Lumenis Pulse™ 120H

Holmium Surgical Laser

Operator's Manual

Lumenis®
Energy to Healthcare

Please note that while every effort has been made to ensure that the data given in this document is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

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/recycling to understand what arrangements Lumenis has made in each EU Member State.

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Introduction

The Lumenis Pulse 120H holmium laser 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 and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

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 or delivery system, contact your local Lumenis representative.

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 120H laser comprises the following main components and features:

- Laser console
- Rotatable control screen
- A dual-pedal footswitch
- Integrated suction pump.
- Fiber support arm
- Security Identification System (SIS) technology
- Green aiming beam

Figure 1: Lumenis Pulse 120H Laser Console

Laser Console

The laser console houses the control screen, integrated suction pump, the laser control keyswitch, emergency stop knob, main On/Off switch, control electronics, laser source and associated optics, and power supply. Fiber optic delivery systems attach to the fiber receptacle on the front of the console, enabling laser energy to be delivered to the treatment site.

Control Screen

The control screen is an LCD monitor that allows you to select treatment settings outside of the sterile field.

Integrated Suction Pump

An integrated suction pump and suction control that determines the suction flow rate. The suction pump can be used in conjunction with the laser.

Footswitch

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

Figure 2: Dual Pedal Footswitch

Fiber Support Arm

The Fiber support arm can be used for routing the fiber and suction tube in an ordered and controlled manner.

Delivery Systems

A variety of fiber optic delivery systems are available for use with Lumenis Pulse 120H laser. Refer to the appropriate delivery system instruction guide for specific operating instructions.

Component Checklist

- Lumenis Pulse 120H laser console
- Detachable dual pedal footswitch
- External door interlock connector
- Keys
- User manual
- Support Arm (installed on the Lumenis Pulse 120H laser console)

Holmium Laser Theory of Operation

A laser, an acronym for Light Amplification of Stimulated Emission of Radiation, produces a highly concentrated beam of light of a given wavelength. Laser energy is generated by converting electrical energy to light energy using a flash lamp. The flash lamp energy is then used to excite the lasing medium, in this case a holmium YAG laser 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 Lumenis Pulse 120H holmium laser 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 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). For example the

Lumenis Pulse 120H can deliver a maximum average power of 120W obtained by delivery of 2J per pulse at a frequency of 60Hz.

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 30W can be performed using the following sets of parameters: 1.5J at 20Hz or 0.5J at 60Hz.

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

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

The selection of appropriate power parameters and delivery system 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.

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 User 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

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

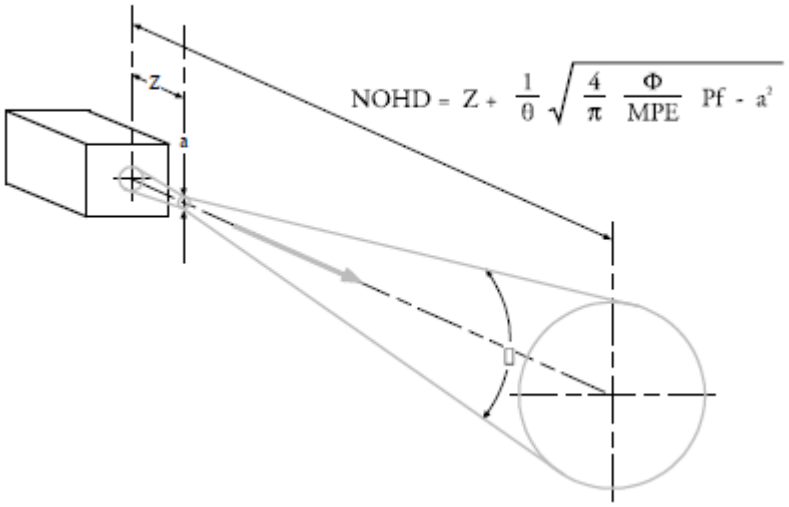
The following formula was used to calculate the worst case NOHD for the Lumenis Pulse 120H holmium laser and compatible delivery systems:

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

where,

Z = The distance of the beam waist from the laser system;

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

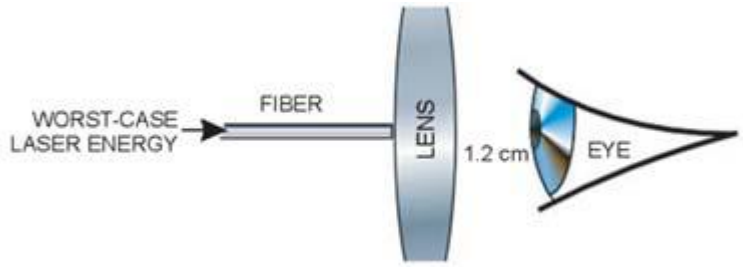


Using this approach we derive the following values:

Wavelength	θ	Φ	**MPE**	**Pf**	**a**	**Z**
Ho:YAG (2.1 µm)	250	6.0 J	5 mJ/cm²	I	0.0365 cm	0 cm

This results in a worst case **NOHD** of **1.6** meters.

All personnel who are within the NOHD are considered to be within the controlled area and must wear eye protection with protection level **DI LB3** according to EN 207 and with a minimum optical density (**OD**) of **3.0**.



Laser safety eyewear must also be resistant to physical damage or photo bleaching resulting from laser exposure as per ANSI Z136.1-1993, section 4.6.2 and Appendix C.

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

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

2. Close the treatment room door during operation of the laser.

3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

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

Additional Ocular Protection

WARNING:

- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- 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 is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.

Electrical Hazards

WARNING:

- Never open the laser 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 if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer’s recommendations and institutional standards.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Fire Hazards

WARNING:

- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The treatment beam can ignite most non-metallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher and water should be readily available.
- When performing procedures in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.

Additional Safety Considerations

CAUTION:

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

Protecting Non-Target Tissues

WARNING:

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

CAUTION:

- To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.
- 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 footswitch. Use caution pressing the laser 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 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.

Safety Indicators

- The round LED on the front displays the activity state of the Lumenis Pulse 120H laser console.

Color	Illumination	Activity state
Blue	Steady	Power **On**
Orange	Steady	**READY** mode
Orange	Blink	Lasing

Figure 3: System State LED

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

Labeling

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

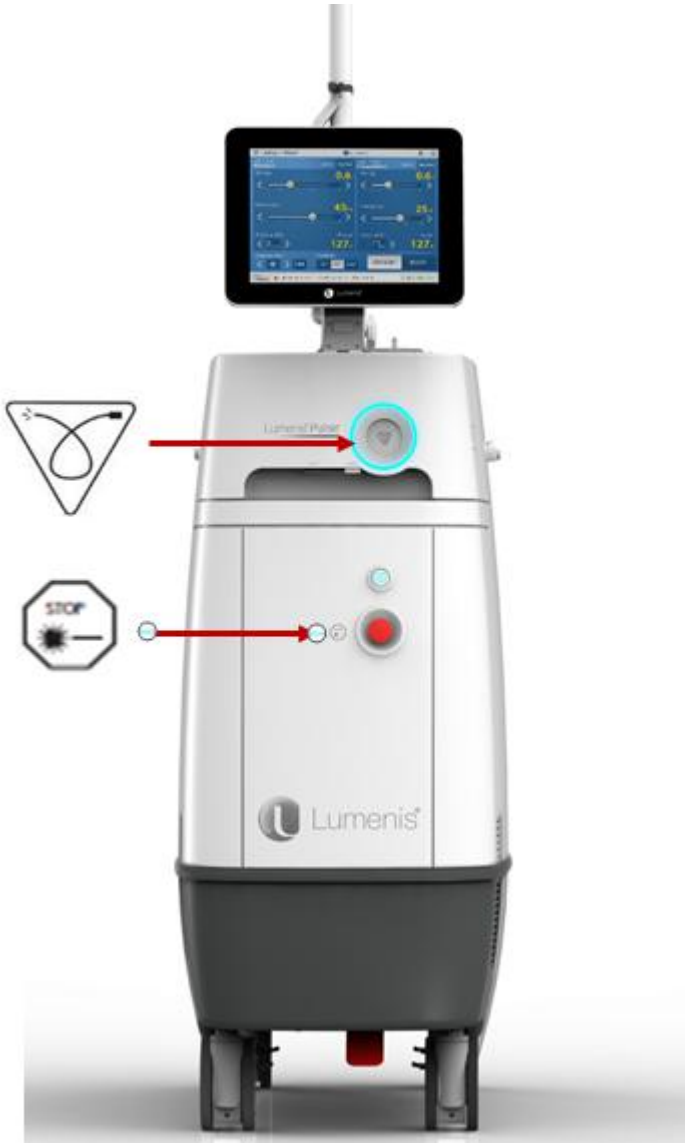


Figure 4: Location of Regulatory Compliance Labels - Front

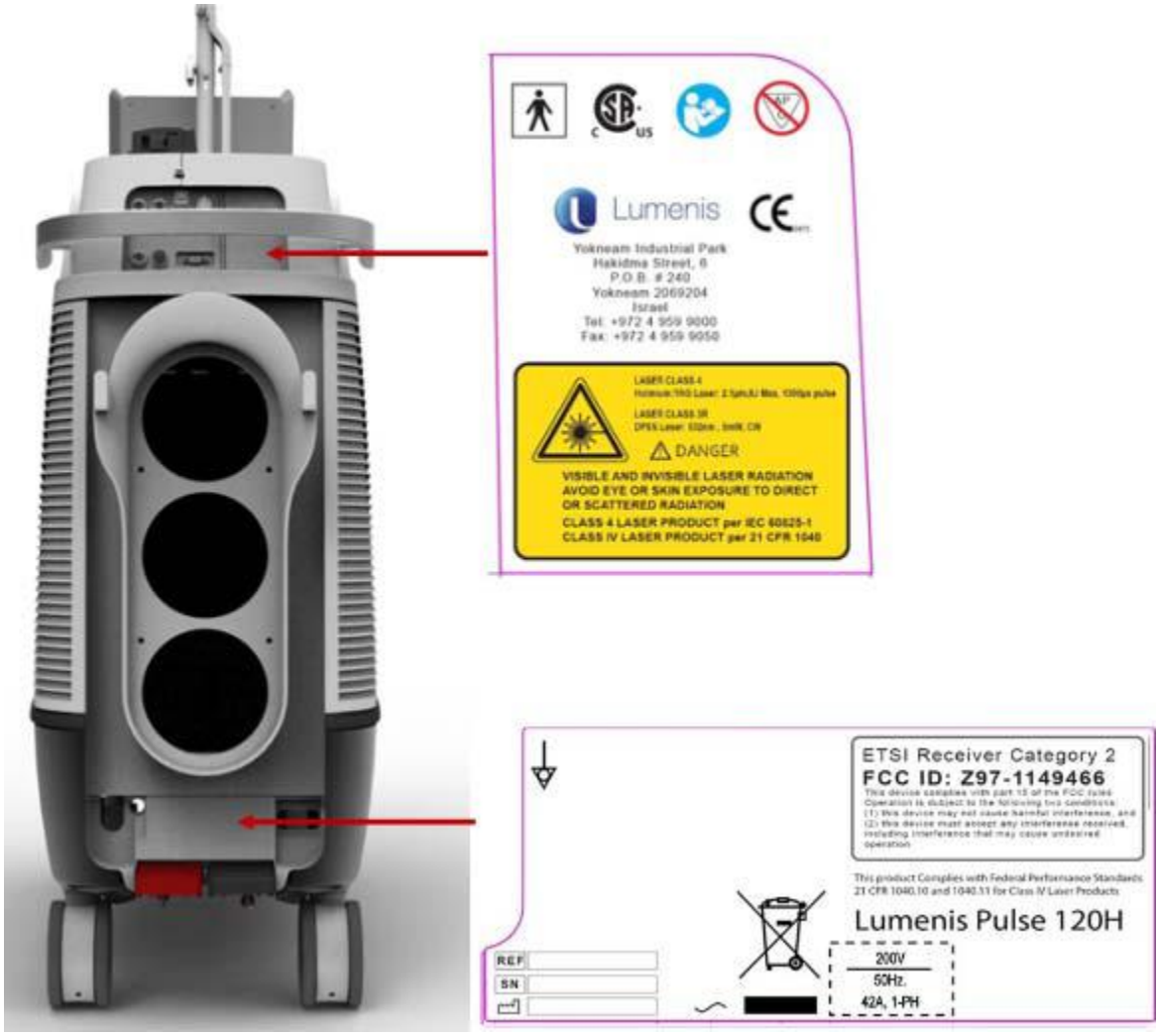


Figure 5: Location of Regulatory Compliance Labels - Rear

Symbols

Figure 6: Regulatory Compliance Labels

Clinical Guide

Lumenis recommends that physicians learn and gather additional knowledge related to the Lumenis Pulse 120H. For details on courses available at Lumenis, contact your Lumenis representative.

Lumenis does not make recommendations regarding the practice of medicine. Laser presets are provided by the software operating system for your convenience. 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.

NOTE:

The Lumenis Pulse 120H system is furnished with predefined parameter sets of treatment parameters, called **Lumenis Presets**. These presets are based on successful results obtained by experienced physicians using Holmium laser systems.

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 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 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, 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 fiber away from the target tissue approximately 2 to 5 millimeters.

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

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

NOTE:

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

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

NOTE:

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

Indications for Use

The Lumenis Pulse 120H System with Delivery Devices and Accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.

Contraindications

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

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

Specific Contraindications in Urology

- Carcinoma of the prostate.

Specific Contraindications in Gynecology

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

NOTE:

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

Warnings and Precautions

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

- Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 µm) wavelength.
- Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until familiar with the instrument's capabilities. Use extreme caution until the biological interaction between the laser energy and tissue is thoroughly understood.
- Due to interaction between flammable gases in the operating field and the laser energy a flash fire may occur. Therefore, during laser procedures, measures to minimize this potential hazard should be practiced (e.g. avoid administration of inhaled general anesthetics; reduce oxygen levels during mechanical ventilation, use of laser resistance endotracheal tubes). The flammability of methane gas must also be considered when treating in or near the perianal area.
- The laser should be used only on tissues that are fully observable. Do not use the laser 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 fiber optic delivery device extends at least 12 mm beyond the end of the scope during laser treatment. Activating the laser when the tip of the delivery device is within the scope can result in penetration of holmium laser energy through the scope and destruction of the scope.
- Use of the laser 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. 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. 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 120H System with Delivery Devices and Accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.

The Lumenis Pulse 120H System with Delivery Devices and Accessories are indicated for use in the performance of specific surgical applications as follows:

Urology

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

Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
  - meniscectomy;
  - plica removal;
  - ligament and tendon release;
  - contouring and sculpting of articular surfaces;
  - debridement of inflamed synovial tissue (synovectomy);
  - loose body debridement;
  - chondromalacia and tears;
  - lateral retinecular release;
  - capsulectomy in the knee;
  - chondroplasty in the knee;
  - chondrornalacia ablation.
- Discectomy including:
  - percutaneous vaporization of the L4-5 and LS-Sl lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery

- Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
    - cholecystectomy;
    - lysis of adhesions;
    - appendectomy;
    - biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon;
    - skin incision;
    - tissue dissection;
    - excision of external tumors and lesions;
    - complete or partial resection of internal organs, tumors and lesions;
    - mastectomy;
    - hepatectomy;
    - pancreatectomy;
    - splenectomy;
    - thyroidectomy;
    - parathyroidectomy;
    - herniorrhaphy;
    - tonsillectomy;
    - lymphadenectomy;
    - partial nephrectomy;
    - opilonidalcystectomy;
    - resection of lipoma;
    - debridement of decubitus ulcer;
    - hemorrhoids;
    - debridement of statis ulcer;
    - biopsy.

ENT Surgery

- Endoscopic endonasal/sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
  - partial turbinectomy
  - ethmoidectomy;
  - polypectomy;
  - maxillary antrostomy;
  - fronta1 smusotomy;
  - sphenoidotomy;
  - dacryocystorhinostomy (DCR);
  - functional endoscopic sinus surgery (FESS).
- Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues
  - Tonsillectomy
  - Adenoidectomy
- Open and laparoscopic gynecological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue).

Gynecological Surgery

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

Gasteroenterology Surgery

- Open and endoscopic gasteroenterology 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, coagualation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in

therapeutic plastic, dennatologic and aesthetic surgical procedures, including:

- scars;
- tattoo removal;
- 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.

Preparing the System for Use

The laser is shipped directly from the factory to your site. Your local Lumenis service representative initially uncrates, inspects, sets up, and installs the laser 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. Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser and any delivery systems used during surgery, including inspecting and cleaning the laser and delivery systems; connecting, disconnecting, and sterilizing the delivery systems; and verifying the aiming beam integrity. These procedures are detailed in this manual and in the delivery system 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 120H components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Verify that the electrical cables are not frayed or split. Contact your local Lumenis service representative if any component appears damaged.

Moving the System

1. Unlock both the front and back wheels in order to move the system.
   - Unlock the front wheels by positioning the front break pedals in the neutral position.
   - Unlock the back wheels, with multidirectional movement, by positioning the back break pedals in the neutral position.
   - Unlock the back wheels, with unidirectional movement, by positioning the left back break pedal down.
2. Move they system to the desired location. Verify that the Lumenis Pulse 120H laser console is a minimum of 50 centimeters (20 inches) from walls, furniture, or other equipment.

3. Lock the laser console wheels by pushing the front or back right brake pedal down.

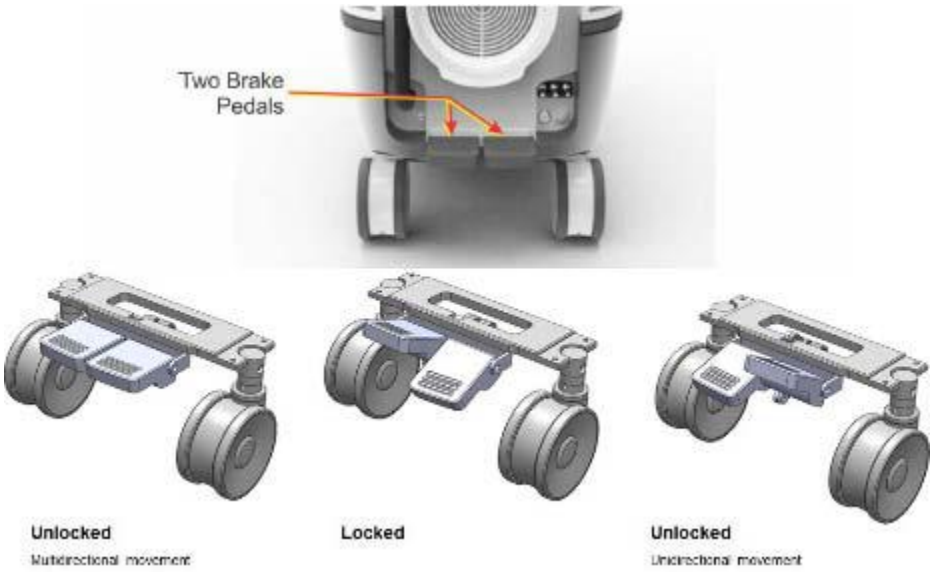


Figure 7: Brake Pedals Configurations

Adjusting the Support Arm

1. Lift the support arm so that it faces straight up, then turn the collar knob clockwise to lock the support arm in place.

2. Adjust the position of the support arm and turn the arm knobs at each joint clockwise to lock the support arm in place.

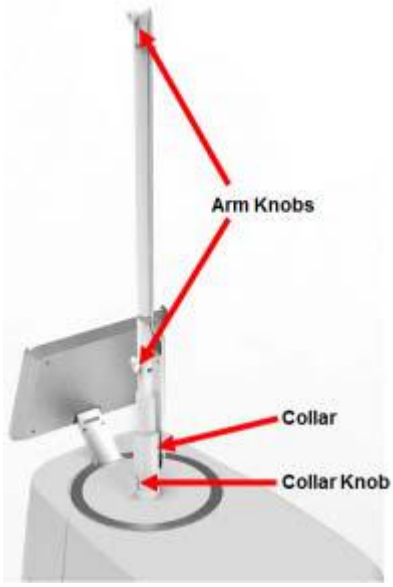


Figure 8: Adjusting the Support Arm

WARNING:

Ensure that the support arm knobs are closed properly in order to prevent unintended arm movement that may pull and cause damage to the fiber.

Adjusting the Screen

1. Unfold the LCD panel.
2. Turn the LCD panel counter-clockwise to the position needed.

3. Adjust the angle of the LCD panel.

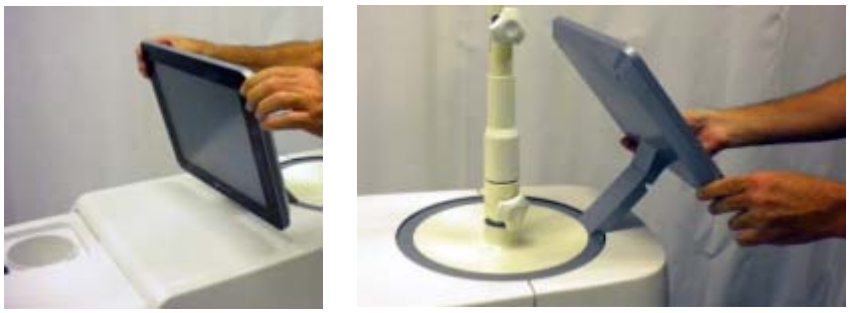


Figure 9: Adjusting the LCD Panel

Connecting the Footswitch

1. Insert the footswitch connector into the footswitch receptacle on the rear of the Lumenis Pulse 120H laser console. Align the red dot of the footswitch connector with the red dot of the receptacle, then push it in.

Figure 10: Connecting the Dual-Pedal Footswitch

NOTE:

If the footswitch is not properly connected when the laser is turned on, **Foot pedal is not connected** appears in the notification bar until the footswitch is properly connected.

Inserting the External Door Interlock Connector

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

The laser 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 (when the external door interlock is used) or if the external door interlock connector is removed, the laser 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.

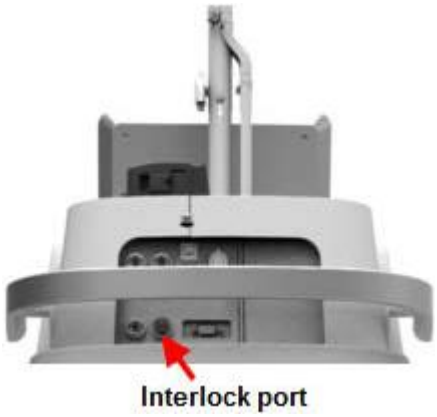


Figure 11: Reinsert the External Door Interlock

Plugging in the Main Power Cable

1. Insert the laser main power plug into the mains power socket. If the laser has a locking plug and socket, connect the plug collar to the socket so that the plug is secure

2. Turn on the main circuit breaker.

Figure 12: Main On/Off switch and Main Power Plug

Connecting the Delivery System

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

WARNING:

- Carefully inspect the delivery system sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system.
- When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- To avoid possible damage to the optical system, use only qualified Lumenis delivery systems. Using other than Lumenis delivery systems may jeopardize safe operation or damage the laser and will void your Lumenis warranty or service contract.
- To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.

NOTE:

The Lumenis Pulse 120H system will only operate with Lumenis-qualified SIS (Secure Identification System) optical delivery fibers. Attaching any other type of fiber will generate an error message and laser emission will be disabled.

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

1. Open the fiber port window by moving the window handle from left to right.

Figure 13: Fiber Port

2. Inspect the delivery system as instructed in the appropriate delivery system instruction guide.

WARNING:
Never inspect the delivery system while it is connected to the laser. Accidental laser exposure can cause severe eye damage.

3. The scrub nurse hands off the laser connector to the circulating nurse.

4. The circulating nurse removes the protective cap from the laser connector.

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

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

WARNING:
When removing the protective cap, hold the laser connector, not the strain relief or fiber optic cable. Pulling on the strain relief or fiber optic cable may damage the delivery system 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.

Connecting the Suction System

The surgeon may use Lumenis Pulse 120H 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.

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 evacuation system.
3. The scrub nurse connects one side of the sterile aspiration tube to the surgical accessory.
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.
5. Pull open the suction pump

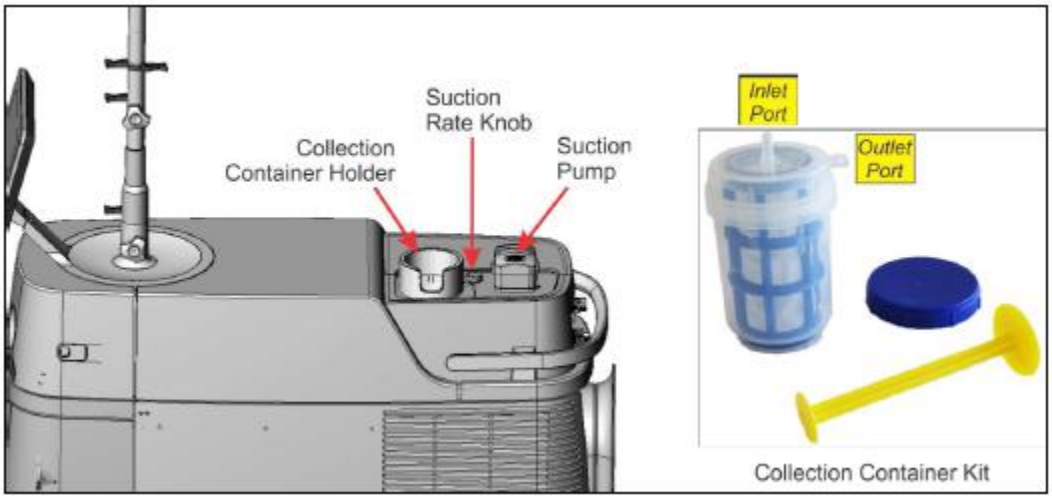


Figure 14: Suction System

Figure 15: Pulling open the Suction Pump

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

WARNING:

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

Figure 16: Directional Arrow for the Aspiration Tube

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

8. Turn the **Suction Rate** knob clockwise to increase or counter clockwise to decrease the suction rate.

Main System Screens

Home Screen Description

Figure 17: Home Screen

The elements of the **Home** screen are detailed as follows (the numbered arrows in figure 18 correlate to the numbered steps below):

Figure 18: 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 to **Turn Off System**.

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

5. **Manage Preset** – 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 19: Specialties Screen

Treatment Screen Description

Figure 20: Treatment Screen

The elements of the **Treatment Settings** are detailed as follows (the numbered arrows in figure 21 correlate to the numbered steps below):

Figure 21: 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.

   - 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 - 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.

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.

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.

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, a notification will display in the notification bar, informing the surgeon of the fiber's status. 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.

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.

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 22: Lasing Indicator

Normal Operation

Emergency Stop Button

In an emergency, press the laser emergency stop button on the front of the laser to immediately disable emission of the laser energy.

Figure 23: Location of the Emergency Button.

NOTE:

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

Verification of Connections

1. Verify that the delivery system is properly connected to the laser.

WARNING:

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

2. If desired by the surgical team, connect the surgical accessory to the suction system.

3. Verify that the footswitch is properly connected.

4. Verify that all persons in the operating room have appropriate laser safety eyewear.

Powering on the System

1. Ensure that keyswitch is in the **Open** position.

2. Press the main **On/Off** button and hold it for one full second, then release.

   - If the keyswitch is in the **Closed** position, the system will only allow you to access reports. To turn the laser on, you will need to restart while the keyswitch is in the **Open** position.

   - The system self-test and warm-up procedure takes approximately one minute to complete. A progress bar appears on the control screen during the self-test and warm-up procedure.

NOTE:

If any fault conditions are encountered during laser start-up and self-test, error messages can appear in pop-up windows or in the notification area on the control screen. Refer to Handling Error Messages and Notifications.

Selecting the Treatment

The **Main Menu** screen appears on the control screen after Lumenis Pulse 120H is powered **On** and the self-test is successfully completed.

1. Verify that the correct specialty is selected.

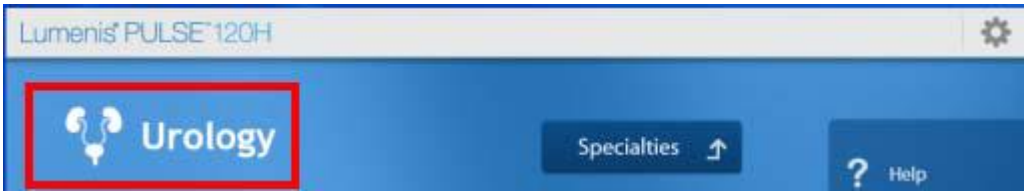


Figure 24: Location of the Specialty Selection

   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.

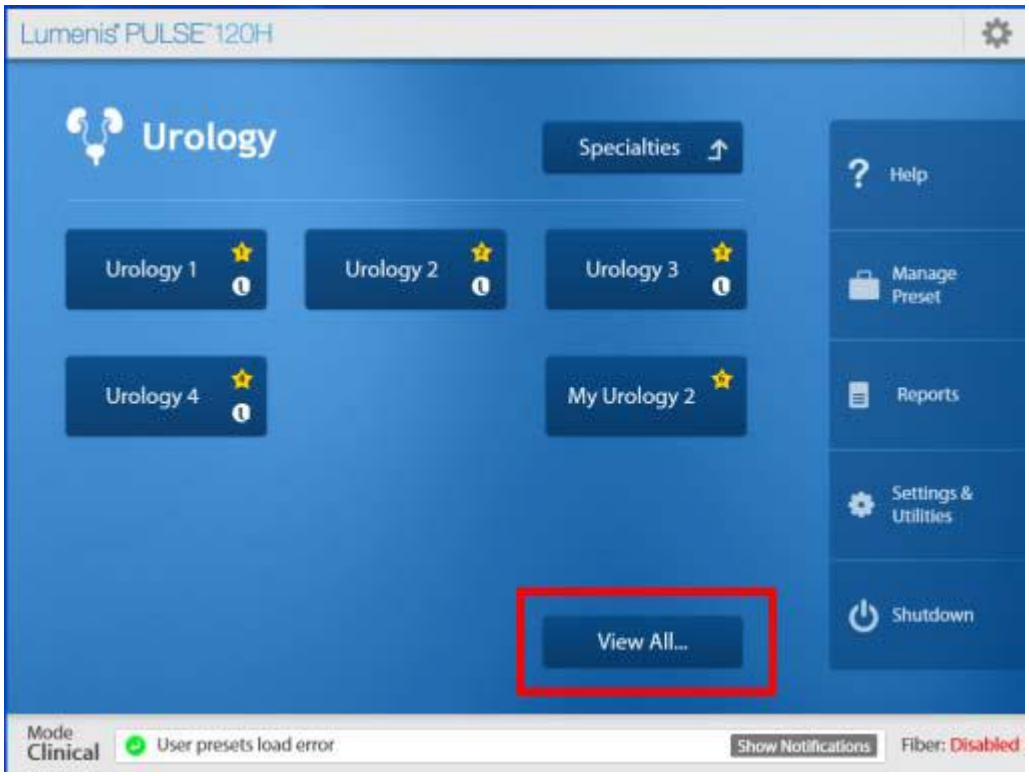


Figure 25: Location of the* View All... *Button

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.

   Drag the slide bar buttons (1) or press the arrows to adjust the Energy and Frequency settings.

   Press the < or > button (2) to decrease or increase the Pulse width.

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 highligted bar.

NOTE:

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

Figure 26: How to Change Treatment Settings

Starting 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. Adjusting Volume and Sound describes how to adjust the volume or switch of 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.

Shutting Down the System

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

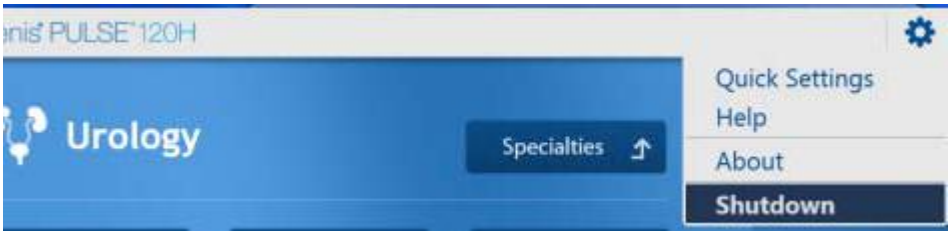
   - Normal System Shut-Down: Press the main **On/Off** button for one second (short press).
   - Forced System Shut-Down: Press the main **On/Off** button for at least five seconds (long press).

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 27: Power Cable on the Cable Rack

7. Disconnect the external door interlock.

8. Clean the exterior surfaces of the laser.

Moving the Laser Console

1. Rotate the LCD panel clockwise and fold it down with the screen facing down.

Figure 28: Folding the LCD Panel

2. Fold the support arm.

   - At each joint, you need to first loosen the knob before you can fold that part of the arm. Tighten the knobs when you are done.

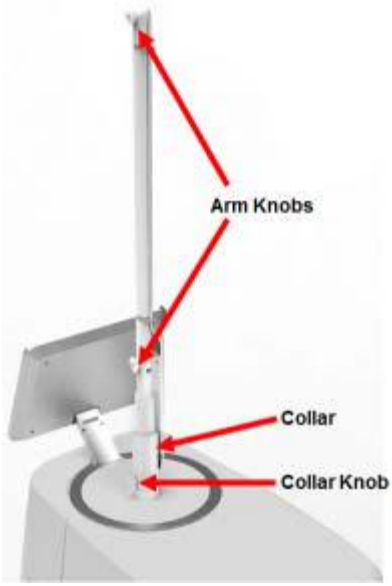


Figure 29: Adjusting the Support Arm

3. Unlock the laser console wheels for unidirectional movement by pushing the right brake pedal up and the left brake pedal down.

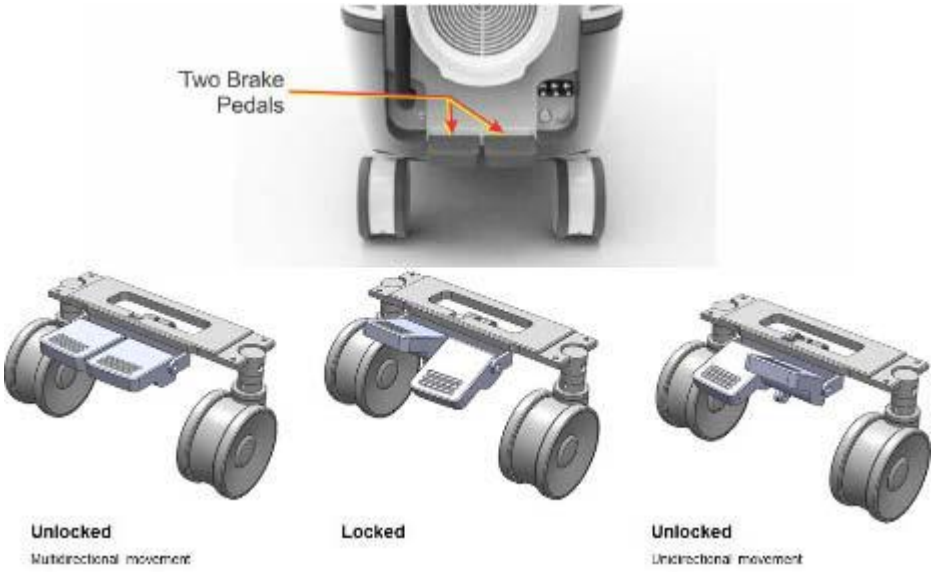


Figure 30: Brake Pedals Configurations

4. Using the laser console handle, move the laser to the desired site.

CAUTION:

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

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 31: Save Settings as a Preset

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

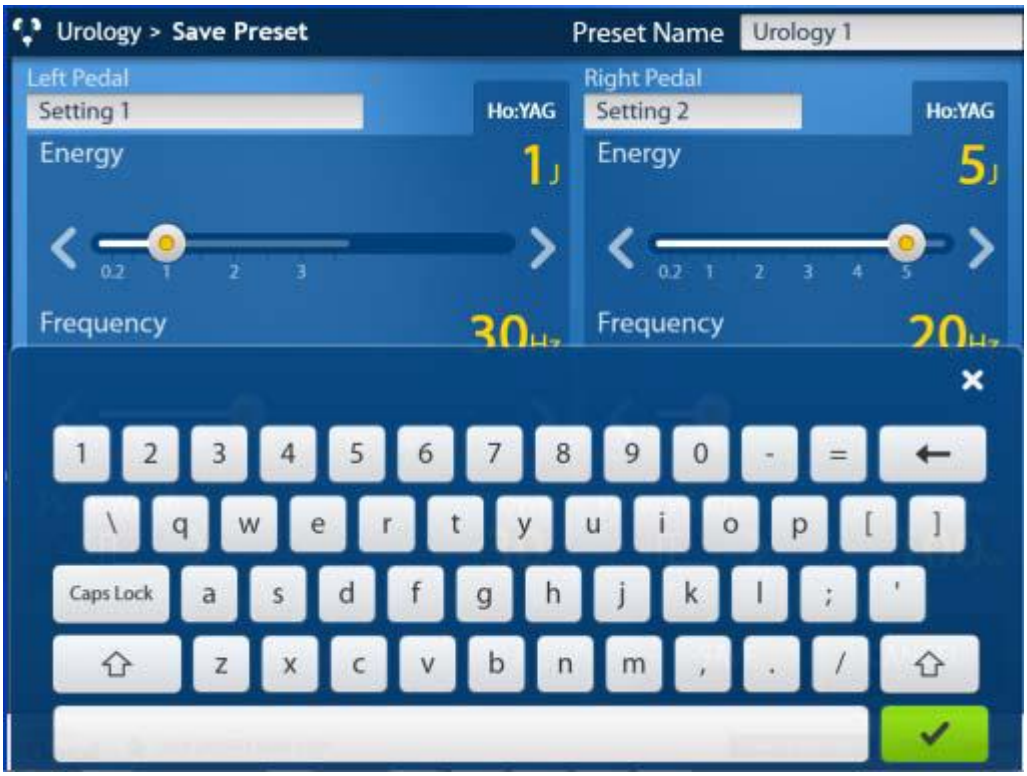


Figure 32: Editing the Preset Name

3. Press the **SAVE** button.

Figure 33: Saving the Preset

Preset Management

Introduction

The Lumenis Pulse 120H offers the use of predefined presets to select treatment parameters. Presets are divided into two groups:

System Presets (hard-coded into Lumenis Pulse 120H)

Hospital Presets (designed by the hospital staff)

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

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

Figure 34: Manage Preset Screen

Choosing Presets

On the **Main Menu** 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 35: View All Presets - Tree Closed

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

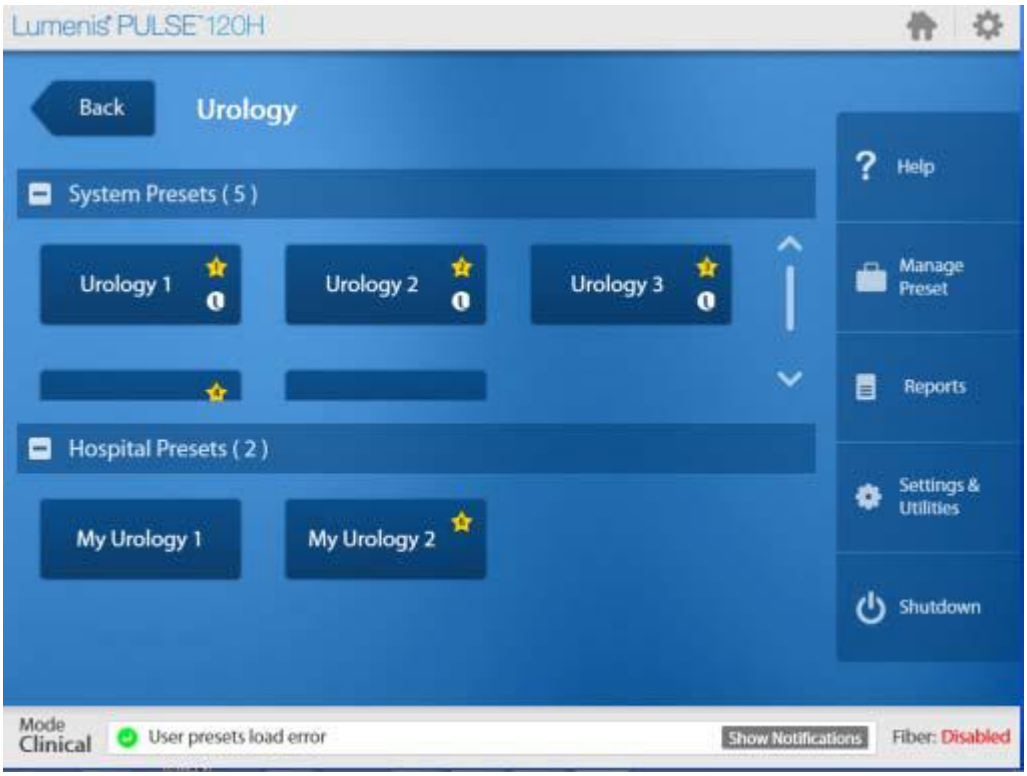


Figure 36: View All Presets - Tree Expanded

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

Creating Presets From Scratch

1. From the **Main Menu** screen, press **Manage Preset**.

2. Press the **New** button.

Figure 37: Manage Presets Screen

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

Figure 38: 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 keyboard pops up.

5. Click **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 **Main Menu** screen, press **Manage Preset**.

2. Press the **Hospital Presets** button.

3. Select anywhere on the row for the preset that you want to edit.

Figure 39: Manage Presets Screen

4. Press the **Edit** button.

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

Figure 40: Edit Preset Screen (With Keyboard Visible)

6. Click **SAVE**.

Duplicating Presets

1. From the **Main Menu** screen, press **Manage Preset**.
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.

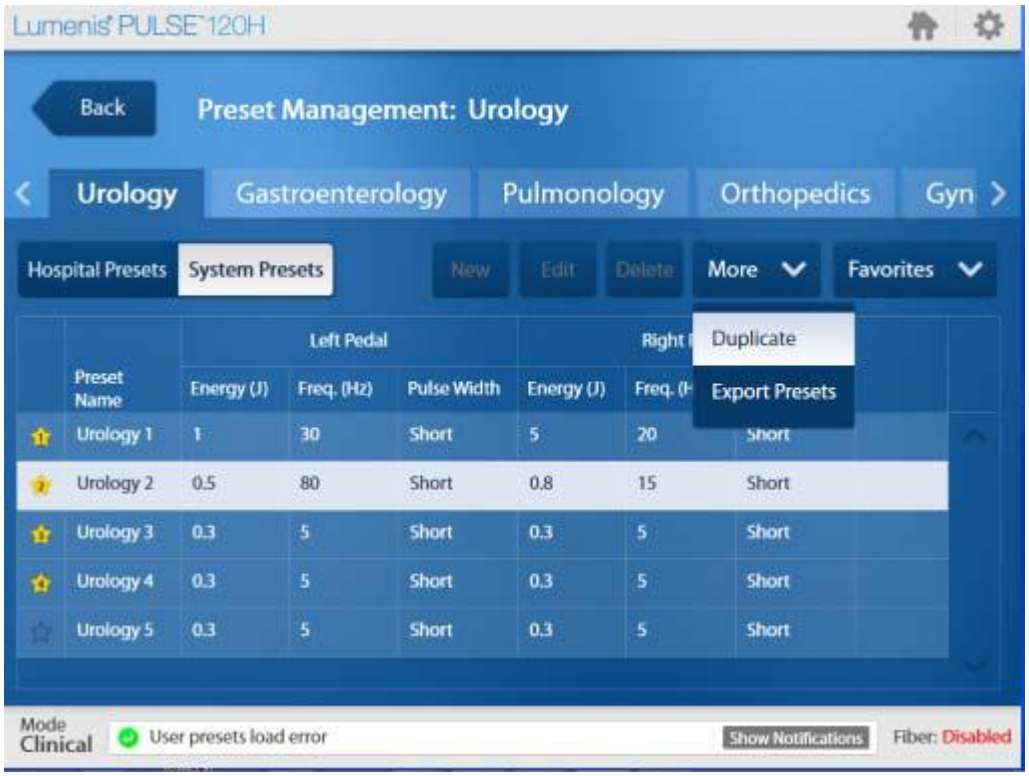


Figure 41: Manage Presets > More >Duplicate

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

Figure 42: Preset Screen (With a Duplicated Preset)

Deleting Presets

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

1. From the **Main Menu** screen, press **Manage Preset**.
2. Press the **Hospital Presets** button.

3. Select anywhere on the row for the preset that you want to delete.

Figure 43: Manage Presets Screen

4. Press the **Delete** button.

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

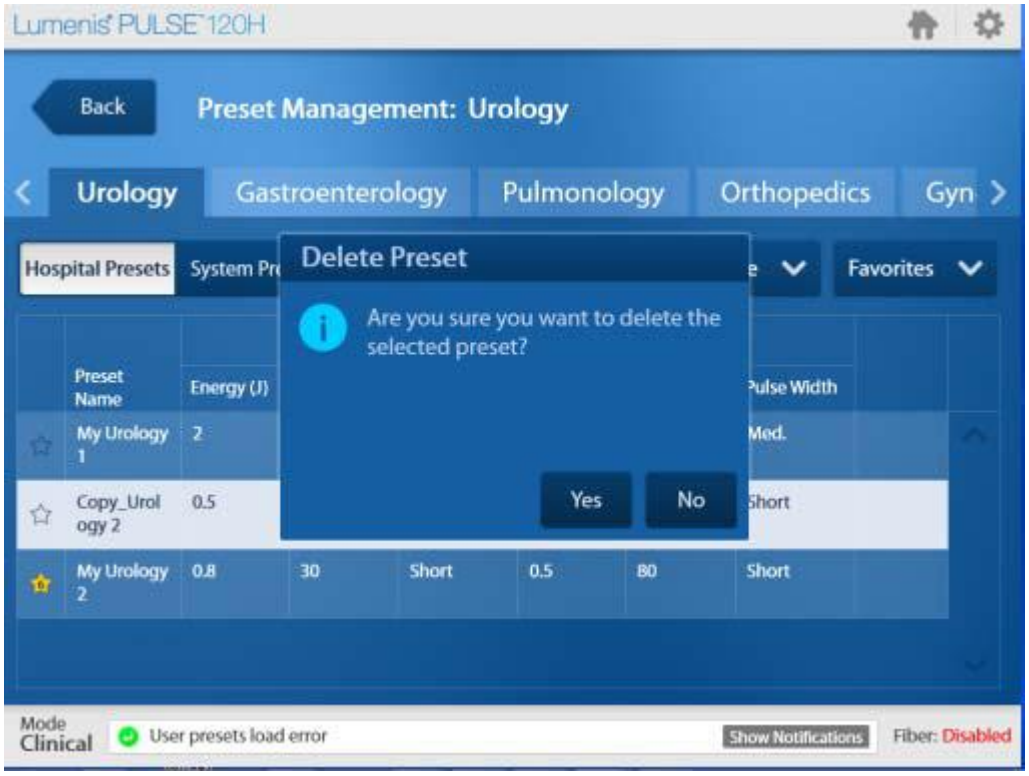


Figure 44: Delete Preset Confirmation Screen

Exporting Presets

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 120H.
2. From the **Main Menu** screen, press **Manage Preset**.
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 45: Manage Presets > More >Export Presets

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

6. Wait until the export operation is completed successfully.

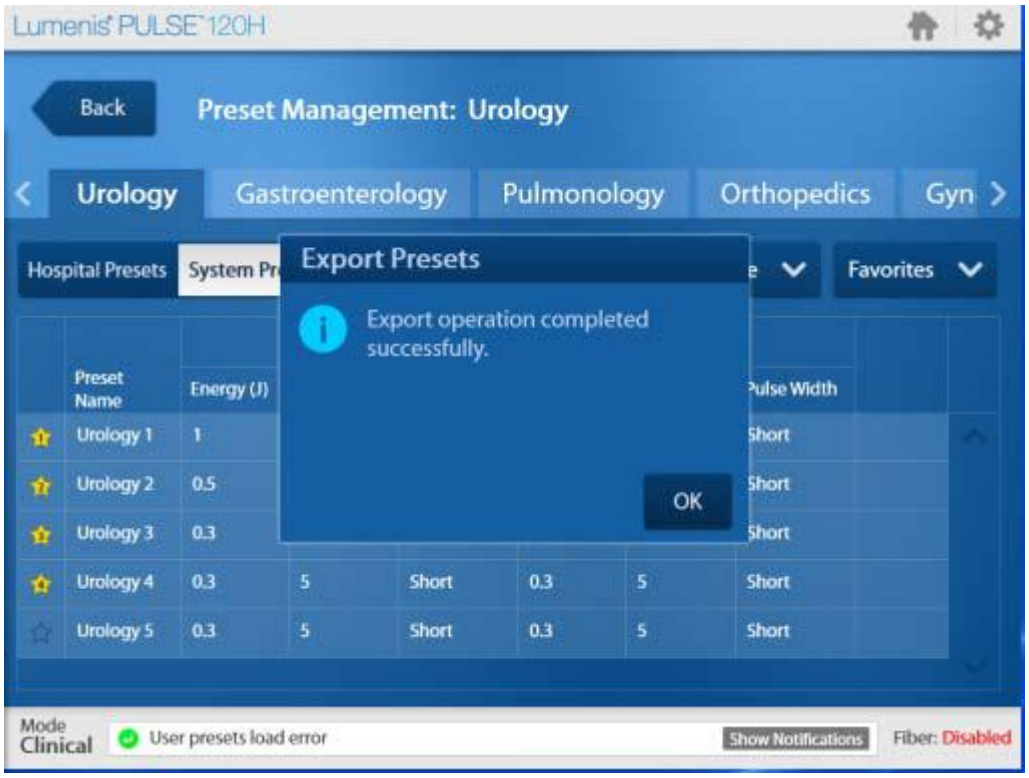


Figure 46: Export Operation Completed

Favorites

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

Changing the Favorite Presets (Add, Remove and Reorder)

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

1. From the **Main Menu** screen, press **Manage Preset**.

2. From the **Manage Preset** screen, press **Favorites** and select **Manage** from the dropdown menu.

Figure 47: Select Favorites > Manage

3. Select the **Preset** that you want to change.

Figure 48: Select Favorites > Manage

4. Perform the action that you want to take (move up, move down, add or remove).

5. Click **OK** to save the changes.

Quick Add a Favorite

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

1. From the **Main Menu** screen, press **Manage Preset**.

2. Select a preset with an empty star.

3. Press **Favorites** and select **Add to Favorites** from the dropdown menu.

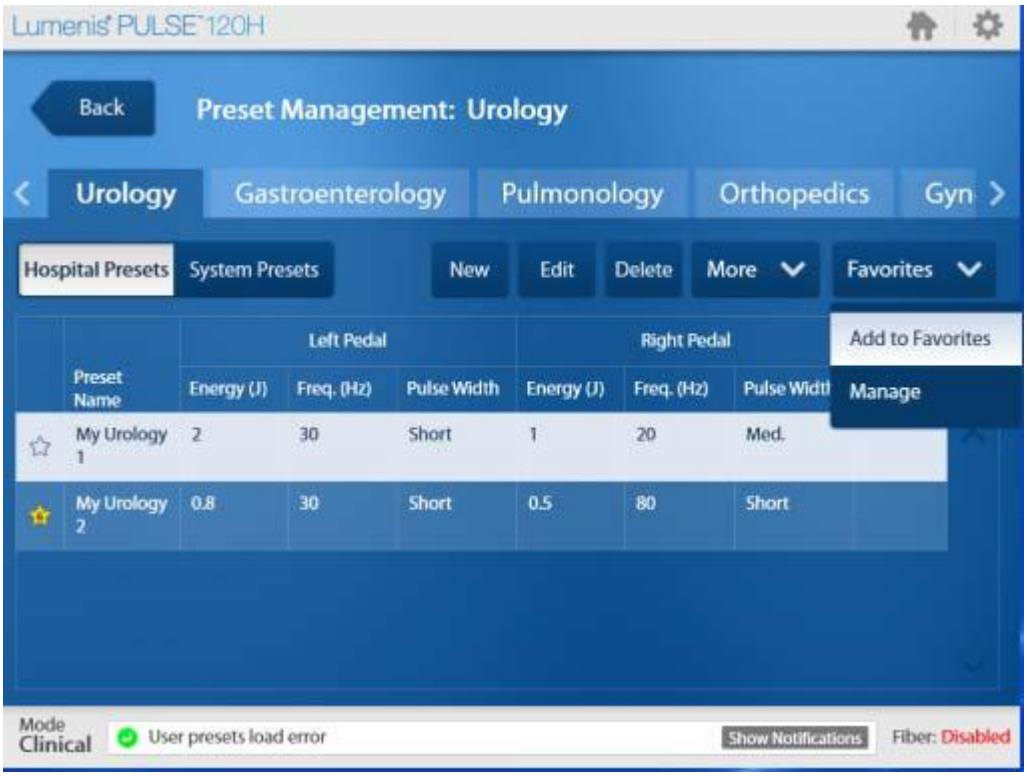


Figure 49: Quick Add a Favorite

Quick Remove a Favorite

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

1. From the **Main Menu** screen, press **Manage Preset**.

2. Select a preset with a yellow star.

3. Press **Favorites** and select **Remove Favorite** from the dropdown menu.

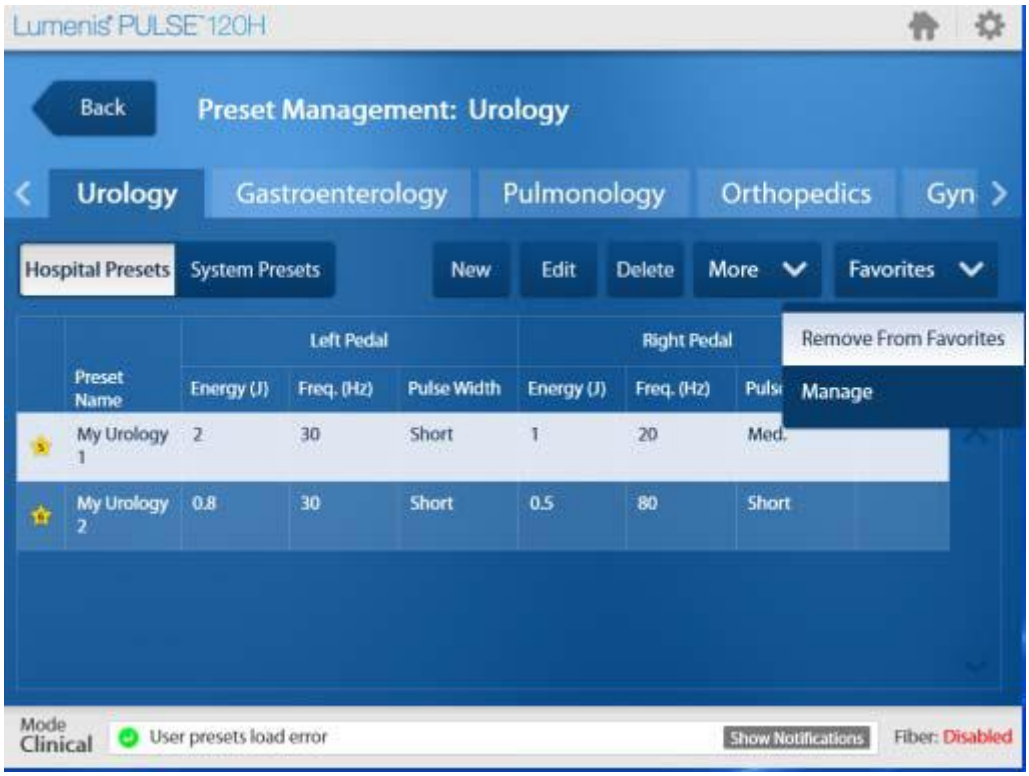


Figure 50: Quick Remove a Favorite

Reports

Lumenis Pulse 120H 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, press the **Reports** button.

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

Figure 51: Reports Screen

Exporting the Reports Log

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 120H.

2. From the **Home** screen, press the **Reports** button.

3. Press the **Export logs to USB** button.

4. In the **Export Logs** confirmation screen, click **OK**.

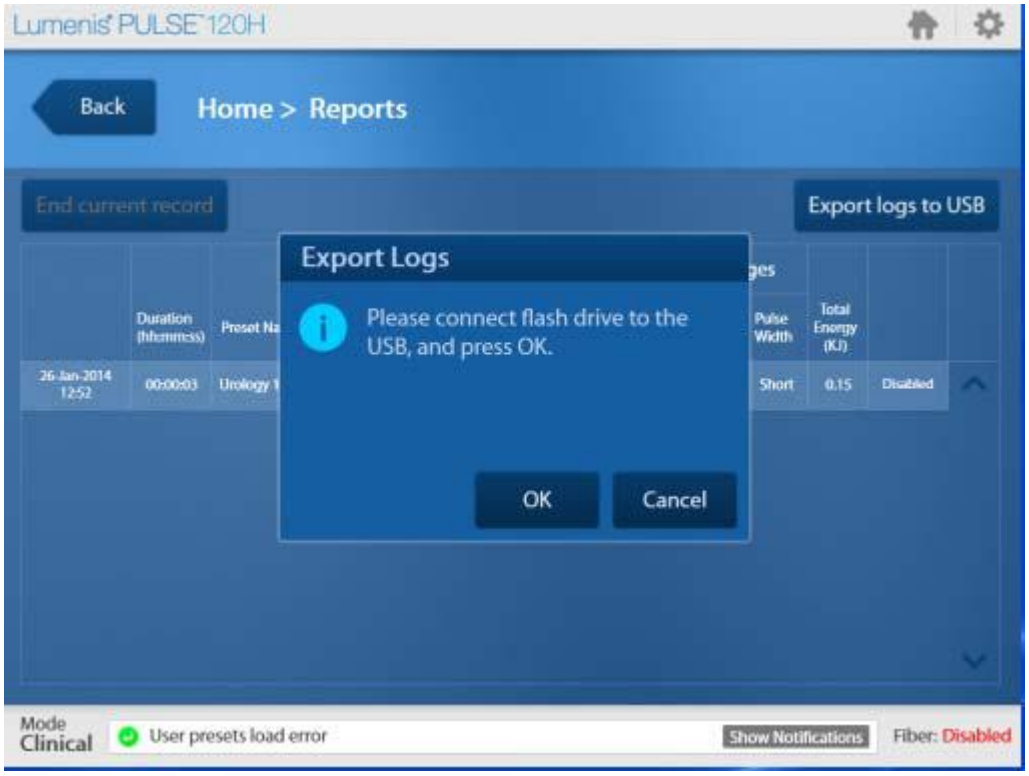


Figure 52: Export Logs Confirmation Screen

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

6. Wait until the export operation is completed successfully.

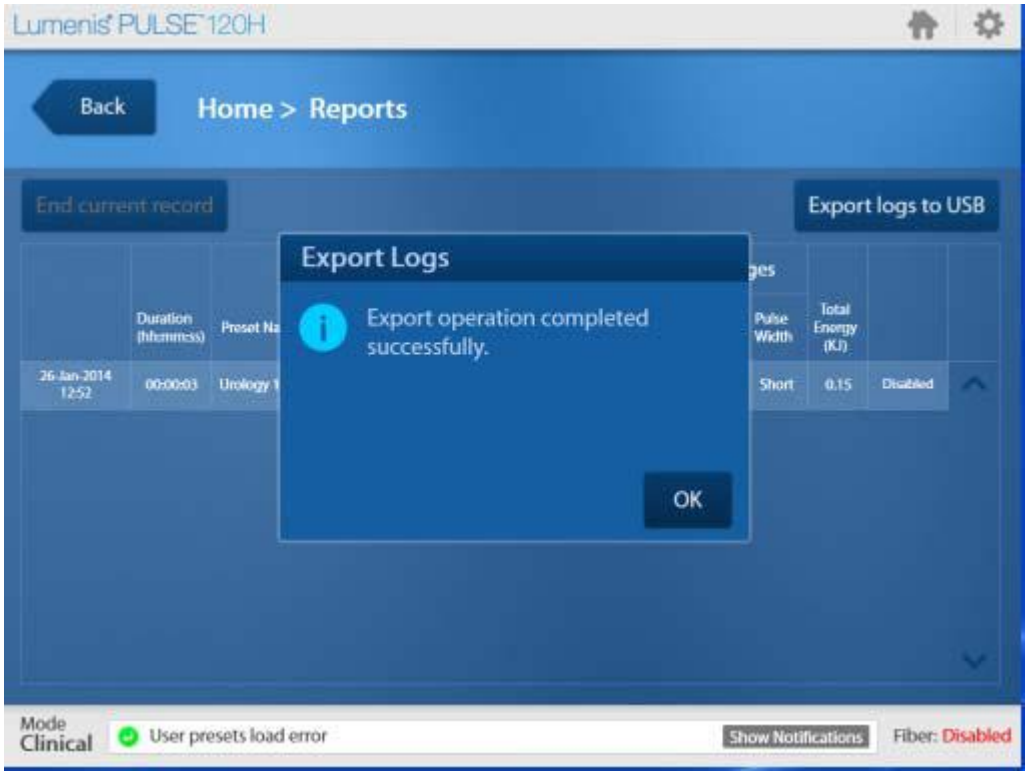


Figure 53: Export Operation Completed

Changing the Default Specialty

When you start up Lumenis Pulse 120H, the **Main Menu** screen automatically displays the default specialty. You can change this in the **Settings & Utilities** screen.

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

2. Press the **Default Specialty** button.

Figure 54: Default Specialty Button

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

Figure 55: Default Specialty Button

4. In the **Change Specialty** screen, 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.

NOTE:

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

Changing Screen Settings

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

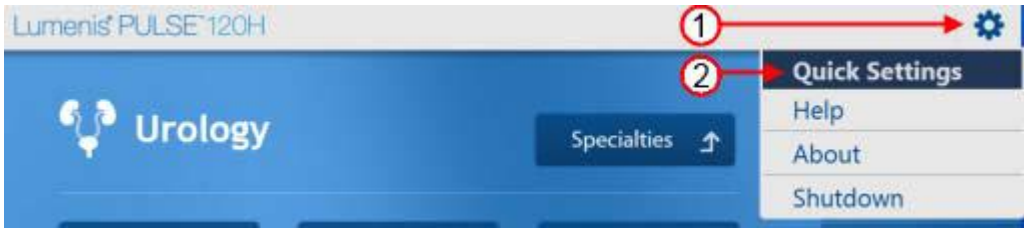


Figure 56: Select Quick Settings

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.

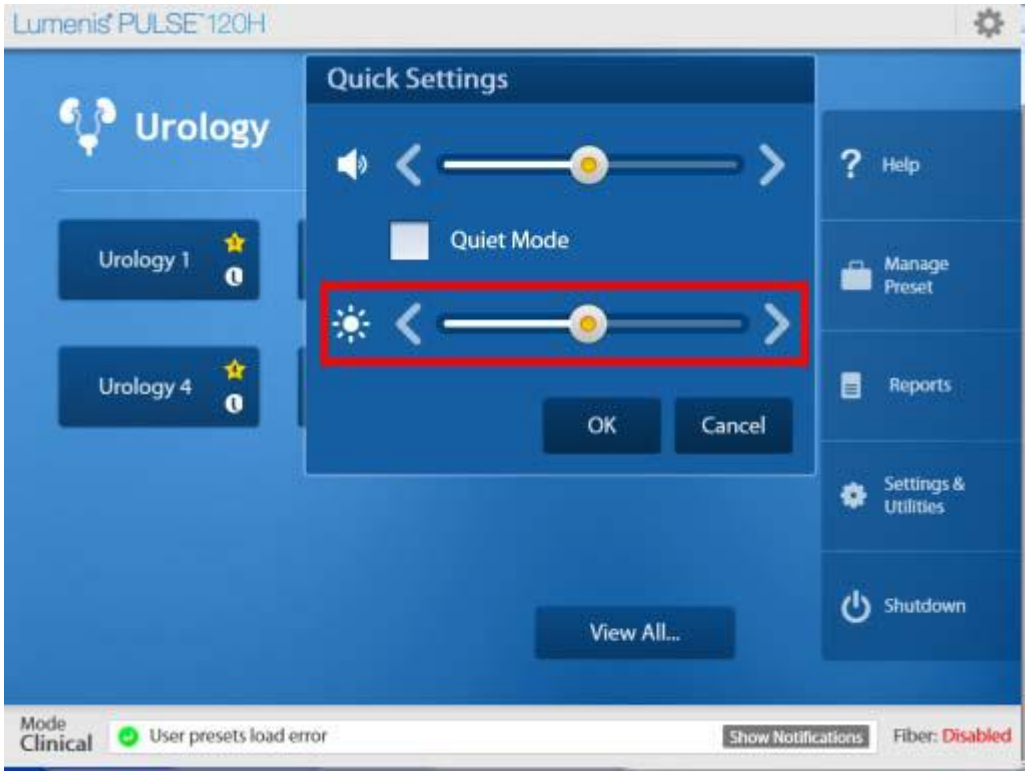


Figure 57: Select Quick Settings

3. Press **OK**.

NOTE:

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

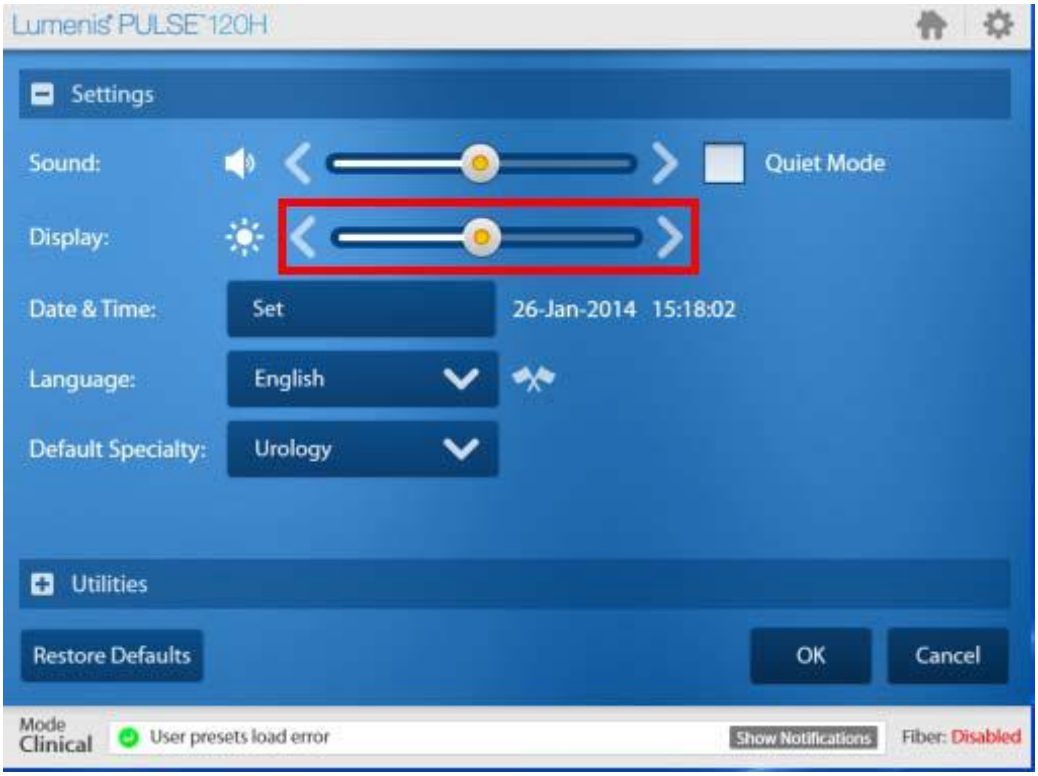


Figure 58: Settings & Utilities > Display Adjustment

Adjusting Volume and Sound

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.

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

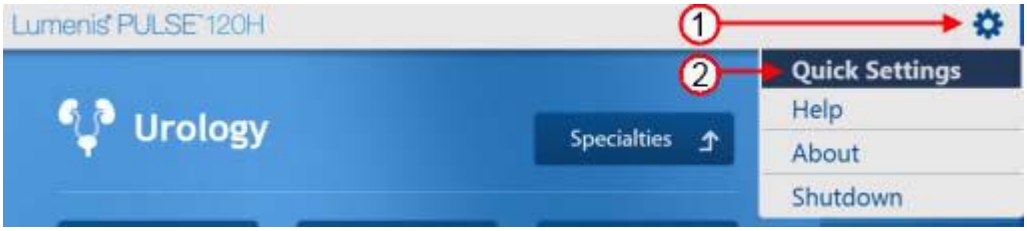


Figure 59: Select Quick Settings

2. In the **Quick Settings** screen that opens, slide the upper slider to the right to increase volume or to the left to decrease volume. If you do not want to hear any voice indications, select the **Quiet mode** check box.

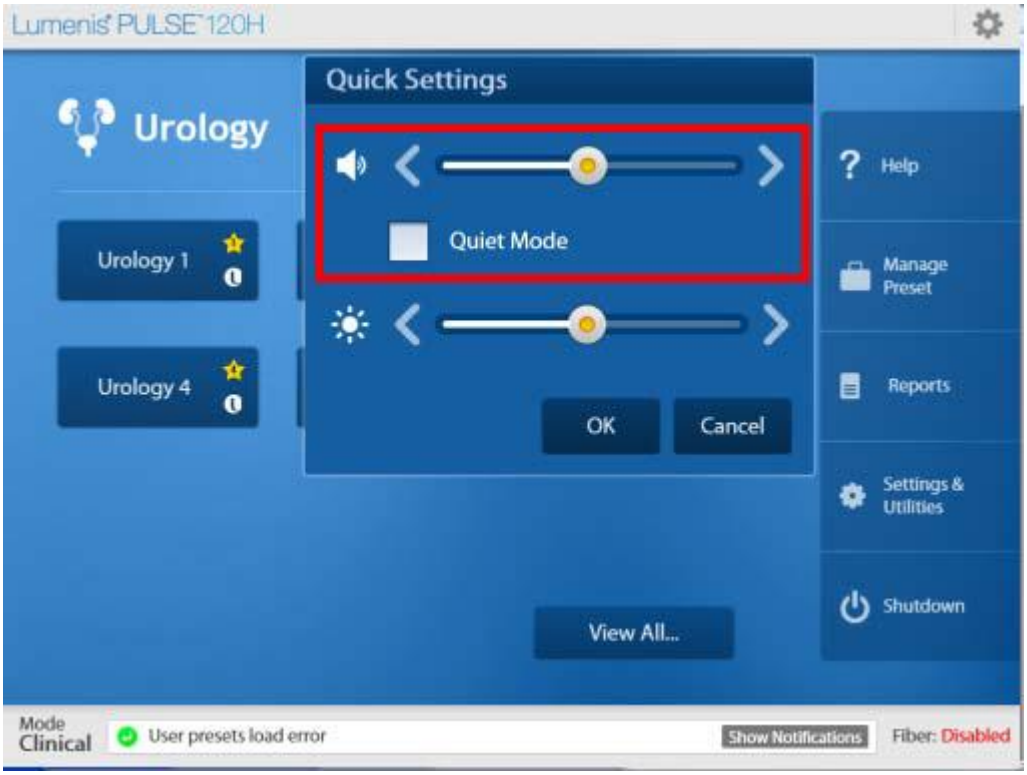


Figure 60: Select Quick Settings

3. Press **OK**.

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

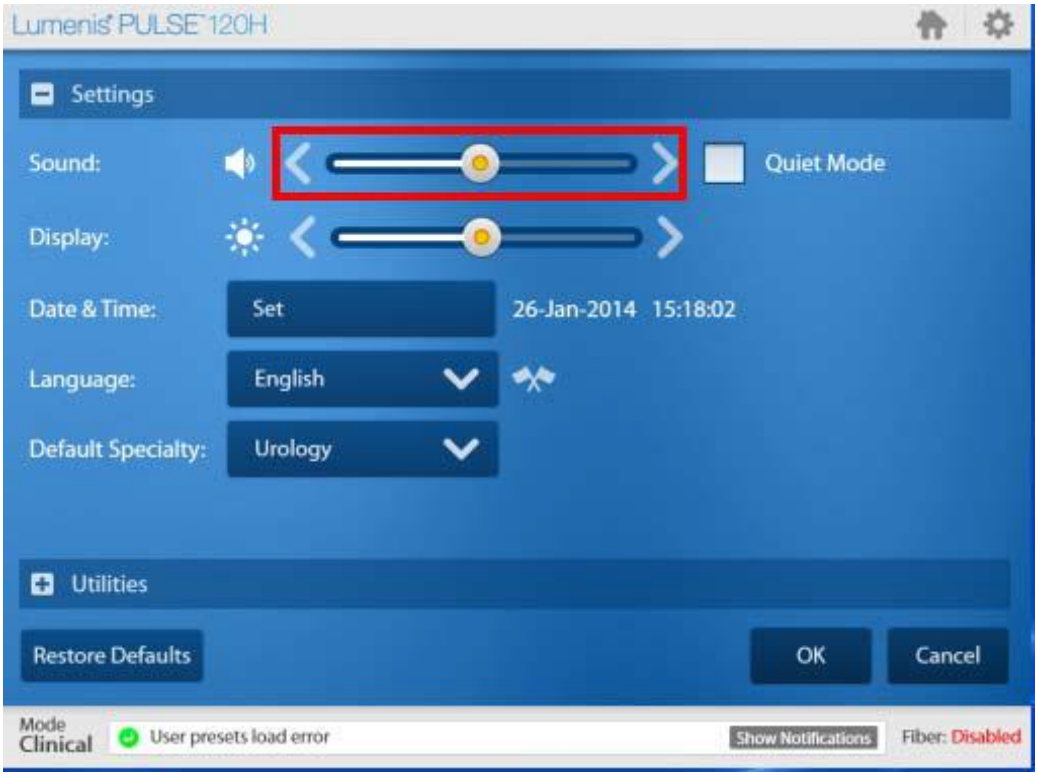


Figure 61: Settings & Utilities > Sound Level Adjustment

Changing Date and Time

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

2. Press the **Set** button.

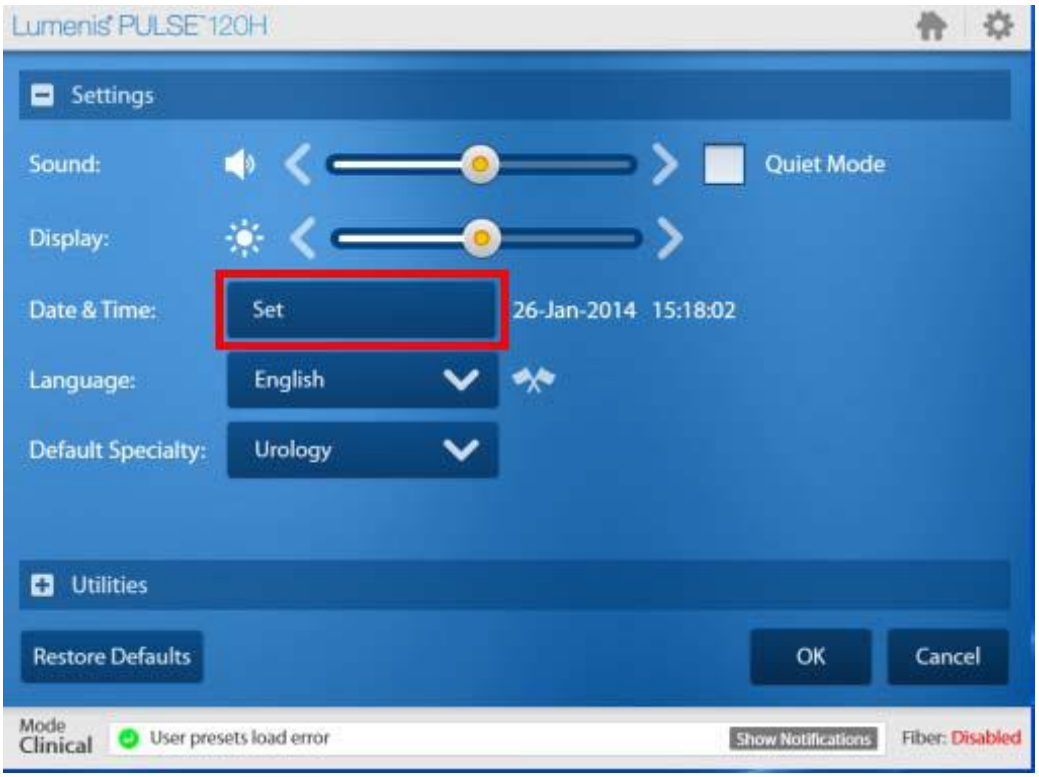


Figure 62: Set Date & Time Button

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

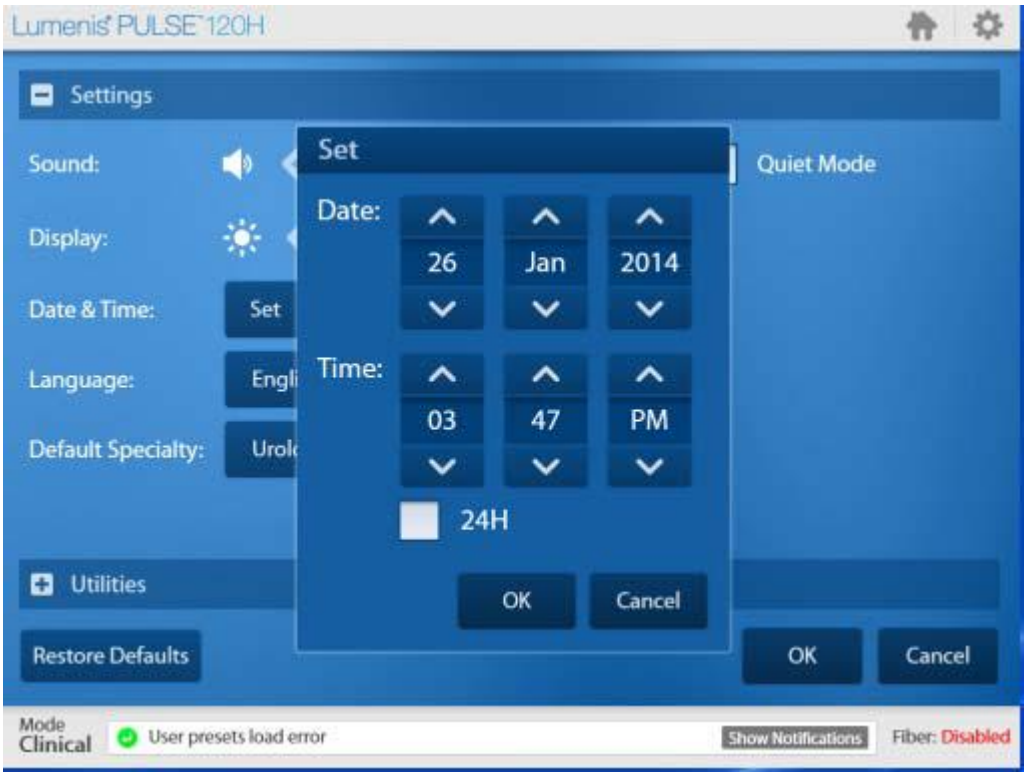


Figure 63: Settings & Utilities > Set Date & Time

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

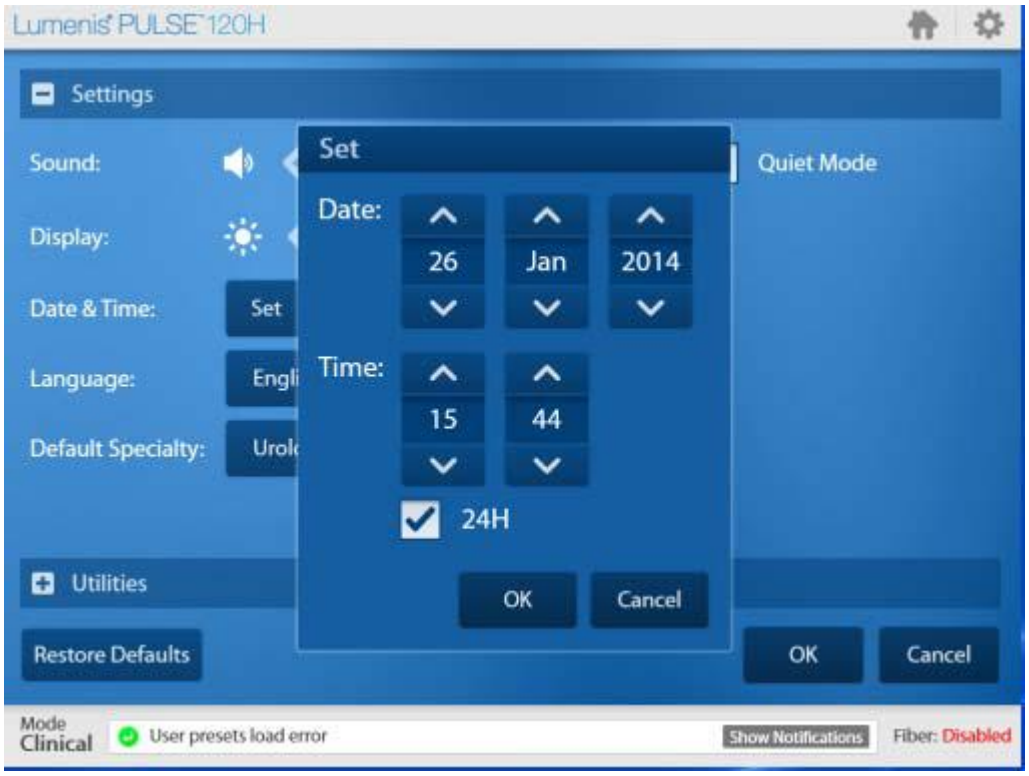


Figure 64: Settings & Utilities > Set Date & Time With 24 Hour Clock

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

Changing Language

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

2. Press the **Language** button.

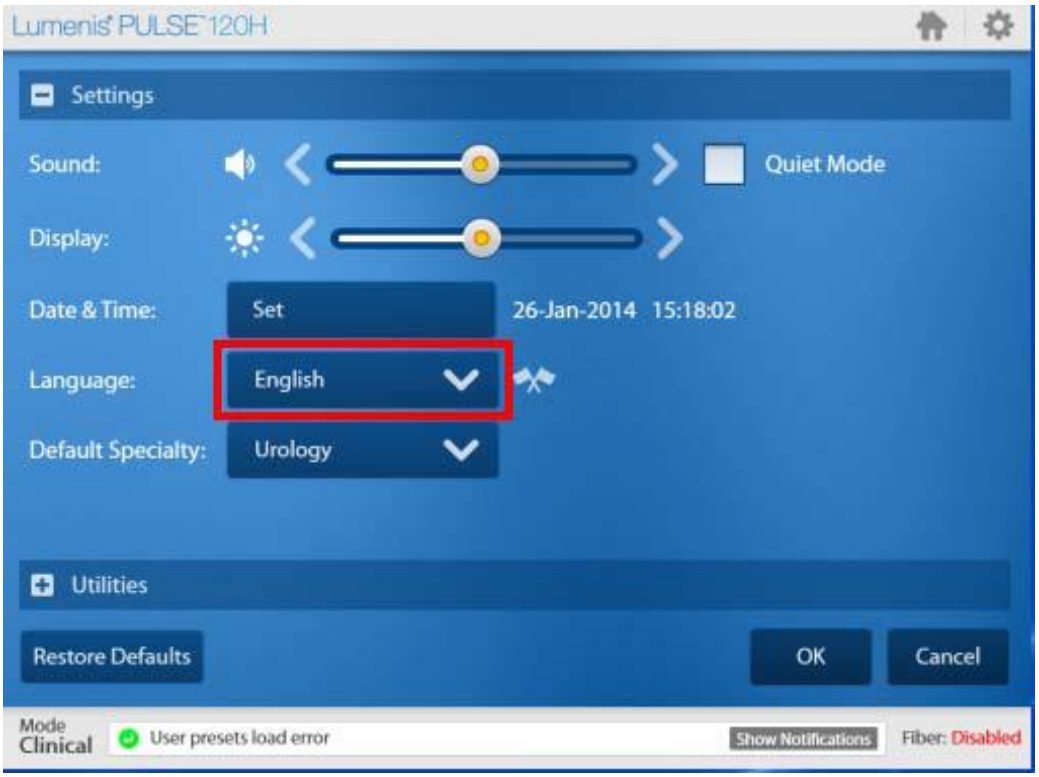


Figure 65: Language Button

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

Figure 66: Settings & Utilities > Change Language

4. In the **Change Language** menu, press **OK**.

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).

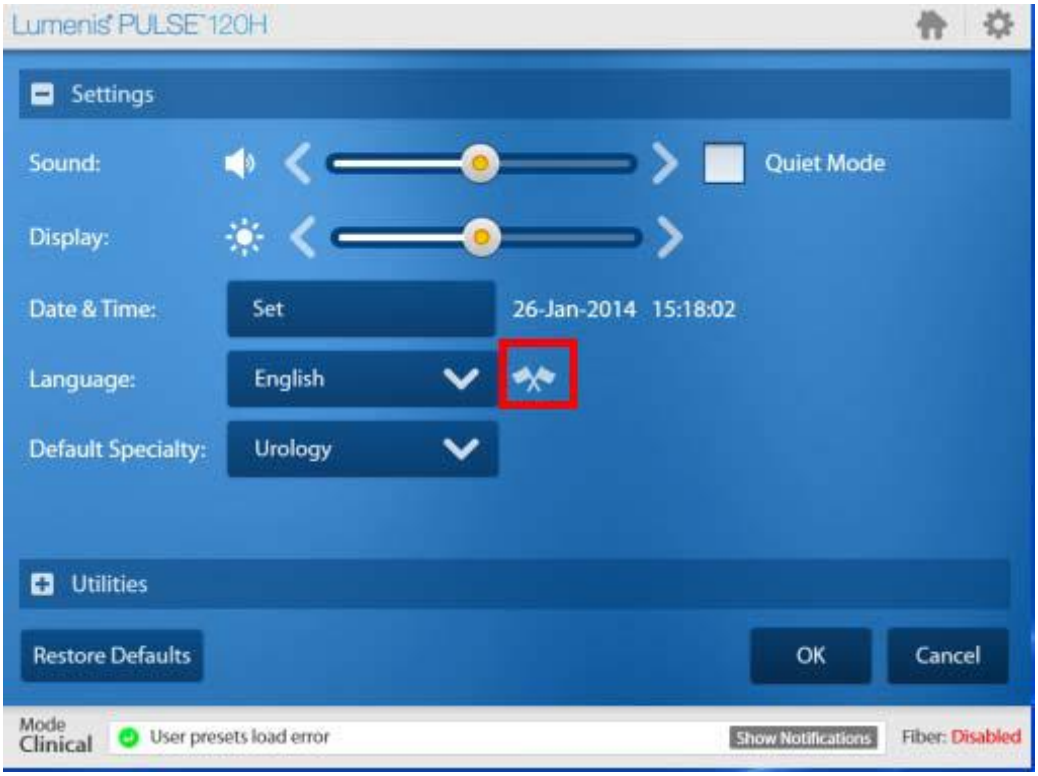


Figure 67: Settings & Utilities > Language Reset Flag

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 120H.

2. From the **Main Menu** screen, press the **Settings & Utilities** button.

3. Press the + next to **Utilities** to expand it.

Figure 68: Set Date & Time Button

4. Insert a USB device.

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

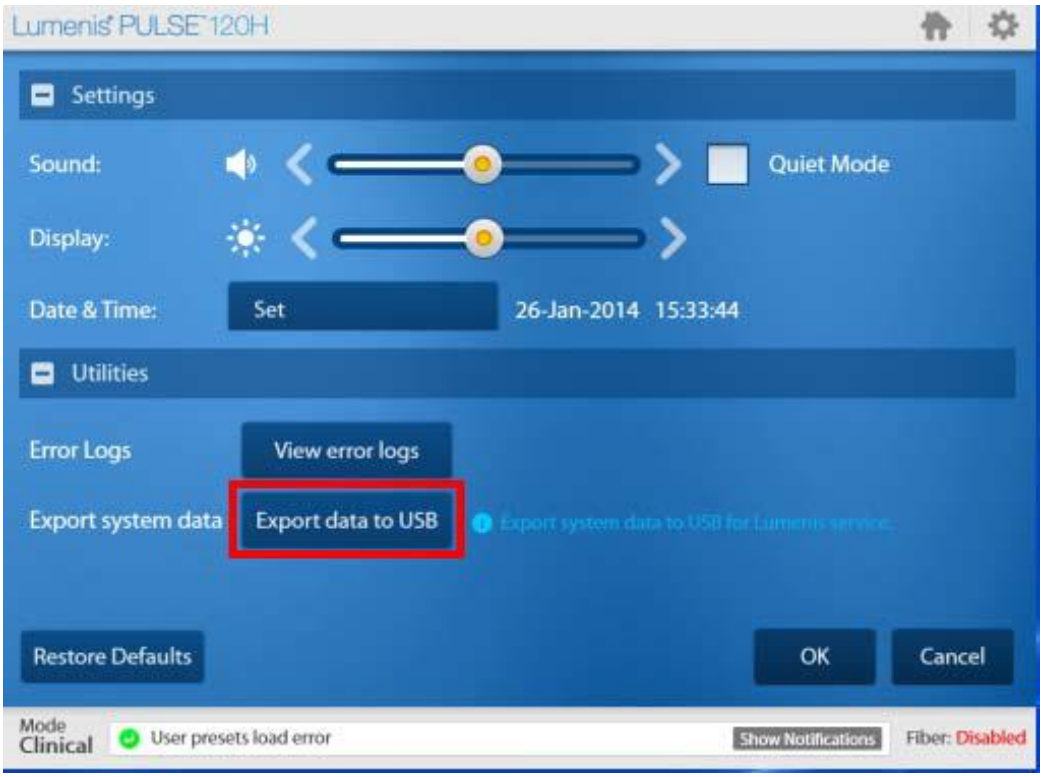


Figure 69: Export Data to USB Button

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

7. Wait until the export operation is completed successfully.

Figure 70: 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 **Main Menu** screen, press the **Settings & Utilities** button.

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

Figure 71: Set Date & Time Button

Help

1. Press the **Help** button.

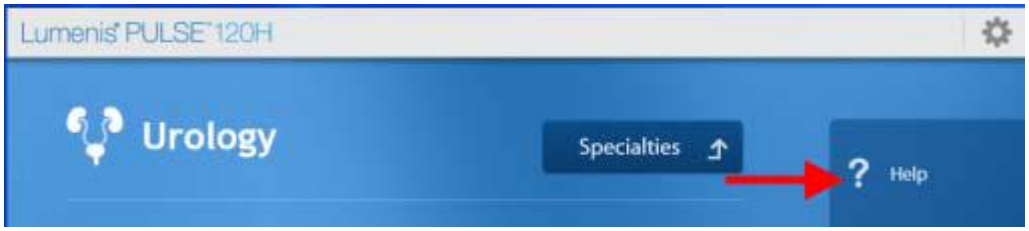


Figure 72: Select Help

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 **Main Menu** screen.

Figure 73: Location of the Back Button

Troubleshooting and Maintenance

Handling Error Messages and Notifications

Notifications and error messages appear in the **Notification bar** at the bottom of the screen. If you press **READY** while there is an error, it opens the **Notifications** screen. You can also open this screen from the notification bar by pressing the **Show Notifications** button.

1. Follow the instructions for the error message or notification.
2. For notifications, press the **Acknowledge** button.

   A check mark will appear to show that you have acknowledged the message and the notification will fade.

   If the notification is ignored, it will remain in the list. However, you may continue lasing with the system.
3. For errors, perform the required task as detailed in the error message. If the error is fixed, the message will fade and no longer appear in the notification bar.

   If the error is not corrected by a user action, the error will not fade and you will be prevented from lasing.
4. Repeat for each error message and notification.

5. Press the **Close** button to exit the **Notifications** screen.

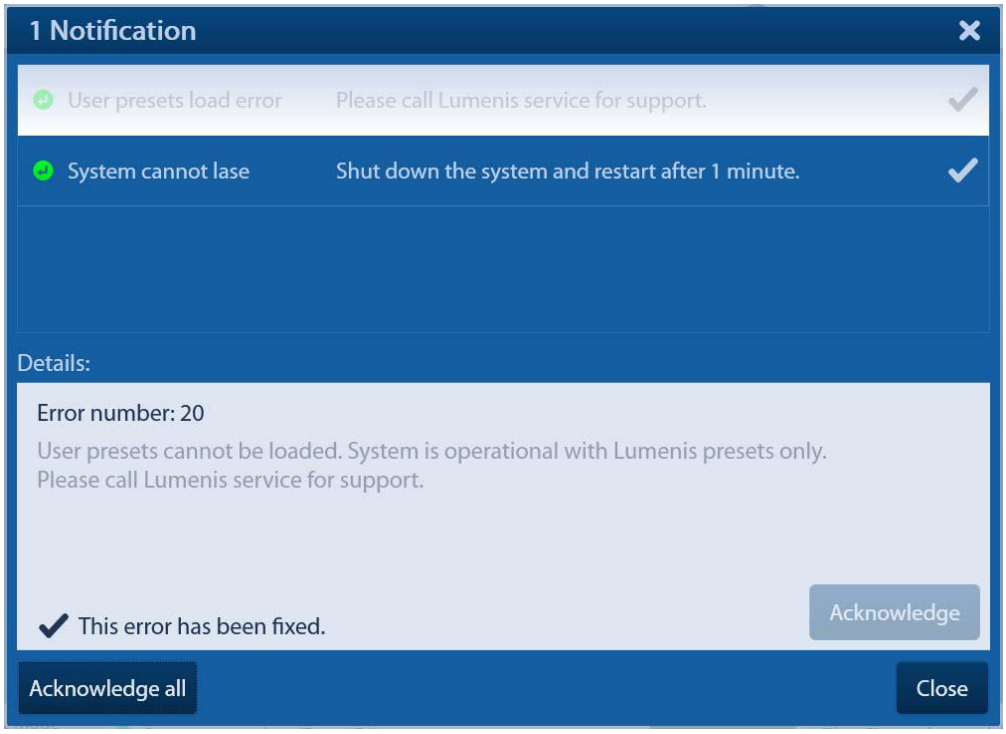


Figure 74: Notifications Screen

Troubleshooting

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

Initialization Problem Screen Pops Up

1. Write down the error number.
2. Press the **Shutdown** button.
3. If the problem re-occurs, contact Lumenis service.
4. Turn on the system with the keyswitch in the Off position.
5. Export logs and send them to Lumenis service.

System Does Not Turn On

The control screen does not illuminate. No blue light in the **On**/**Off** switch and around the delivery system port.

1. Plug in the laser.
2. Set the laser's main circuit breaker to the **On** (up) position.
3. Turn on the main electrical service power.
4. Use another 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 delivery system.
3. Lower the intensity of the endoscopic camera light.
4. Inspect and, if necessary, replace the debris shield.
5. Contact your local Lumenis service representative.

No Laser Emission

1. Replace the delivery system.
2. Inspect and, if necessary, replace the debris shield.
3. Contact your local Lumenis service representative.

A Notification Appears on the Control Screen

1. Acknowledge the error in the notification window and follow the suggested steps intended to clear the fault.
2. If the condition continues, turn off the laser for five seconds, and then turn it back on.
3. If the indication reappears, record the error number and contact your local Lumenis service representative.

Fiber Exceeded Recommend # of Uses. It is Advised to Replace the Fiber

1. Be aware that the fiber has exceeded the recommended number of uses.
2. You will continue to operate with it until it reaches the maximum number of uses allowed.

“Popping” or “Tapping” Coming Sound from the Fiber Port

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

1. Replace both the fiber and the debris shield.

Fiber Burn Back

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

1. Renew the fiber tip by stripping and cleaving the fiber.

Power Lmited

A limitation may be the result of a specific fiber that is used.

1. Choose appropriate fiber type for increased power.

Fiber Expired

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

Unrecognized Fiber

1. Replace the fiber with a Lumenis compatible one and resume normal operation.
2. If problem persists, contact Lumenis 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 failsafe 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	
Inspect cables and all external surfaces for damage.	Weekly	Hospital/Clinic Staff	If damage is found, call Lumenis Service.
Inspect electrical connections.	Weekly	Hospital/Clinic Staff	If damage is found, call Lumenis Service.
Check remote interlock connection and emergency stop button.	Weekly	Hospital/Clinic Staff	If interlock and/or button do not perform as required, call Lumenis Service.
Inspect/replace the debris shield	Weekly or if required by low output energy.	Hospital/Clinic Staff	If output energy is still low after replacing the shield, call Lumenis Service.
Deionizer and particle filters replacement.	Annually	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
Electrical safety checks.	Annually (or as required by institutional procedures).	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
Check and perform energy detectors calibration procedure.	Annually, or as required if system does not perform to specifications, or occurrence of error messages.	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.

Hospital/Clinic Staff Maintenance

Visual Inspection

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

Routine Exterior Cleaning

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

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

CAUTION:

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

Remote Interlock Check

Laser beam emission is disabled when the remote interlock plug is not connected or is improperly connected to the rear panel, even if it is not wired to an actual door interlock. To check this:

1. Set the system to **Standby** mode.
2. Unplug the remote interlock plug.
3. Try to select **Ready** mode. The system should display the following warning message in the notification bar: **Verify door closed**.
4. If the system does not display the warning message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

Emergency Stop Button Check

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

1. With the system **On**, press down on the emergency stop button; the system will turn itself off.
2. Turn the button clockwise to release it; the system will automatically restart itself.
3. Press the **Ready** button on the LCD to enable lasing.

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

Inspect / Replace the Debris Shield

If you hear an abnormal popping sound while delivering the treatment beam, accompanied by a dramatic reduction in treatment effect, the debris shield and/or the optical fiber have probably failed; you should immediately stop treatment and inspect both the debris shield and the fiber.

NOTE:

Refer to the delivery system's instruction guide for fiber inspection instructions.

The debris shield is a replaceable part that protects the laser system's optical components from damage by a failed delivery system. The debris

shield is like a fuse: you only need to replace it if inspection reveals that it is damaged.

1. Open the debris shield panel, located on the upper right of the Lumenis Pulse 120H laser console.

Figure 75: Location of the Debris Shield

2. Grasp the debris shield handle and pull the shield out of the receptacle.

CAUTION:

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

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3. Inspect the debris shield optic to verify that it is free of any burn marks, scratches, dust, or fingerprints. If the optic is damaged or dirty, replace it with a new one.

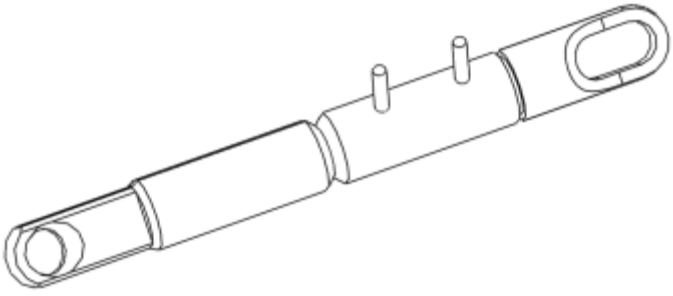

Figure 76: Inspect the Debris Shield Optic

4. Holding the debris shield handle, position the shield so that the pin is aligned with the pin receptacle and re-insert it into the debris shield receptacle.

5. Close the panel.

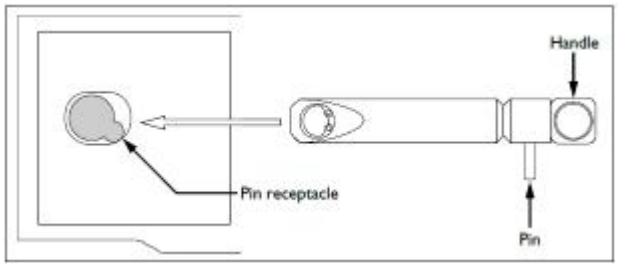

Figure 77: Reinsert the Debris Shield

Spare debris shields are located in the compartment at the rear of the laser console. A notification appears in the notification bar when there is no spare in the compartment.

Professional Maintenance

This section covers checks, calibrations and maintenance that require internal access to the Lumenis Pulse 120H console and special skills.

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 your local Lumenis representative.

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 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 120H 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 an external power meter.

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

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

1. Verify that all personnel are wearing the 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 as instructed in the Normal Operation chapter of 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, discontinue this procedure and contact your local Lumenis service representative.

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 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 Customer Service.

System Requirements and General Information

Installation

The laser is shipped directly from the factory to your site. Your local Lumenis service representative initially uncrates, inspects, sets up, and installs the laser 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.

Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser 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

- Scissors
- Fiber stripper
- Cleaving tool
- Fiber inspection scope
- Safety glasses
- Collection container kit
- Single use sterile aspiration tubing
- Single use non sterile tubing
- SlimLine SIS 200, 365, 550, 1000
- SlimLine EZ SIS 200, 365, 550
- SlimLine Steam Sterilization Tray
- Xpeeda D/S/L Fiber
- SlimLine Endo SIS 200, 365, 550
- SlimLine GI SIS 365

Electrical Requirements

Electrical Utilities

The Lumenis Pulse 120H holmium laser is available with single-phase (200-240 VAC, <46A, 50-60 Hz). Electrical power should be setup according to the model ordered. The service technician will configure the system during installation for the site voltage and verify that the installed power plug is compatible with the receptacle provided by the hospital.

Systems Designed For Use in the European Community under MDD

To comply with Council Directive 93/42/EEC concerning medical devices and to comply with EN harmonized standards IEC/EN 60601- 1 “Medical Electrical Equipment - Part 1: General Requirements For Safety 1: Collateral Standard: Safety Requirements For Medical Electrical Systems” and IEC/EN 60601-2-22 “Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment”, the 200-240 VAC configured laser must be connected by means of a dedicated single-phase, 46 A, 200-240 VAC wall socket and plug combination. Leakage current for this laser does not exceed 500 µA. The 63 A, 230 ±

10% VAC wall socket and lockable plug combination must comply with 60309-1 “Plugs, socket-outlets and couplers for industrial purposes - Part 1: General requirements” and IEC/EN 60309-2 “Plugs, socket-outlets and couplers for industrial purposes - Part 2: Dimensional interchangeability requirements for pin and contact-tube accessories”.

This equipment has been tested and found to comply with the limits in standard IEC/EN 60601-1-2 “Medical Electrical Equipment - Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.” These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in accordance with the instruction manual.

Removable or Lockable Wall Socket and Plug Configurations

If the laser is installed with a removable plug or wall socket and lockable plug combination prior to installation, the customer’s engineer or electrical contractor will be responsible for ensuring that the proper electrical requirements are available at the site.

Systems Designed For Use Outside of Europe

When installed with a removable or lockable wall plug, the socket and wall plug connection must be rated for 50A @ 60 Hz, 63A @ 50 Hz, 250 VAC. In most instances, customers must purchase a suitable electrical connection kit locally.

Systems Designed For Use in European Community under MDD

To comply with the European Community Medical Device Directive93/42/EEC, the 63 A, 230 ± 10% VAC wall socket and lockable plug combination must comply with EN 60309.

Compliance With International Standards

Refer to the Lumenis website (www.Lumenis.com) to view a complete list of international regulatory standards that the Lumenis Pulse 120H system is designed to comply with.

In accordance with the regulation a recommended routine inspection and maintenance schedule is provided in the System Requirements and General Information section of this manual.

In compliance with these standards, the system is equipped with the following:

Emergency Stop Button

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

Keyswitch

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

WARNING:

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

Laser Emission Indicators

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

The system also verbalizes **"READY"** and **"STANDBY"** with a voice indicator when the system is transitioned from mode to mode.

External Door Interlock

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

Protective Housing

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

Safety Shutter

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

Manual Reset

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

Electronic Fault Detection Circuitry

If any of the electronic system monitors detect a fault condition, laser exposure cannot occur. The high voltage power supply disables, the safety shutter closes, and the footswitch disables.

Safety Interlocks

The laser has a safety interlock on the fiber optic laser connector.

Precision of Displayed Values

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

Space Requirements

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

Specifications

Specifications are subject to change without notice.

Treatment Beam

Wavelength	2.1 µm
Maximum Average Power	120W
Pulse Energy	0.2 – 6J
Pulse Frequency	5 - 80Hz
Max Pulse Duration	1300µs
US FDA CDRH laser classification:	Class IV
European EN 60825 laser classification:	Class 4

Aiming Beam

Type:	DPSS
Power:	5 mW maximum, continuous wave
Settings:	Low, medium & high
Wavelength:	532 nm
Laser classification:	Class IIIa / Class 3R
Color:	Green

Input Power

200-240 VAC, <46A, 50-60 Hz

Chiller

Gas-based chiller providing cold water.

Cooling Air Requirements

Minimum 50 cm (20 in) from walls.

Physical Characteristics

Dimensions (W x H x L):	47 x 105 x 116 cm 15 x 41.3 x 45.7 inches
Weight	240 kg. / 529 lbs.
Power Cable Length	7 meters (23 feet)
Footswitch Cable Length	5 meters (16.4 feet)

Environmental Requirements (Operating)

Temperature range:	10 – 30°C (50 – 86°F)
Maximum humidity:	75% at 30°C (86°F) non-condensing
Atmospheric pressure:	77 – 106 kPa

Environmental Requirements (Storage and Transportation)

Temperature range:	(-20) – 70°C [(-4) – 158°F]
Maximum humidity:	95% at 30°C (86°F) non-condensing
Atmospheric pressure:	77 – 106 kPa

Laser Safety Eyewear

The following laser safety eyewear complies with DIN EN 207, ANSI Z136.1 and Z87.1-2003 standards as noted in the laser safety section of this manual.

ANSI standard laser safety eyewear

Part Number	Product Name
AX-1002033	Glasses, Safety, Holmium (2100 nm)

External Door Interlock Pin Assignments

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

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

Pin assignments are as follows:

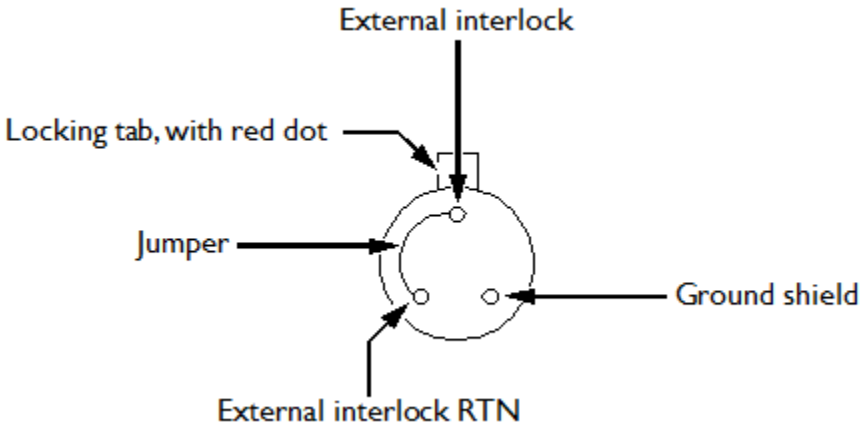

Figure 78: External Door Interlock Pin Assignments (solder side of plug shown)

Customer Service

Customer Service and Warranty

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

Lumenis Center	Address	Telephone/Fax
Lumenis Ltd.	Yokneam Industrial Park 6 Hakidma Street P.O.B. 240 Yokneam 2069204, Israel	Tel:+ 972.4.959.9000 Fax:+ 972.4.959.9050
Lumenis, Inc.	2033 Gateway Place, Suite 200 San Jose, CA 95110, USA	Tel:+ 1.408.764.3000 Fax:+ 1.408.764-3999
Lumenis GmbH, Germany	Heinrich Hertz Str. 3 D-63303 Dreieich-Dreieichenhain Germany	Tel:+ 49 (0) 6103.8335.0 Fax:+ 49 (0) 6103.8335.300
Lumenis Co. Ltd., Japan	3rd Floor, Time-24 Building., 2-4-32 Aomi Koto-ku, Tokyo 135-8073, Japan	Tel:+ 81.3.6743.8300 Fax:+ 81.3.6473.8301
Lumenis Ltd. China	4th floor, South Tower, Kerry Centre, No.1 Guang Hua Road Beijing 100020, China	Tel:+86.10.5737.6677 Fax:+86.10.5737.6767

Appendix A: EMC Guidance and Manufacturer's Declaration

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Lumenis Pulse 120H is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 120H should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Lumenis Pulse 120H uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
		The Lumenis Pulse 120H 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.

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity The Lumenis Pulse 120H is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 120H 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 line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 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 120H requires continued operation during power mains interruptions, it is recommended that the Lumenis Pulse 120H be powered from an uninterruptible power supply or a battery.
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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Lumenis Pulse 120H is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 120H should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Lumenis Pulse 120H, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz	
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 120H is used exceeds the applicable RF compliance level above, the Lumenis Pulse 120H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM]. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Lumenis Pulse 120H			
The Lumenis Pulse 120H is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lumenis Pulse 120H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lumenis Pulse 120H 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
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.			