Lumenis® PULSE™ 60H

Holmium Surgical Laser
Operator's Manual

TEMPORARY

PLACEHOLDER

Lumenis®
Energy to Healthcare

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Revision A

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.

Please visit www.Lumenis.com/Homepage/About2/Recycle to understand what arrangements Lumenis has made in each EU Member State.

CE 0483

EC REP

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Chapter 1: Introduction

The Lumenis Pulse 60H holmium laser system provides 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 operator's manual and the appropriate optical fiber instruction guides, 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.
- No modification of this equipment is allowed.

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.

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 misuse of the device.

System Description and Main Features

The Lumenis Pulse 60H laser system comprises the following main components and features:

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

Figure 1: Lumenis Pulse 60H Laser System Console

Laser System Console

The laser system console houses the control screen, emergency stop knob, main On/Off switch, remote interlock, 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

The user interface language is configured by the Lumenis service engineer during system installation. The user may change the language as desired from the list of available languages.

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 60H laser system. Lumenis fibers incorporate Security Identification System (SIS) technology. Refer to the appropriate optical fiber's instruction guide for specific operating instructions.

Chapter 2: Theory of Operation

General 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 60H 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 60H can deliver a maximum average power of 60W, i.e., by delivery of 4 Joules x 15 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 it into particles versus disintegrating it 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.

Theory of Operation – Moses Mode

The Lumenis Pulse 60H holmium laser emits a laser beam at a wavelength of 2100nm. This wavelength is strongly absorbed by water. 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. Holmium laser energy is also very effective in lithotripsy of calculi.

In a liquid environment when laser is emitted from the holmium fiber tip, the water surrounding the tip heats to above the boiling temperature and a vapor bubble is created. The vapor bubble expands from the fiber tip towards the target tissue or stone. As only a portion of the pulse is sufficient to create the vapor bubble, the remaining pulse energy travels through the void contained in the bubble, and is less attenuated compared to travel through liquid water.

When the distance between the fiber tip and the target is very small, this phenomenon is not observed, as most of the energy reaches the target tissue. In contact, the laser is therefore the most efficient. However, when distance is increased, the relative energy that reaches the target is greatly decreased, leading to reduced ablation efficiency of the laser energy. The laser efficiency is therefore much dependent on the distance between the fiber tip and the target. This is defined as the regular mode currently available for all system applications.

The **Moses** mode introduces a modulation to the energy pulse that enables emission of a controlled portion of energy to create the vapor bubble, while leaving a larger portion as the effective energy portion that travels through the vapor bubble to reach the target tissue. Laser efficiency is therefore less dependent on the distance between the fiber tip and the target, and laser energy is delivered with higher precision.

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. Defocusing (increasing the fiber distance from the tissue) is a common method for decreasing power density on tissue. When using the **Moses** feature, due to its higher precision and reduced dependence on fiber tip distance from the target, this technique will be less effective.

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 60H	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 60H	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. Install an external door remote interlock that automatically disables the laser when the treatment room door is opened.
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 cables 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

- Ensure that no electrical cabling is routed near any component of the suction system, including both tubes (aspiration and drainage), collection container and the operating room's hazardous waste container (not supplied by Lumenis).
- Ensure that all optical fibers and any part of the suction system, including both tubes (aspiration and drainage), collection container, the operating room's hazardous waste container (not supplied by Lumenis) and 3rd party accessories are made of non-conductive material.

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.
- The round LED on the front displays the activity mode of the Lumenis Pulse 60H laser console:

Color	Illumination	Activity Mode
Blue	Continuous	Power **On**/**Standby**
Orange	Continuous	**READY** Mode
Orange	Blinking	Lasing

Figure 3: System Mode LED Indicator

Warning, Certification and Identification Labels

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

Figure 4 displays the identification and certification labels affixed to the system.

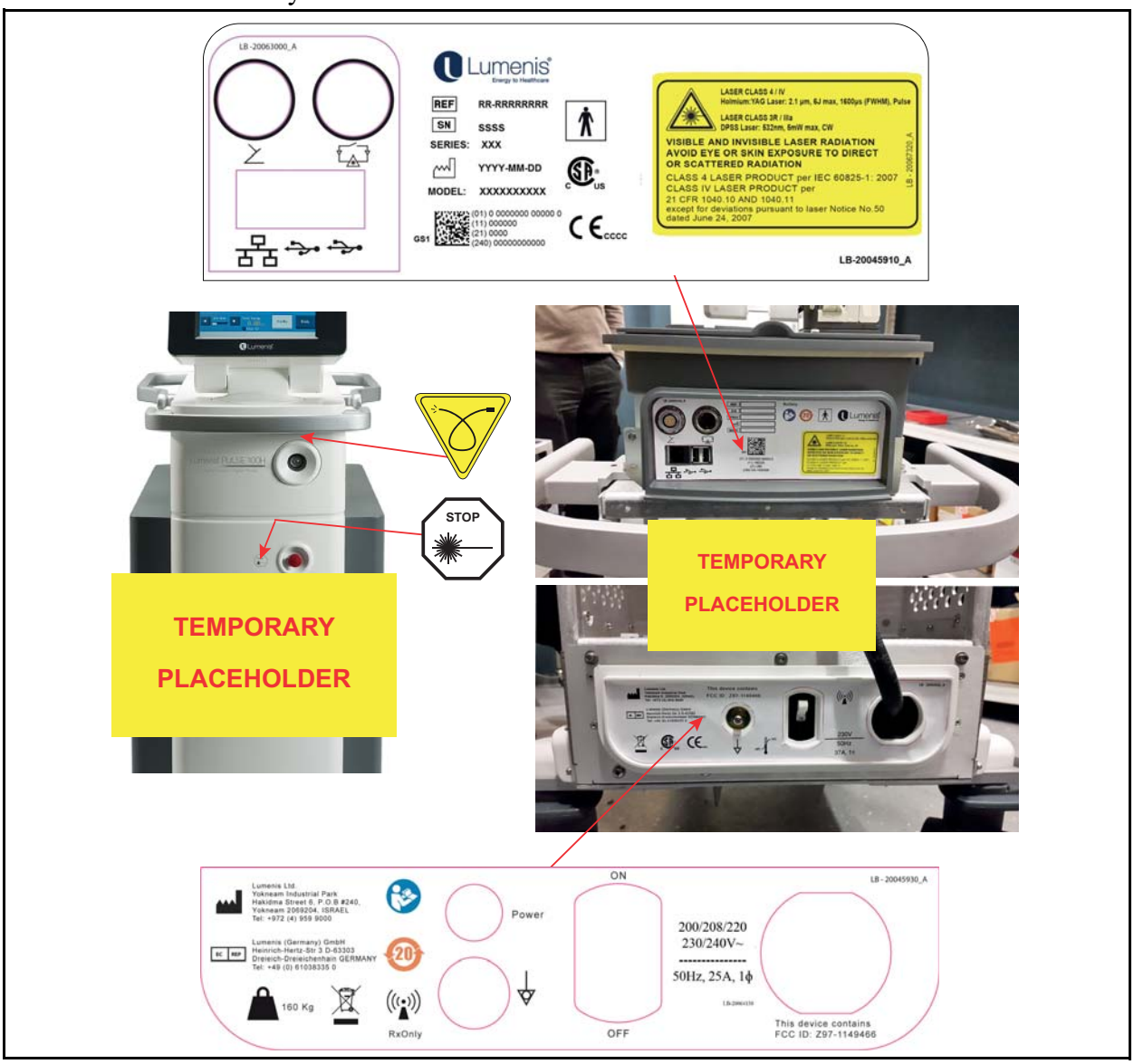
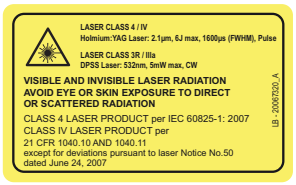


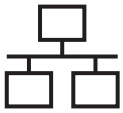
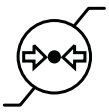
Figure 4: Location of Regulatory Compliance Labels (for illustration purposes only)

Description of System Labels:

The labels located on the system's panels, components and packaging contain the following information (For illustration purposes only):

Symbol	*Description*
Lumenis® Energy to Healthcare	Lumenis, Energy to Healthcare
CE 0483	CE Compliance
EC REP	Authorized Representative in the European Community
	Manufacturer
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
SERIES	Series Number
MODEL	Model Name
	Follow Instruction for Use
200/208/220 230/240V~ --- 50Hz, 25A, 1 ϕ LB-20064130 *	Electrical Requirements (*values are for illustration purposes only)
	Type BF Equipment

Symbol	*Description*
This device contains: FCC ID: Z97-1149466	**FCC Identification Label:** This device contains: FCC ID: Z97-1149466
	Non-Ionizing Electromagnetic Radiation
	**Laser Class IV Label:** Laser Class 4/IV Holmium:YAG Laser: 2.1µm, 6J max. 1600 µs (FWHM), Pulse 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
	Emergency Laser Stop
	Fiber Connection Port (Aperture)
	External Interlock Connection
	Footswitch Connection
Rx Only	In the USA: 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

Symbol	Description
	RoHS Compliance (China)
	Ethernet Connection Port
	USB Connection Port
	Equipotential Earth Connection Pin
	Unique Device Identifier (UDI) Code, Type GS1
WARNING **Grounding reliability can only be achieved when the EQUiPMENT is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade"** **0363-076-01 Rev. B**	**Power Cable Warning:** **WARNING** Grounding reliability can only be achieved when the EQUIPMENT is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade"
	Temperature Limitation (located on shipping crate)
	Humidity Limitation (located on shipping crate)
	Atmospheric Pressure Limitation (located on shipping crate)

Chapter 4: Clinical Guide

Lumenis recommends that physicians learn and gather additional knowledge related to the Lumenis Pulse 60H 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, while increasing the pulse width may reduce retropulsion.

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 60H system including the delivery devices with 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/orthopedics, discectomy, ENT surgery, gynecological surgery/gynecology, general surgery, gastroenterology, thoracic and pulmonary surgery, dermatology, and plastic surgery, podiatry, neurosurgery and ophthalmology.

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 60H system with delivery devices and accessories is 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 60H 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 L5-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
  - > Pilonidal cystectomy
  - > 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 sinusotomy
  - > 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 60H components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Verify that the electrical cables are not frayed or split.
- Check and verify that there are no cracks or breaks in the system's protective outer covers.
- Contact your Lumenis Customer Service if any component appears damaged.

Moving the Laser Console

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 attempt to lift the system using the handles.
- When pulling the system by the handle, it is recommended to set the front brake pedals to the multi-directions position (see Figure 5), and the rear brakes to the uni-directional position, such that the system will not "swim around" while you are pulling it.
- Ensure that you do not block/cover any of the system ventilation openings; any such blockage may cause system overheating.

NOTE:

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

1. Unlock both the front and back wheels in order to move the system.
   - Set the front wheel brake pedals to the middle position (**multi-directional**).
   - Set the rear wheel brake pedals to the upper position (**uni-directional**).
2. Move they system to the desired location. Verify that the Lumenis Pulse 60H laser console is a minimum of 50 centimeters (20 inches) from walls, furniture, or other equipment.
3. Lock all wheels by pressing the brake pedals down to the locked position.

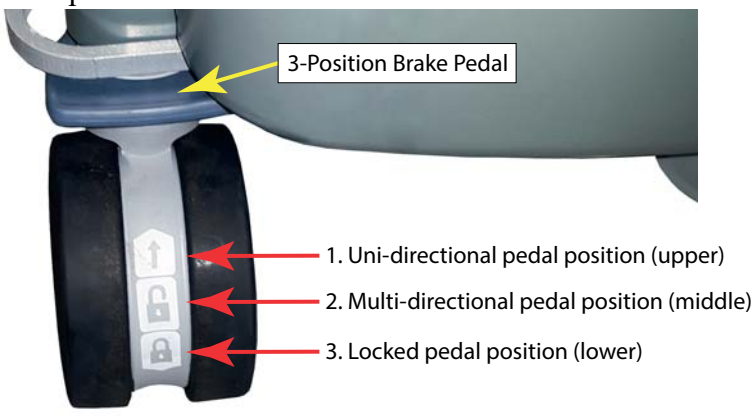


Figure 5: Brake Pedal Configurations

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.

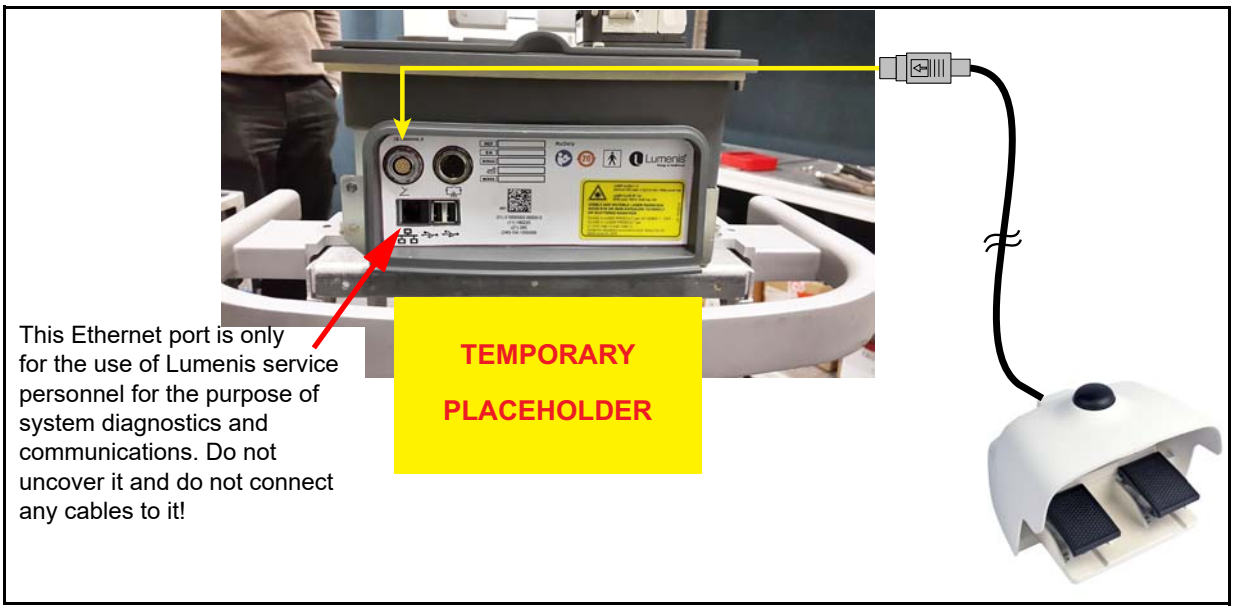


Figure 6: Connecting the Dual-Pedal Footswitch

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 if the operating room doors are opened or the external door interlock connector is disconnected while the laser system is lasing.

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.

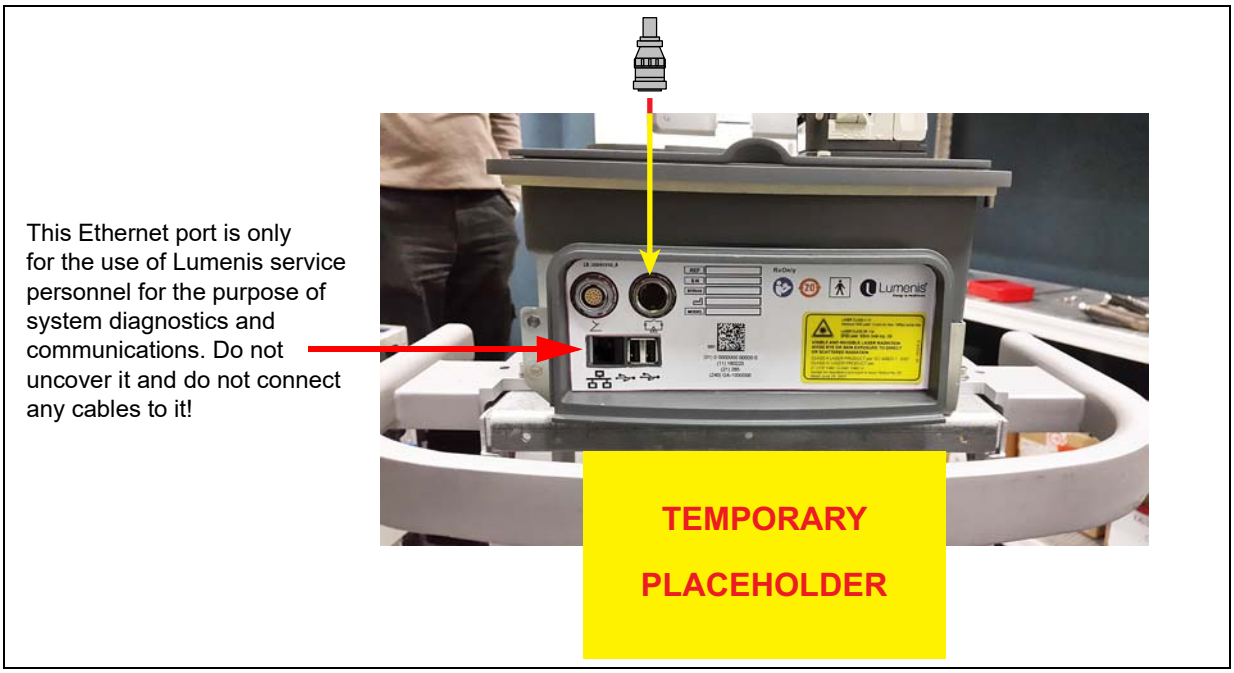


Figure 7: Connect the External Door Interlock Connector

Plugging in the Mains Power Cable

1. Ensure that the laser system's main power circuit breaker is in the off (down) position.

2. Insert the laser system's mains 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.

3. Turn on the laser system's mains power circuit breaker (up position).

CAUTION:

Ensure that the Lumenis P60H laser system is positioned such that the main power plug will be easily accessible.

WARNING:

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

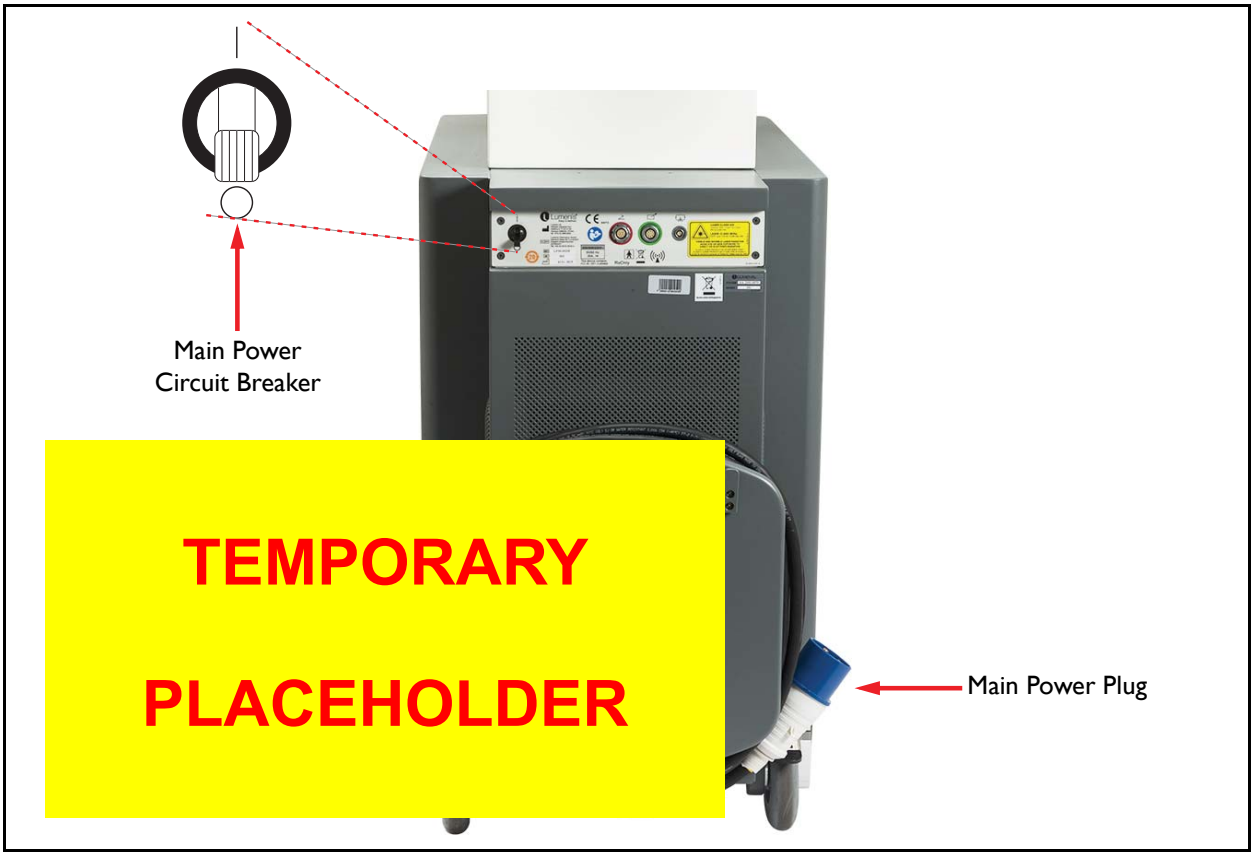


Figure 8: Main On/Off switch and Main Power Plug

Installing the Fiber Arm Support[1]

If the fiber arm support assembly was delivered with the system, install it by following these steps:

1. Remove the plastic cap from the arm port on the top panel of the system's console.
2. Take the arm adapter from the kit and screw it into the arm port (**A**).
3. Insert threaded knob (**B**) on to the proximal end of the articulated fiber arm (**C**) into the adapter (already in the arm port). Press it all the way in.

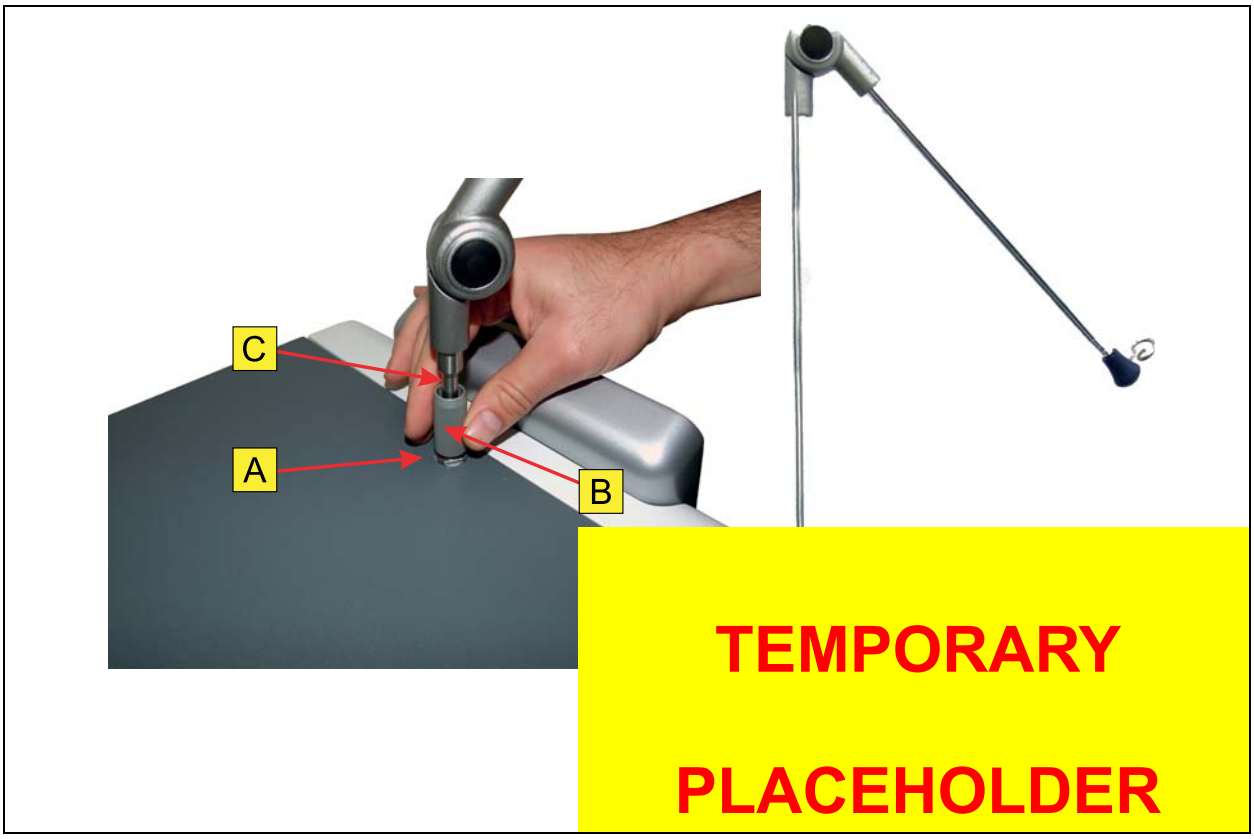


Figure 9: Installing the Fiber Support Arm

1. Optional purchase equipment, to be installed only by Lumenis-certified service technicians.

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 or jeopardize safe operation, 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.
- Always check the expiration date on the optical fiber packaging; do not use an optical fiber whose expiration date has passed.

NOTE:

SIS (Secure Identification System) enabled Lumenis Pulse 60H laser system 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. Ensure that the laser system is set to Standby mode when connecting/ replacing a fiber
2. 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.

3. The scrub nurse hands off the laser connector to the circulating nurse while securing the distal tip of the fiber in the sterile field.

4. The circulating nurse removes the protective cap from the fiber's connector and from the system's connection port.

5. 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.

6. The circulating nurse sterilizes the loop at the distal end of the articulated fiber arm (if available) and the scrub nurse threads the distal end of the fiber through the loop.

Figure 10: 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 60H laser system will only operate with Lumenis-qualified SIS (Secure Identification System) optical fibers. Attaching any other type of fiber will disable laser emission.

Connecting the Suction System[1]

The surgeon may use the Lumenis Pulse 60H laser's built-in suction system to remove tissue, liquids, stones or other debris into the collection container. The Lumenis-supplied disposables required for this are:

- Collection container kit.
- Sterile aspiration tube.
- Non-sterile drainage tube.

CAUTION:

Use only disposable accessories supplied by Lumenis. Non others are authorized for use.

1. Insert a new collection container into the designed holder in the laser system.
2. The circulating nurse connects one side of a non-sterile drainage tube to the collection container's **Outlet** port. Connect the other side to the operating room's hazardous waste container.

WARNING:

Ensure that the operating room's hazardous waste container (not supplied by Lumenis) is made of non-conductive material.

3. The scrub nurse connects one side of the sterile aspiration tube to the sterile surgical accessory while keeping it in the sterile field.
4. The scrub nurse hands off the other side of the sterile aspiration tube to circulating nurse. The circulating nurse connects this side of the tube to the collection container's **Inlet** port.

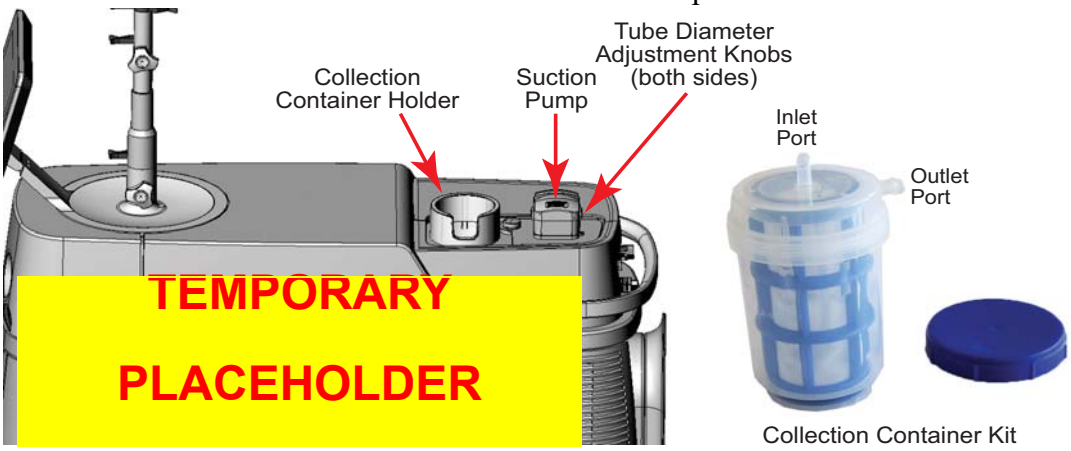


Figure 11: Suction System

1. Optional purchase equipment, to be installed only by Lumenis-certified service technicians.

5. Pull open the suction pump.

Figure 12: Pulling open the Suction Pump

6. Insert the drainage tube into the channel in the suction pump.

7. Set the system's suction pump to the correct drainage tube's inner diameter: pull open the suction pump. Using the adjustment wheels on both sides of the suction pump (**1**), adjust the inner diameter of the suction tube (**2**) to 6.4 mm. Insert the drainage tube as instructed in the following steps.

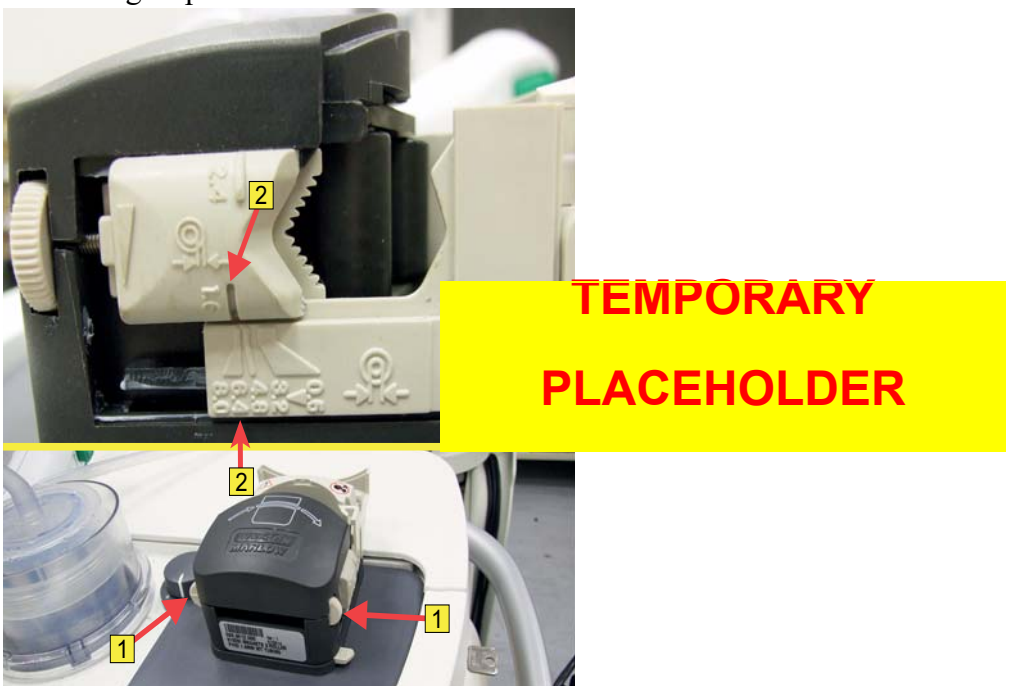


Figure 13: Adjusting the Suction System to the Drainage Tube's Inner Diameter and Wall Thickness

WARNING:

Aspiration flows in the direction of the arrow on the pump head. Always verify that the drainage tube is loaded in the required direction.

Figure 14: Directional Arrow for the Aspiration Tube

8. Route the drainage tube through the suction pump as shown in Figure 14 and connect it to the outlet port of the collection container.

9. Close the suction pump until you feel it 'snap' into place.

10. Adjust the suction rate on the control panel.

If the suction system does not function properly, or does not operate at all, a warning to this effect will be indicated on the display. The laser system may still be used without suction.

NOTE:

The storage drawer adjacent to the suction system is designed to hold two spare blast shields and laser safety glasses.

Main System Screens

Home Screen Description

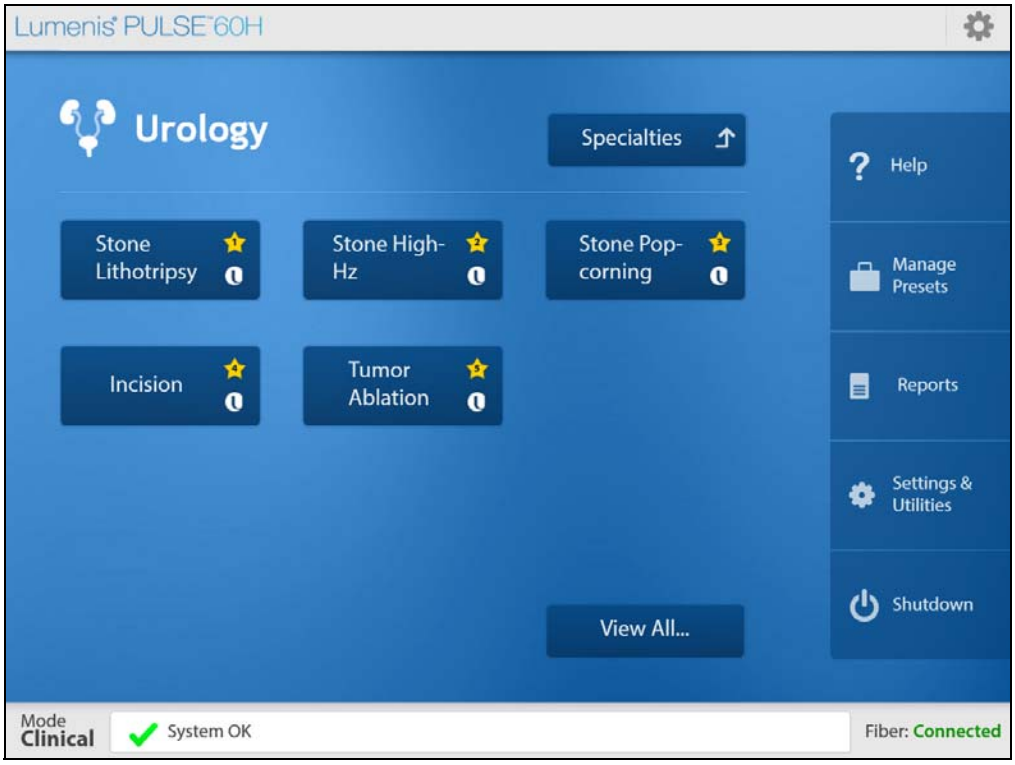


Figure 15: Home Screen

The elements of the **Home** screen are detailed as follows (the numbered arrows in Figure 16 correlate to the numbered steps below):

Figure 16: Home Screen Legend

1. Specialty – Identifies the currently-selected surgical specialty. This can be set as a default specialty in the Settings and Utilities screen.

2. **Specialties** – Press this button to access the **Other Specialties** screen. Here you may select another surgical specialty.

3. Utilities Cogwheel – Press this icon to access **Quick Settings**, **Help**, **About** and system **Shutdown**.

4. **Help** – Press this button to access the system's software help utility.

5. **Manage Presets** – Press this button to access the Presets Management screen. Here you may create new presets with your proprietary names and parameter protocols, or edit existing ones.

6. **Reports** – Press this button to access the Reports and Treatment Logs screen. On this screen you may view the treatment logs of the procedures performed by the system. The logs can also be exported a USB mass storage device (disk-on-key).

7. **Settings & Utilities** – Press this button to access the Settings and Utilities screen. Here you may configure or re- configure several of the system's functional utilities.

8. **Shutdown** – Press this button to perform an orderly shutdown of the system.

9. **Fiber** – Identifies the fiber connection status.

10. **Notification Bar** – Notifications and error messages will appear in this bar.

11. **Presets** – Lumenis Presets are hard-coded into the system software and are marked with the Lumenis logo. Hospital Presets are designed and entered to the system by the hospital's surgeons. Any settings entered or re-entered on the main Treatment screen during a procedure, may be saved and named as a Hospital Preset.

    The presets displayed on the **Home** screen are those defined as Favorites and are marked with a numbered star.

    Press the **View All…** button to display all of the available presets, not only those defined as Favorites.

    After you press the **Preset** button the system will transition to the **Main Treatment** screen.

Specialties Screen Description

Select the surgical specialty that best meets your needs. Presets are defined for each surgical specialty.

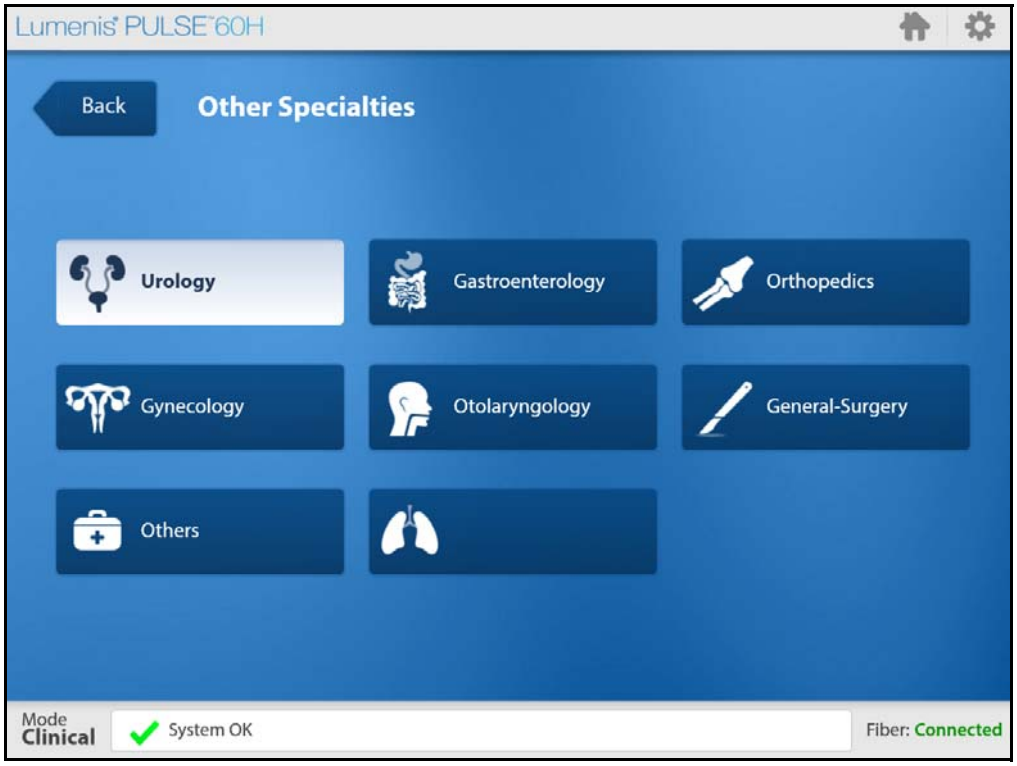


Figure 17: Specialties Screen

Treatment Screen Description

Figure 18: Treatment Screen

The elements of the **Treatment Settings** are detailed as follows (the numbered arrows in Figure 19 correlate to the numbered steps below):

Figure 19: Treatment Beam Delivery via Right or Left Pedals

1. **Specialty** and **Preset** - This displays the chosen specialty and preset the settings are based on. If you change the settings, the name of the preset will be displayed in italics and an asterisk will be added.
2. **Pedal Name** - This is the name of the settings chosen for each footswitch pedal. This name can be changed by editing the preset.
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.
4. **Aiming Beam** - This shows the selected aiming beam intensity: low, medium, or high. The aiming beam can also be set to **Blinking**.
   - At laser system turn on, the aiming beam setting defaults to the **Medium** level.
   - The aiming beam is automatically set to **Off** when no fiber is connected to the system.
   - Press the < or > button to adjust the aiming beam to a higher or lower intensity.

5. **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.
6. **Suction Control**[1] - The suction system is controlled from the set of three buttons at the bottom of the **Main Treatment** screen. By default, the suction system is **Off**:
   - **On** button active: suction operates constantly.
   - **Off** button active: suction remains off, even while the system is in **READY** mode.
   - **Auto** button active: suction will turn on and off simultaneously with lasing.

CAUTION:

The suction pump will not operate if the door is not closed properly. If the door is opened during operation suction will be set to **Off**. In order to resume operation set the suction mode to **On/Auto** mode.

7. **STANDBY/READY** mode selection - **STANDBY/READY** buttons determine whether pressing the footswitch will activate the laser (**READY** mode) or not (**STANDBY** mode):
   - A **READY** voice signal is generated when the system is transitioned to **READY** mode.
   - A **STANDBY** voice signal is generated when the system is transitioned to **STANDBY** mode.
   - The system will automatically transition from **READY** to **STANDBY** mode if the system is idle for more than 30 minutes.

WARNING:

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

1. Optional purchase equipment; consult with your Lumenis representative.

8. **Fiber Status Area** - Certain Lumenis SIS fiber delivery systems for the Lumenis Pulse 120H are designed to allow several surgical treatments, while others are limited to only one treatment. When a fiber is connected, the system immediately knows:
   - How many treatments have been performed with the fiber.
   - How many treatments are recommended before you replace the fiber.
   - If all allocated treatments are exhausted and the fiber is expired.
   - If the delivery system has any power limitations.

   Every time the fiber is connected to the system, the fiber status area will indicate the fiber mode. There are four fiber modes, color-coded according to the status:
   - **Normal mode** (green) – The fiber is working within operational limits.
   - **Grace mode** (orange) – You are advised to replace the fiber, because it exceeded recommended usage. However, you can continue to work. The **Fiber exceeded recommend # of uses. It is advised to replace the fiber** error message will also appear inside the notification bar.
   - **Fiber expired** (red) – You cannot work with this fiber. The **Fiber expired** recoverable error message will also appear inside the notification bar.
   - **Unrecognized Fiber** (red) – You cannot work with this fiber. The **Lumenis SIS fiber not detected** recoverable error message will also appear inside the notification bar.

By pressing the icon in the **Fiber Status Area**, additional information regarding the number of sessions used and the number of recommended sessions for the fiber in use will be displayed.

NOTE:

For detailed information on the number of treatments each Lumenis SIS fiber is designed to perform, refer to the instruction guide delivered with the fiber.

9. **Total Energy Indicator** - This indicator displays the total laser energy applied to the surgical site during the treatment procedure, calibrated in KiloJoules. Pressing the indicator on the main screen (see Figure 19) opens a Reset pop-up (shown on the left).
   - The total energy indicator should be reset to zero between patients, and:
   - When switching between preset modes (relevant for both pedals), including both Lumenis and user-generated presets.
   - The total energy displayed in the reports is not affected when resetting the total energy on the screen (reset dialog shown on left).

10. Recall Original Preset Parameters - If you changed the preset's operating parameters during the course of operation, you can press this icon to recall the all of the presets original parameters to the screen.

Laser Emission Indication

Lasing appears on the control screen and an audible signal sounds at all times during treatment to alert you that laser energy is being emitted. The audible signal is different for the right and left pedals.

Figure 20: Lasing Indicator

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 laser energy emission and operation of the suction system (see Figure 21).

NOTE:

When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits shut the system from the screen (or if not possible, by the front panel emergency stop switch). Only then, to completely power down the system set the laser system's main circuit breaker - located on the rear panel - to the **Off** position, and disconnect the mains power cable.

Figure 21: Controls for turning off the laser system

Safety Eyewear

Verify that all persons in the operating room are equipped with and wearing 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 Up the System

1. Set the laser system's main power circuit breaker (on the rear panel) to the **On** (up) position. There is a green LED adjacent to the power breaker that illuminates when the power breaker is turned on; this means that electrical power is being supplied to the system's modules.

2. A laser self-test and water temperature configuration routine (bringing the water to 5°C) begins. This routine may take up to ten minutes depending on the temperature of the water in the cooling system. When the routine is successfully completed, the **Login** screen displays on the control panel.

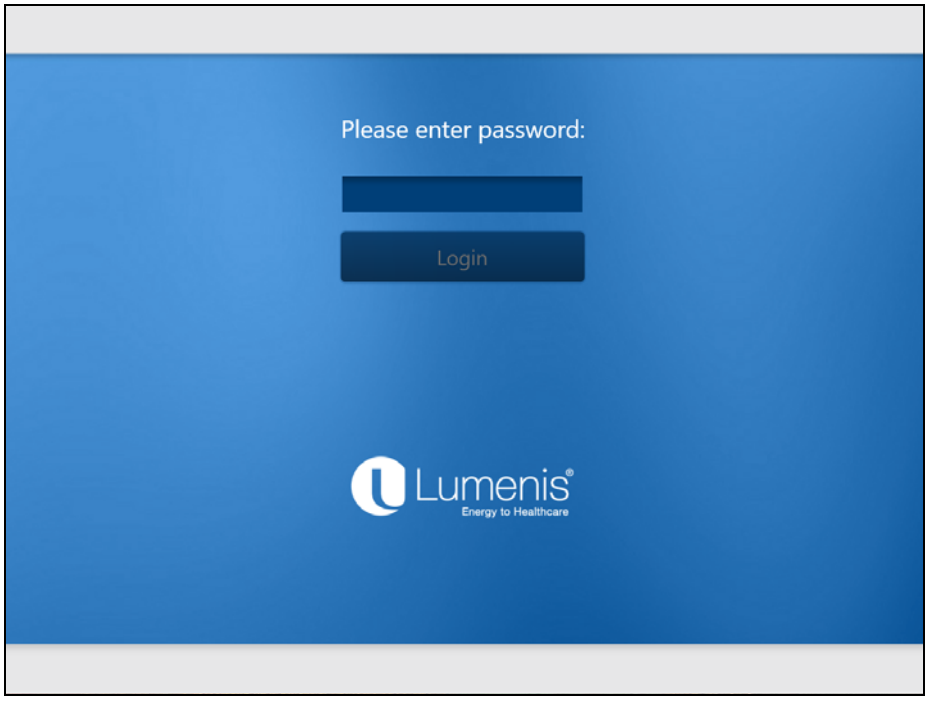


Figure 22: Login Screen

3. Press the empty field above the **Login** button; a virtual keyboard will appear. Type in the 4-digit password and press the green ✓ button on the keyboard.

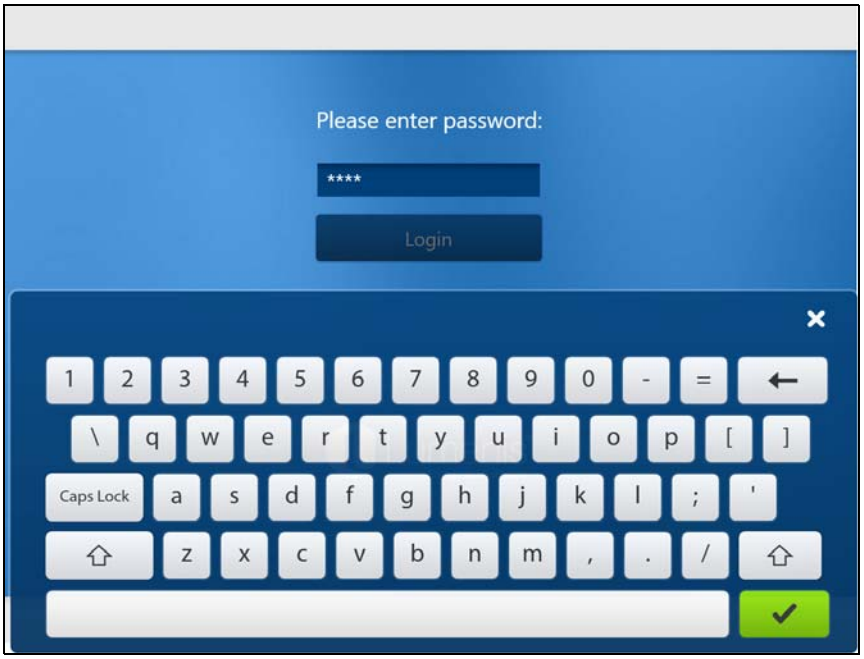


Figure 23: Login Keyboard

4. Press the **Login** button; the system will perform several more internal tests and then present the **Home** screen.

Figure 24: Home Screen

CAUTION:

- Power on the system and prepare it for operation well in advance of the scheduled surgical procedure, such that there will be sufficient time to troubleshoot any problems without disturbing the schedule of surgeries.
- Ensure that you do not block/cover any of the system ventilation openings; any such blockage may cause system overheating.
- 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.
- When you connect the system's power cable to the wall electrical socket (and before you come to turn the system on), you must ensure that the system is turned off. If it turns on by itself when connected discontinue use, disconnect from the wall socket and contact Lumenis Customer Service.
- If you attempt to turn the system off and it remains turned on, discontinue use, disconnect from the wall socket and contact Lumenis Customer Service

Restarting the Laser System

If it becomes necessary to restart the system:

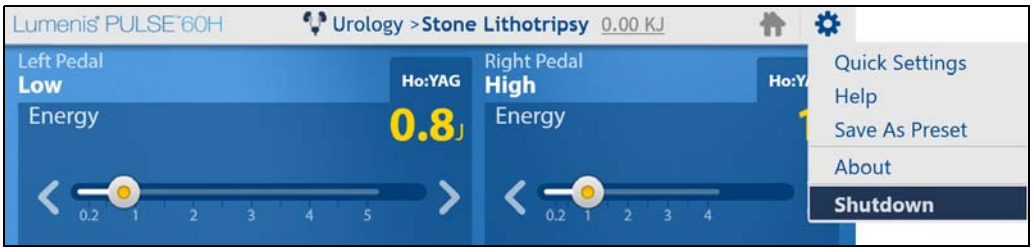


Figure 25: Shutting Down the System

1. Press the **Cogwheel** icon in the top-right corner of the screen, and then press the **Shutdown** option in the drop-down menu.
2. Power down the system by turning the main On/Off switch on the lower-rear panel to the Off position.
3. Wait 10 seconds and turn the main On/Off switch back on.
4. Power up the system by pressing the **Standby** button on the front panel.

Setting the Treatment Parameters and Controls

The **Home** screen appears on the control screen after Lumenis Pulse 60H is powered **On**, the self-test is successfully completed and you complete the **Login** procedure.

1. Verify that the correct specialty is selected.

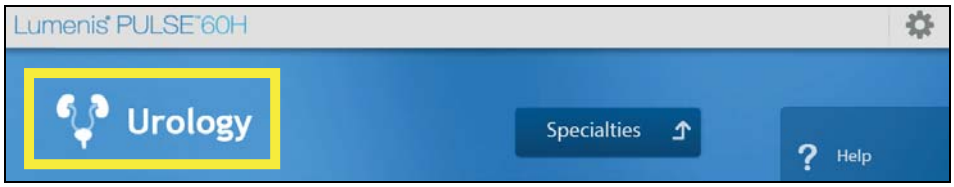


Figure 26: Location of the Specialty Selection

If you need to change the specialty, press **Specialties** and select the correct specialty.

2. Select the preset that most closely relates to the treatment.

   If the desired preset does not appear, press the "**View All...**" button.

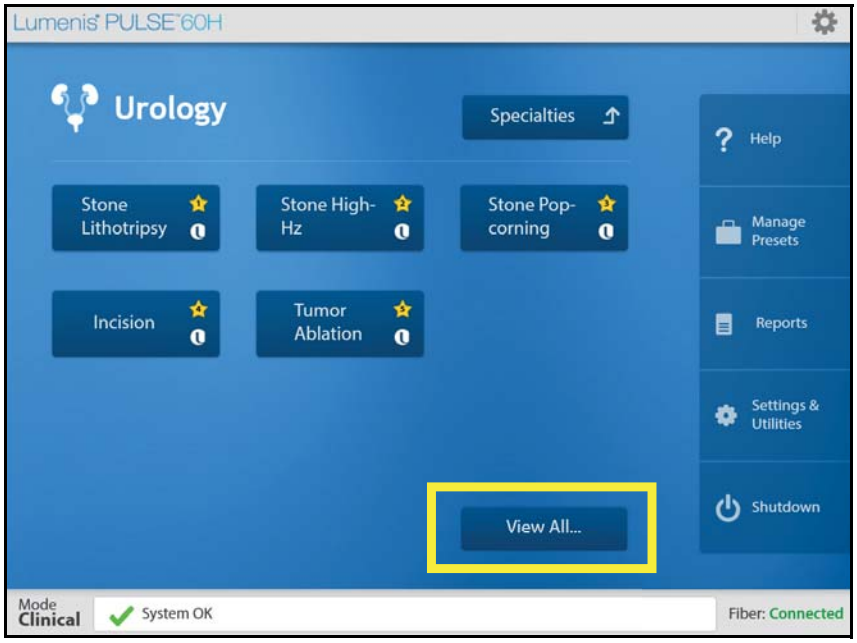


Figure 27: Location of the* View All... *Button

3. Verify that the parameters for the preset are correct for the treatment. Do not exceed the maximum energy or power settings for your delivery system, as specified in the instruction guide which accompanied that device.

WARNING:

Use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Incorrect treatment settings can cause serious tissue damage.

4. Edit the parameters if necessary. Parameters on each side of the screen can be updated independently. Parameters on the left side of the screen will be activated when you press the left footswitch pedal and vice-versa.

   - Refer to Figure 28: drag the slide bar buttons (**A**) or press the arrows to adjust the **Energy** and **Frequency** settings.

   - Press the < or > button (**B**) to toggle the **Pulse Width** between **Short**, **Medium** or **Long**.

NOTE:

The energy and frequency can be changed independently. However their maximum setting is related one to the other. This limitation will be reflected in the length of the highlighted bar.

NOTE:

Maximum energy and frequency may be limited for a specific SIS fiber delivery system.

   - **Power**: the output power display (**C**) ids a function of the energy and frequency settings; as you move these sliders you will see the power display (in Watts) changing.

5. **Aiming Beam**: press the < or > button (**D**) to toggle the aiming beam intensity; press the Blink button to toggle between a continuous aiming beam to a blinking one (during lasing).

6. **Suction**[1]: use these buttons (**E**) to switch between **Suction On**, **Suction Off**, or **Automatic** operation while the system is lasing.

7. In order to revert to the original presets, press the **Undo** button (**G**).

1. Optional purchase equipment, consult with your Lumenis representative.

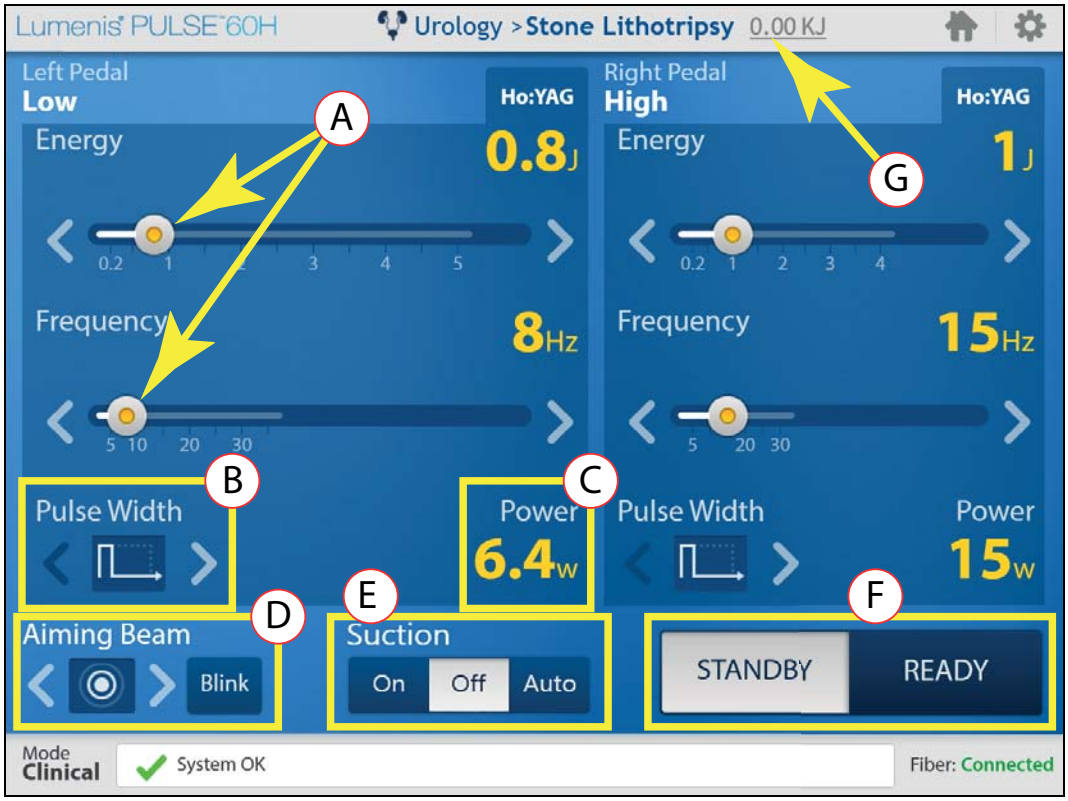


Figure 28: How to Change Treatment Settings

Starting the Laser Treatment

1. Turn on the aiming beam, and set it 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 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 delivery system laser connector are not damaged. Refer to “Inspect / Replace the Debris Shield” and the section in the appropriate delivery system instruction guide (look under “Inspect the laser connector”).

WARNING:

- Do not use the delivery system if the aiming beam is set to high intensity and is still weak or not visible; the fiber optic cable may be damaged. A damaged cable 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 or delivery system 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 or delivery system if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to non-target tissue and possible injury.

NOTE:

When using the delivery system 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. Position the aiming beam on the target tissue.
4. Press the **READY** button to switch to **READY** mode.

WARNING:

Always verify your parameter settings on the screen before setting the system to **READY** mode.

NOTE:

A **Ready** voice signal is generated when the system is transitioned to **Ready** mode. A **standby** voice signal is generated when the system is transitioned to **Standby** mode. The voice signals are generated in the language that was selected in the "Changing Language" section. The "Adjusting Volume and Sound" section describes how to adjust the volume or switch off the voice signals.

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

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

   As the laser delivers the treatment beam, **Lasing** appears 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.

7. Use the footpedal **Ready/Standby** button (on the top of the footswitch) to switch between **Ready** and **Standby** modes.

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

WARNING:

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

Operating in Moses Mode with Moses Fibers

Lumenis **Moses** fibers with SIS technology are designed to work with the Lumenis Pulse 60H configured to **Moses** mode. When a Moses fiber is connected to the system it will be recognized by the system and the Moses mode feature will be available to the user.

Selecting Moses Mode Treatment

Moses mode will be automatically appear on the Treatment screen once a **Moses** fiber is connected to the system.

Figure 29: Moses "A" mode control

- **Moses** mode is available for use either with the left or right pedal, independently, in short pulse width only.
- When the system is started, the default fiber default with is **Regular** (**Moses** mode off), using regular pulses.
- To use **Moses** mode, ensure that a Moses fiber is connected to the system and press the **Mode** button (see Figure 29).

When the system transitions from **Regular** pulse mode to **Moses** mode, it displays a pop-up note regarding the distance travelled by the laser pulses through water. Press **OK** to proceed.

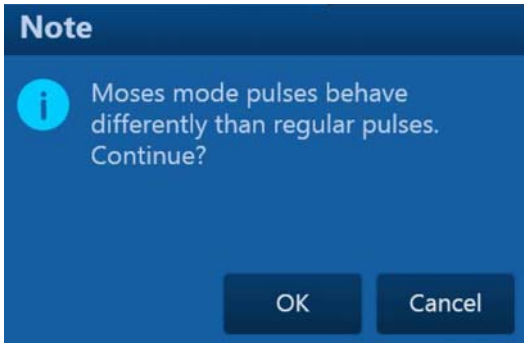


Figure 30: Moses mode pop-up note

For certain **Moses** fibers, two **Moses** mode settings are available, optimized for different tissue distance. This setting is selected by pressing the **Moses** mode button again.

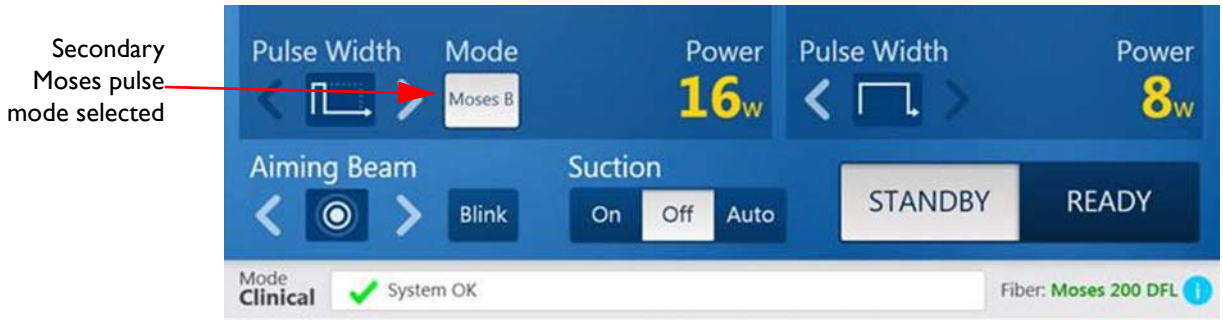


Figure 31: Moses Mode "B" selected

The **Mode** button on the screen is a toggle switch; every time you press it, it will transition between **Regular**, **Moses A** and **Moses B**.

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 frame appears around the appropriate footswitch settings area on the control screen, the animated lasing icon also appears 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 lasing.

   - The suction system will automatically stop if the **Suction Auto** button is pressed on the **Treatment** screen.

   - The suction system will **NOT** stop automatically if the **Suction On** button is pressed on the **Treatment** screen, the suction system will continue to operate regardless of the laser operation mode (**Standby**/**Ready**).

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. 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 fiber's instruction guide.
3. Fold down the fiber support arm (if installed on the system).
4. Set the laser system's main power circuit breaker to the Off (down) position.
5. Remove and process the suction system's collection container and tubes according to the hospital's bio-hazardous waste protocol.
6. Fold down the control panel if the system is going to be moved.
7. Remove the main power plug from the wall receptacle and wrap the power cable around the cable rack (see Figure 32).
8. Remove the footswitch connector from the laser system. and hang it from the footswitch storage mounts, if the system is going to be moved (see Figure 32).
9. Disconnect the remote interlock if the system is going to be moved.
10. Clean the exterior surfaces of the laser system.

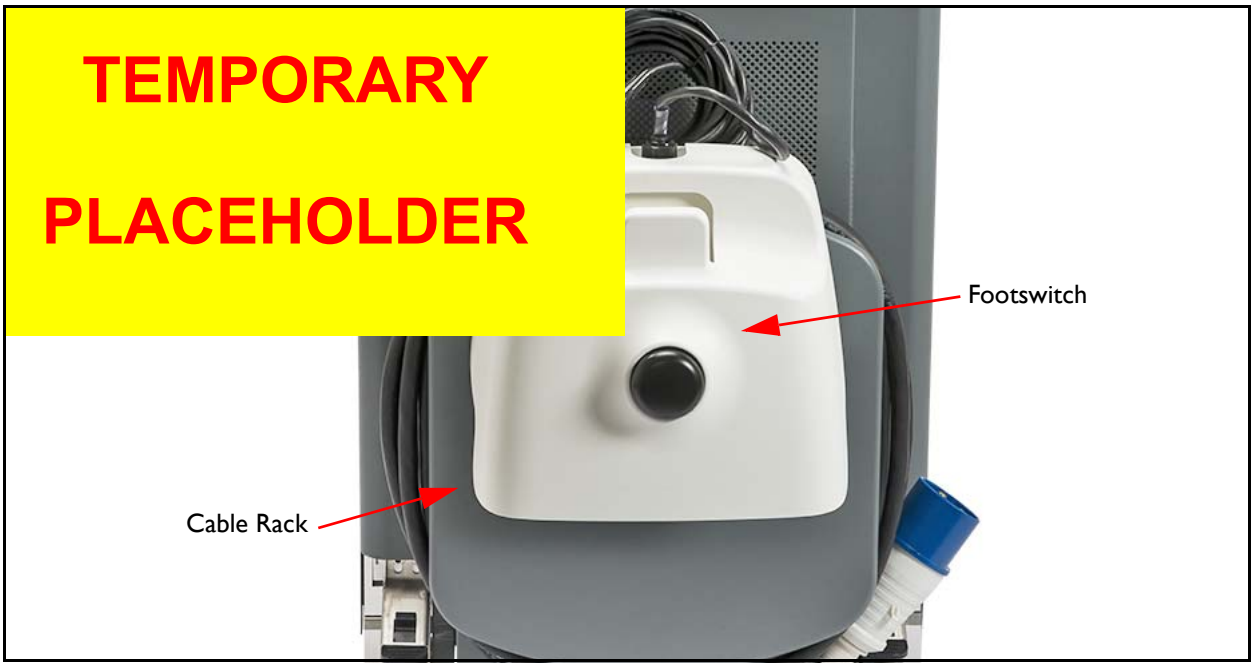


Figure 32: Laser Console Cable Rack and Footswitch Storage Mounts

Shutting Down the System

1. Press the main **On/Off** button and wait until the system powers down.

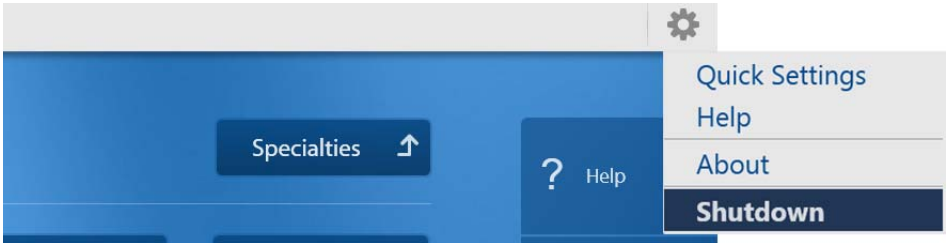
   - Normal System Shut-Down: Press the main **On/Off** button for one second (short press).
   - Forced System Shut-Down: Press the main **On/Off** button for at least five seconds (long press).

NOTE:

Use the Forced System Shut-Down method only when the system does not respond.

NOTE:

You can also perform a normal system shut-down from the control screen by selecting **Shutdown** from the cogwheel icon.



2. Disconnect the delivery system from the laser.

   - If the delivery system is single-use, discard it. If it is multiple-use, prepare the delivery system for reuse as instructed in the appropriate delivery system instruction guide.

3. Turn off the mains circuit breaker.
4. Remove the main power plug from the wall receptacle.
5. Remove the footswitch connector from the laser.

6. Wrap the power cable around the cable rack.

   - If you want to hang the footswitch on the laser console, wrap the power cable around the footswitch and hang it on the rear of the Lumenis Pulse 120H laser console.

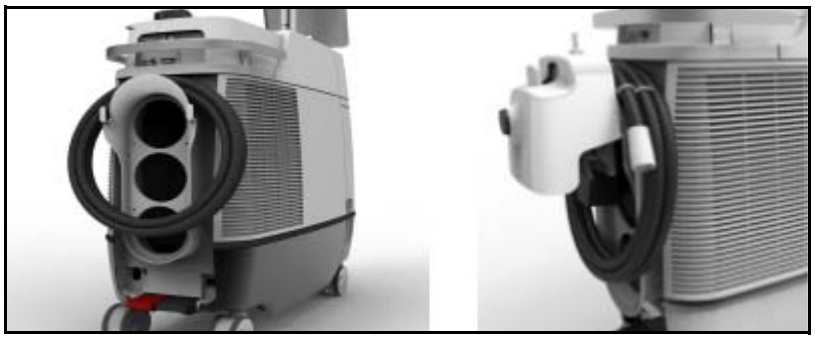


Figure 33: Power Cable on the Cable Rack

7. Disconnect the external door interlock.

8. Clean the exterior surfaces of the laser.

Advanced Operations

Saving Settings as Presets

Saving presets is performed from the **Main Treatment** screen. When changes are made to an existing preset from that screen, the preset will be in edited mode (fonts change and an asterisk appears). Then you can save these settings as a new preset.

1. From the **Treatment Menu** screen, press the cogwheel and select **Save As Preset**.

Figure 34: Save Settings as a Preset

2. Press inside the **Preset Name** field and type in the new name using the virtual keyboard. When you are done, press the green check mark key on the keyboard.

Figure 35: Editing the Preset Name

3. Press the **SAVE** button.

Figure 36: Saving the Preset

Preset Management

Introduction

The Lumenis Pulse 60H offers the use of predefined presets to select treatment parameters. Presets are divided into two groups:

System Presets (hard-coded into Lumenis Pulse 60H).

Hospital Presets (defined by the hospital staff).

The **Home** screen displays the presets that are defined as **Favorites**, which are marked with a star. Presets defined by hospital staff do not contain this mark.

You can save any settings defined on the **Treatment** screen during a procedure as a **Hospital Preset**.

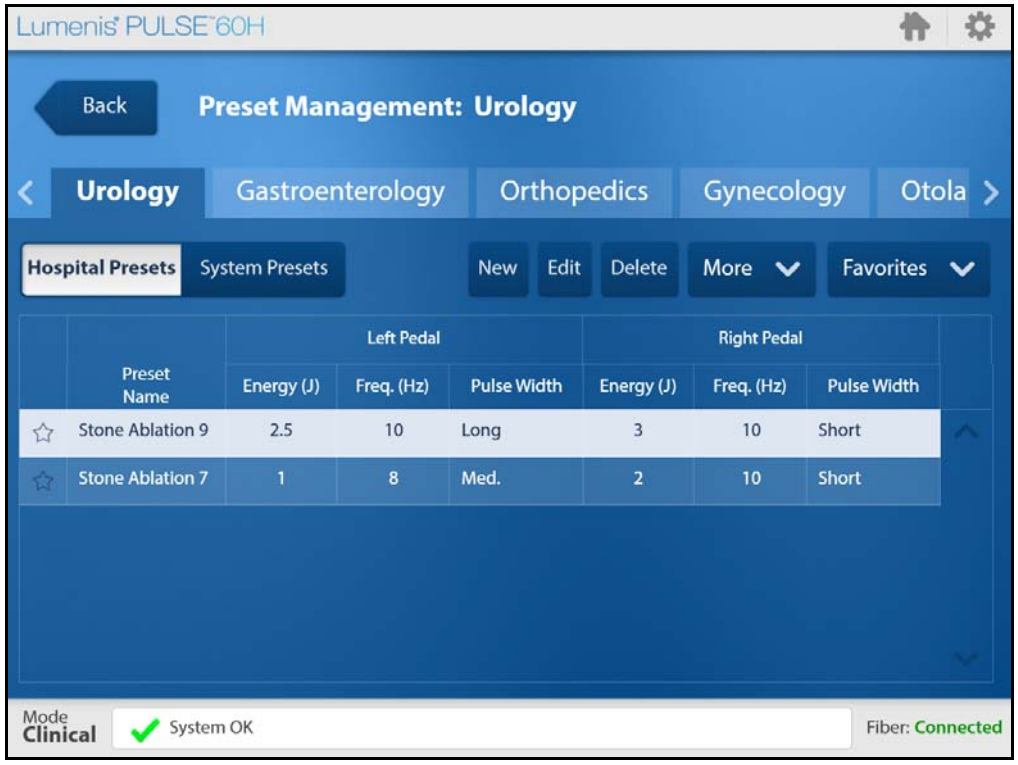


Figure 37: Manage Presets Screen

Choosing Presets

On the **Home** screen, press the **View All…** button to display all of the available presets, not only those defined as **Favorites**. The presets are organized in two groups: **System Presets** and **Hospital Presets**.

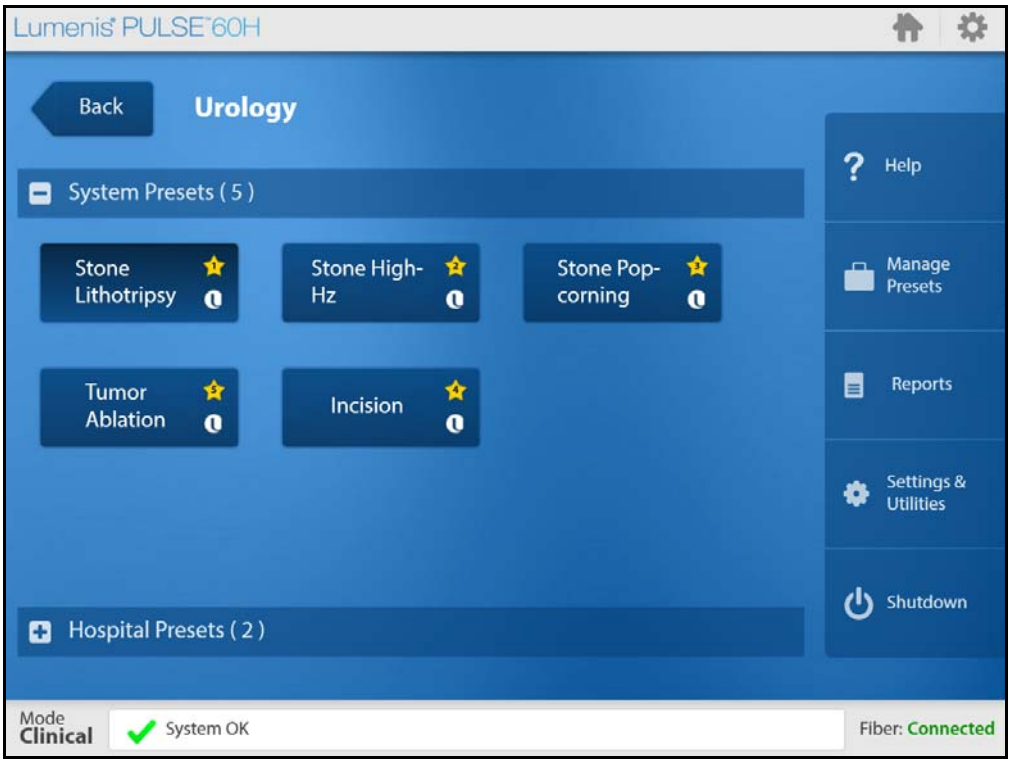


Figure 38: View All Presets - Tree Closed

To open the list of a preset group, press the + sign. If all of the presets do not fit into the screen, a scroll bar appears to the right of the preset group.

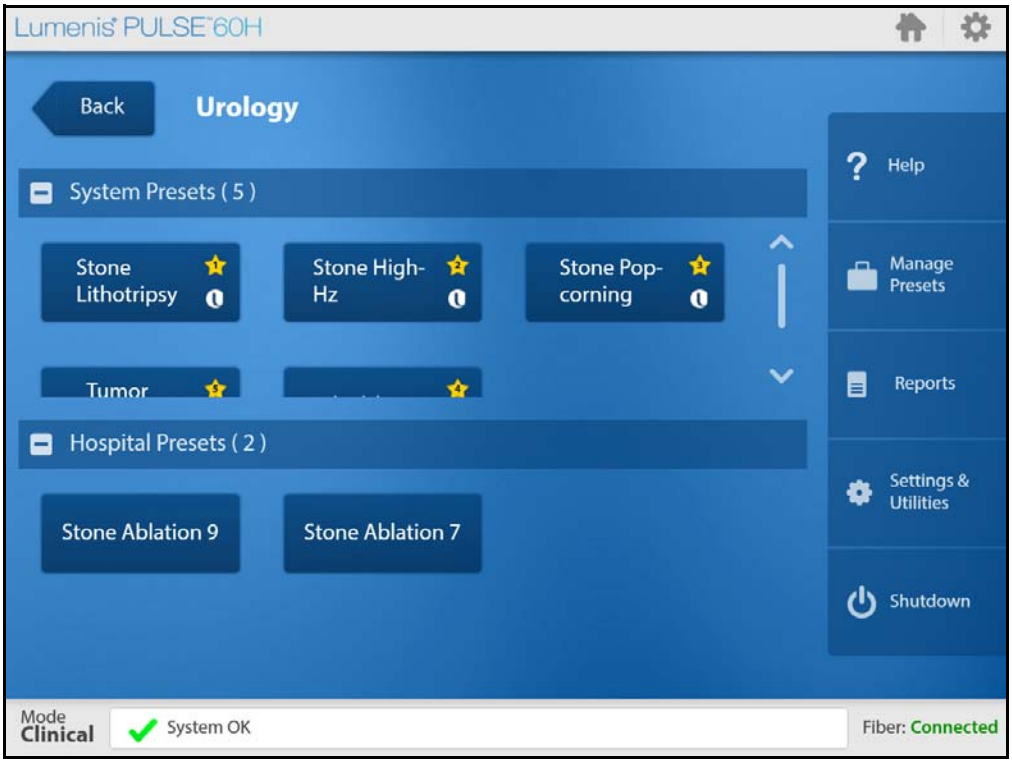


Figure 39: View All Presets - Tree Expanded

After you press the **Preset** button, the system will transition to the appropriate **Treatment** screen.

Creating New Presets

1. From the **Home** screen, press **Manage Presets**.
2. Press the **New** button.

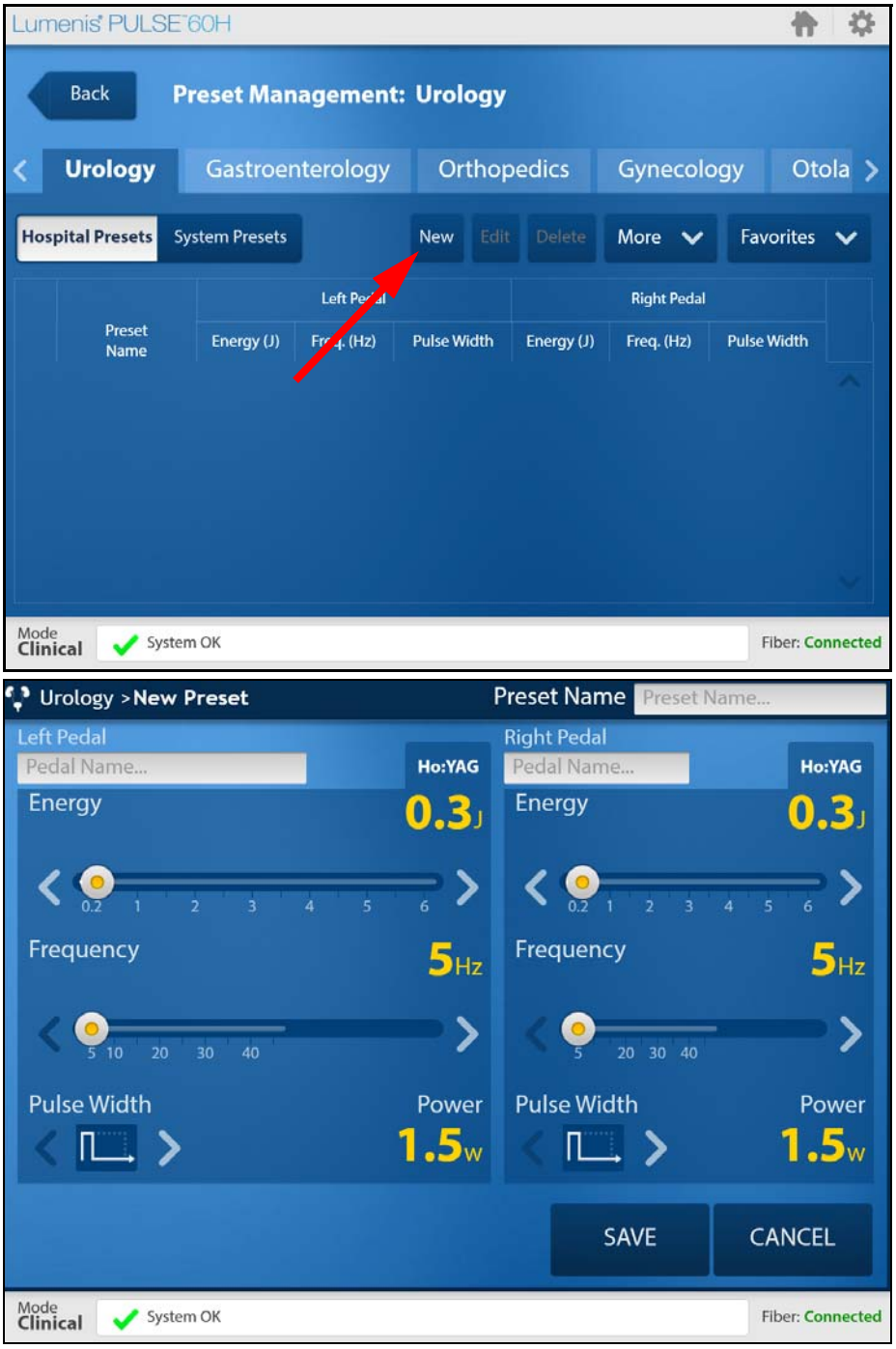


Figure 40: Creating a New Preset

3. In the **New Preset** screen, create the names and settings that you want.

Figure 41: New Preset Screen

4. Edit the **Preset Name** and the names of operations performed by each footswitch pedal.When you press inside a text field, a virtual keyboard pops up.

5. Press **SAVE**.

Editing Presets

You can only edit hospital presets. To create a new preset based on an system preset, first duplicate the preset, then edit it.

1. From the **Home** screen, press **Manage Presets**.
2. Press the **Hospital Presets** button.
3. Select anywhere on the row for the preset that you want to edit.

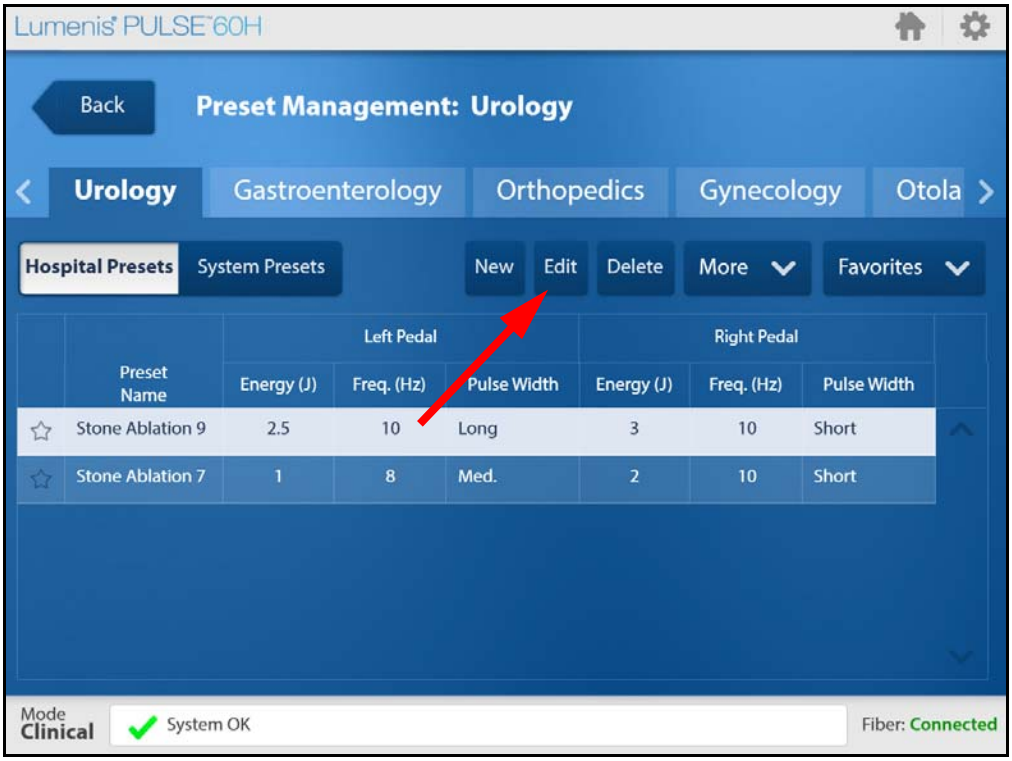


Figure 42: Manage Presets Screen

4. Press the **Edit** button.

5. In the **Edit Preset** screen, create the names and settings that you want. When you press inside a text field, a virtual keyboard pops up.

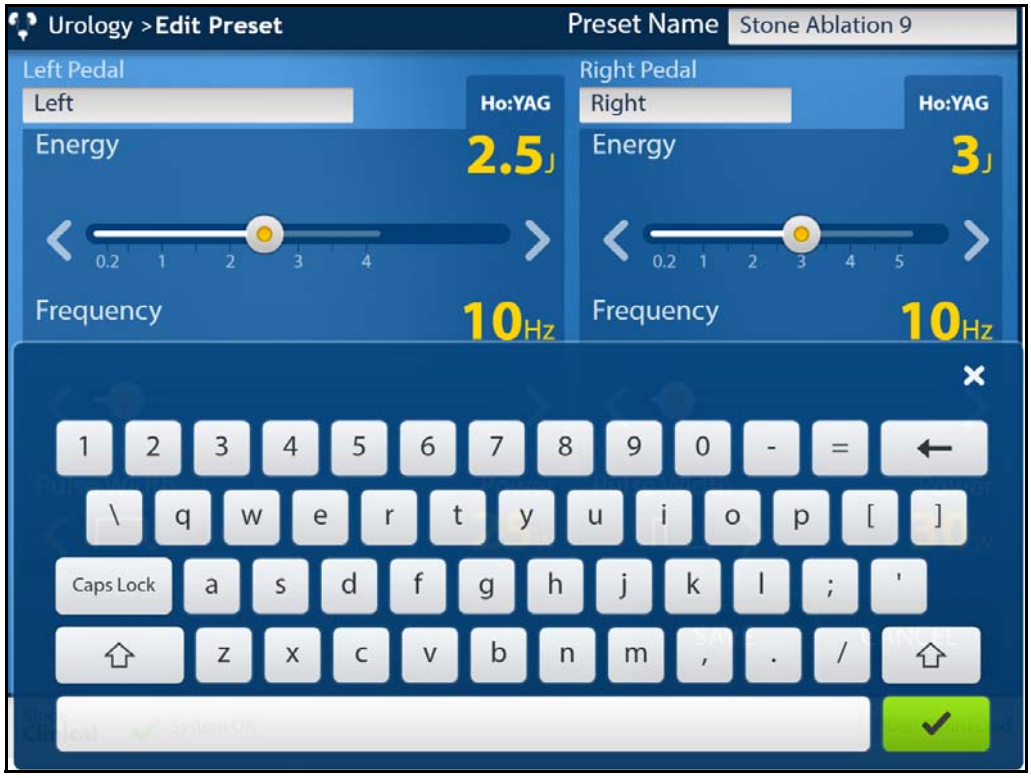


Figure 43: Edit Preset Screen (With Keyboard Visible)

6. Press **SAVE**.

Duplicating Presets

1. From the **Home** screen, press **Manage Presets**.
2. Select anywhere on the row for the preset that you want to duplicate. If you don't see the preset, press **Hospital Presets** button.
3. Press the **More** button and select **Duplicate** from the dropdown menu.

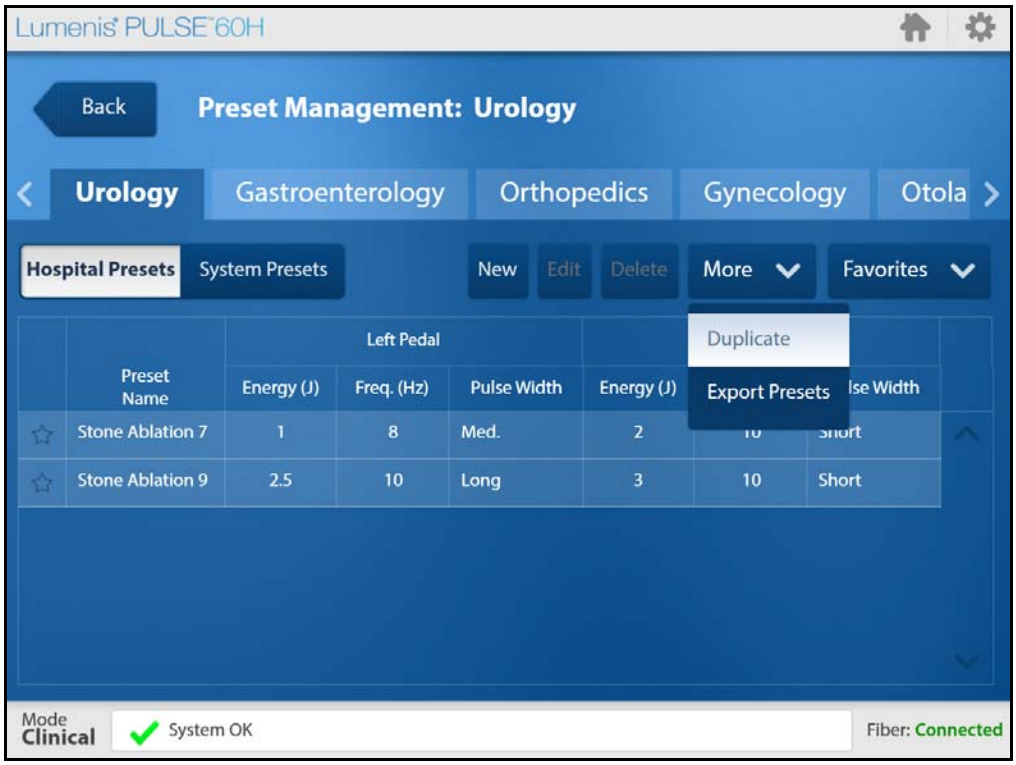


Figure 44: Manage Presets > More >Duplicate

4. The duplicated preset automatically appears with the **Copy_** prefix under **Hospital Presets**.

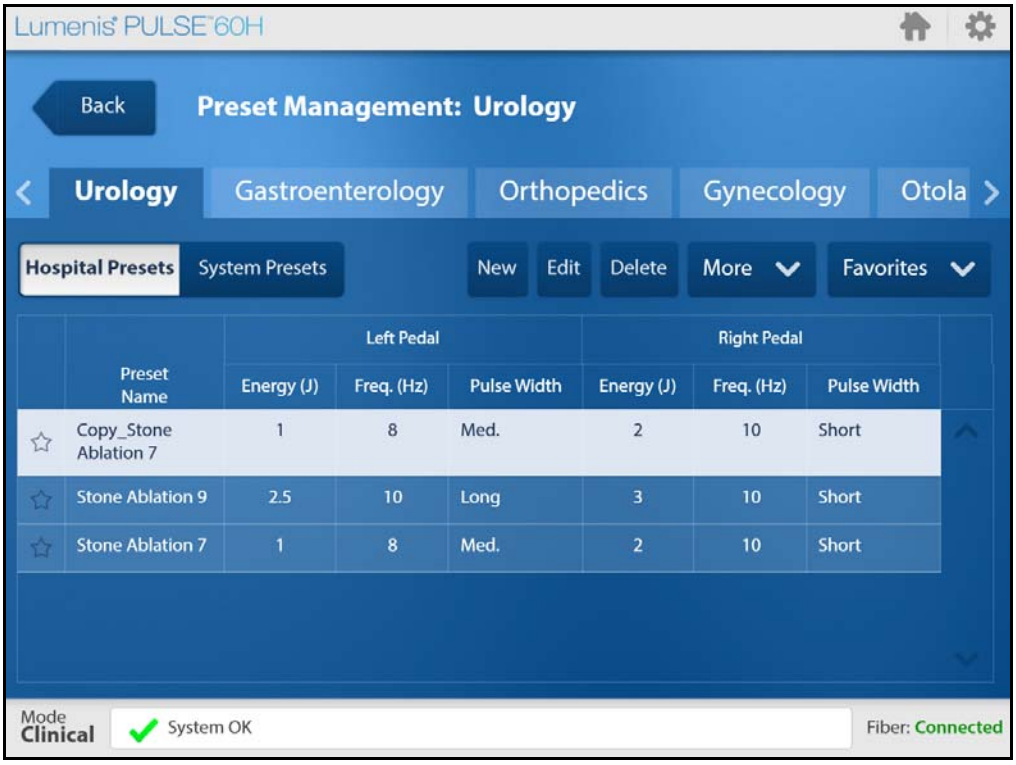


Figure 45: Preset Screen (With a Duplicated Preset)

Deleting Presets

You can only delete hospital presets. You cannot delete system presets.

1. From the **Home** screen, press **Manage Presets**.
2. Press the **Hospital Presets** button.
3. Select anywhere on the row for the preset that you want to delete.

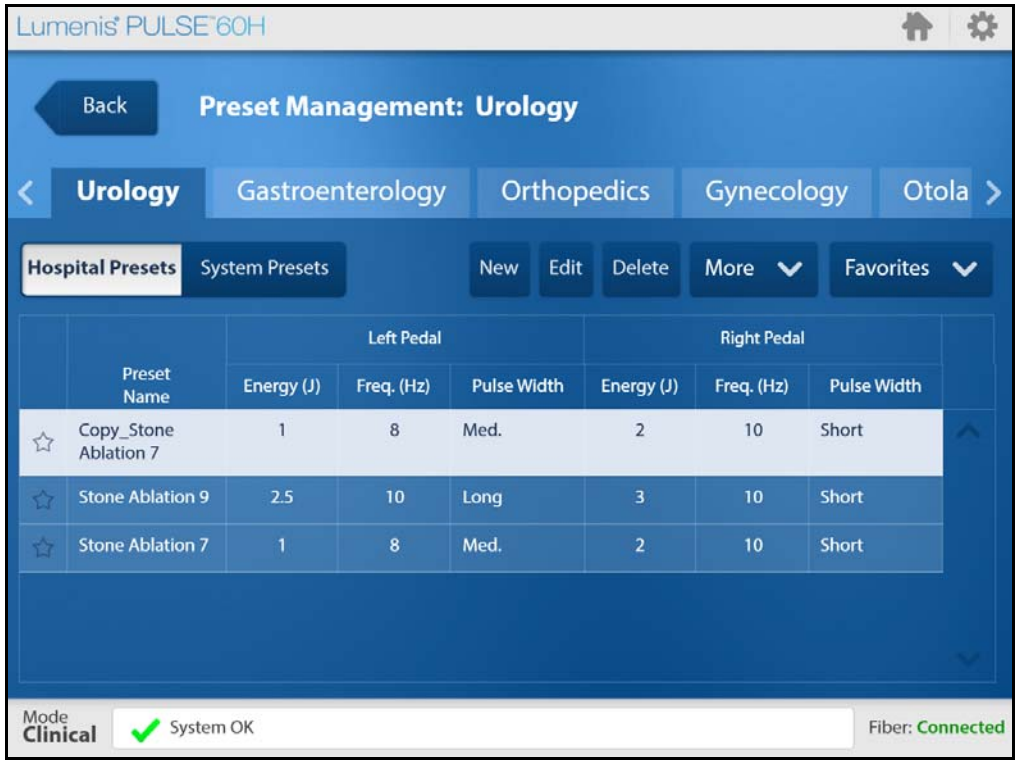


Figure 46: Manage Presets Screen

4. Press the **Delete** button.
5. In the **Delete Preset** confirmation screen, press **Yes**.

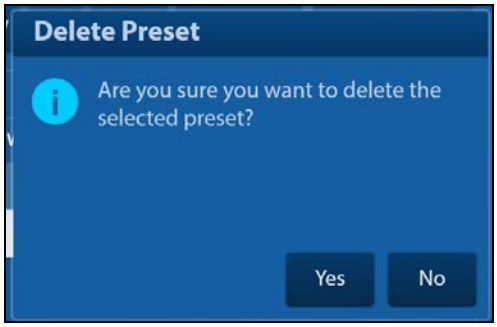


Figure 47: Delete Preset Confirmation Screen

Exporting Presets

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 60H.
2. From the **Home** screen, press **Manage Presets**.
3. Select anywhere on the row for the preset that you want to export. If you don't see the preset, press **Hospital Presets** button.
4. Press the **More** button and select **Export Presets** from the dropdown menu.

Figure 48: Manage Presets > More >Export Presets

5. In the **Export data to USB** menu, press **OK**.

6. Wait until the export operation is completed successfully.

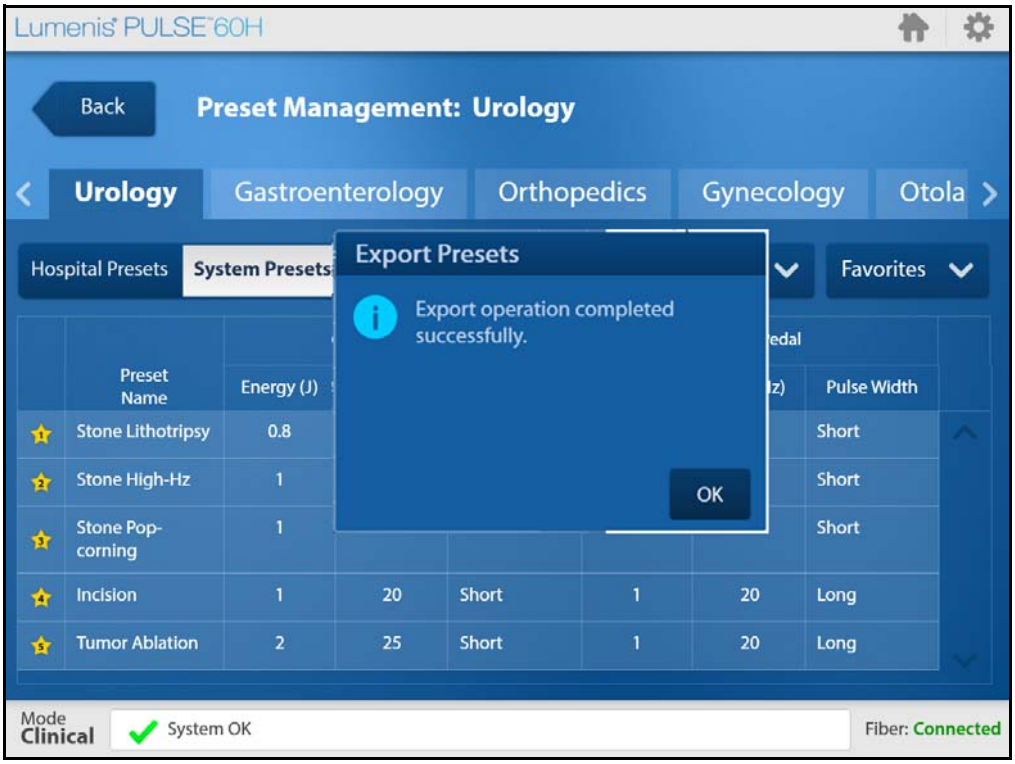


Figure 49: Export Operation Completed

Favorites

Every specialty has its own favorite presets that you can select directly from the **Home** screen.

Changing the Favorite Presets (Add, Remove and Reorder)

The **Home** screen has positions for nine favorite presets. You can place any preset in each of the 9 positions.

1. From the **Home** screen, press **Manage Presets**.
2. From the **Manage Presets** screen, press **Favorites** and select **Manage** from the dropdown menu.

Figure 50: Select Favorites > Manage

3. To add an existing, non-favorite preset to your list of favorites, press the **Add a favorite** button.

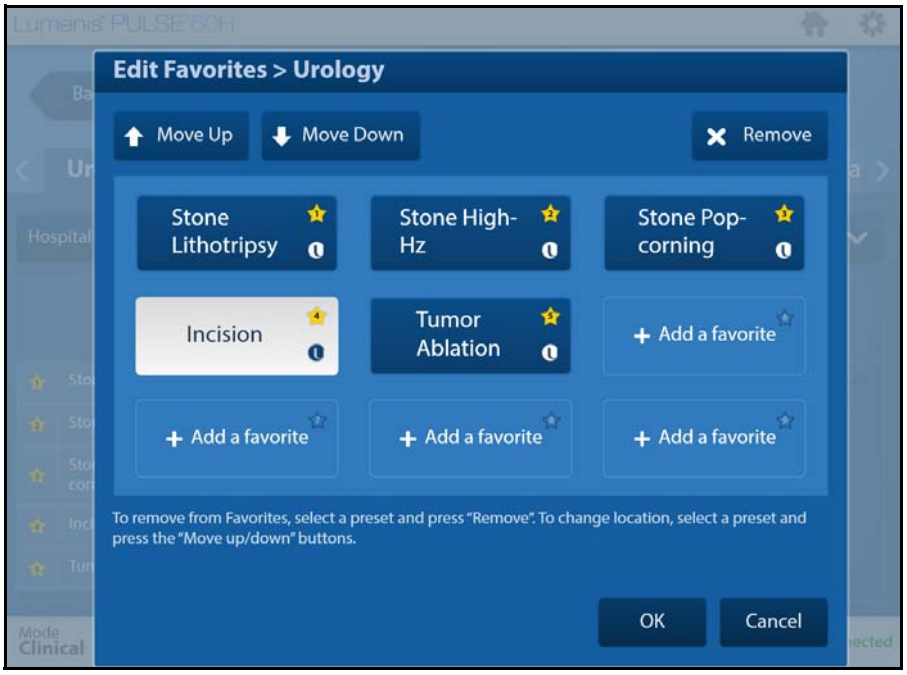


Figure 51: Select Favorites > Manage

4. Press a non-favorite preset to select it. Press the **Add** button to add it to the favorites.

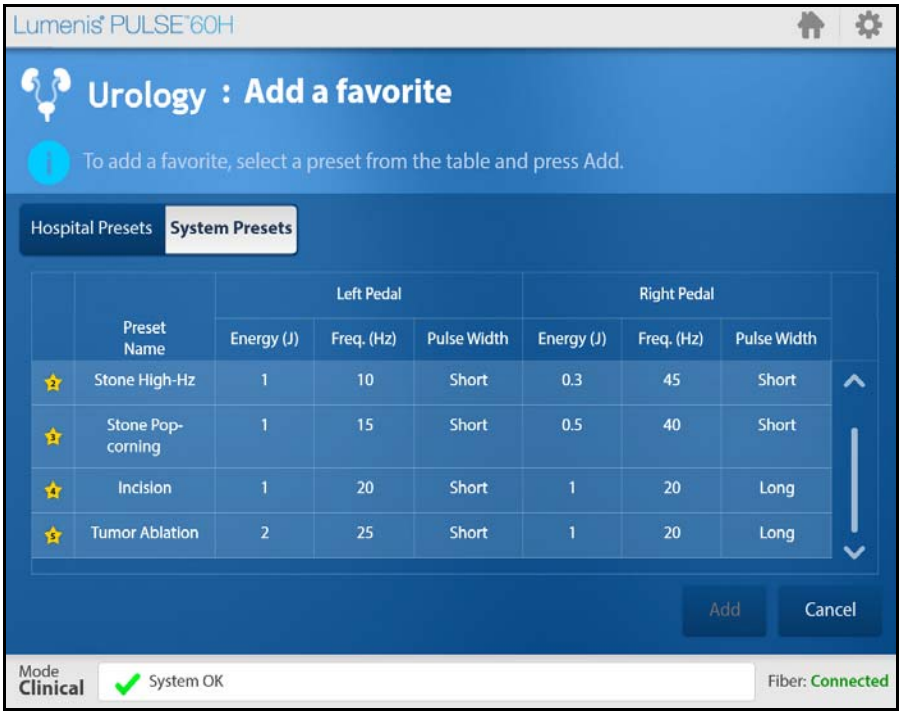


Figure 52: Add a Favorite Screen

5. Press the **Move Up** or **Move Down** button to position the new favorite in the desired spot (number) in the list.

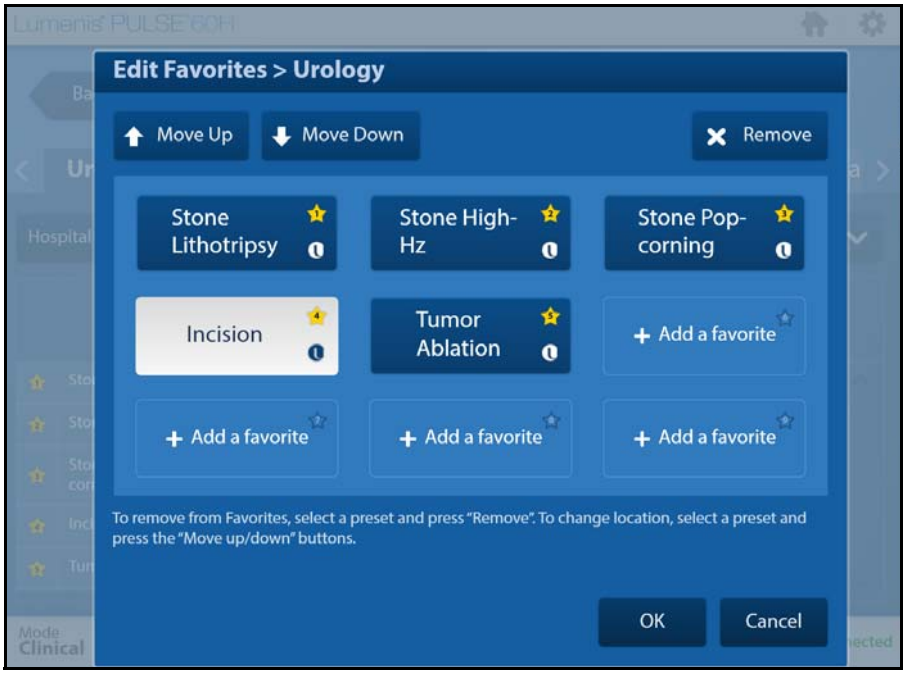


Figure 53: New Preset Added to Favorites

6. Press **OK** to save the new **Preset** to the **Favorites**.

7. **Press** Cancel to exit without making any changes to the **Favorites**.

Favorite: Quick Add

The **Home** screen has positions for 9 favorite presets. You can place any preset in each of the 9 positions.

1. From the **Home** screen, press **Manage Presets**.
2. Select a preset with an empty star.
3. Press **Favorites** and select **Add to Favorites** from the dropdown menu.

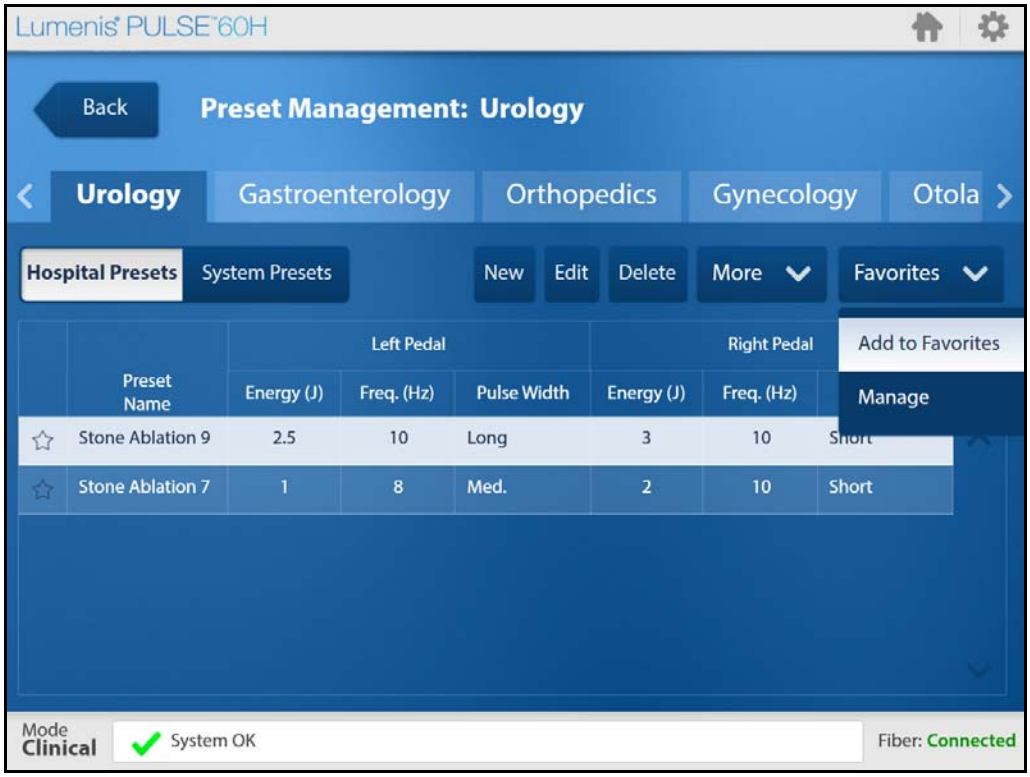


Figure 54: Quick Add a Favorite

Favorite: Quick Remove

The **Home** screen has positions for 9 favorite presets. You can place any preset in each of the 9 positions.

1. From the **Home** screen, press **Manage Presets**.
2. Select a preset with a yellow star.
3. Press **Favorites** and select **Remove Favorite** from the dropdown menu.

Figure 55: Quick Remove a Favorite

Reports

Lumenis Pulse 60H automatically generates a report of each treatment.

1. To view a summary of the reports listed in chronological order with the most recent treatment on top; from the **Home** screen, press the **Reports** button.

2. You can export the reports as log files, for more detailed analysis, to a USB storage device.

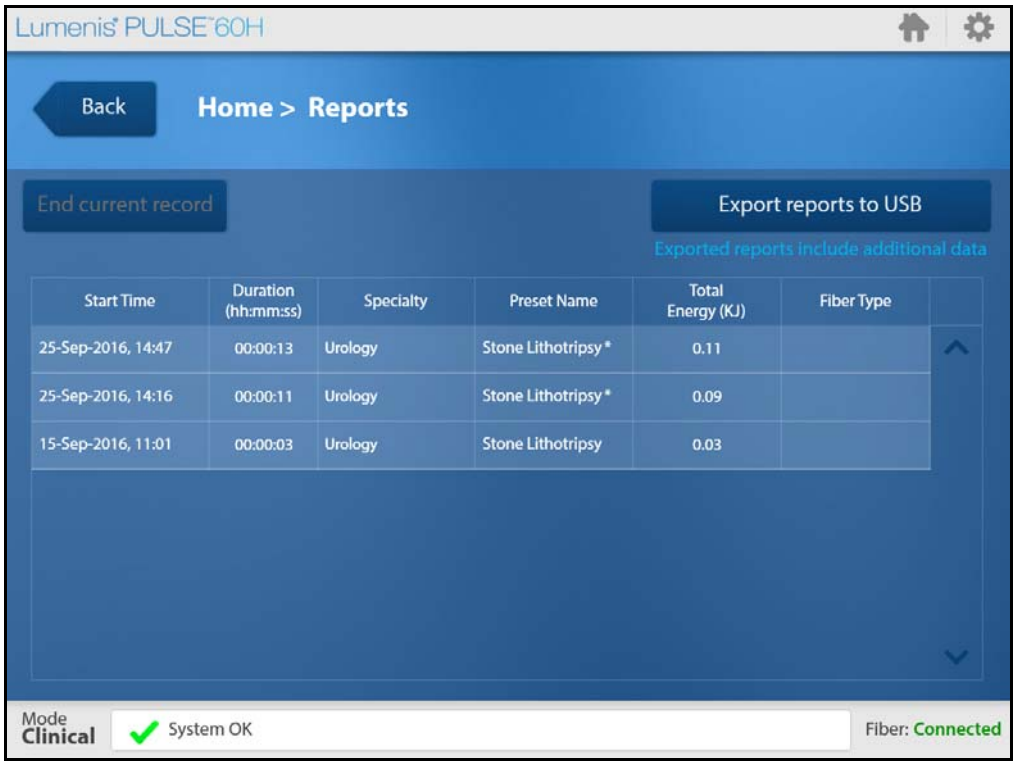


Figure 56: Reports Screen

Exporting the Reports

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 60H.
2. From the **Home** screen, press the **Reports** button.
3. Press the **Export reports to USB** button.
4. In the **Export Reports** confirmation screen, press **OK**.

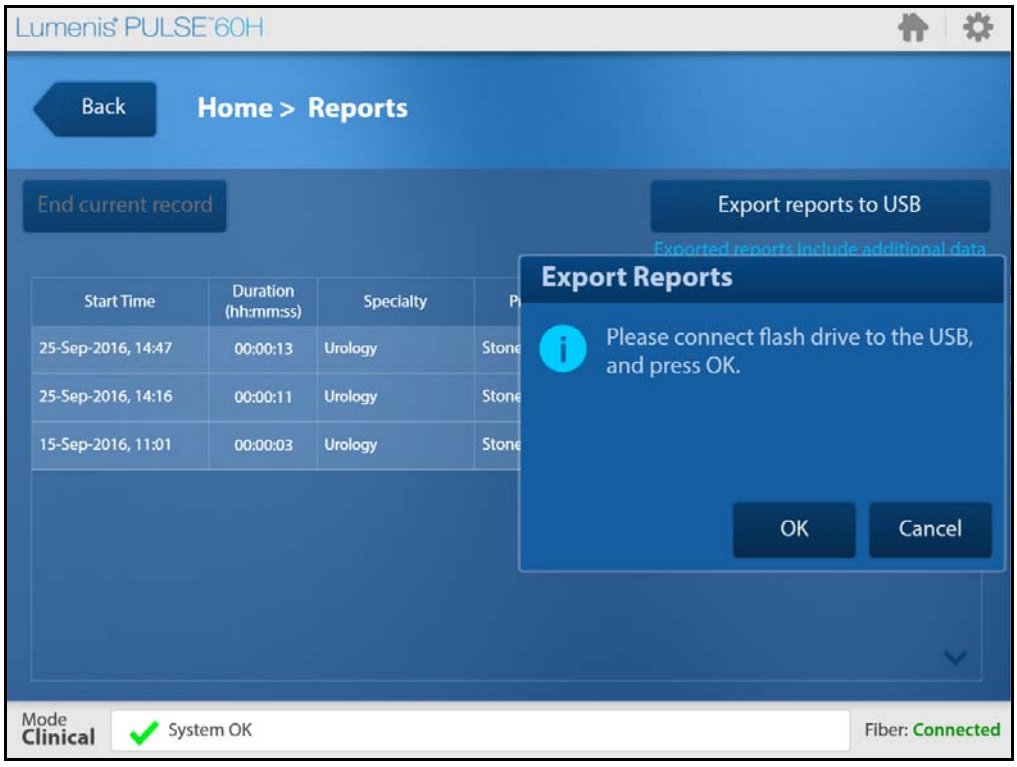


Figure 57: Reports Export Confirmation Screen

5. Wait until the export operation is completed successfully and press the **OK** button.

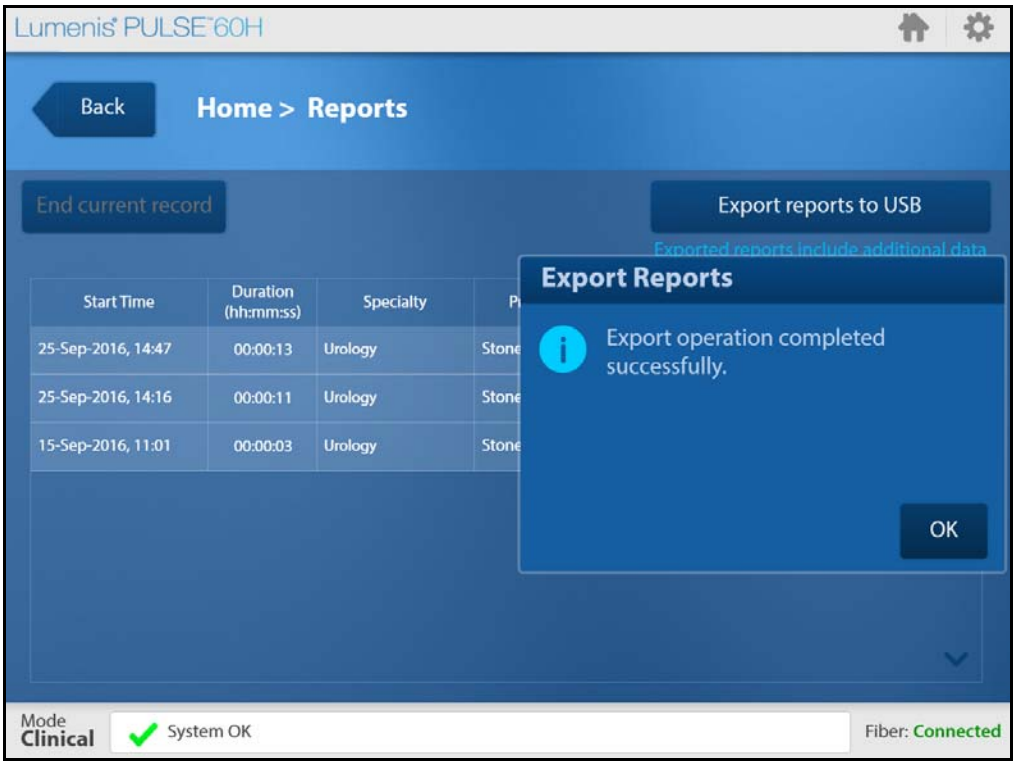


Figure 58: Reports Export Operation Completed

Date(MM/dd/yyyy)	Start time	Preset Name	Lasing Duration: (hh:mm:ss)	Total Energy(KJ)	Fiber type	Suction modes used	Pedal	Energy setting(J)	Frequency setting(Hz)	Pulse width	Lasing duration per setting (hh:mm:ss)	Total energy per settings (KJ)
9/10/2014	15:52:28	Tumor Ablation	0:00:50	0.54	Xpeeda, DSL	Off;						
							Left	1	15	Low	0:00:10	0.1
							Right	1	30	Low	0:00:10	0.1
							Left	1	50	Low	0:00:20	0.2
							Right	1.4	40	Low	0:00:10	0.14
9/8/2014	12:44:36	HoLEP	0:00:10	0.02	SlimLine, 550	Off;						
							Left	0.2	5	Low	0:00:10	0.02
9/8/2014	12:43:53	HoLEP	0:00:10	0.2	Xpeeda, DSL	Off;						
							Left	2	50	Low	0:00:10	0.2
9/8/2014	12:41:35	Vaporization	0:00:10	0.02	Xpeeda, DSL	Off;						
							Left	0.2	5	Low	0:00:10	0.02
9/8/2014	12:39:06	Vaporization	0:00:10	0.2	SlimLine 550	Off;						
							Left	2	60	Low	0:00:10	0.2
9/8/2014	12:21:54	PCNL	0:00:40	0.24	Xpeeda, DSL	Off;						
							Left	1	20	Low	0:00:10	0.1
							Right	0.2	5	Low	0:00:10	0.02
							Left	1	20	Low	0:00:10	0.1
							Right	0.2	5	Low	0:00:10	0.02
9/8/2014	12:00:29	PCNL	0:00:40	0.16	SlimLine, 550	Off;						
							Left	1	20	Low	0:00:10	0.1
							Right	0.2	5	Low	0:00:10	0.02
							Left	0.2	5	Low	0:00:20	0.04

Figure 59: Sample of Reports Export (for illustration only)

Changing the Default Specialty

When you start up Lumenis Pulse 60H, the **Home** screen automatically displays the default specialty. You can change this in the **Settings & Utilities** screen.

1. From the **Home** screen, press the **Settings & Utilities** button.
2. Press the **Default Specialty** button.

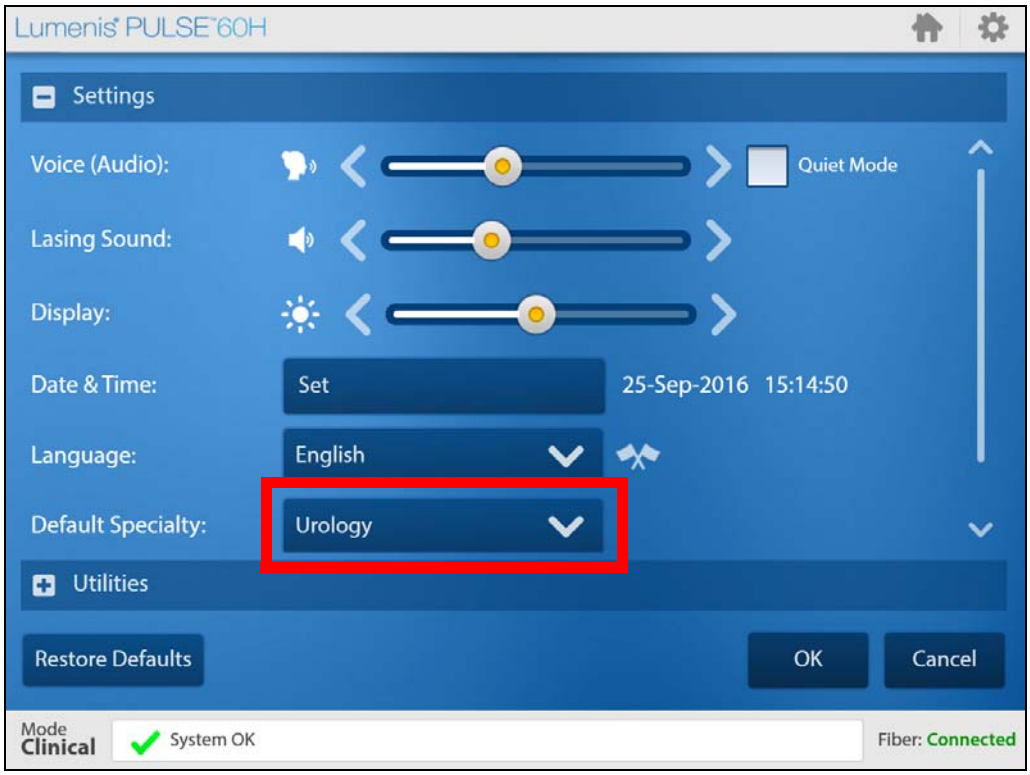


Figure 60: Default Specialty Button

3. From the **Change Specialty** pop-up, press the specialty that you want to become the default specialty.

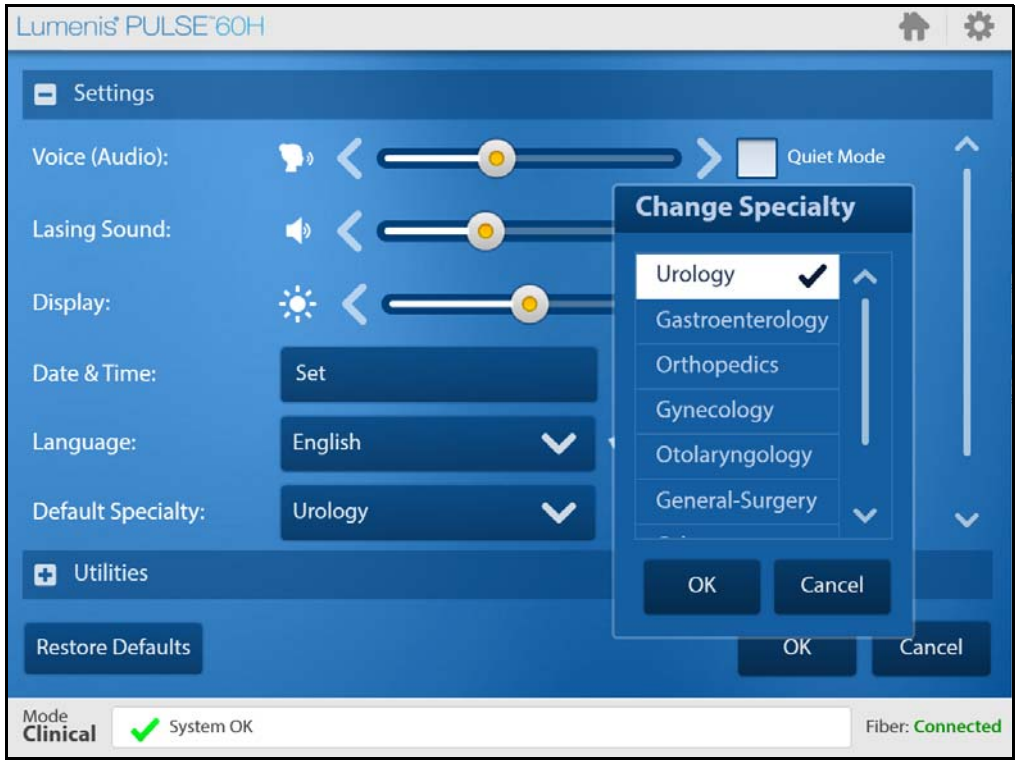


Figure 61: Default Specialty Button

4. In the **Change Specialty** pop-up, press **OK**.
5. In the **Settings & Utilities** screen, press **OK**.

Other Operations

Turning Off the Aiming Beam

1. To turn off the aiming beam press the < (decrease intensity) until the minimum aiming beam intensity is reached. Then press the < for several seconds.

2. Confirm or cancel the request to turn off the aiming beam.

WARNING:

Use extreme care if the aiming beam has been turned off. Operating the laser without the aiming beam may result in laser exposure to non-target tissue and possible injury.

CAUTION:

- If the aiming beam has been turned off and you leave the treatment screen, when you return to the **Treatment** screen the aiming beam will return to the default medium intensity.
- If the aiming beam has been turned off a pop-up message will appear requiring that you verify knowing that the aiming beam is turned off. Press the verification button in order to proceed with the surgical procedure.

Changing Screen Settings

1. Press the cogwheel in the upper-right corner and select **Quick Settings**.

Figure 62: Select Quick Settings

2. In the **Quick Settings** screen that opens, slide the lower slider to the right to increase screen brightness or to the left to decrease screen brightness.

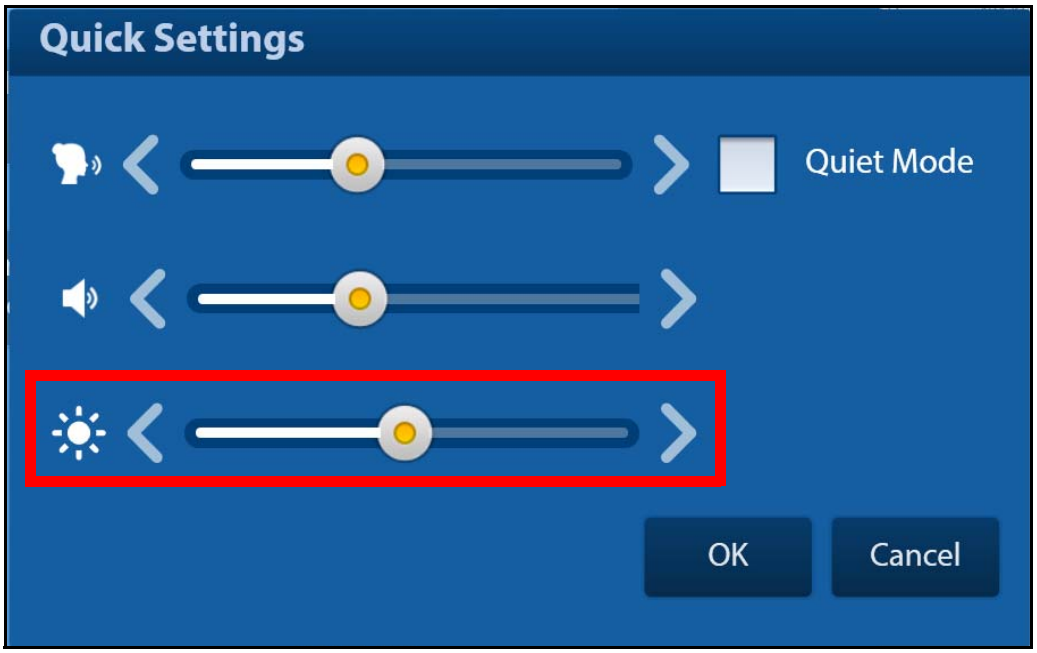


Figure 63: Quick Settings Pop-Up Screen

NOTE:

Checking the **Quiet Mode** check box does not affect the signal that is emitted during lasing or any other sounds that are directly related to safety.

3. Press **OK**.

NOTE:
You can also edit the screen settings in the **Settings & Utilities** screen.

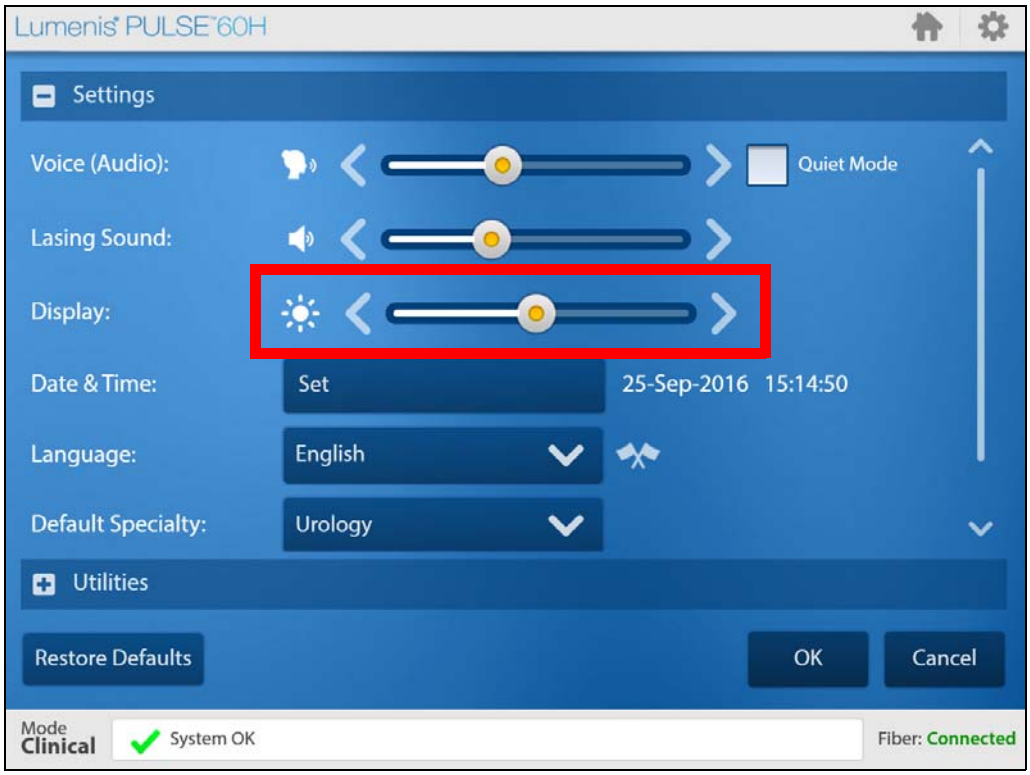


Figure 64: Settings & Utilities > Display Adjustment

Adjusting Volume and Sound Indications

1. Press the cogwheel in the upper-right corner and select **Quick Settings**.

Figure 65: Select Quick Settings

2. **Sound Indications:**

   - In the **Quick Settings** screen that opens, slide the upper slider to the right to increase volume or to the left to decrease the volume of the **voice** indications, or:

   - Slide the middle slider to the right to increase volume or to the left to decrease the volume of the **beeping** indications.

3. If you do not want to hear any voice indications, select the **Quiet mode** check box; the voice indications will be replaced with a sound indication.

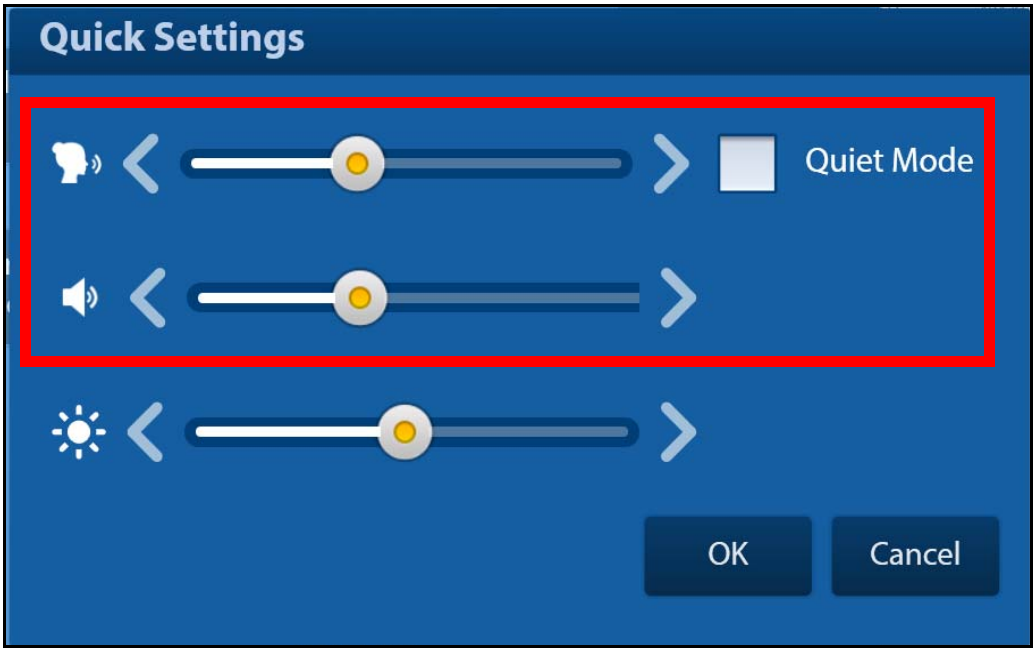


Figure 66: Quick Settings Pop-Up Screen

4. Press **OK**.

NOTE:

You can also edit the screen settings in the **Settings & Utilities** screen.

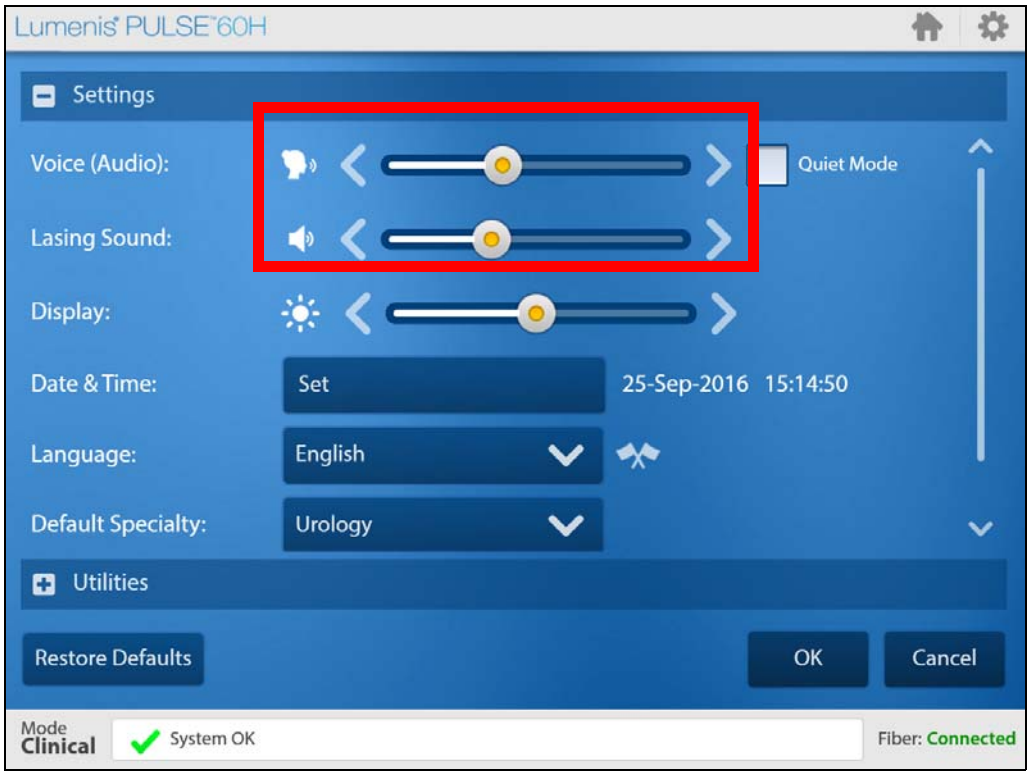


Figure 67: Settings & Utilities > Sound Indications Level Adjustments

Changing Date and Time

1. From the **Home** screen, press the **Settings & Utilities** button.
2. Press the **Set** button.

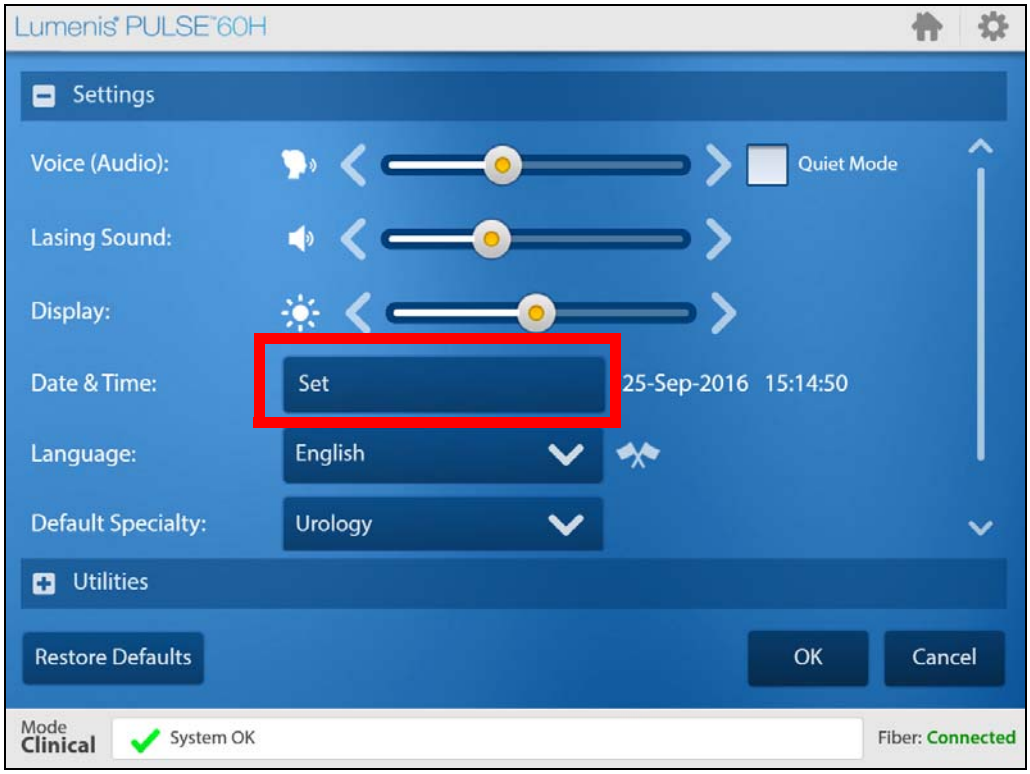


Figure 68: Set Date & Time Button

3. In the **Set** screen that opens, press the up and down arrows to set the date and time.

Figure 69: Settings & Utilities > Set Date & Time

If you prefer a 12 hour clock, clear the 24H check box.

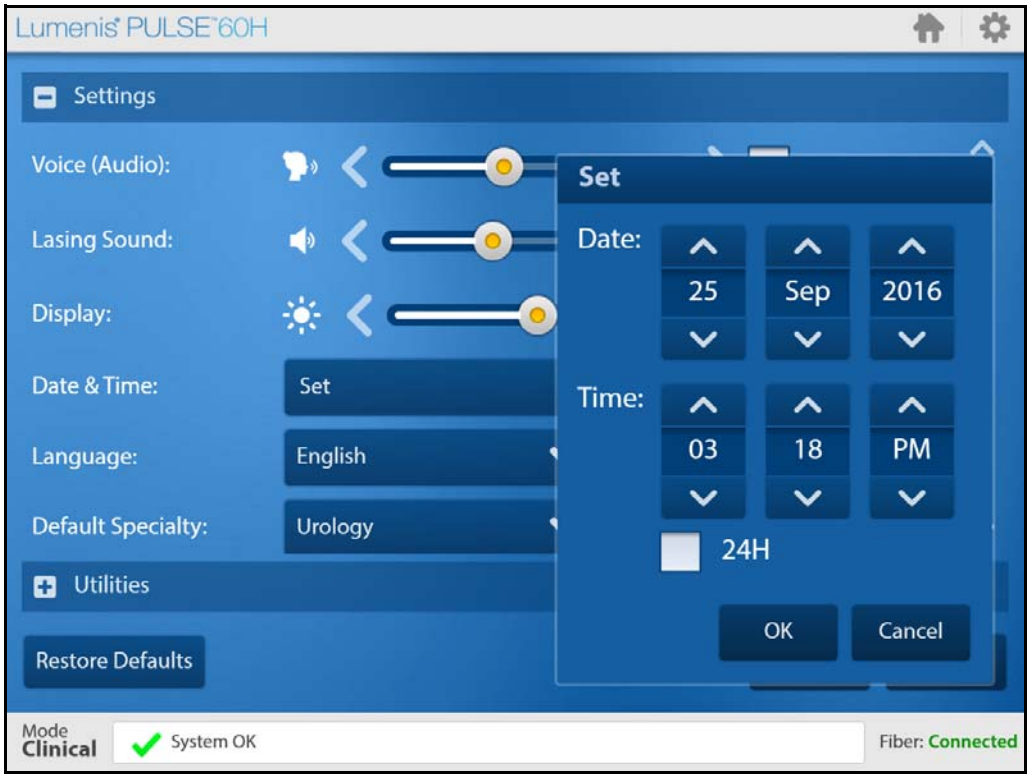


Figure 70: Settings & Utilities > Set Date & Time With 12 Hour Clock

4. In the **Set** menu, press **OK**.
5. In the **Settings & Utilities** menu, press **OK**.

Changing the Interface Language

1. From the **Home** screen, press the **Settings & Utilities** button.
2. Press the **Language** button.

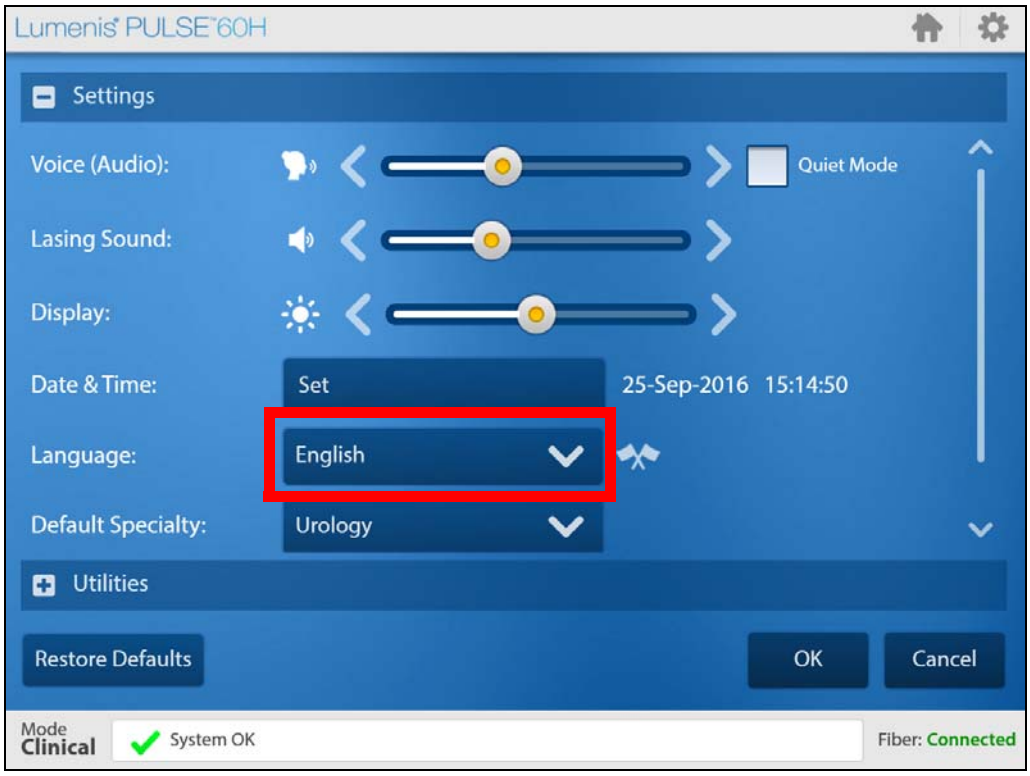


Figure 71: Language Button

3. In the **Change Language** screen that opens, select the language that you want to change to.

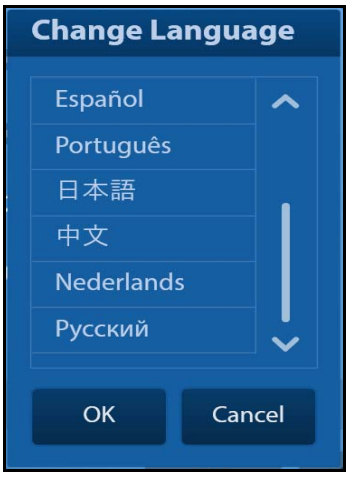


Figure 72: Settings & Utilities > Change Language

4. The available languages are: English, French, German, Italian, Spanish, Portuguese, Chinese, Japanese, Dutch and Russian.
5. On the **Change Language** menu press the **OK** button (see Figure 72).
6. On the **Settings** screen press the **OK** button (see Figure 73).
7. Press the **Cancel** or **Home** button to return to the **Home** screen without changing the language.

NOTE:

If you accidentally change the language to one that you do not know how to read, open the language drop down menu and the flag will appear next to the language in which it was installed (local language).

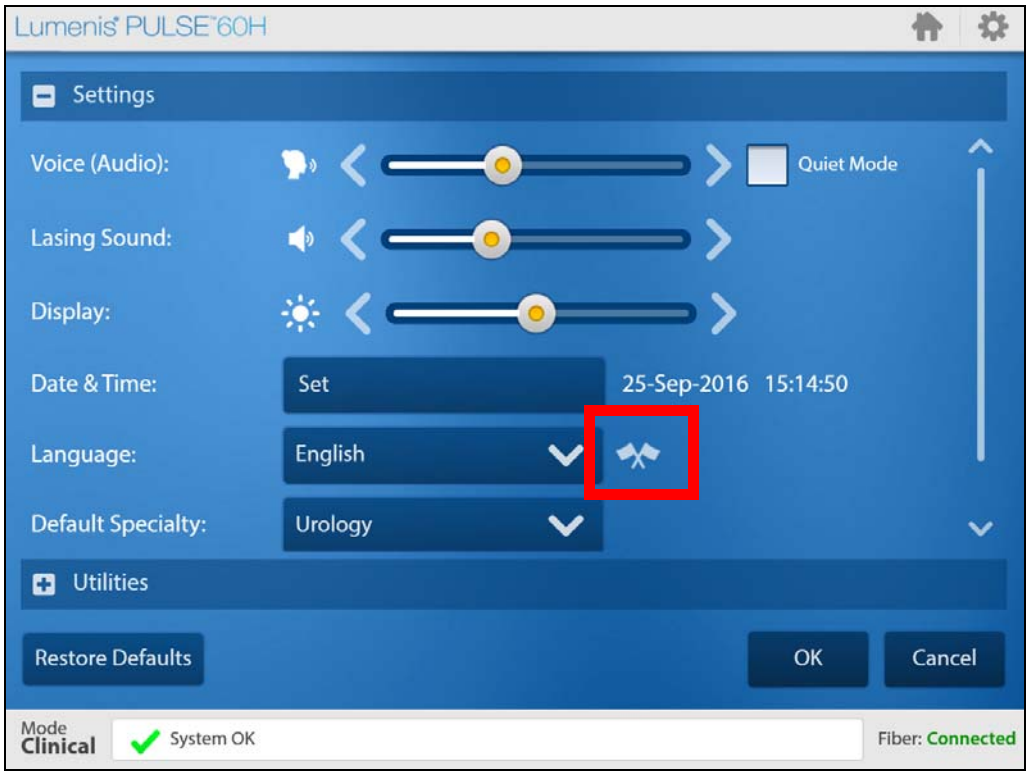


Figure 73: Settings & Utilities > Language Reset Flag

Exporting Service Log

The option to export the service log enables you to send data about the system to a Lumenis service person that can help that person understand a problem that you encountered.

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 60H.
2. From the **Home** screen, press the **Settings & Utilities** button.
3. Press the + next to **Utilities** to expand it.

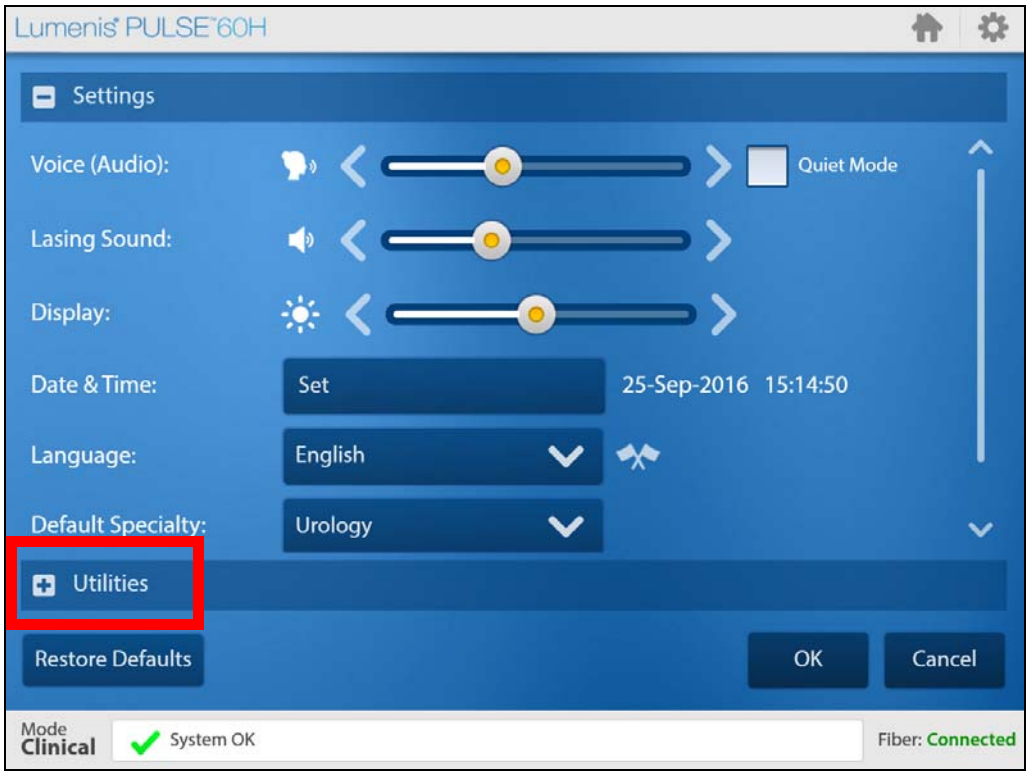


Figure 74: Set Date & Time Button

4. Insert a USB device.

5. Press the **Export data to USB** button.

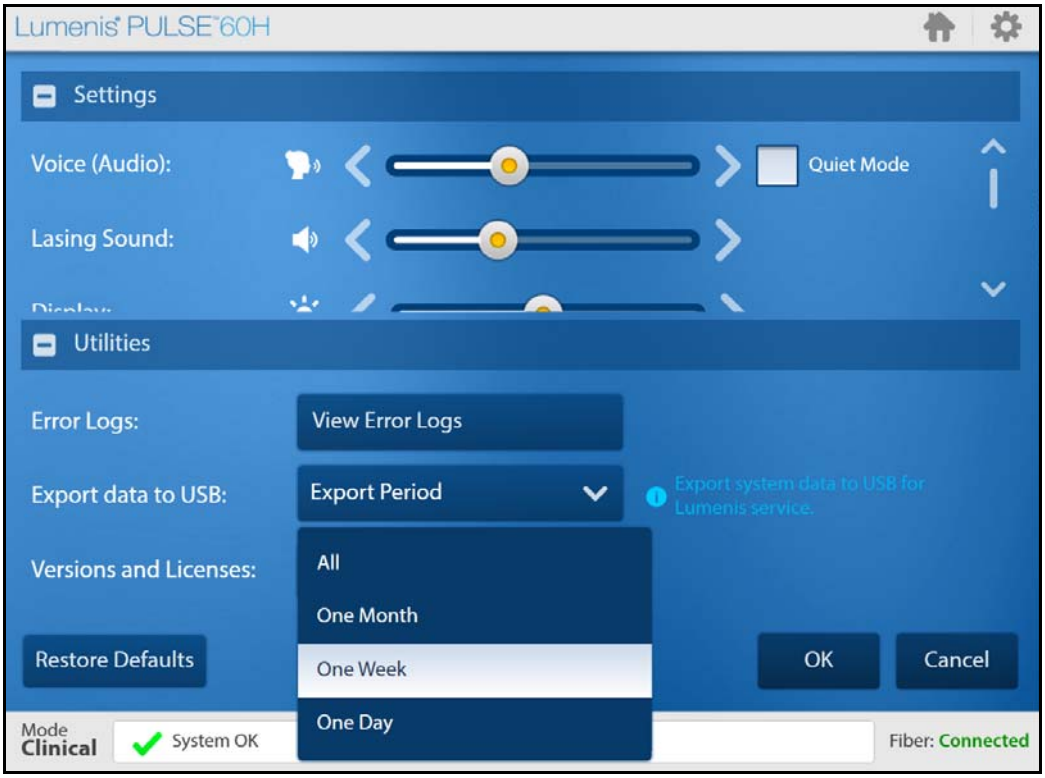


Figure 75: Export Data to USB Button

6. In the **Export data to USB** pop-up menu press one of the following backup period options:

   - **All**
   - **One Month**
   - **One Week**
   - **One Day**

7. Press **OK**.

8. Wait until the export operation is completed successfully.

9. Press **OK** to close the pop-up.

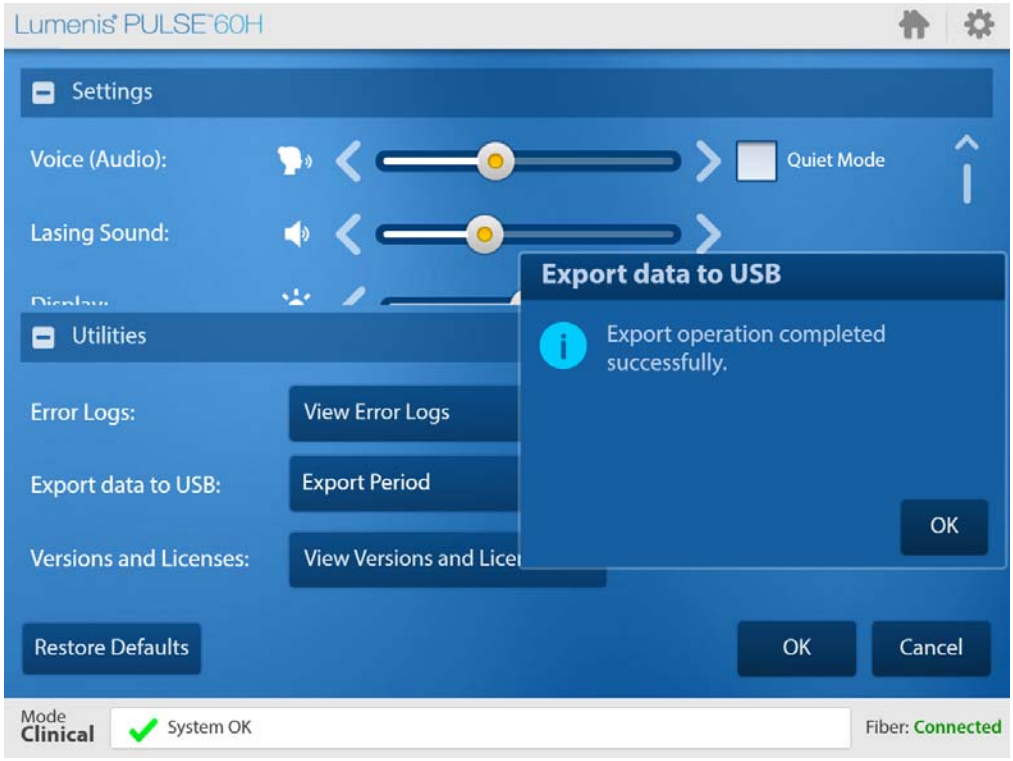


Figure 76: Export Operation Completed

Restoring Default Settings

You can set all of the settings that are shown in the **Settings & Utilities** menu to their default settings.

1. From the **Home** screen, press the **Settings & Utilities** button.

2. Press the **Restore Defaults** button.

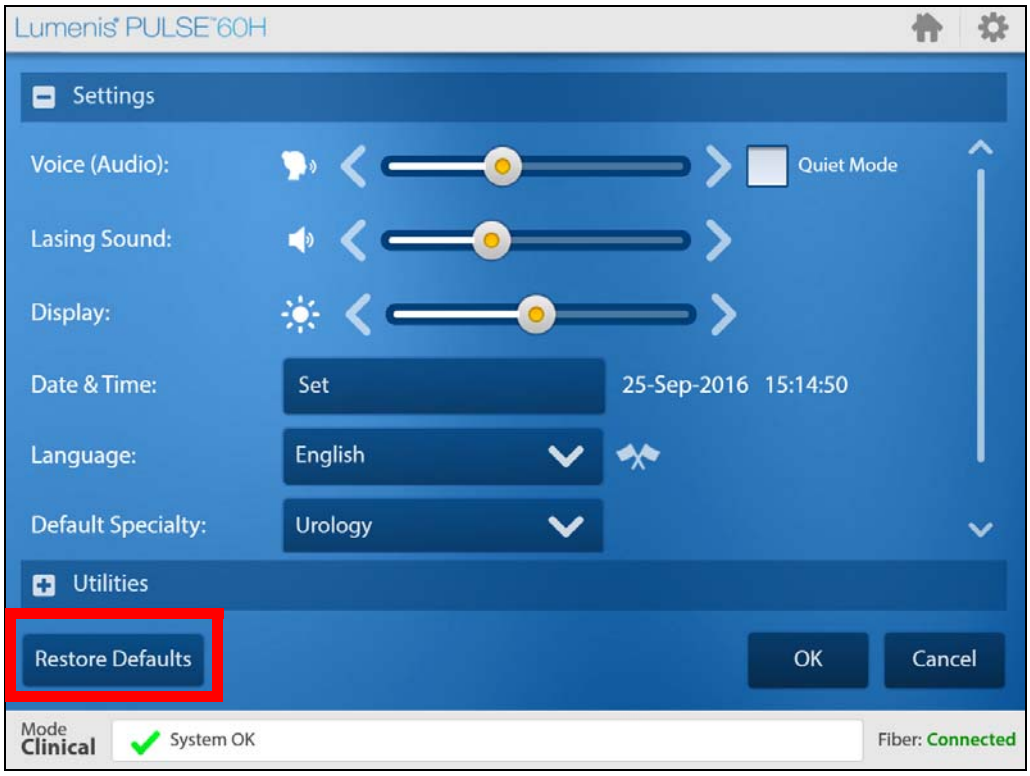


Figure 77: Restore System Defaults

Case Saver Mode

A system state that enables the user to continue using the system safely, however with reduced power capability in instances where:

1. There is a technical limitation. In such cases the system will require the user to acknowledge working with reduced power capability.

2. The current environmental conditions are not optimal. In such cases the system will work with reduced power capability or offer the user to lower the room temperature and humidity in order to return to maximum power capability.

Help

1. Press the **Help** button.

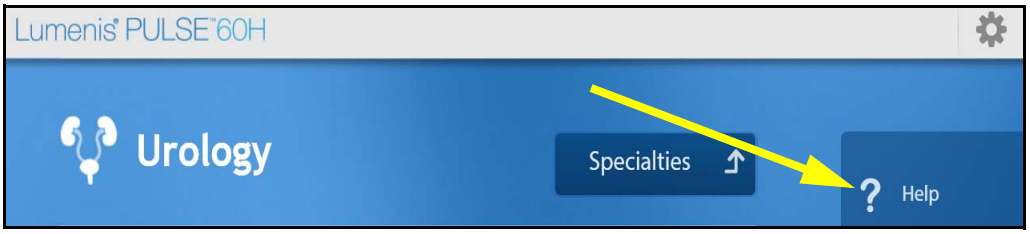


Figure 78: Select Help

2. In the left pane, select the topic that you want. Press the + sign to expand each group of topics.

3. The topic that you are interested in appears in the main pane on the right.

NOTE:

When a help topic contains more information than can fit on the screen, a scroll bar appears on the right. Some topics include subtopics that you can press to open.

4. When you are done, press the **Back** button to return to the **Home** screen.

Figure 79: Location of the Back Button

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.

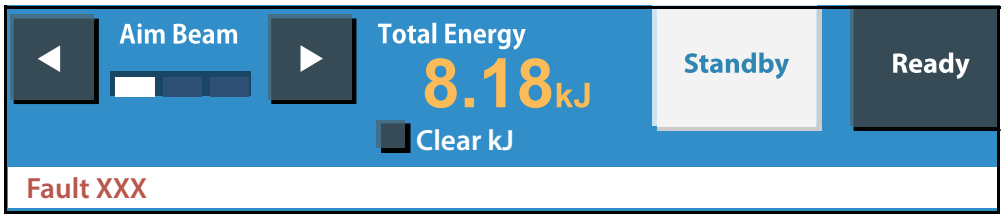


Figure 80: Notification Bar

Troubleshooting

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

ALL THE TROUBLESHOOTING INSTRUCTIONS IN THIS CHAPTER ARE TEMPORARY PLACEHOLDERS. THIS CHAPTER WILL BE UPDATED WHEN THE ERROR LIST IS COMPLETE.

Initialization Error Message Appears

1. Write down th
2. Restart the sy
3. If the problem

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). If the message does not clear restart the system. If restarting the system does not clear the message, contact Lumenis Customer Service.
- 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. If the message does not clear restart the system. If restarting the system does not clear the message, contact Lumenis Customer Service

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 24°C (50 and 75°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.

Non-Specific Events of Unusual System Behavior

In the event of the system behaving in an unusual manner or being non-responsive (i.e., touch-screen not responding, screen not responding when fiber connected), proceed as follows:

1. Power the system down completely and restart it. proceed with normal operation.
2. If problem persists, contact Lumenis Service.

Message Appears: Attach an Authorized Fiber

SIS enabled Lumenis Pulse 60H laser system 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.	Before each procedure, and weekly.	Hospital/Clinic Staff	If damage is found, call Lumenis Customer Service.
Inspect electrical connections.	Before each procedure, and weekly.	Hospital/Clinic Staff	If damage is found, call Lumenis Customer Service.
Check remote interlock connection and emergency stop button.	Before each procedure, and weekly.	Hospital/Clinic Staff	If interlock and/or button do not perform as required, call Lumenis Customer Service.
Inspect/replace the debris shield	Before each procedure, and 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.

To ensure safe and efficient operation, the system must be checked annually by Lumenis-authorized technical personnel, who will perform vital maintenance procedures and test all facets of the system's operation.

WARNING:

No modification of this equipment is allowed.

NOTE:

Lumenis will provide upon request circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist service personnel to repair system components.

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 and cabling.

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. Acknowledge the on-screen message.
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 laser energy emission and suction when pressed. To check this interlock:

1. With the system **On**, press down on the emergency stop button; the system will display an appropriate on-screen message.
2. Disengage the emergency stop button and acknowledge the message.
3. Restart the laser system.
4. Press the **Ready** button on the LCD or footswitch; verify that the system has transitioned to **Ready** mode.
5. Power down the system.
6. 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. Open the panel cover.

Figure 81: Locate the debris shield

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

Figure 82: 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. Clean the debris shield's optic if it is dirty, or replace it if damaged. If the optic is free of dirt or damage, reinsert the debris shield into the receptacle as instructed below.

Discard the damaged debris shield.

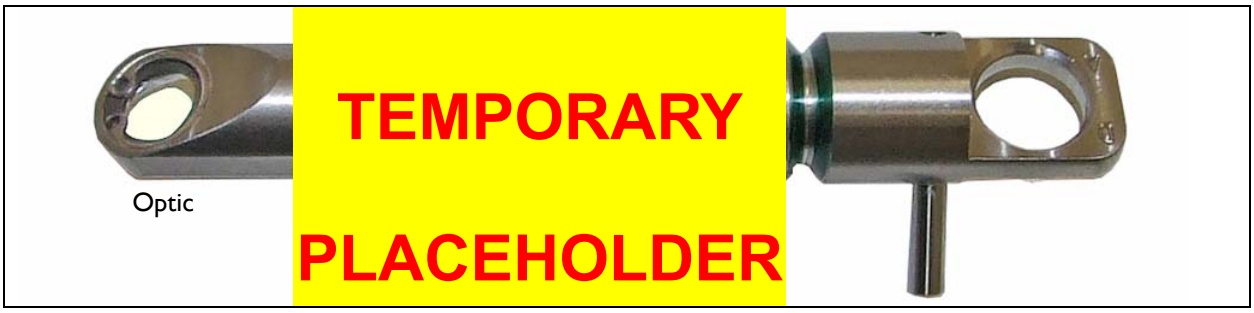


Figure 83: Inspect the Debris Shield Optic

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.

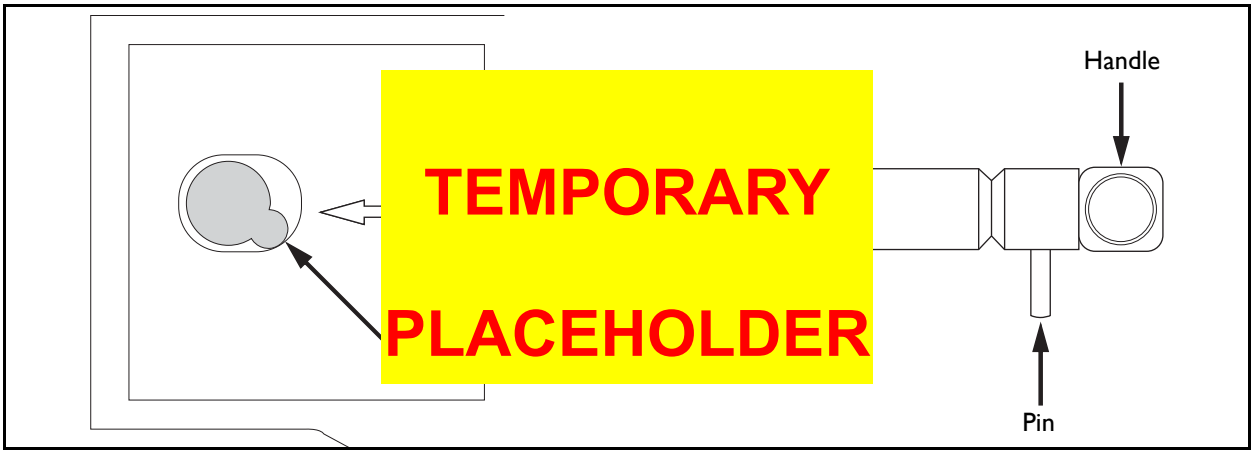


Figure 84: Reinsert the Debris Shield

Professional Maintenance (to be updated by Yehudit and reviewed by Yoav)

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

CAUTION:

The Lumenis Pulse 60H 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 60H 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 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 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
- Sterile aspiration tubing (qty? specs?)
- Drainage tubing (qty? specs?)
- Suction handpiece

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

The Lumenis Pulse 60H laser system is available in the following electrical configurations:

- 200/208/220/230/240V~, 50Hz (factory set), 25A max, single-phase.
- 200/208/220/230V~, 60Hz (factory set), 27A max, single-phase.

Frequency is factory set according to the model ordered. Voltage is set by Lumenis-certified service technicians to one above available voltages to fit local voltage.

The line wires in the power cable must be connected to the building's power, and the green/yellow wire must be connected to the building's ground.

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

This also includes availability of:

- One of above detailed nominal voltage / frequency options.
- 30A / 32A socket and wall plug that comply with local codes.
- Circuit breaker (type C) that complies with local codes.

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 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.

External Door Interlock Pin Assignments

The external door interlock is a safety feature that immediately transitions the laser system into **Standby** mode, effectively stopping laser energy emission if the treatment room door is opened, or the interlock plug is removed while laser energy is being emitted.

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:

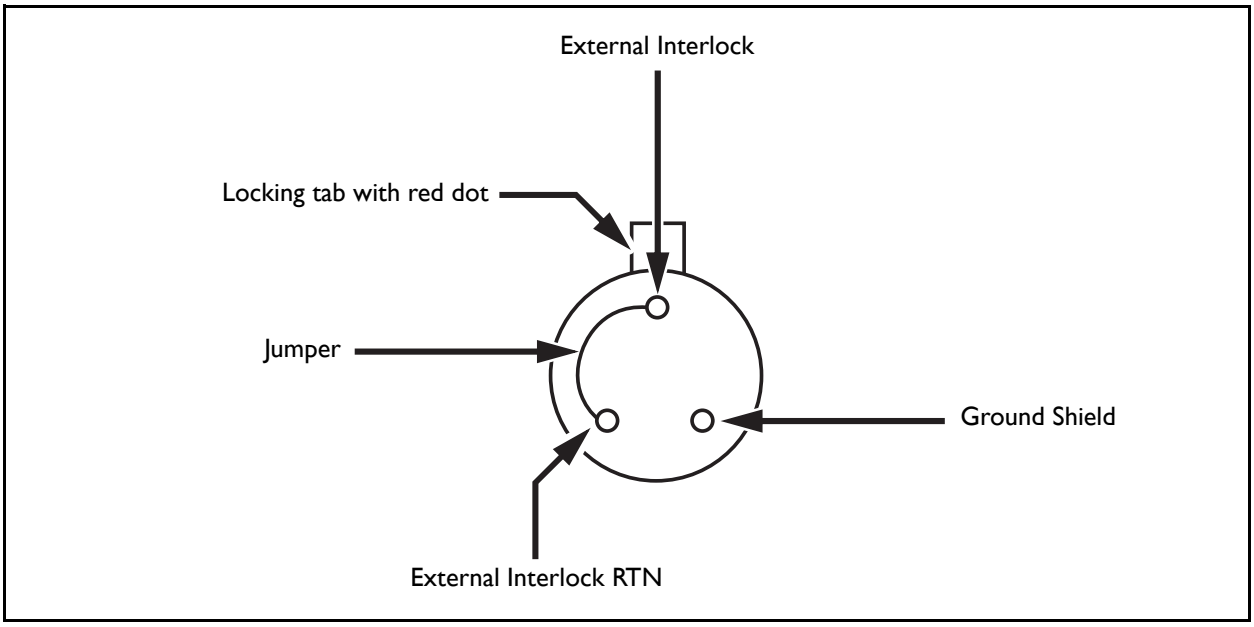


Figure 85: External Door Interlock Pin Assignments (solder side of plug shown)

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 laser energy emission and suction in emergency situations.

Login Password

A unique password is required to log into the laser system's software operating program. Without this password access to the program is denied and laser energy emission will not be possible.

Laser Emission Indicators

A laser emission indicator appears on the control screen to alert you that laser energy is being emitted, the LED ring around the fiber connection port illuminates continuously in orange in **Ready** mode and blinks orange during lasing. During lasing, 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 laser energy emission if the treatment room door is opened while the laser system is in **Ready** mode or lasing.

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 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 footswitch is pressed and the system is lasing.

Manual Restart

In the event of the system behaving in an unusual manner or being non-responsive, it should be manually restarted; normal operation may be resumed.

Electronic Fault Detection Circuitry

The fault detection circuitry constantly monitors the system for fault situations and, if required, will disable laser energy emission and suction until the fault situation is resolved.

Safety Interlocks

The laser system has safety interlocks on the optical fiber laser connector. Laser energy emission is disabled if a fiber is not connected.

Precision of Displayed Values

The energy and rate values displayed on the control screen are factory set. 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. The delivered system energy is controlled to fit the commanded parameters by up to 20%.

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	1.0 to 60W
Repetition rate	45 Hz
Energy	0.2 - 3.5 Joules
Pulse width	0.15 to 1.6 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
Input power parameters	
Nominal voltage and frequency	• 200/208/220/230/240V~, 50Hz (factory set) • 200/208/220/230V~, 60Hz (factory set)
Current (maximum)	• 25A @ 50 Hz • 27A @ 60 Hz
Utility connection	Single-phase, grounded
System electrical classifications	
Operation	Continuous
Type of Protection against Electric Shock	Class I
Degree of protection against electric shock for applied parts	BF
Protection against ingress of water (console)	IPX0
Protection against ingress of water (footswitch)	IP68
Cooling	
Method	Internal water-to-air heat exchanger
Cooling air requirements	Minimum 50 cm (20 in) from walls
Physical parameters	
Size (W × D × H) cm (in.)	46 × 91 × 99 cm (18 × 36 × 39 in.)
Weight	160 kg (353 lbs.)
Power cable length	5 m (16.4 ft.)
Footswitch cable length	6 m (19.7 ft.)

Environmental requirements (operating conditions)	
Temperature	10 – 24°C / 50– 75°F
Humidity	35 to 75% at 24°C/75°F
Pressure	77 – 106 kPa
Max. altitude	2,240 m (7,350 ft.)
Environmental requirements (storage and transport conditions)	
Temperature - unpacked storage	10 to 40°C (50 to 104°F)
Temperature - packed transport	-20 to 70°C (-4 to 158°F)
Humidity - unpacked storage	30 to 75%
Humidity packed transport	10 to 95%

Laser Safety Eyewear

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

Compatible Optical Fibers

The laser system is intended for use only with Lumenis-authorized accessories. 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 contact information of the Lumenis Customer Service center closest to you, refer to the Lumenis Website (http://www.lumenis.com/contact1).

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

Appendix A: EMC Guidance and Manufacturer's Declaration

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Lumenis Pulse 60H system is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 60H system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF conducted emissions CISPR 11	Group A	The Lumenis Pulse 60H system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF radiated emissions CISPR 11	Class A	Lumenis Pulse 60H system is 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 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 per phase, and therefore is exempt from these requirements.

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity The Lumenis Pulse 60H system is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 60H system 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 ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	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 60H system requires continued operation during power mains interruptions, it is recommended that the Lumenis Pulse 60H system 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 60H system is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 60H system 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>Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz</td><td>3 V 150 kHz to 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the Lumenis Pulse 60H system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 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>Radiated RF
IEC 61000-4-3</td><td>3 V/m 80 MHz to 2.5 GHz</td><td>3 V/m 80 MHz to 2.5 GHz</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 60H is used exceeds the applicable RF compliance level above, the Lumenis Pulse 60H system 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 60H laser system			
The Lumenis Pulse 60H system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lumenis Pulse 60H system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lumenis Pulse 60H 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.			