenis Customer Service.

Message Appears: Rate high

The pulse rate delivered is at least 20% more than the selected level.

- Press the **Standby** button to clear the message, then press the **Ready** button and resume normal operation. If the condition continues, turn off the laser system for five seconds, then turn it back on. If the condition persists, contact your Lumenis Customer Service.

Message Appears: Rate low

The pulse rate delivered is less than 80% of the selected level.

- Press the **Ready** button to clear the message. If the condition continues, turn off the laser system for five seconds, then turn it back on. If the condition persists, contact Lumenis Customer Service.

Routine Periodic Maintenance

Regular cleaning, inspection, testing, and repair are the basis of any effective preventive maintenance program. Such a program helps keep the system in top working order and ensures the reliability of safety interlocks and fail-safe mechanisms.

A recommended routine inspection and maintenance schedule is provided below.

Inspection/Service	*Frequency*	*Performed By*	*Remarks*
Routine exterior cleaning.	As required by hospital/ clinic protocol.	Hospital/Clinic Staff	None
Inspect cables and all external surfaces for damage.	Weekly	Hospital/Clinic Staff	If damage is found, call Lumenis Customer Service.
Inspect electrical connections.	Weekly	Hospital/Clinic Staff	If damage is found, call Lumenis Customer Service.
Check remote interlock connection and emergency stop button.	Weekly	Hospital/Clinic Staff	If interlock and/or button do not perform as required, call Lumenis Customer Service.
Inspect/replace the debris shield	Weekly or if required due to low output energy.	Hospital/Clinic Staff	If output energy is still low after replacing the shield, call Lumenis Customer Service.
Deionizer and particle filters replacement.	Annually	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
Electrical safety checks.	Annually (or as required by institutional procedures).	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
Check and perform energy detectors calibration procedure.	Annually, or as required if system does not perform to specifications, or occurrence of error messages.	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.

Hospital/Clinic Staff Maintenance

Visual Inspection

The exterior of the system should be inspected once a week to ensure that there are no loose cable connections and that there is no damage to the system.

Routine Exterior Cleaning

The external surfaces of the system (console, LCD panel) and the footswitch should be cleaned when the system is received, and thereafter as required by clinic protocol.

The outer surfaces of the system may be wiped clean with a soft, lint-free cloth dipped in 70% isopropyl alcohol, or a hospital-grade disinfectant solution.

CAUTION:

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

Remote Interlock Check

Laser beam emission is disabled when the remote interlock plug is not connected or the connected door is not closed. To check this:

1. Set the system to **Ready** mode.
2. Unplug the remote interlock connector plug; the system should display the following message in the notification bar: **Check Interlock**. re-insert the interlock connector plug.
3. Open the connected door; the system should display the following message in the notification bar: **Check Interlock**.
4. If the system does not display the message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

Emergency Stop Button Check

The **Emergency Stop Button** is designed to disable the laser system when pressed. To check this interlock:

1. With the system **On**, press down on the emergency stop button; the system will turn itself off.
2. Restart the laser system by turning the keyswitch.
3. Press the **Ready** button on the LCD or footswitch to enable lasing.

If this is not the situation, discontinue use and contact Lumenis Service.

Inspect the Debris Shield

The debris shield protects the internal optical components of the laser system from damage by a faulty or misused optical fiber.

Remove the Debris Shield

1. Turn off the laser system.
2. Locate the debris shield panel covering on the upper right-hand side of the laser console.
3. Remove the panel covering with your fingers.

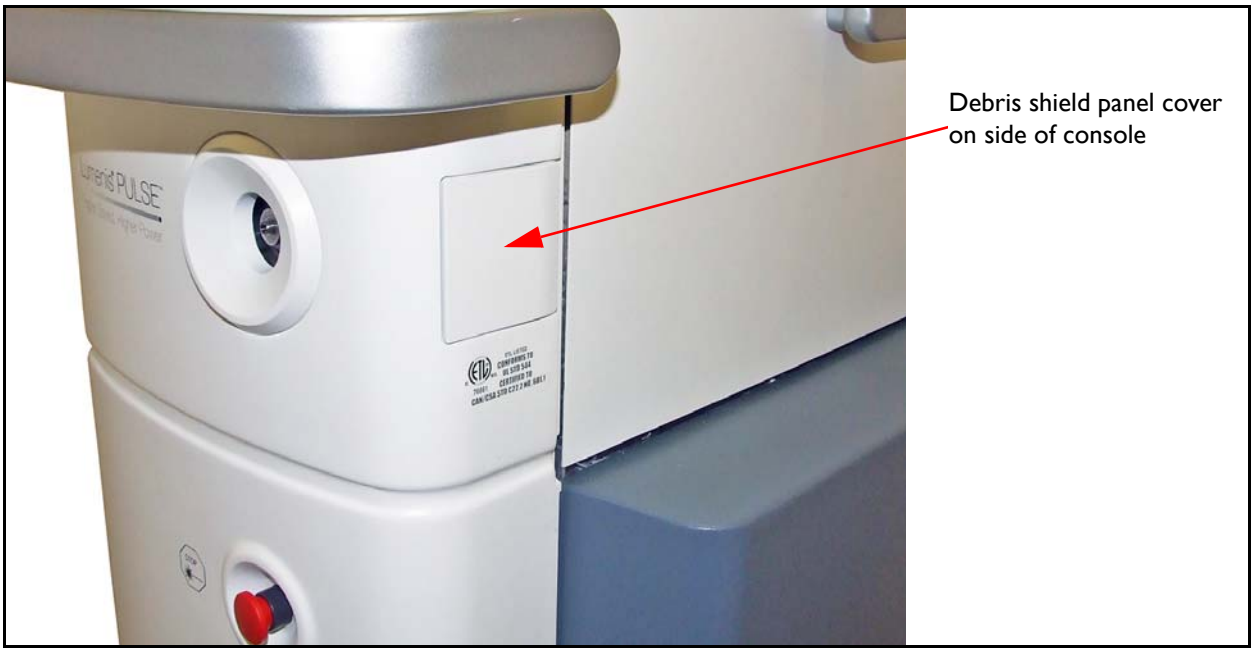


Figure 13: Locate the debris shield

4. Grasp the debris shield handle, and pull the shield out of the receptacle.

Figure 14: Remove the debris shield

Inspect the Optic

Inspect the debris shield optic to verify that it is free of any burn marks, scratches, dust, or fingerprints. If the optic is damaged or dirty, replace it as instructed in Change the Debris Shield Optic in this section. If the optic is free of damage, reinsert the debris shield into the receptacle as instructed below.

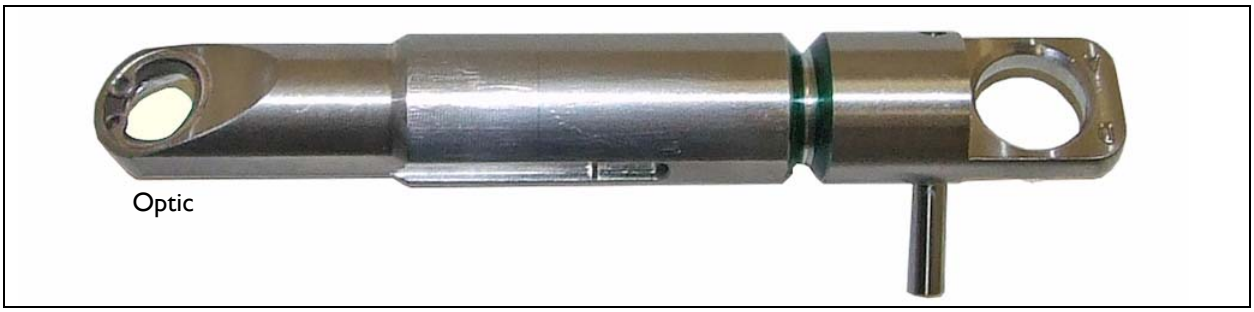


Figure 15: Inspect the Debris Shield Optic

Reinsert the Debris Shield

1. Holding the debris shield handle, position the shield so that the pin is aligned with the pin groove.
2. Insert the debris shield into the debris shield receptacle.
3. Replace the panel covering.
4. Restart the laser system.

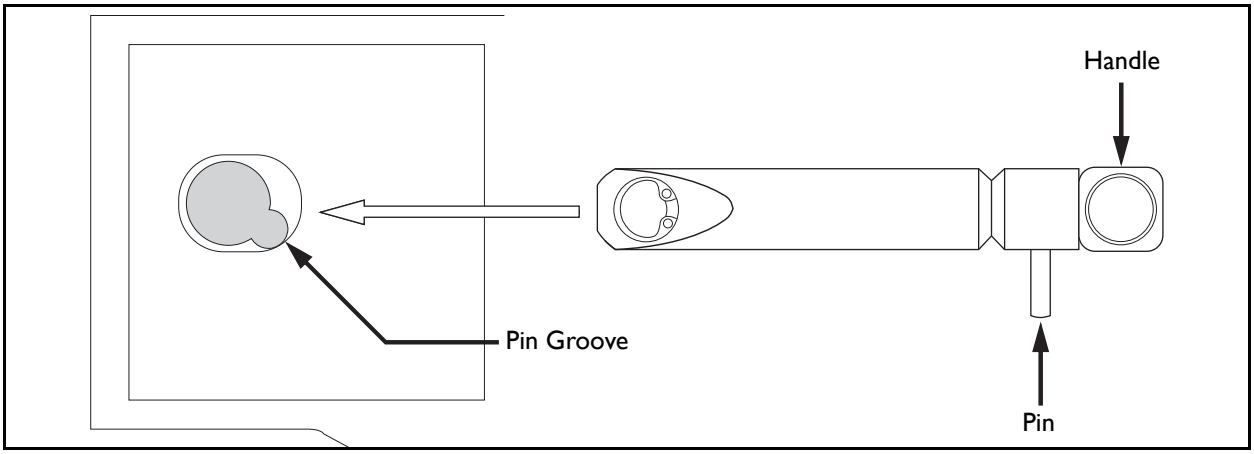


Figure 16: Reinsert the Debris Shield

Change the Debris Shield Optic

1. Use snap ring pliers to remove the snap ring that secures the debris shield optic to the body of the shield.
2. Carefully turn over the debris shield holder, and allow the debris shield optic and spring washer to drop onto a lens cleaning tissue.
3. Open the vial containing the new debris shield optic.

CAUTION:
To avoid contamination, do not touch the surface of the debris shield optic with your fingers.

4. Carefully turn over the vial, and allow the optic to drop onto a lens cleaning tissue.
5. Lay the debris shield over the new debris shield optic.
6. Hold the lens cleaning tissue over the debris shield optic opening, and slowly turn over the debris shield until the optic is facing up.
7. Place the spring washer over the debris shield optic.
8. Hold the debris shield optic and spring washer in place with the lens cleaning tissue, and use snap ring pliers to insert the snap ring over the spring washer. Ensure that the snap ring is in place and secure before releasing the snap ring pliers.

Figure 17: Change the Debris Shield Optic

Professional Maintenance

This section covers checks, calibrations and maintenance that require internal access to the laser system's console and special skills.

CAUTION:

The Lumenis Pulse 50H or 100H laser system may only be serviced by Lumenis certified field service engineer using an approved service manual.

WARNING:

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

Energy Detectors Calibration

Energy detectors check and calibration must be performed by an engineer or technician qualified to work with laser equipment. Questions regarding this procedure should be referred to Lumenis Customer Service.

DISCLAIMER:

Calibration is a service procedure to be done only by Lumenis-certified service engineers or customers who have taken and passed a Lumenis Service Certification Training course. Adjustment by anyone other than a trained Lumenis service engineer or a certified customer voids any existing manufacturer's warranty on the instrument. A service manual for the laser system may be purchased from Lumenis. It is company policy not to distribute service tools outside of the Lumenis service organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

The Lumenis Pulse 50H or 100H system incorporates internal energy detectors which are used to control lasing energy. The energy detectors check compares the internal energy reading to the reading from a calibrated external power meter

WARNING:

All personnel in the immediate area must wear eye protection rated specifically for the Holmium laser system.

NOTE:

Optical components must be clean before the energy detectors check is performed.

1. Verify that all personnel are wearing appropriate laser safety eyewear.
2. Position a calibrated, external power meter 15 cm (6 inches) from the output end of the optical fiber.
3. Turn on the laser system as instructed earlier in this manual.
4. Set the laser system to deliver **5** Watts of laser energy.
5. Target the aiming beam at the detector disc of the external power meter.
6. Set the laser system to **Ready** mode.
7. Press the footswitch to deliver the laser energy into the detector disc of the external power meter. Maintain delivery of the laser energy for 20 seconds.
8. Release the footswitch and record the external power meter's reading.
9. If the external power meter reading falls above or below ±20% of the requested energy on your laser system, discontinue this procedure and contact Lumenis Customer Service.

Chapter 8: System Requirements and General Information

Installation

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

Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser system and any delivery systems used during surgery.

If your scheduled surgical procedure requires disposable delivery devices or accessories, it is helpful to have extra items ready and available in the treatment room should they be needed to complete a procedure.

CAUTION:

For Canada, the system must be installed and operated according to CAN/CSA-Z386-08: Laser safety in health care facilities.

Accessories

- Safety eyewear
- SlimLine SIS 200, 365, 550, 1000
- SlimLine EZ SIS 200, 365, 550
- Xpeeda D/S/L optical fiber
- SlimLine Endo SIS 200, 365, 550 optical fibers
- SlimLine GI SIS 365 optical fiber

Tools (Optional)

- Scissors
- Optical fiber stripper
- Cleaving tool
- Optical fiber inspection scope
- SlimLine steam sterilization tray

Electrical Requirements

Refer to the System Specifications section in this manual.

Electrical Utilities

Lumenis Pulse 50H or 100H laser systems are available in several electrical configurations. Electrical power should be setup according to the model ordered. The line wires in the power cable shall be connected to the building power, and the green/yellow wire must be connected to the building ground.

The customer's engineer or electrical contractor will be responsible for ensuring that the proper electrical requirements are available at the site.

Systems Designed For Use Outside of Europe

For the 200-230 VAC configuration, supply the electrical power from a dedicated 200, 208, or 230 VAC, single-phase, 50-60 Hz supply mains in accordance with local codes. The socket and wall plug connection must be rated for 30A @ 60 Hz or 30A @ 50 Hz and voltage of 200 ±10% VAC or 208 ±10% VAC or 230 ±10% VAC.

Systems Designed For Use in European Communities Under the MDD

To comply with the European Communities Medical Device Directive 93/ 42/EEC, and harmonized standards EN 60601-1 and EN 60601-2-22, the 230 ±10%VAC configured laser must be either permanently connected to a 32A, 230 ±10% VAC, single-phase, 50 Hz supply mains in Hard-Wired Configurations UM-20006520EN, Rev. A Page 69 accordance with national wiring regulations, or connected by means of a dedicated single-phase, 32A, 230 ±10% VAC wall socket and lockable plug combination designed to ensure the connection is "mechanically secured against accidental loosening". Such a connection will ensure compliance with EN 60309 for this device. Wiring should be rated at 32A. Leakage current for these lasers does not exceed 500 µA.

External Door Interlock Pin Assignments

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

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

Pin assignments are as follows:

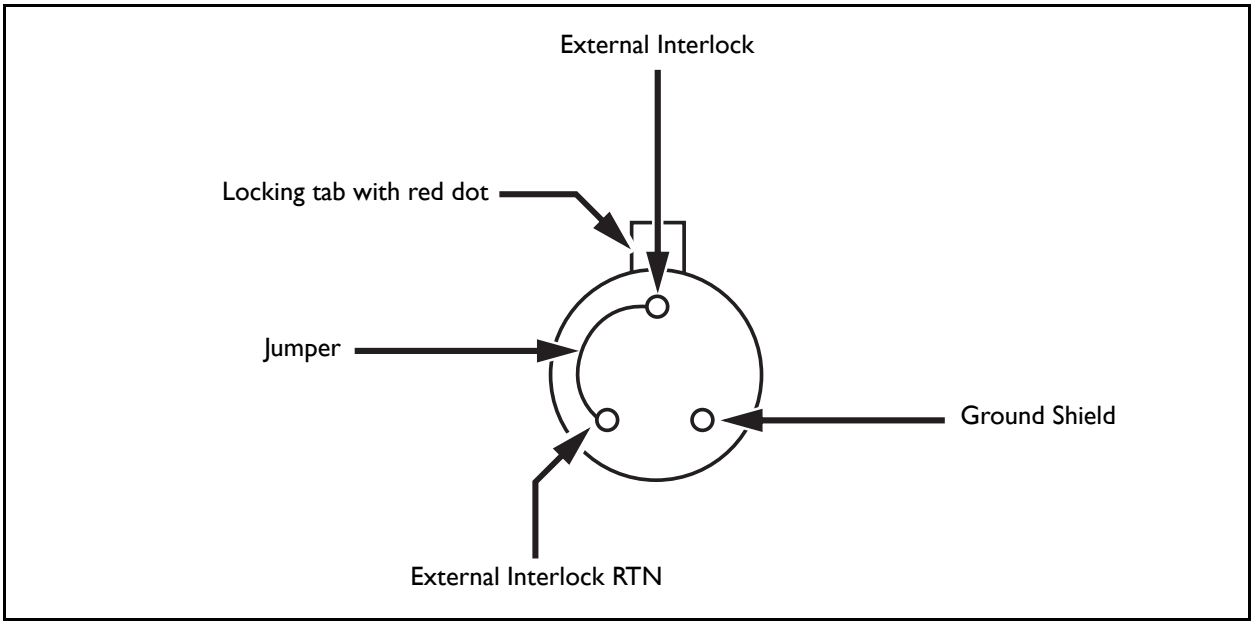


Figure 18: External Door Interlock Pin Assignments (solder side of plug shown)

Compliance With International Standards

In compliance with international standards for laser medical equipment, the system is equipped with the following:

Emergency Stop Button

The laser system has an emergency stop button knob that, when pushed, immediately disables the laser system in emergency situations.

Keyswitch

Laser energy can be emitted only when the keyswitch is turned to the **Open** position. The key can only be removed in the off position, and the laser system only operates with the key in place. When treatment is complete, always remove and secure the key to prevent unauthorized use of the laser system.

WARNING:

Unauthorized use of this system may expose the operator/patient to potential electrical energy and laser radiation hazards.

Laser Emission Indicators

A laser emission indicator appears on the control screen to alert you that laser energy is being emitted. During the treatment beam delivery, the laser system emits an audible signal correlating to the pedal used.

External Door Interlock

An external door interlock outlet and plug are provided to disable the laser system if the treatment room doors are opened while the laser system is in **Ready** mode.

Protective Housing

The laser system has a protective housing that prevents unintended human access to laser radiation. No sections of the protective housing can be easily opened without special tools. This housing is to be opened only by a Lumenis-certified technician.

Safety Shutter

The laser system features a safety shutter that prevents the treatment beam from exiting the laser system. The safety shutter opens only when the laser system is in **Ready** mode and the footswitch is pressed.

Manual Reset

If laser emission is interrupted during treatment (e.g., main electrical power loss), the laser system automatically turns **Off**. To resume treatment, you must manually restart the laser system using the main **On**/**Off** button.

Electronic Fault Detection Circuitry

If any of the electronic system monitors detect a fault condition, laser emission is disabled. The high voltage power supply disables, the safety shutter closes, and the footswitch disables.

Safety Interlocks

The laser system has a safety interlock on the optical fiber laser connector.

Precision of Displayed Values

The precision of the energy and rate values displayed on the control screen are factory preset to within ±5% of a calibrated standard. The energy of every pulse is monitored by two internal detectors to ensure that no safety hazard is caused by failure of a single component. If the delivered system energy deviates from the commanded parameters by more than 20%, you are notified and can continue lasing following acknowledgment. Following 5 such occurrences in a single session this becomes a fatal error and lasing cannot continue (laser system shuts down).

Space Requirements

Position the laser console a minimum of 50 centimeters (20 inches) from walls, furniture, or other equipment.

System Specifications

Output parameters	
Treatment laser beam	
Laser type	Holmium:YAG (Ho:YAG), pulsed
Laser wavelength	2.1 µm
Laser Classifications	
FDA classification	Class IV medical device
EN 60825 classification	Class 4 laser
Power	
Lumenis Pulse 50H:	1.0 to 50W
Lumenis Pulse 100H:	1.0 to 100W
Energy	0.2 - 3.5 Joules
Repetition rate	
Lumenis Pulse 50H:	5 to 25 Hz
Lumenis Pulse 100H:	5 to 53 Hz
Pulse width	0.15 to 0.6 ms
Aiming beam	
Laser Type	Green DPSS, continuous wave
Laser wavelength	532 nm
Laser Classifications	
FDA classification	Class IIIa laser
EN 60825 classification	Class 3R laser
Power	5 mW maximum
Input power recommended service	
Voltage	200/208/230 VAC ±10%
Frequency	50/60 Hz
Current	• 30A @ 208/230 VAC @ 60 Hz • 30A @ 200/208/230 VAC @ 50 Hz
Utility connection	Single-phase grounded outlet
Cooling	
Method	Internal water-to-air heat exchanger
Cooling air Requirements	Minimum 46 cm (18 in) from walls
Physical parameters	
Size (W × D × H) cm (in.)	46 × 91 × 99 cm (18 × 36 × 39 in.)
Weight	200 kg (441 lbs.)
Power cable length	7 m (23 ft.)
Footswitch cable length	5.2 m (17 ft.)
Environmental requirements (operating conditions)	
Temperature	10 – 30°C / 50– 86°F
Humidity	30 to 75% at 30°C/86°F

Pressure	77 – 106 kPa
Max. altitude	3,050 m (10,000 ft.)
Environmental requirements (non-operating conditions)	
Temperature	10 to 40°C (50 to 104°F)
Humidity	30 to 75% at 30°C/86°F

Laser Safety Eyewear

Refer to Laser Safety Eyewear in the Safety and Regulatory section of this manual for detailed laser safety eyewear information.

Replacement Parts Part Numbers

Debris shield (glass and holder)	SPSA-10090190
Debris optic (glass only)	SPOP-10025270
Laser system key	5107-0146

Compatible Optical Fibers

The laser system is intended for use only with Lumenis-qualified optical fibers. Contact Lumenis Customer Service for a list of available products.

Decontamination of Returned Equipment

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

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

Customer Service and Warranty

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."

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

Appendix A: EMC Guidance and Manufacturer's Declaration

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Lumenis Pulse 50H & 100H systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 50H & 100H systems should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Lumenis Pulse 50H & 100H systems use 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	The Lumenis Pulse 50H & 100H systems are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	The system consumes more than 16A momentary current per phase, and therefore is exempt from these requirements.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The system consumes more than 16A momentary current per phase, and therefore is exempt from these requirements.

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity The Lumenis Pulse 50H & 100H systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 50H & 100H systems should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV common mode	± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Lumenis Pulse 50H or 100H systems requires continued operation during power mains interruptions, it is recommended that the Lumenis Pulse 50H or 100H systems be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Lumenis Pulse 50H & 100H systems are is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 50H & 100H systems should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY test</th><th>IEC 60601 TEST LEVEL</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Lumenis Pulse 50H & 100H systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz</td><td>3 V</td><td>$d = 1.17\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m 80 MHz to 2,5 GHz</td><td>3 V/m</td><td>$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.23\sqrt{P}$ 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 metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">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 Lumenis Pulse 50H or 100H is used exceeds the applicable RF compliance level above, the Lumenis Pulse 50H or 100H systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [MEDICAL EQUIPMENT or MEDICAL SYSTEM].
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Lumenis Pulse 50H or 100H laser system			
The Lumenis Pulse 50H & 100H systems are is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lumenis Pulse 50H or 100H systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lumenis Pulse 50H & 100H as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz $d = 1.17\sqrt{P}$**	**800 MHz to 2,5 GHz $d = 2.33\sqrt{P}$**
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.			