Lumenis® PULSE™ 120H

Holmium Surgical Laser
Operator 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.

CAUTION:

In the USA: Federal law restricts this device to sale by or on the order of a physician.

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

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

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

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

Please visit **http://www.lumenis.com/Service-Support/Recycle** to understand what arrangements Lumenis has made in each EU Member State.

CE 0483

EC REP

Authorized Representative in the European Community:
Lumenis (Germany) GmbH
Heinrich-Hertz-Strasse 3
D-63303 Dreieich-Dreieichenhain
Germany
Tel: +49 (0) 6103.8335.0

Manufactured by 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
www.Lumenis.com

Table of Contents

Introduction **7**
Manual Conventions 8
System Description and Main Features 9
Component Checklist 11

Holmium Laser Theory of Operation **12**
Laser Power Parameters 12
Moses Capability 13

Safety **15**
Introduction 15
Optical Hazards 15
Electrical Hazards 17
Fire Hazards 18
Additional Safety Considerations 18
Protecting Non-Target Tissues 19
Safety Indicators 21
Warning, Certification and Identification Labels 22

Clinical Guide **27**
Effect on Soft Tissue 28
Effects on Stones 28
Indications for Use 29
Contraindications 30
Warnings and Precautions 30
Complications 32
Detailed Indications for Use 33

Preparing the System for Use **39**
Moving the System 40
Adjusting the Fiber Support Arm 41
Adjusting the Screen 42
Connecting the Footswitch 43

Ethernet, VGA and USB Connection Ports 44
Inserting the External Door Interlock Connector 45
Plugging in the Main Power Cable 46
Connecting the Delivery System 47
Connecting the Suction System 49

Main System Screens 52
Home Screen Description 52
Specialties Screen Description 55
Treatment Screen Description 56

Normal Operation 62
Emergency Stop Button 62
Verification of Connections 62
Powering on the System 63
Selecting the Treatment 63
Starting Laser Treatment 66
Shutting Down the System 68
Moving the Laser Console 69

Advanced Operations 72
Moses Capabilities 72
Additional Capabilities 78
Saving Settings as Hospital Presets 80
Preset Management 82
Favorites 96
Reports 100
Changing the Default Specialty 103
Other Operations 105
Help 120

Troubleshooting and Maintenance 122
Handling Error Messages and Notifications 122
Troubleshooting 124
Routine Periodic Maintenance 127

Hospital/Clinic Staff Maintenance 128
Professional Maintenance 132

System Requirements and General Information 134
Installation 134
Accessories 135
Electrical Requirements 135
Compliance With International Standards 136
Space Requirements 138
Specifications 139

Customer Service 143
Warranty 143
Returning Equipment 143
Customer Feedback 143

Appendix A: EMC Compliance 144
Electromagnetic Emissions 144
Electromagnetic Immunity 145

Appendix B: Intentional RF Radiation 146

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.

In the USA:

CAUTION:

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

Lumenis lasers and delivery systems are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser 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
- Rotating control screen
- Dual-pedal footswitch
- Integrated suction pump[1]
- Fiber support arm
- Security Identification System (SIS) technology
- Green aiming beam

Figure 1: Lumenis Pulse 120H Laser Console

1. Optional purchase equipment

Laser Console

The laser console houses the control screen, integrated suction pump (optional), 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 connect 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[1]

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

1. Optional purchase equipment

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.

CAUTION:

The system suction unit should only be used during endoscopic procedures with Lumenis validated aspiration equipment.
Third party accessories are not authorized for use.

Component Checklist

- Lumenis Pulse 120H laser console.
- Detachable dual-pedal footswitch.
- External door interlock connector.
- Keys
- Operator manual.
- Fiber support arm.

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 2100 nm. This wavelength is strongly absorbed by water. Since soft tissue is comprised primarily of water, holmium laser energy can be used effectively for excision, incision, ablation, and vaporization. Holmium laser energy is also very effective in lithotripsy of calculi.

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 mid-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 2 Joules per pulse at a frequency of 60 Hz.

Holmium laser systems can deliver the same average power at different settings to achieve different laser tissue effect. Changing the energy of each pulse can be described as the “bite size” of the laser effect, whereas the frequency as the “bite rate”. For example, setting the system at 30W can be performed using the following sets of parameters: 1.5J at 20 Hz or 0.5J at 60 Hz.

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 a rapid 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 required.

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.

Moses Capability

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

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

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

NOTE:

Moses capability requires the use of dedicated Lumenis **Moses** supported fiber and it is available only for systems that incorporate Moses capability which has been activated. A complete discussion of Moses capability and fibers may be found in the Advanced Operations chapter in the section named Moses Capabilities.

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. De-focusing (increasing the fiber distance from the tissue) is a common method for decreasing power density on tissue. When using the Moses capability, due to its reduced dependence on fiber tip distance from the target, this technique may be less effective.

Safety

Introduction

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

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

CAUTION:

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

Optical Hazards

Laser Safety Eyewear

The following specifications were calculated for this system:

System	Wavelength Used	Maximum Permissible Exposure	Nominal Ocular Hazard Distance
Lumenis Pulse 120H	2.1 µm	50 J/m^2	1.6 M

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

System	Wavelength Used	Minimum Optical Density	Protection Level
Lumenis Pulse 120H	2.1 µm	3.0	DI LB4

WARNING:

- Select the appropriate laser safety eyewear, for the specific laser in use, by verifying that the above specifications are indicated on the laser safety eyewear that is at your disposal.
- Always provide eye protection for the patient. Wet thick cloths or wet gauze 4 x 4s can be use together with the patient protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.
- For periorbital treatment, always protect the patient with dulled, metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.

Laser safety eyewear must meet all additional requirements as per ANSI Z136.1 and EN 207.

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

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser.
3. Install an external door remote interlock that automatically disables the laser when the treatment room door is opened.

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

WARNING:

- Smoke evacuation may be required if using the laser in open-air procedures.
- Do not connect any USB flash drives, network or VGA cable to the system during operation. Doing so may negatively affect performance.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Lumenis Pulse 120H, including Lumenis Pulse 120H cables. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, delivery devices and cables, other than those provided by Lumenis, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING:

- Lumenis Pulse 120H is intended for use only in operating rooms, within a professional healthcare facility environment, except for near HF SURGICAL EQUIPMENT, and outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging.
- Lumenis Pulse 120H needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance, with regard to electromagnetic disturbances for the expected service life of 7 years.

NOTE:

The system is designed to avoid unintended lasing, and an error message will appear in case the system cannot laser within ±20% from the requested settings, see Chapter Troubleshooting and Maintenance for error handling details.

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 make sure that the footswitch is not being operated while 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**/**Standby**
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.
- A warning tone or audible voice message is emitted if the system is switched to **READY** mode while there is no fiber connected to the system.
- When lasing, the lasing emission indicator displays on the screen.

Warning, Certification and Identification Labels

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

Figure 4 displays the identification and certification labels affixed to the system and the symbols displayed in the labels:

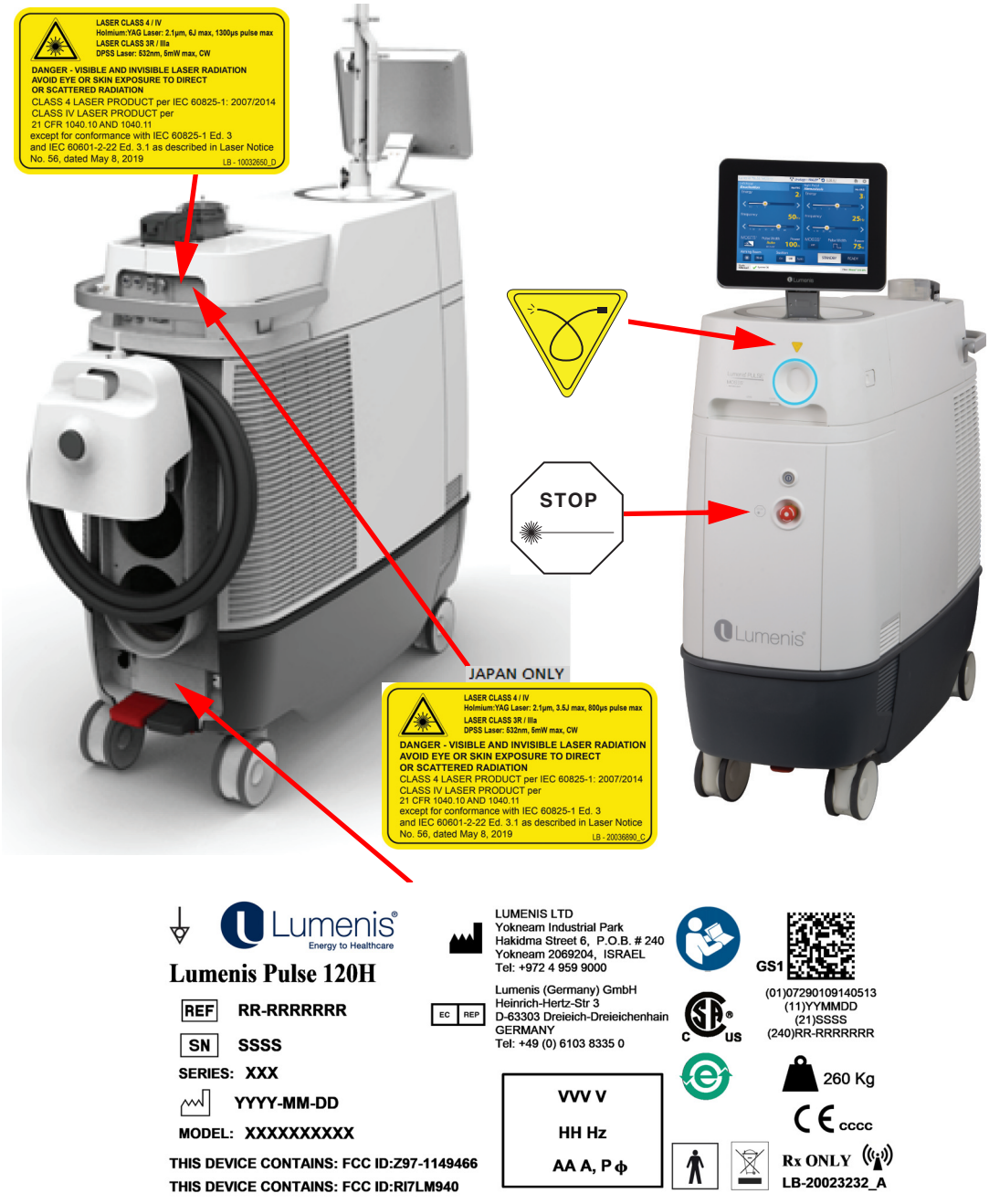
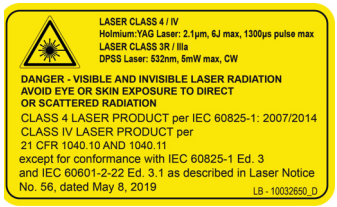


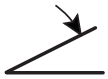
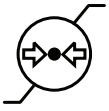
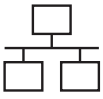
Figure 4: Location of Warning, Identification and Certification Labels Affixed to the System (for illustration purposes only)

Explanation of the symbols used in the labels

As required by national and international regulatory agencies, appropriate warning labels have been mounted in the specified locations. Figure 4 displays the warning, identification and certification labels affixed to the system:

Symbol	Description
Lumenis® Energy to Healthcare	Lumenis, Energy to Healthcare
CE 0483	CE Compliance
EC REP	Authorized Representative in the European Community
	Manufacturer
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
SERIES	Series Number
MODEL	Model Name
	Follow Instruction for Use
230V 50HZ 37 A, ϕ1	Electrical Requirements
	Equipotential Connection Pin
	Type BF Equipment
IP N1N2	Mechanical and Liquid Ingress

Symbol	Description
Rx ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
THIS DEVICE CONTAINS: **FCC ID: Z97-1149466** **THIS DEVICE CONTAINS:** **FCC ID: RI7LM940**	FCC identification: This device contains: FCC ID: Z97-1149466 FCC ID: RI7LM940
	Emergency Laser Stop
	Fiber Connection Port (Aperture)
	Laser Class Label Holmium:YAG Laser: 2.1µm, 6J max, 1300µs pulse max LASER CLASS 3R / IIIa DPSS Laser: 532nm, 5mW max, CW **DANGER-VISIBLE AND INVISIBLE LASER RADIATION** **AVOID EYE OR SKIN EXPOSURE TO DIRECT** **OR SCATTERED RADIATION** CLASS 4 LASER PRODUCT per IEC 60825-1: 2007/2014 CLASS IV LASER PRODUCT per 21 CFR 1040.10 & 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 as described in Laser Notice No. 56, dated May 8, 2019
For JAPAN ONLY: 	Laser Class Label LASER CLASS 4 / IV Holmium:YAG Laser: 2.1µm, 3.5J max, 800µs pulse max LASER CLASS 3R / IIIa DPSS Laser: 532nm, 5mW max, CW **DANGER-VISIBLE AND INVISIBLE LASER RADIATION** **AVOID EYE OR SKIN EXPOSURE TO DIRECT** **OR SCATTERED RADIATION** CLASS 4 LASER PRODUCT per IEC 60825-1: 2007/2014 CLASS IV LASER PRODUCT per 21 CFR 1040.10 & 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 as described in Laser Notice No. 56, dated May 8, 2019
	External Interlock Connection

Symbol	Description
	Footswitch Connection
	CSA Compliance
	Unique Device Identifier (UDI) Code, Type GS1
	System Weight
	Product contains RF Transmitter
	Waste of Electrical and Electronic Equipment (WEEE) compliance
	RoHS Compliance (China)
	Temperature Limitation
	Humidity Limitation
	Atmospheric Pressure Limitation
	USB Connection
	Ethernet Connection
	Keyswitch On/Off

Symbol	Description
WARNING **Grounding reliability can only be achieved when the EQUiPMENT is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade"** **0363-076-01 Rev. B**	Power Cable Label: Grounding reliability can only be achieved when the EQUIPMENT is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade".
	Protective Earth (ground)
	On/Off button on front panel
	On/Off power switch on back panel (main circuit breaker)

Clinical Guide

Lumenis recommends that physicians learn and gather additional knowledge related to the Lumenis Pulse 120H. For details on courses and training sessions 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 pre-clinical studies. The 2100 nm 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.

Effect on Soft Tissue

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.

Effects on Stones

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. Firstly, decreasing the laser energy and increasing the pulse frequency to maintain the required power output. Secondly, by using the MOSES mode that was shown to reduce retropulsion.

NOTE:

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.

In China, Korea and Taiwan the Lumenis Pulse 120H system with Delivery Devices and Accessories are intended for use in surgical procedures that require incision, excision and ablation (vaporization and removal) of soft tissue and for Lithotripsy.

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-resistant 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 6 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.

NOTE:

Verify that you power-up the system after transportation and/or prior to beginning of procedure and verify that system is ready for operation.

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
  - ✍Opilonidal cystectomy
  - ✍Resection of lipoma
  - ✍Debridement of decubitus ulcer
  - ✍Hemorrhoids
  - ✍Debridement of statis ulcer
  - ✍Biopsy

ENT Surgery

- Endoscopic endonasal/sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
  - ✍Partial turbinectomy
  - ✍Ethmoidectomy
  - ✍Polypectomy
  - ✍Maxillary antrostomy
  - ✍Frontal 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

Gynecological Surgery

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

Gastroenterology Surgery

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

Pulmonary Surgery

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

Dermatology and Plastic Surgery

- Incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in therapeutic plastic, dermatologic 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 displays 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 brake pedals in the neutral position.
   - Unlock the back wheels, with multi-directional movement, by positioning the rear brake pedals in the neutral position.
   - Unlock the back wheels, with unidirectional movement, by positioning the left rear brake pedal down.
2. Move the system to the required 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.

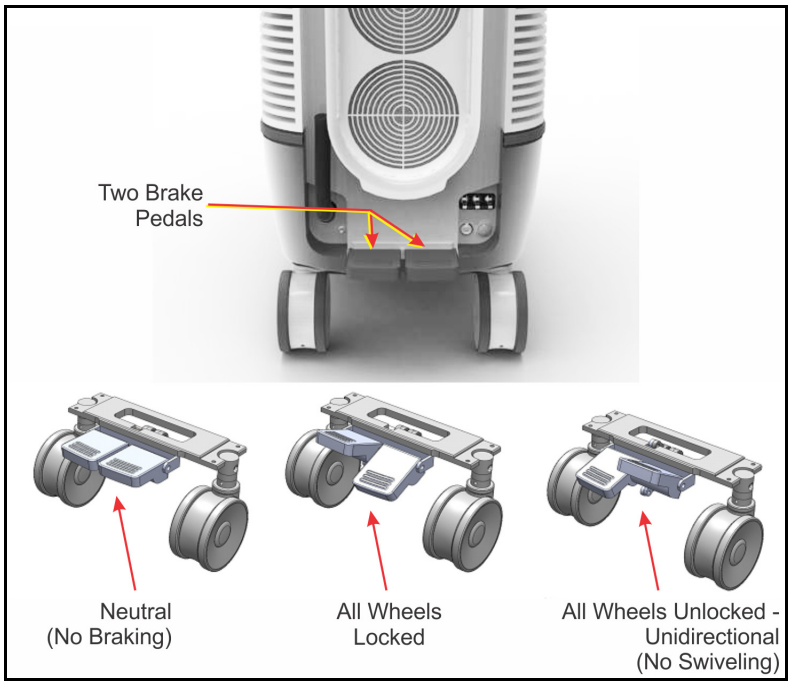


Figure 5: Brake Pedals Configurations

Adjusting the Fiber Support Arm

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

2. Adjust the position of the fiber support arm and turn the arm knob clockwise to lock it in place.

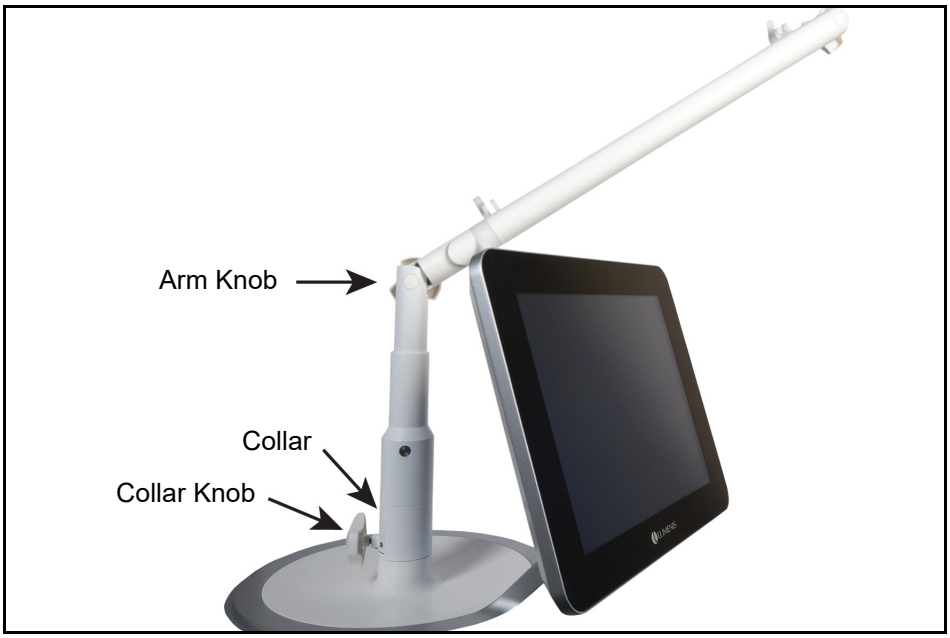


Figure 6: Adjusting the Fiber Support Arm

WARNING:

Ensure that the fiber support arm knob is 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.

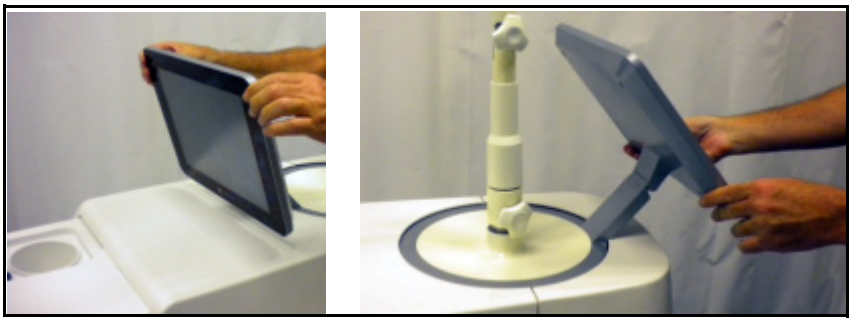


Figure 7: Adjusting the LCD Panel

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.

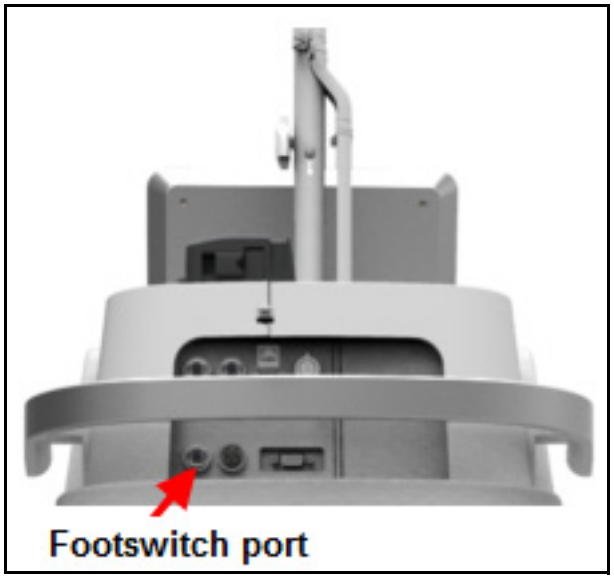


Figure 8: Connecting the Dual-Pedal Footswitch

NOTE:

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

Ethernet, VGA and USB Connection Ports

One Ethernet connection port, one VGA port and two USB connection ports are available in the console's upper service panel. These ports are covered and should be kept so at all times, with the exception of Lumenis-authorized service personnel who may use them for diagnostic testing. Hospital personnel may use the USB port for exporting system reports and service reports. (Refer to Reports.)

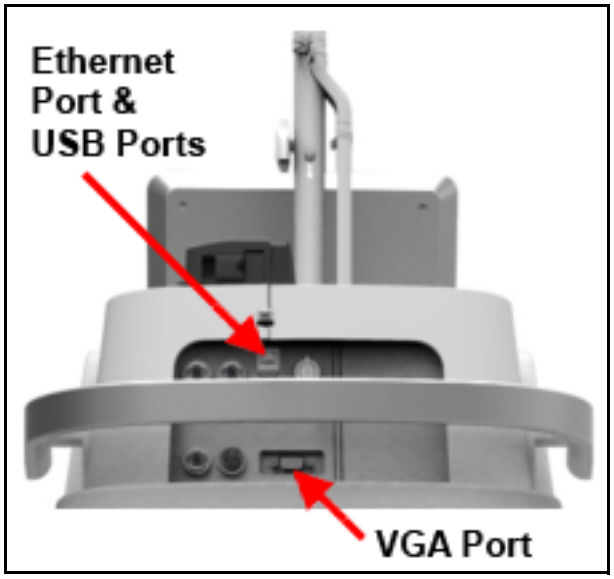


Figure 9: Ethernet, USB and VGA connection ports

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 displays 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.

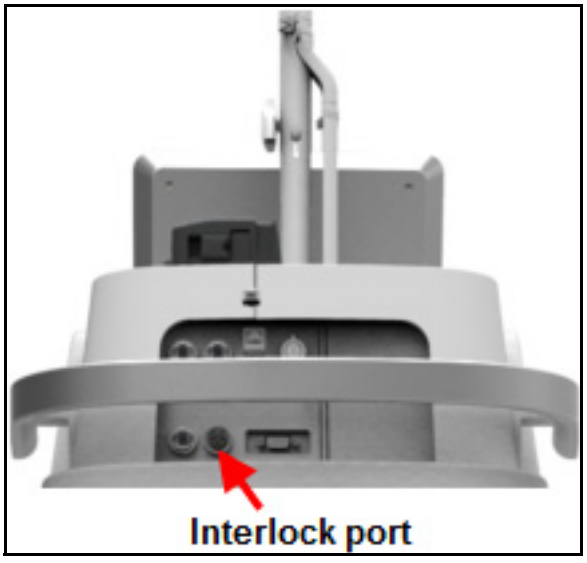


Figure 10: Reinsert the External Door Interlock

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.

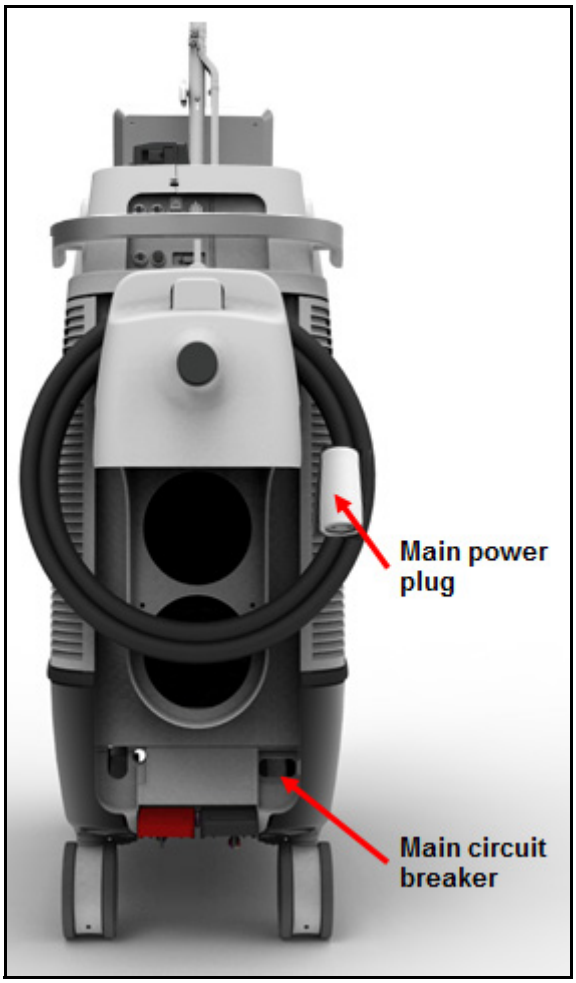


Figure 11: Main On/Off switch and Main Power Plug

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 verify the laser system is in standby mode before disconnecting the delivery system

NOTE:

The SIS enabled Lumenis Pulse 120H system will only operate with Lumenis-qualified SIS (Secure Identification System) optical delivery fibers. Connecting 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 right to left.

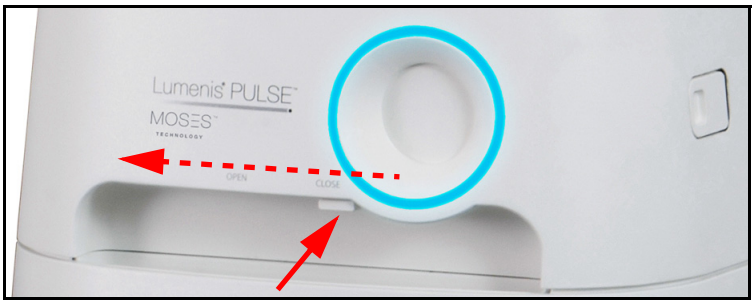


Figure 12: Fiber Port

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** displays 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[1]

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

CAUTION:

Use only Lumenis-approved accessories. **Third party accessories are not authorized for use**.

Refer to Figure 13

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

WARNING:

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

3. The scrub nurse connects one side of the sterile aspiration tube to the 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 (see Figure 14).

1. Optional purchase equipment (not available in Japan and on 30A systems).

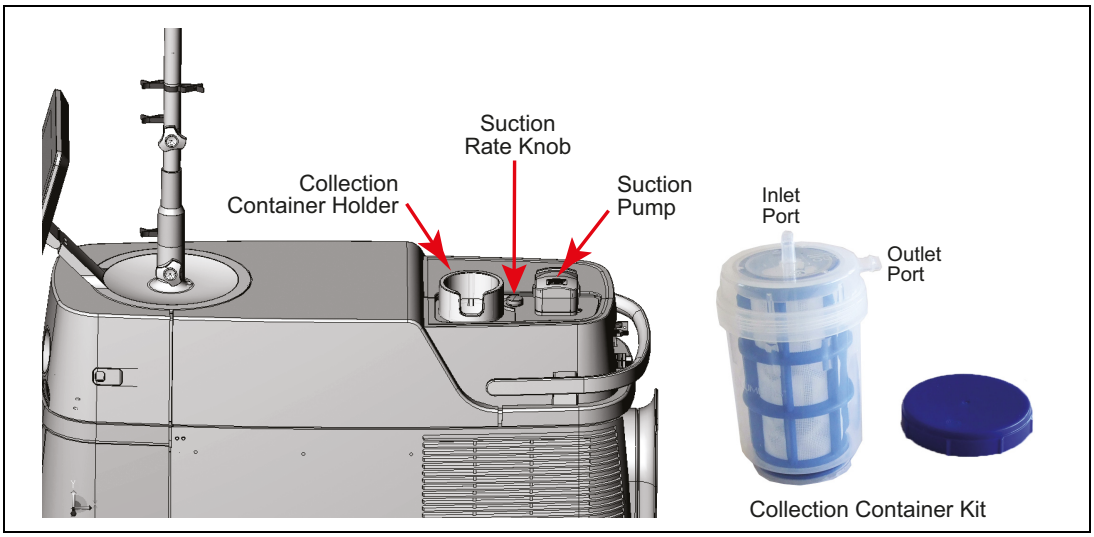


Figure 13: Suction System

Figure 14: 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 15: 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.

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

Main System Screens

Home Screen Description

Figure 16: Urology Home Screen

The elements of the **Home** screen are detailed as follows (the numbered circles in Figure 17 correlate to the numbered steps below):

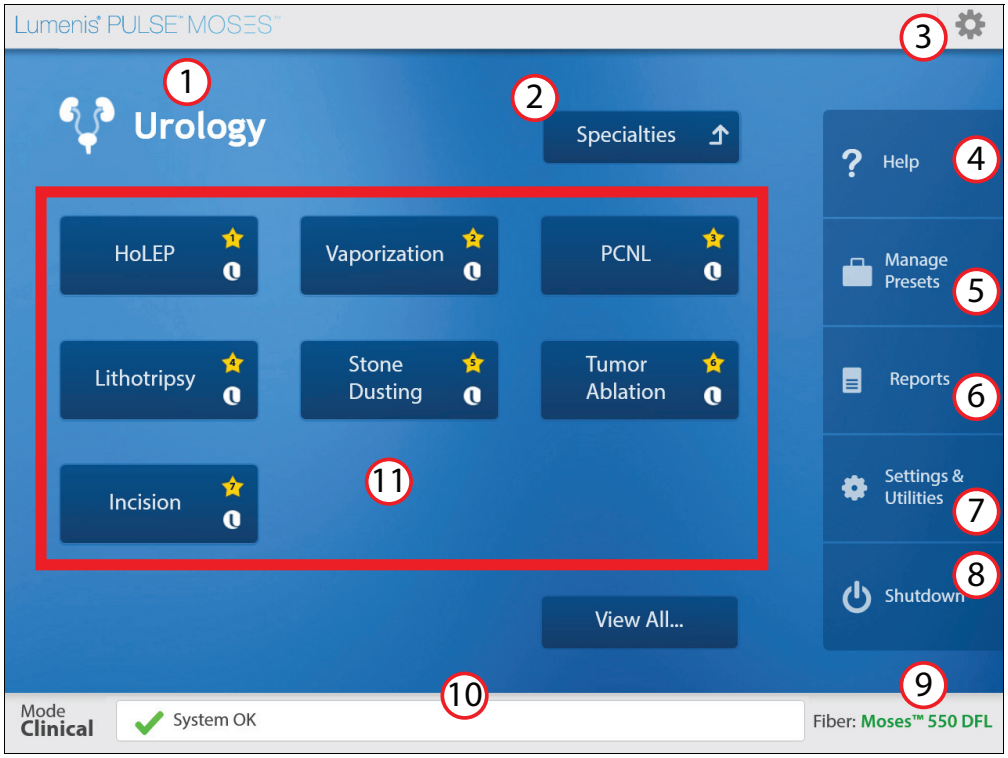


Figure 17: Home Screen Legend (sample for Urology)

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 (upper-right corner) 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 Presets** – Press this button to access the Presets Management screen. Here you may create new presets with your proprietary names and parameter protocols, or edit existing ones.

6. **Reports** – Press this button to access the Reports and Treatment Logs screen. On this screen you may view the treatment logs of the procedures performed by the system. The logs can also be exported to 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 display 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 display the **Main Treatment** screen.

Specialties Screen Description

Press the Specialties button on the Home screen and select the surgical specialty that best meets your needs. Presets are defined for each surgical specialty.

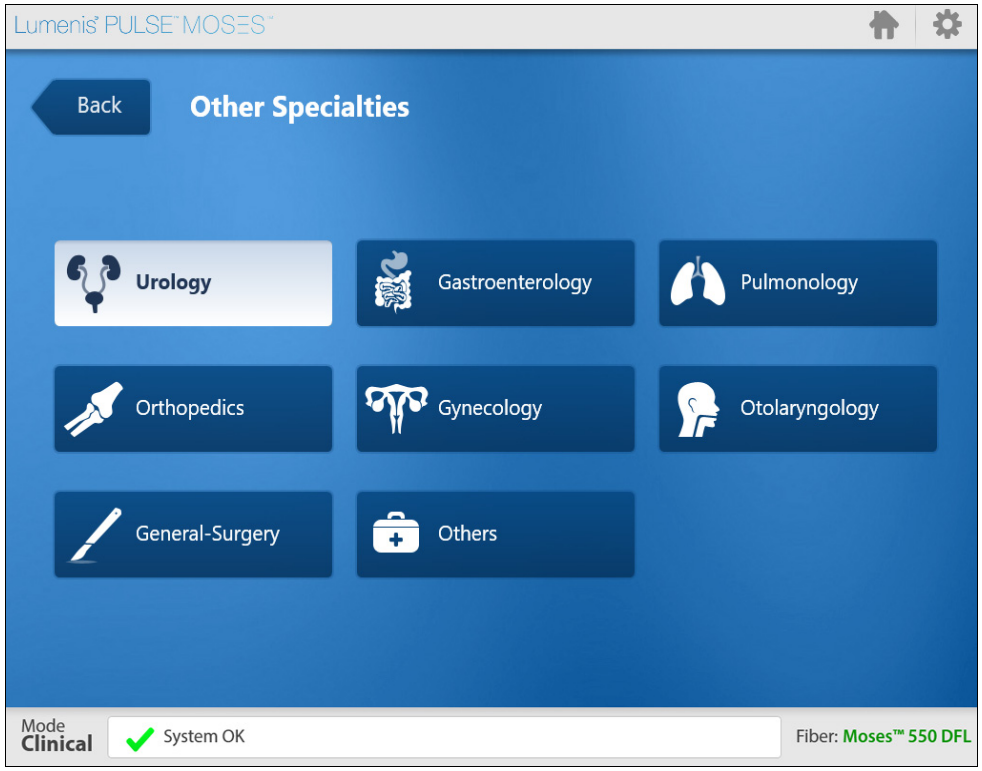


Figure 18: Specialties Screen

Treatment Screen Description

Figure 19: Treatment Screen

The elements of the **Treatment Settings** are detailed as follows (the numbered arrows in Figure 20 correlate to the numbered steps below):

Figure 20: Treatment Beam Delivery via Right or Left Pedals

1. **Specialty** and **Preset** - This displays the selected specialty and preset that the settings are based on. If you change the settings, the name of the preset will display in italics and an asterisk will be added.
2. **Pedal Name** - This is the name of the settings selected 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**, Moses option and **Pulse width** settings for lasing when the corresponding pedal is pressed.
4. **Aiming Beam** - This shows the selected aiming beam intensity: **Off**, **Low**, **Medium** or **High**. The aiming beam can also be set to **Blinking**.
   - At laser system turn on, the aiming beam setting defaults to the **Medium** level.
   - The aiming beam is automatically set to **Off** when no fiber is connected to the system.
   - Press the indicator to open a pop-up menu (shown on the left) where you can select the required mode: **Low**, **Medium**, **High**, or **Off**.

5. **Notification Bar** - Errors and notifications display 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 Notificationsfor a list of advisory indications, their probable causes, and solutions.
6. **Suction Control**[1] - The suction system is controlled from the set of three buttons at the bottom of the **Main Treatment** screen. By default, the suction system is **Off**:
   - **On** button active: suction operates constantly.
   - **Off** button active: suction remains off, even while the system is in **READY** mode.
   - **Auto** button active: suction will turn on and off simultaneously with lasing.

CAUTION:

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

7. **STANDBY/READY** mode selection - **STANDBY/READY** buttons determine whether pressing the footswitch will activate the laser (**READY** mode) or not (**STANDBY** mode):
   - A **READY** voice signal is generated when the system switches to **READY** mode.
   - A **STANDBY** voice signal is generated when the system switches to **STANDBY** mode.
   - The system will automatically switch from **READY** to **STANDBY** mode if the system is idle for more than 5 minutes.

WARNING:

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

1. Optional purchase equipment; this section applies only to systems with factory-installed suction systems. (Not available in Japan)

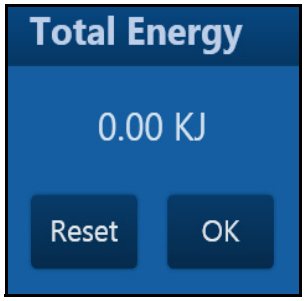
8. **Fiber Status Area** - Certain Lumenis SIS fiber delivery systems for the Lumenis Pulse 120H are designed to allow several surgical treatments, while others are limited to only one treatment. When a fiber is connected, the system immediately knows:
   - How many treatments have been performed with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

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

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

NOTE:

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



9. **Total Energy Indicator** - This indicator displays the total laser energy applied to the surgical site during the treatment procedure, calibrated in Kilojoules.
   Pressing the underlined **kJ** value (top right of main screen - Figure 20) opens a **Reset** pop-up (shown on the left).
   - The total energy indicator should be reset to zero between patients, and:
   - When switching between preset modes (relevant for both pedals), including both Lumenis and user-generated (Hospital) presets.
   - The total energy displayed in the reports is not affected when resetting the total energy on the screen (reset dialog shown on left)

10. In order to revert to the original presets, press the **Undo** icon (top middle of main screen - Figure 20).

11. **Moses Operation Mode** - The Moses capability can be used only in conjunction with Lumenis Moses supported fiber. When a Moses supported fiber is connected to the system it will be recognized by the system and the Moses capability will be available.

    A complete discussion of Moses capabilities and fibers as well as additional capabilities may be found in the *Advanced Operations* chapter in the sections called Moses Capabilities and Additional Capabilities.

12. **Pulse Width** - When Moses mode is **Off**, this button opens a pop-up menu (shown on the left) where you can select the set the pulse width to: short, medium, or long.

Laser Emission Indication

Lasing displays 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.

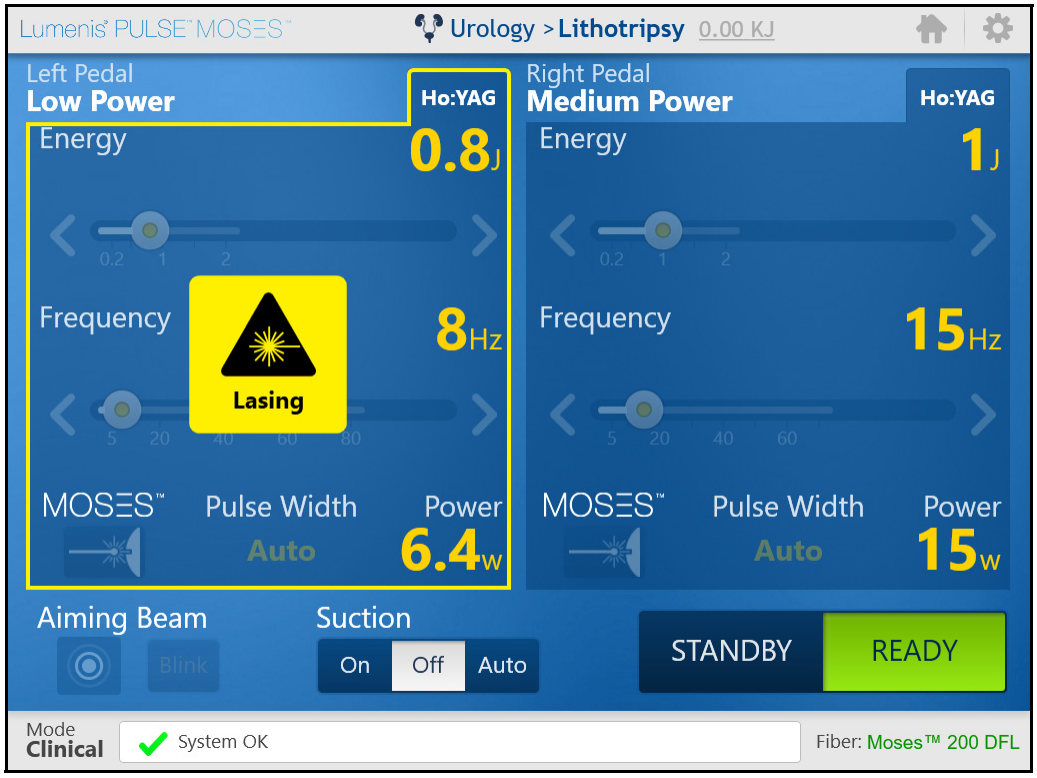


Figure 21: Lasing Indicator

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 22: Location of the Emergency Button

NOTE:

When the main power cable is connected to the electrical source, some internal circuits remain energized. To deenergize 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 required 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 the 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 displays 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 display 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 displays 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.

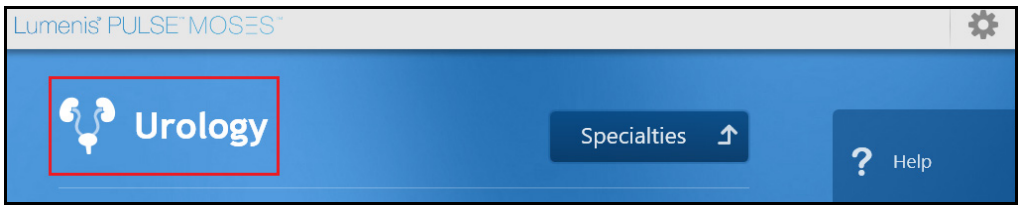


Figure 23: Location of the Specialties Selection

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 required preset does not display, press the "**View All...**" button.

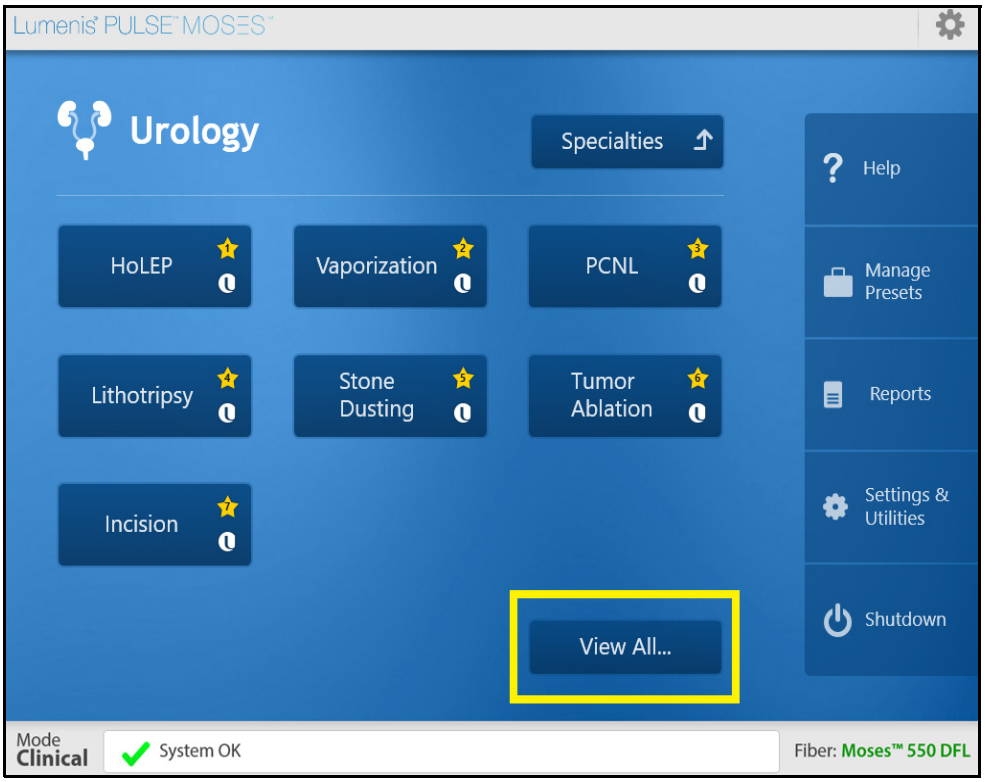


Figure 24: Location of the* View All... *Button

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:

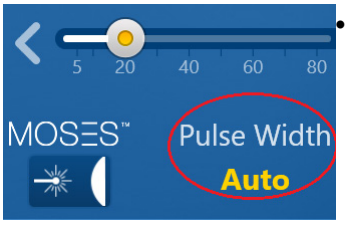
Use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Incorrect treatment settings can cause serious tissue damage.

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

Refer to Figure 25 (numbered circles are referred to in the Steps below):

Figure 25: How to Change Treatment Settings

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



- **STEP 2:** When connecting a Moses supported fiber, the **MOSES** button is set according to the relevant preset (**2**). To modify the active Moses mode, open the Moses options pop-up menu, where you may select the Moses mode (see the Advanced Operations chapter in the section named Moses Capabilities). This will also set the **Pulse Width** to **AUTO**, and you will not be required to select it**.**

- **STEP 3:** In regular mode (i.e. Moses is **OFF**) press the **Pulse Width** button (**3**) to open a pop-up menu (shown on the left) where you may select the use of short, medium, or long pulse width.
- **STEP 4:** In order to revert to the original presets, press the **Undo** icon (**4**).

NOTE:

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

NOTE:

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

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

5. Verify that your foot is on the appropriate footswitch pedal for the left-side or right-side parameter settings on the screen.
6. Press the footswitch that corresponds to the required set of parameters to deliver the treatment beam.

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

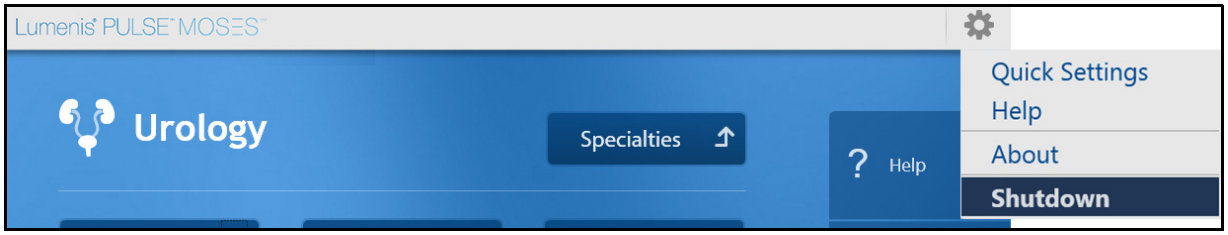
WARNING:

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: perform a normal system shut-down from the control screen by selecting **Shutdown** from the cogwheel icon (upper-right corner).



   - 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.

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 footswitch cable around the footswitch and hang it on the rear of the Lumenis Pulse 120H laser console.

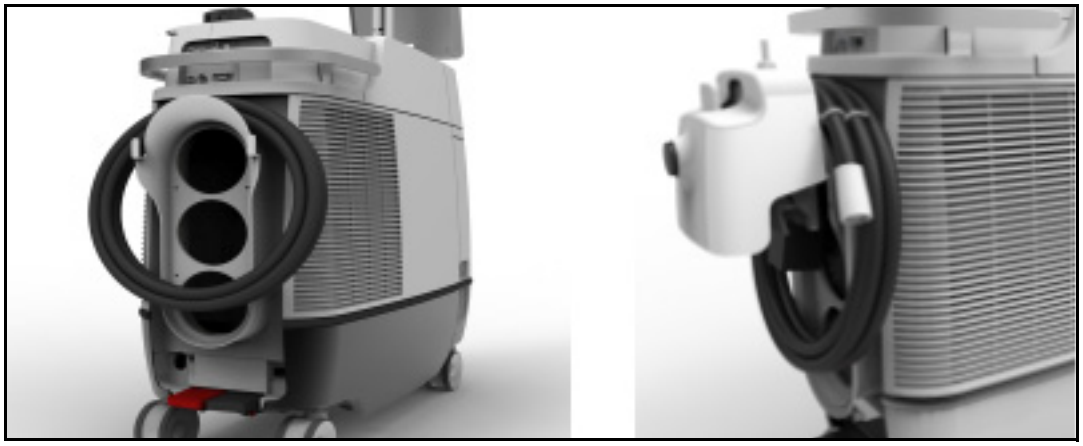


Figure 26: Power Cable on the Cable Rack

7. Disconnect the external door interlock.
8. Clean the exterior surfaces of the laser.

Moving the Laser Console

1. Disconnect the optical fiber from the system.
2. Rotate the LCD panel clockwise and fold it down with the screen facing down.

Figure 27: Folding the LCD Panel

3. Fold the fiber support arm.

   - First loosen the arm knob before you fold upper section of the arm. Tighten the knob when you are done.

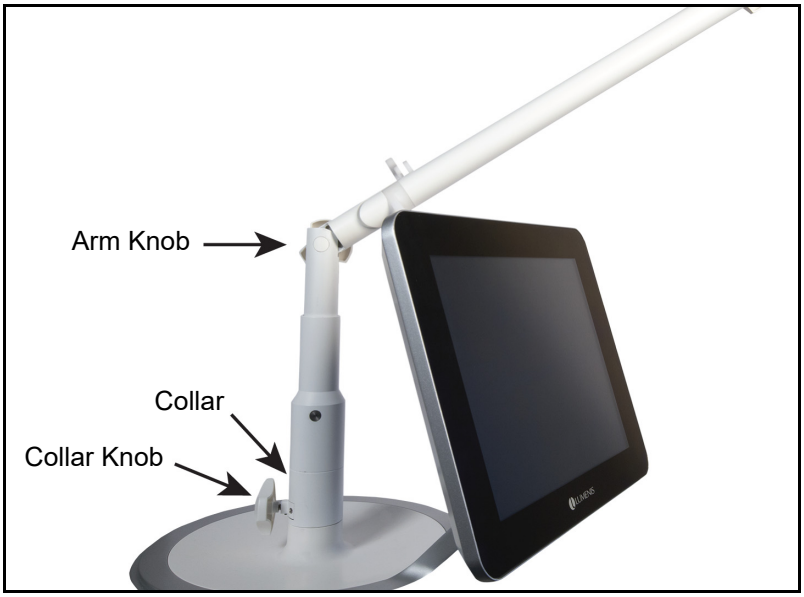


Figure 28: Adjusting the Fiber Support Arm

4. Unlock the laser console wheels for unidirectional movement by pushing the left brake pedal down.

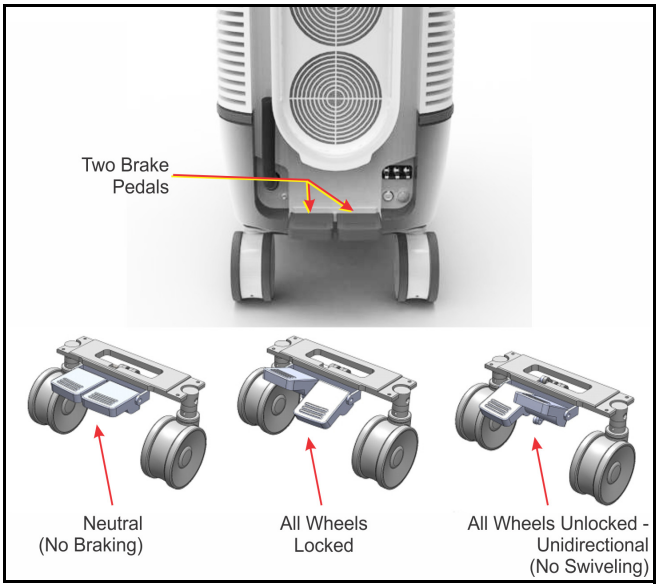


Figure 29: Brake Pedals Configurations

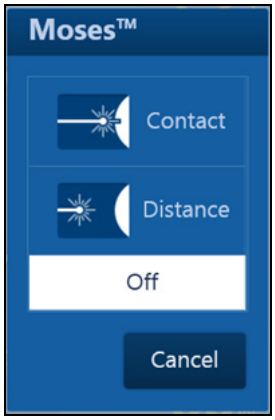
5. Using the laser console handle, move the laser to the required site.

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

Moses Capabilities



If the system incorporates Moses capability, and a Lumenis **Moses** supported fiber is connected to the system (see Figure 30), an indicator (the enabled MOSES button) displays. Press this indicator to open a pop-up menu (shown on the left) where you may select the Moses operation mode.

When the **MOSES** button indicator is **Off**, the system is operating in regular mode.

The pop-up menu shown on the left shows all available options for the purpose of illustration. Note that not all options are available with all Moses supported fibers.

Moses-Enabled Applications and Fibers Used In These Applications

Moses mode will be enabled only when connecting the appropriate Lumenis fibers and selecting presets according to the table below:

Specialty	Preset	Available Moses Mode	Compatible Moses Fibers
Urology	Lithotripsy Stone Dusting PCNL Tumor Ablation Incision	Contact Distance OFF	Moses 200 D/F/L Moses 365 D/F/L Moses 550 D/F/L Xpeeda (Contact only)
	HoLEP[a]	ON OFF	Moses 550 D/F/L
	Vaporization[b]	ON OFF	Xpeeda[b]
Gastroenterology Pulmonology Orthopedics Gynecology Otolaryngology General Surgery	All related presets	Contact Distance OFF	Moses 200 D/F/L Moses 365 D/F/L Moses 550 D/F/L Xpeeda (Contact only)

a. Moses mode for **HoLEP** preset is not available on the 30A system configuration.
b. **Vaporization** preset and **Vaporization Moses mode** for Xpeeda are not available on the 30A system configuration.

Table 1: Moses-Enabled Applications and Fibers Used

Selecting Moses Mode

The **Moses Mode** will be available in the **Treatment** screen, once a Moses supported fiber is connected (see lower right corner for fiber connection).

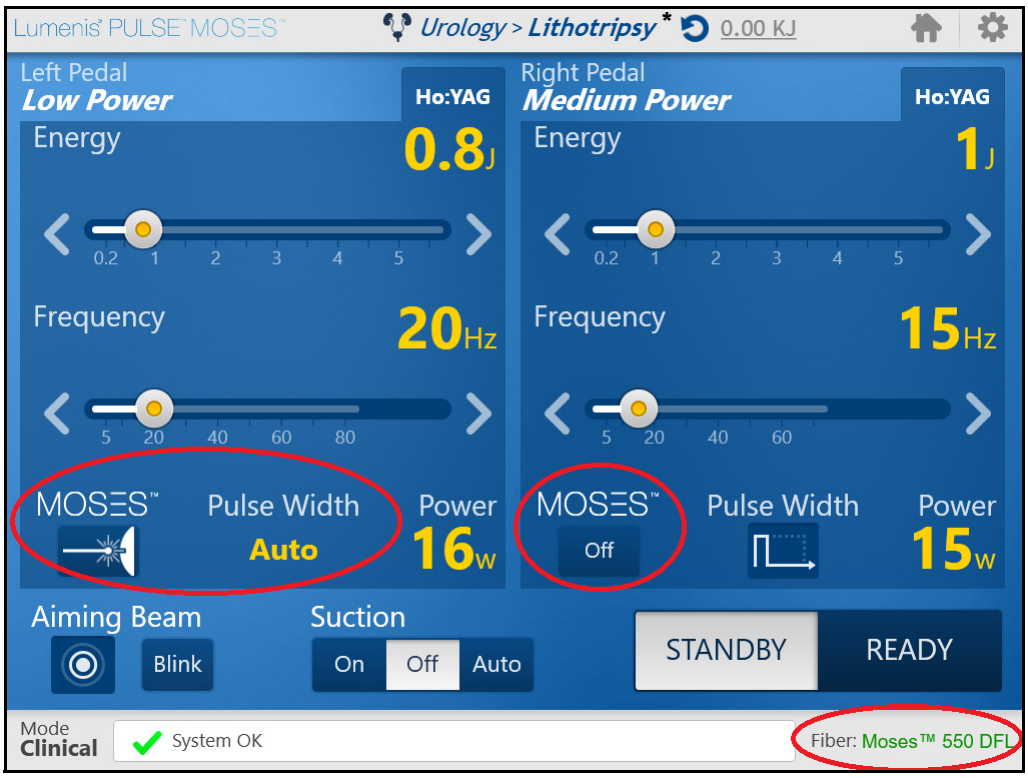


Figure 30: Treatment Screen with Active Moses Capability

Moses mode is available for use by either the left or right pedal, independently.

When starting the Lumenis Pulse 120H system with a MOSES fiber connected, default Moses mode is automatically selected in the following presets: Lithotripsy, Stone Dusting, PCNL, HoLEP and Vaporization.

In order to modify **Moses** mode, press the **MOSES** button.

Enabled Presets for Moses-Enabled Applications

For some **Moses** supported fibers, several Moses mode settings are available, optimized for various operating parameters. These settings are selected by pressing the **MOSES** button; a pop-up menu displays, allowing you to select the parameter, as explained in the following sections.

1. Stones (and Other Ureteroscopy) Related Presets

The Moses modes for stone treatments are available when Lumenis Moses fibers are connected (according to Table 1 on page 72) to the P120H laser system and the **Lithotripsy** or **Stone Dusting**, **PCNL** presets are selected (or **Tumor ablation** or **Incision** for other soft tissue application). Different Moses modes are available according to treatment distance optimizations. The setting is selected by pressing the **MOSES** button, a pop-up menu displays, allowing you to select the desired mode i.e. Mo**ses Contact**, **Moses Distance** or **Regular** mode (**OFF**).

2. HoLEP[1] Preset

The **Moses** mode for **HoLEP** is available only when the Lumenis Moses 550 D/F/L fiber is connected to the P120H laser system and the **HoLEP** preset is selected. Figure 31 displays the Moses mode; the selection button appears when you press the **MOSES** button on the operating screen.

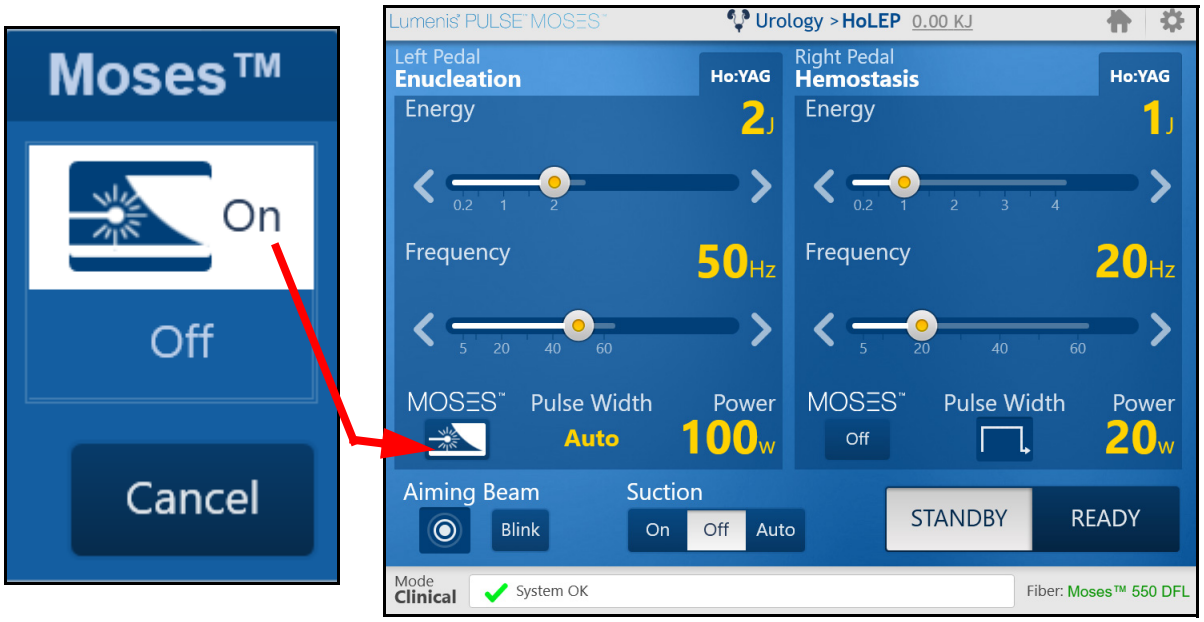


Figure 31: HoLEP Preset and Available Moses Mode

This will also set the **Pulse Width** to **AUTO**, and you will not be required to select it**.**

Pressing the **Off** button switches the system back to regular pulse mode, and the **Pulse Width** options will again be accessible.

1. Moses mode for HoLEP preset is not available for 30A system configuration.

3. Vaporization Preset[1]

The **Moses** mode for **Vaporization** is available only when a Lumenis Xpeeda D/S/L fiber is connected to the P120H laser system and the **Vaporization** preset is selected. Figure 32 displays the Moses mode selection button- appears when pressing the **MOSES** button on the operating screen.

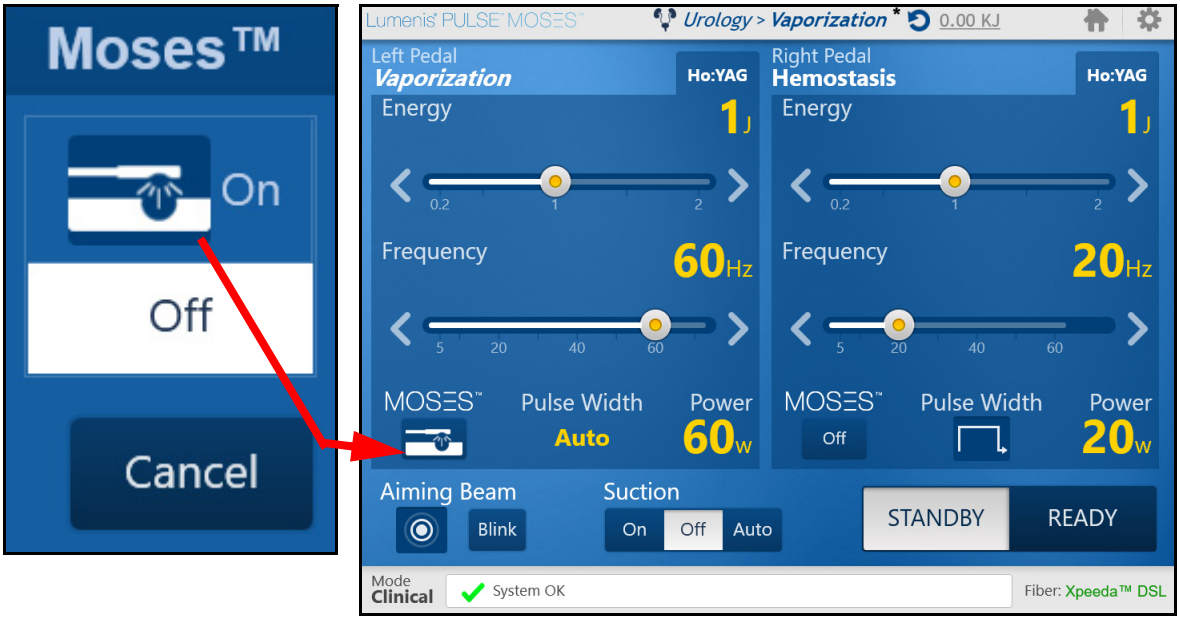
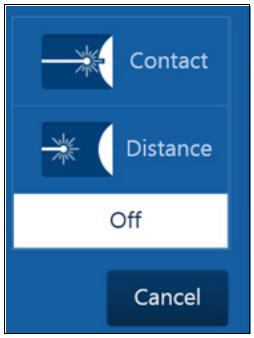


Figure 32: Vaporization Preset and Available Moses Mode

This will also set the **Pulse Width** to **AUTO**, and you will not be required to select it**.**

Pressing the **Off** button switches the system back to regular pulse mode, and the **Pulse Width** options will again be accessible.

4. Other Specialties and Presets



The **Moses** modes for different specialties (non-urology) are available when Lumenis Moses fibers are connected (according to Table 1 on page 72) to the P120H laser system and the desired preset is selected. Different Moses modes are available according to treatment distance optimizations. The setting is selected by pressing the **MOSES** button, a pop-up menu displays, allowing you to select the desired mode i.e. **Moses Contact**, **Moses Distance** or **Regular** mode (**OFF**).

1. Vaporization preset is not available for 30A system configuration.

Moses Presets

If a Moses preset is selected before a Moses supported fiber has been connected, the Lumenis Pulse 120H system default mode for Moses will be set to **Off**.

Moses presets can be saved only from existing presets as follows:

- by renaming System presets and editing and setting Moses mode
- by duplicating and editing Hospital presets via the **Manage Presets** option on the Right-hand side of the home screen.

To save a Moses preset, first make sure a Moses supported fiber is connected, then do the following:

1. From the treatment screen's cogwheel (upper-right corner), select the **Save as Presets** option.
   (Alternatively, via the **Manage Presets**, then edit or duplicate.)
2. The screen which opens should allow you to see the Moses buttons.
3. You can select any Moses option and save the preset - see instructions in the **Saving Settings as Hospital Presets** section.
4. The Moses settings will be saved as a part of the Hospital preset.

Additional Capabilities

This system has an Extended Frequency Range (EFR)[1] enabling additional combinations within the performance envelop when connecting Moses fiber, allowing system lasing up to 120Hz.

EFR – Supported Fibers

The additional setting combinations are supported by the following Lumenis fibers:

- Moses 200 D/F/L
- Moses 365 D/F/L
- Moses 550 D/F/L

1. Available only in certain Lumenis Pulse 120H configurations.

Operation Mode Display

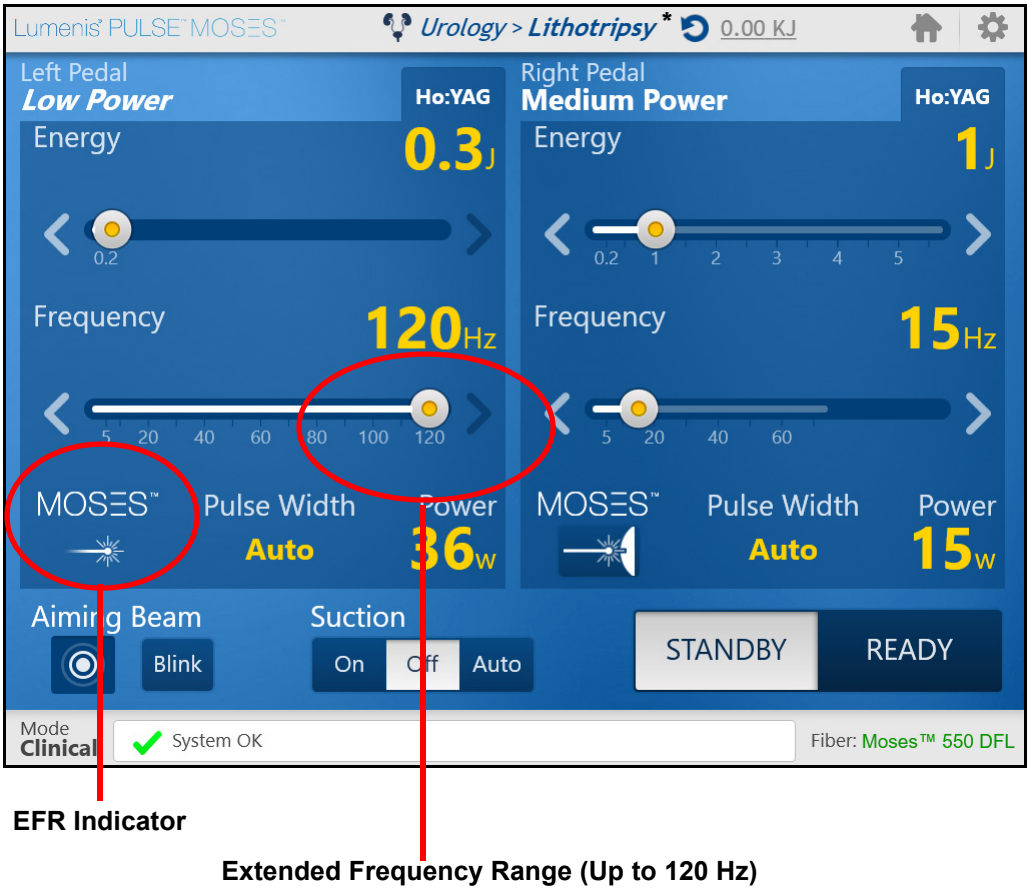


Figure 33: Operation Mode Display

Saving Settings as Hospital 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 displays). Then you can save these settings as a new Hospital preset.

1. From the **Treatment Menu** screen, press the cogwheel (upper-right corner) and select **Save As Preset**.

NOTE:

The **Moses** mode can be saved as part of the Hospital Preset settings.

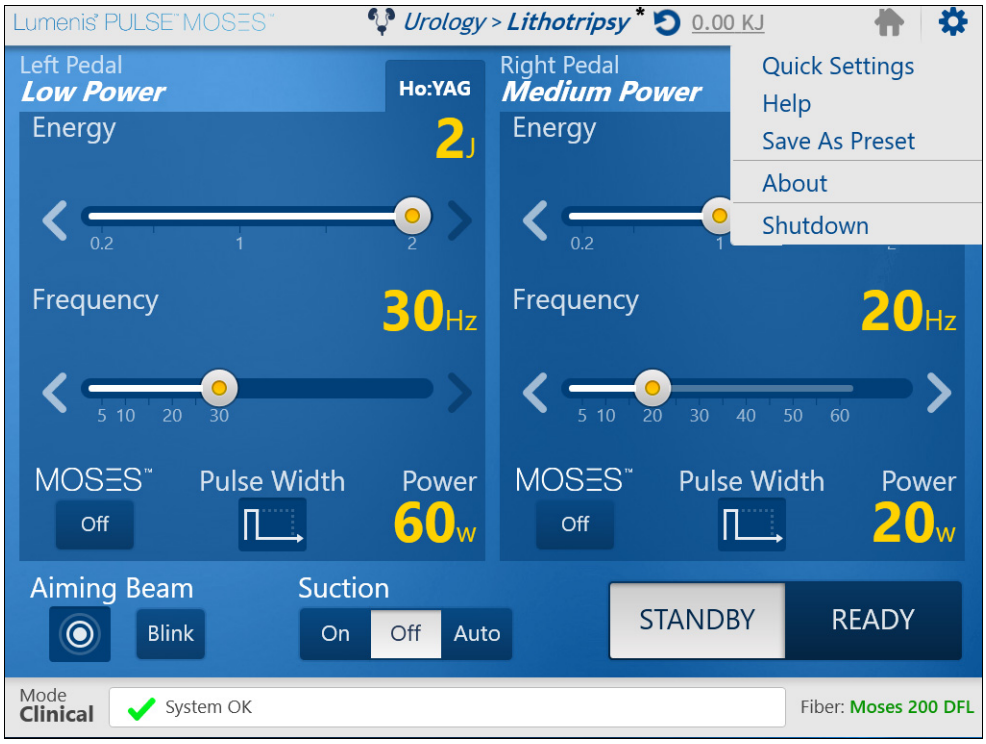


Figure 34: Save Settings as a Preset

2. Press inside the **Preset Name** field. Backspace to erase the current name - as applicable, and type in the new name using the virtual keyboard that pops up.

3. When you are done, press the green check mark key on the keyboard.

4. If required, you can repeat steps 2 and 3 above for each of the pedal names (i.e. press the pedal name field > rename > click the green check mark).

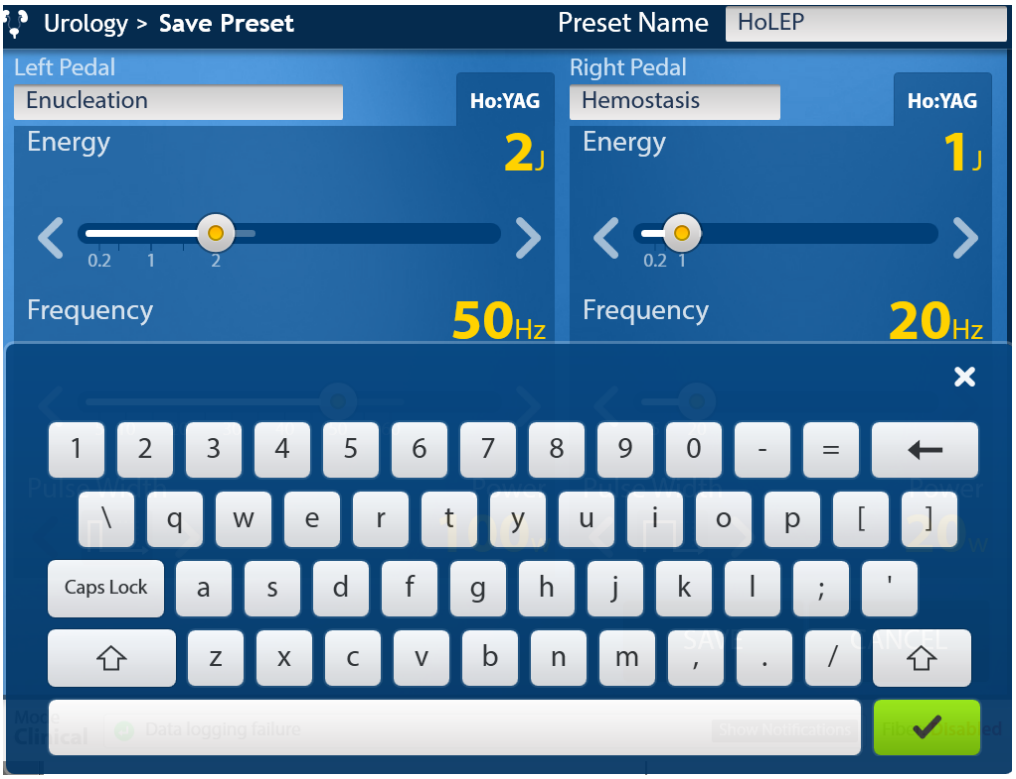


Figure 35: Editing the Preset Name

5. Press the **SAVE** button.

Figure 36: 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** (defined 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**.

This can be selected from the home screen's Right-hand menu **Manage Presets** button.

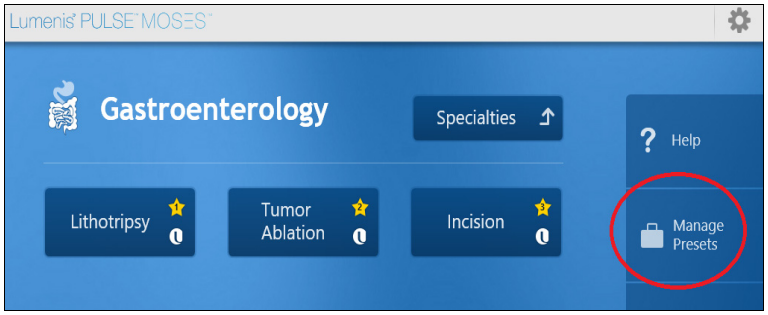


Figure 37: Manage Presets Screen

Selecting Presets

On the bottom right of 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**.

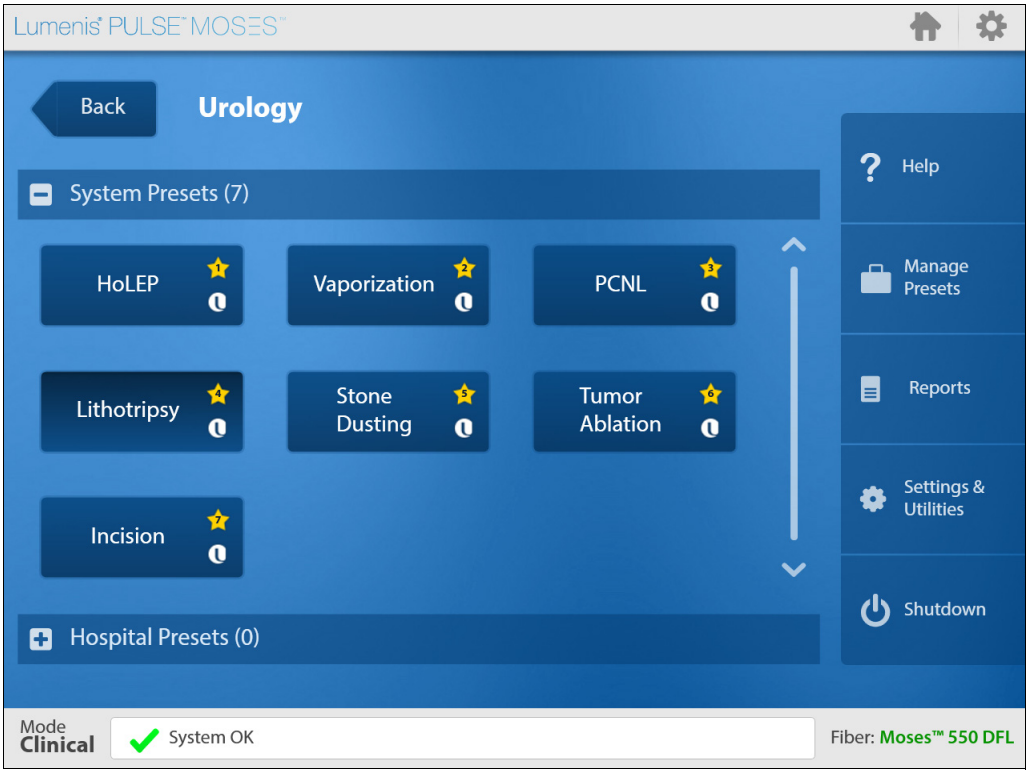


Figure 38: View All Presets - Tree Closed

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

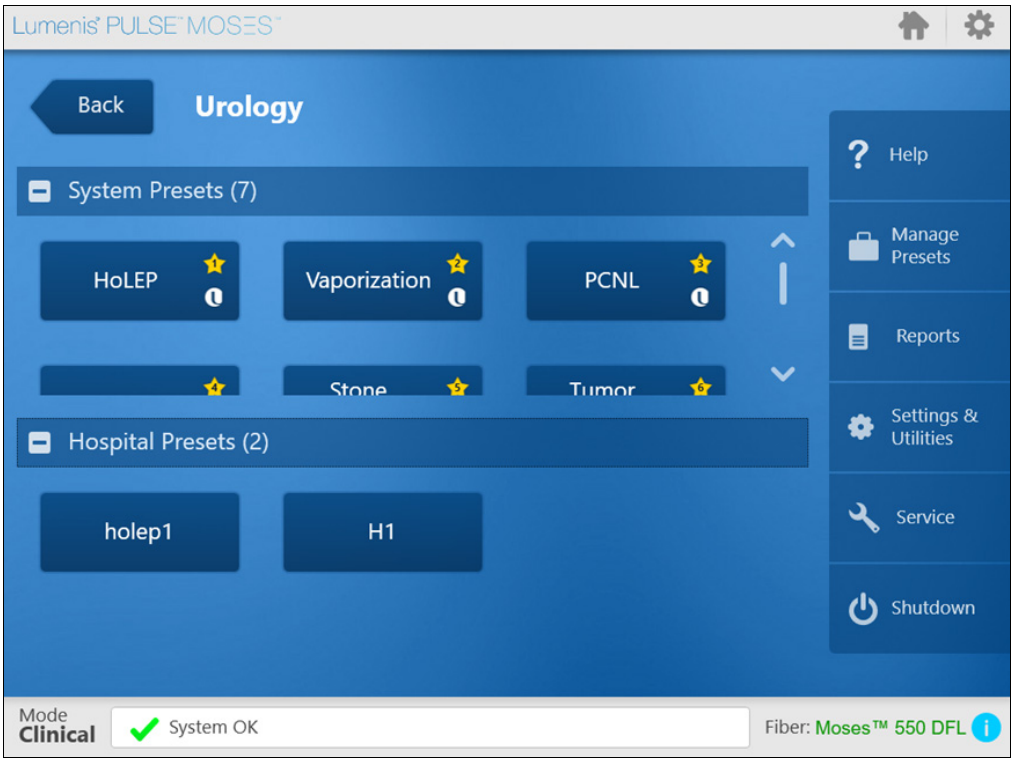


Figure 39: View All Presets - Tree Expanded

After you select (press) the **Preset** button, the system will switch to the **Main Treatment** screen.

Creating New Presets

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

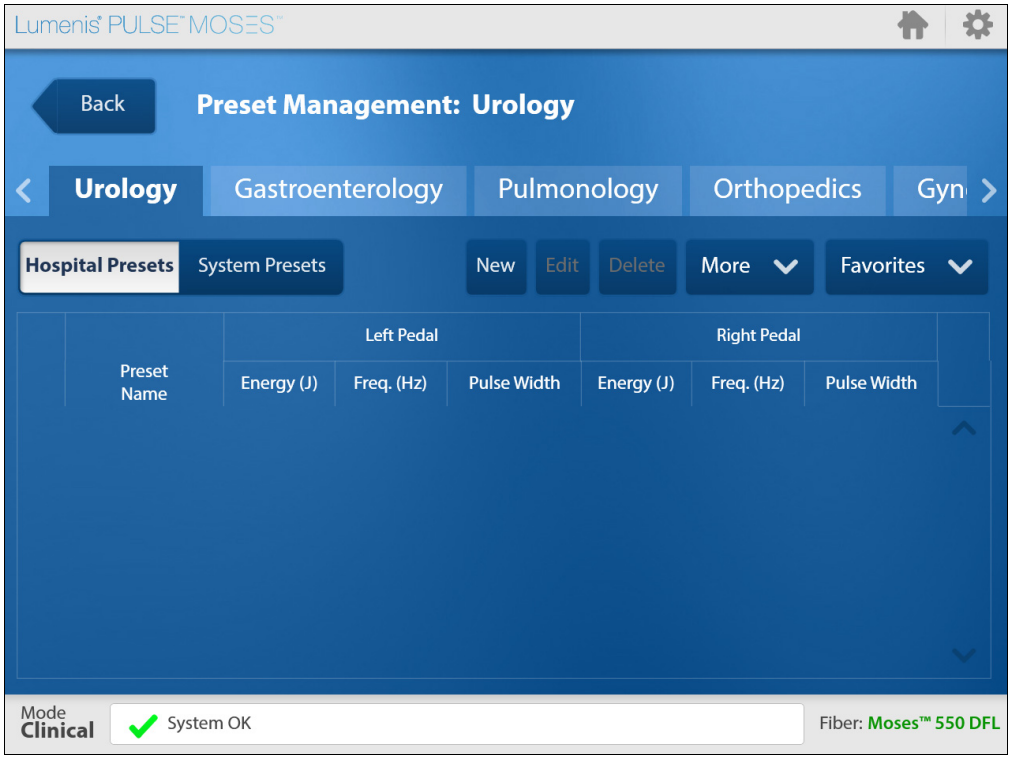


Figure 40: Manage Presets Screen

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

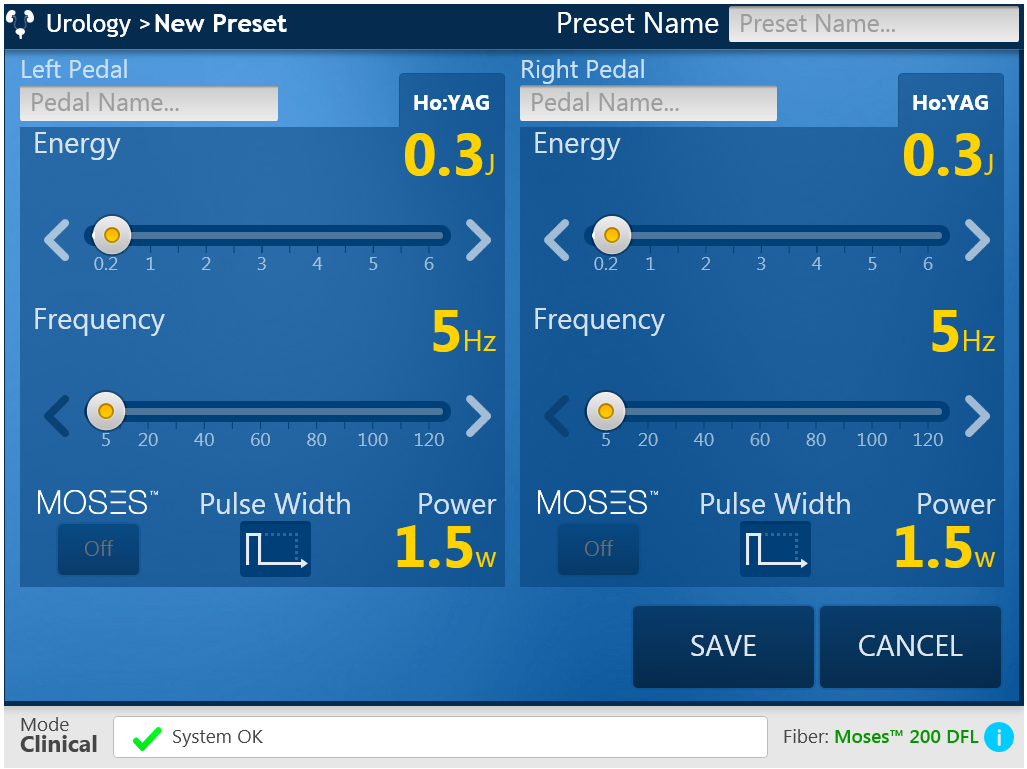


Figure 41: New Preset Screen

5. 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.

6. When you are done, press the green check mark key on the keyboard.

7. Press **SAVE**.

NOTE:

When creating a new preset using the **New** command (see Figure 40), the **Moses** option will not be available for use on the **Treatment** screen (see Figure 41), nor will manual selection of the **Moses** preset be possible.

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 Presets**.
2. Press the **Hospital Presets** button.
3. Select anywhere on the row of the preset that you want to edit.

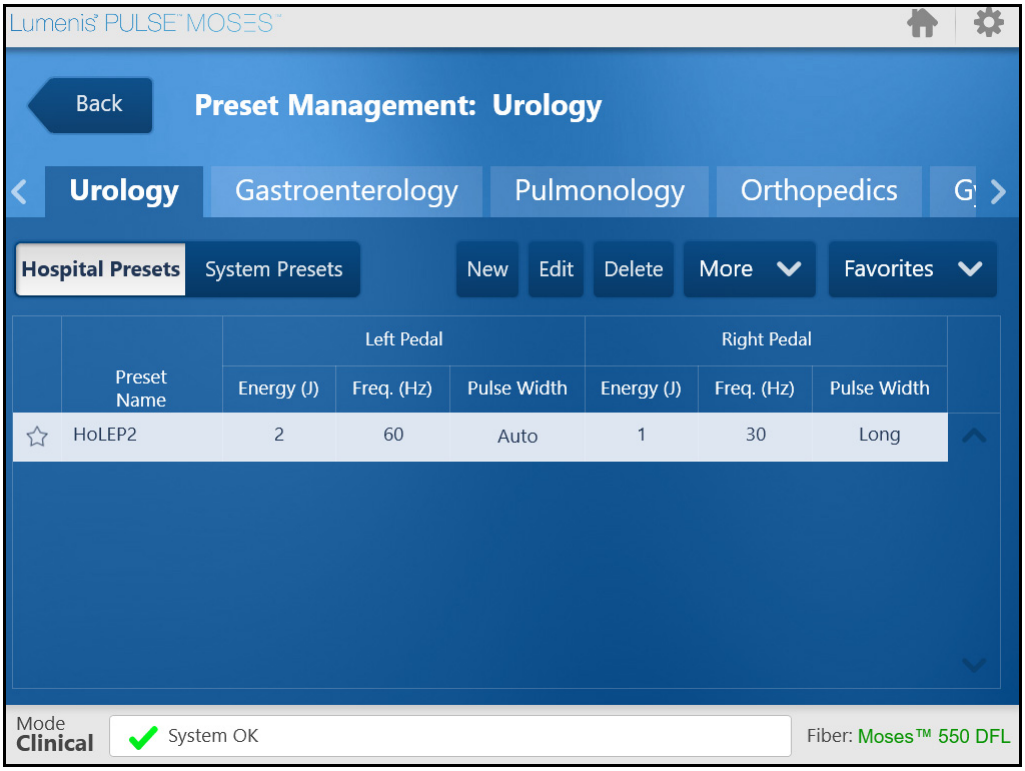


Figure 42: Manage Presets Screen

4. Press the **Edit** button.

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

Figure 43: Edit Preset Screen (With Keyboard Visible)

6. When you are done, press the green check mark key on the keyboard.
7. Press **SAVE**.

Duplicating Presets

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

Figure 44: Manage Presets > More > Duplicate

4. The duplicated preset automatically displays with a serial-number suffix following the **Preset Name**, under **Hospital Presets** (i.e., **PCNL1**, **HoLEP2**).

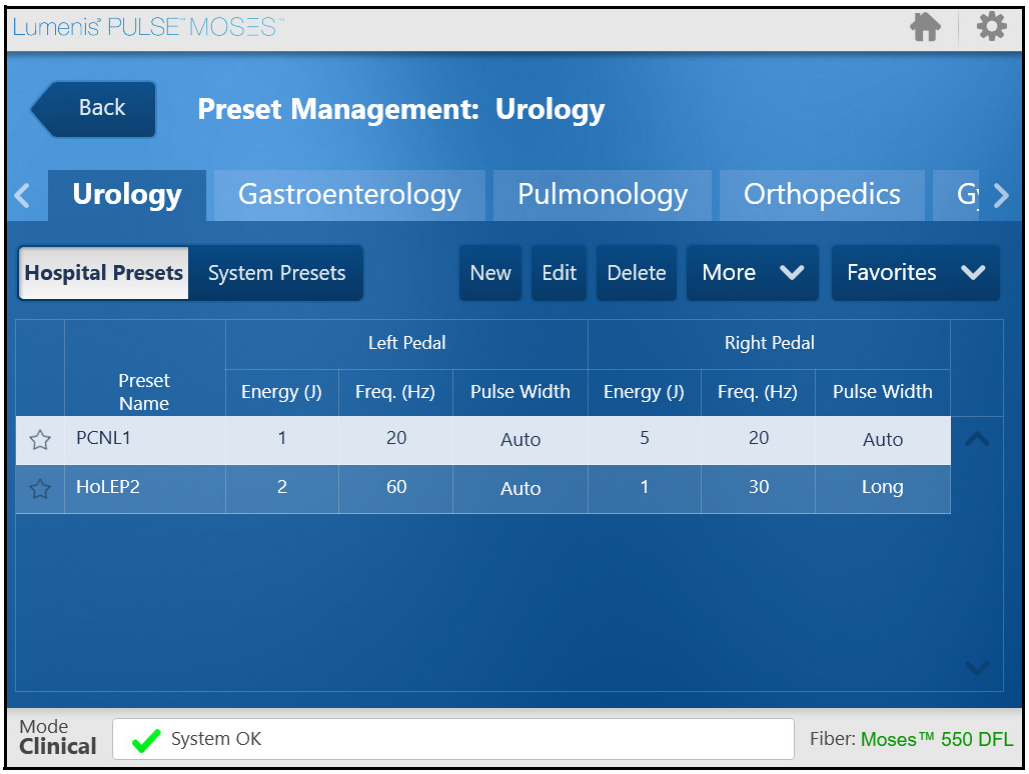


Figure 45: Preset Screen (With a Duplicated Preset)

Deleting Presets

You can only delete Hospital Presets. You cannot delete System Presets.

1. From the **Main Menu** screen, press **Manage Presets**.
2. Press the **Hospital Presets** button.
3. Select anywhere on the row of the preset that you want to delete, and then press the **Delete** button.

Figure 46: Manage Presets Screen

4. In the **Delete Preset** pop-up, press **Yes**.

Figure 47: Delete Preset Confirmation Screen

Exporting Presets

1. Insert a USB storage device into the USB port at the rear of the Lumenis Pulse 120H.
2. From the **Main Menu** screen, press **Manage Presets**.
3. Select anywhere on the row of the preset that you want to export. If you don't see the preset, press the **Hospital Presets** button.
4. Press the **More** button and select **Export Presets** from the dropdown menu.

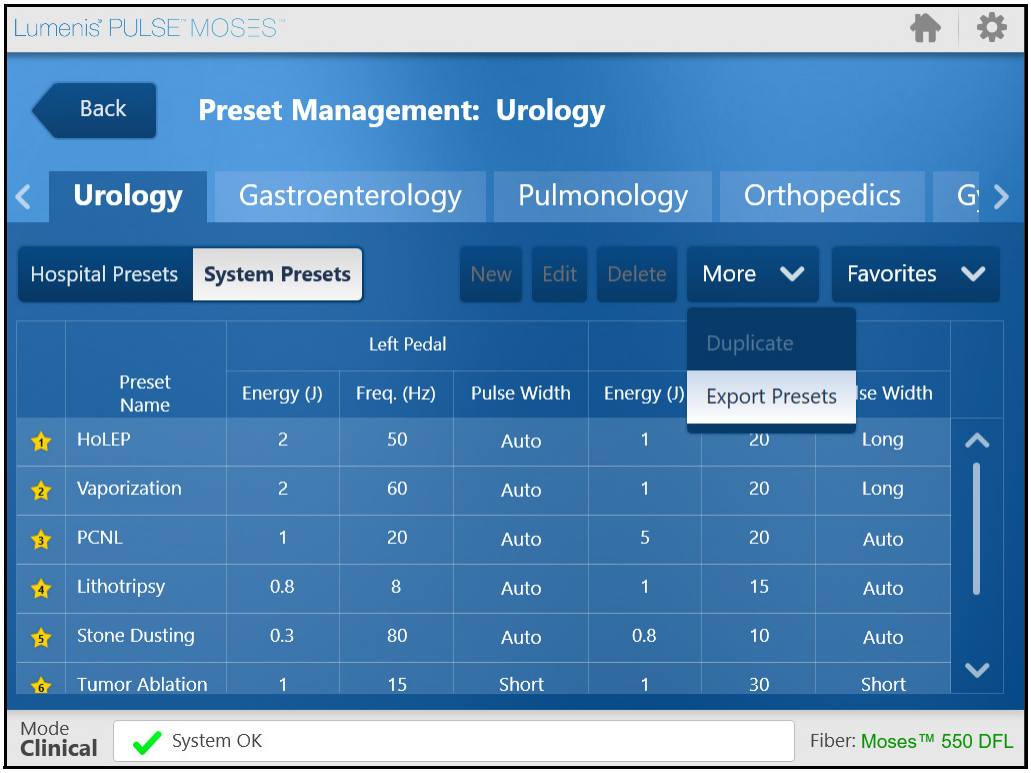


Figure 48: Manage Presets > More > Export Presets

5. In the **Export data to USB** pop-up, press **OK**.
6. Wait until the export operation is completed successfully.

Figure 49: Export Operation Completed

Favorites

Every specialty has its own favorite presets that you can directly select from the **Home** screen. You may choose to **Add** a new preset to the **Home** screen, **Remove** a favorite, and **Re-Order** all the presets on the **Home** screen to appear in the order you desire. These operations are discussed in the following sections.

Add a Preset to the Home Screen Favorites

1. From the **Home** screen, press **Manage Presets** (**A**, see Figure 50).
2. From the **Preset Management** screen, press the **Favorites** button (**B**) and select **Add to Favorites** (**C**) from the dropdown menu.

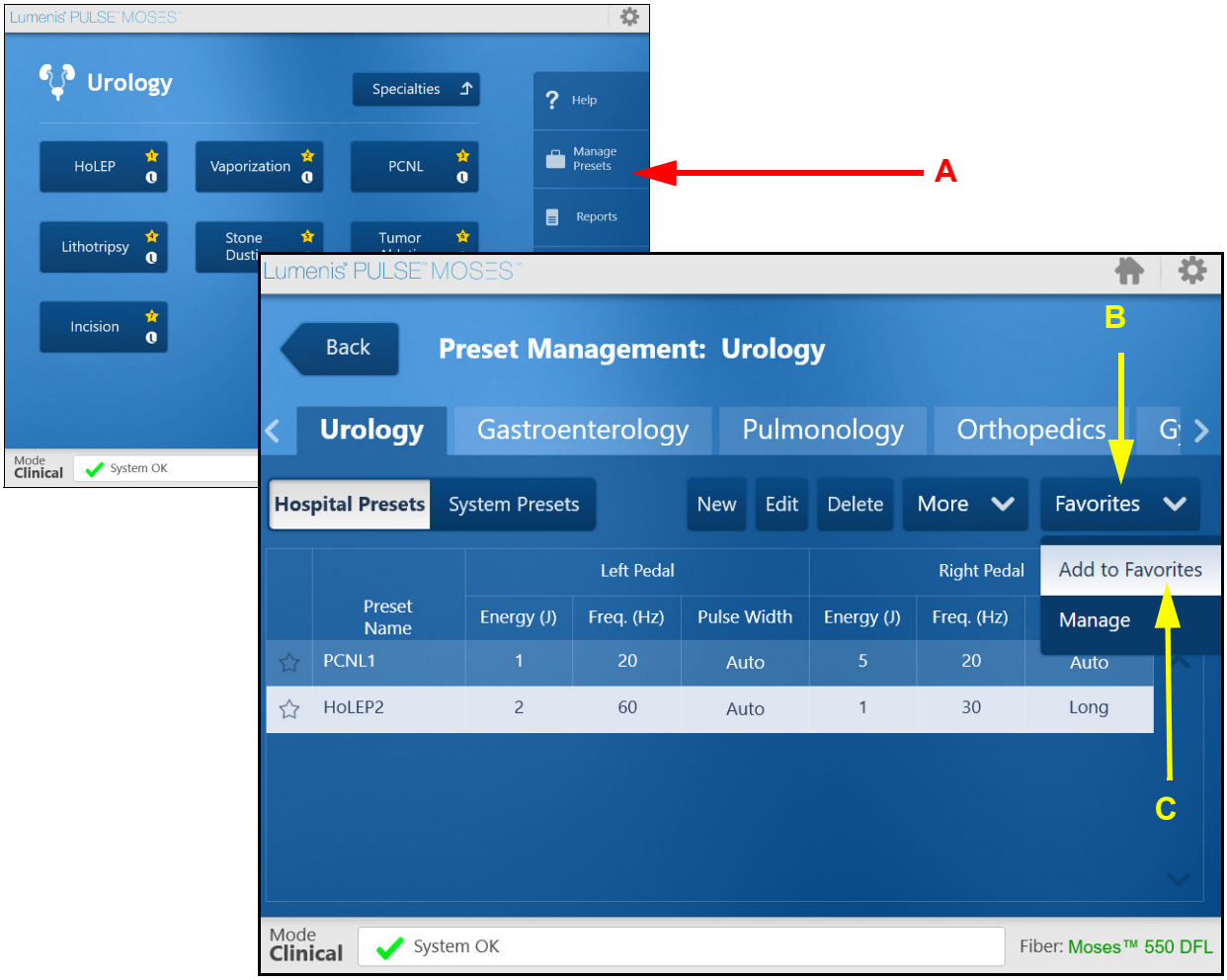


Figure 50: Preset Management - Add to Favorites (1)

3. The wireframe star in the preset's line will turn into a yellow star, and the preset will appear as a **Favorite** in the **Home** screen the next time you access it.

Figure 51: Preset Management - Add to Favorites (2)

Remove a Preset From the Home Screen Favorites

1. From the **Home** screen, press **Manage Presets** (**A**, see Figure 52).

2. On the **Preset Management** screen, select a favorite preset by pressing it (**B**), press the **Favorites** button (**C**) and select **Remove from Favorites** (**D**) from the dropdown menu.

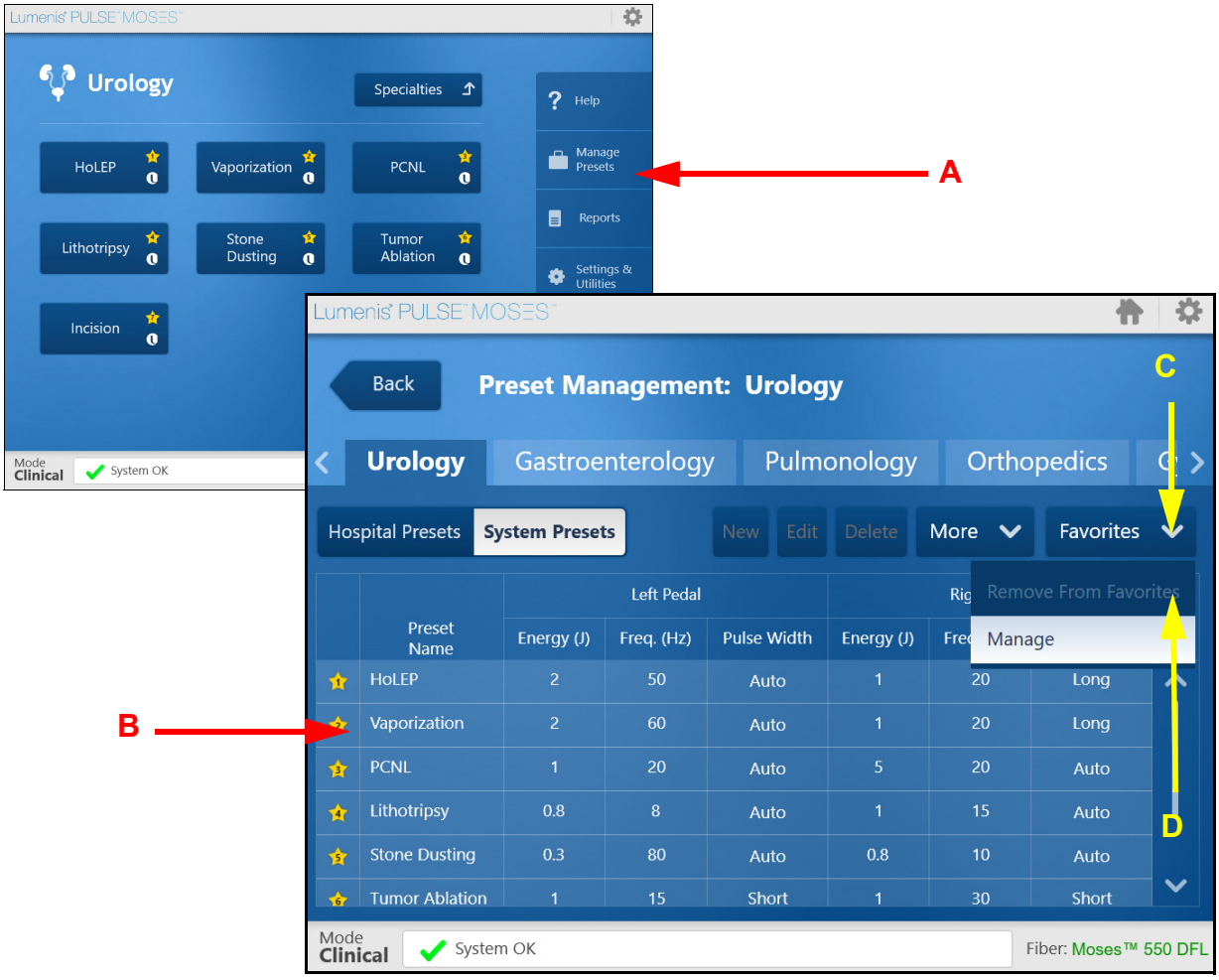


Figure 52: Preset Management - Remove from Favorites

3. The yellow star in the preset's line will turn into a wireframe, and the preset will ***not*** appear as a **Favorite** the next time you access the **Home** screen.

Re-Order the Presets on the Home Screen

The **Edit Favorites** pop-up has positions for nine Favorite presets. You can place any preset in each of the nine positions. Once all nine positions are filled, you will need to remove an existing Favorite in order to replace it with a new Favorite.

1. Select a **Favorite** preset by pressing it; press the ↑ **Move Up** or ↓ **Move Down** button to reposition the Favorite (i.e., **PCNL**) to the desired location (**3**) the list.
2. Press the ✖ **Remove** button to remove a preset from the system's **Home** screen.
3. You may also add a new **Favorite** preset to the list of **Hospital** favorites on the **Home** screen from this pop-up; press the ✚ **Add a Favorite** button to display the **Add a Favorite** screen and select a *Non-Favorite* procedure (wireframe star, not yellow). Press the **Add** button to pop-up the **Edit Favorites** window; press the **OK** button to save the new configuration of favorites.

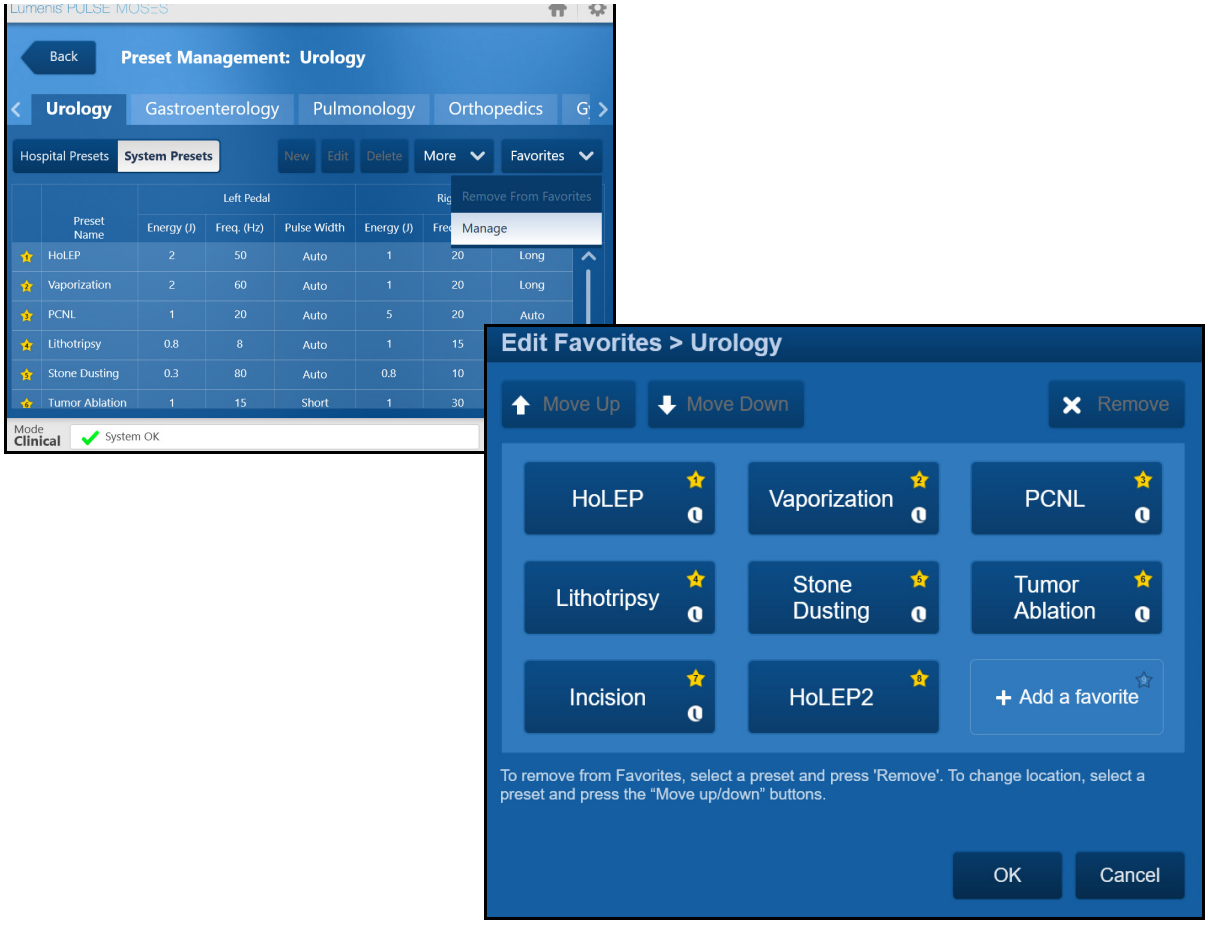


Figure 53: Edit Favorites Pop-Up Window

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 to a USB flash drive, for more detailed analysis.

Figure 54: Reports Screen (data shown is for illustration purpose only)

Exporting the Reports

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 reports to USB** button.
4. In the **Export Reports** confirmation screen, press **OK**.

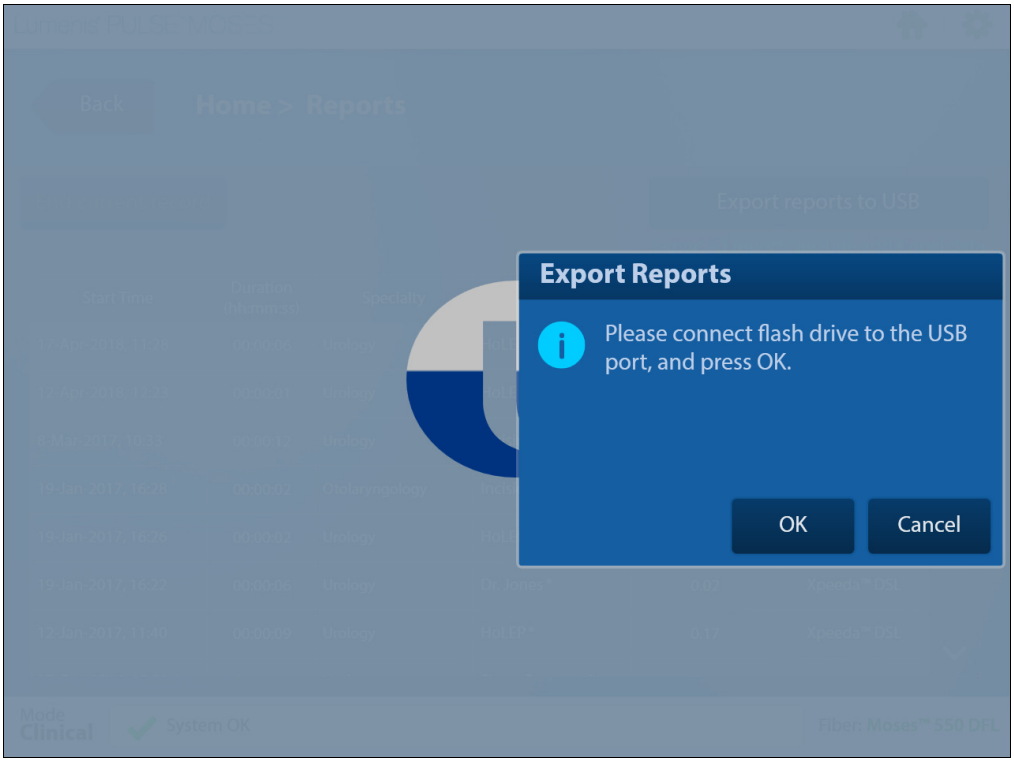


Figure 55: Reports Export Confirmation Screen

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

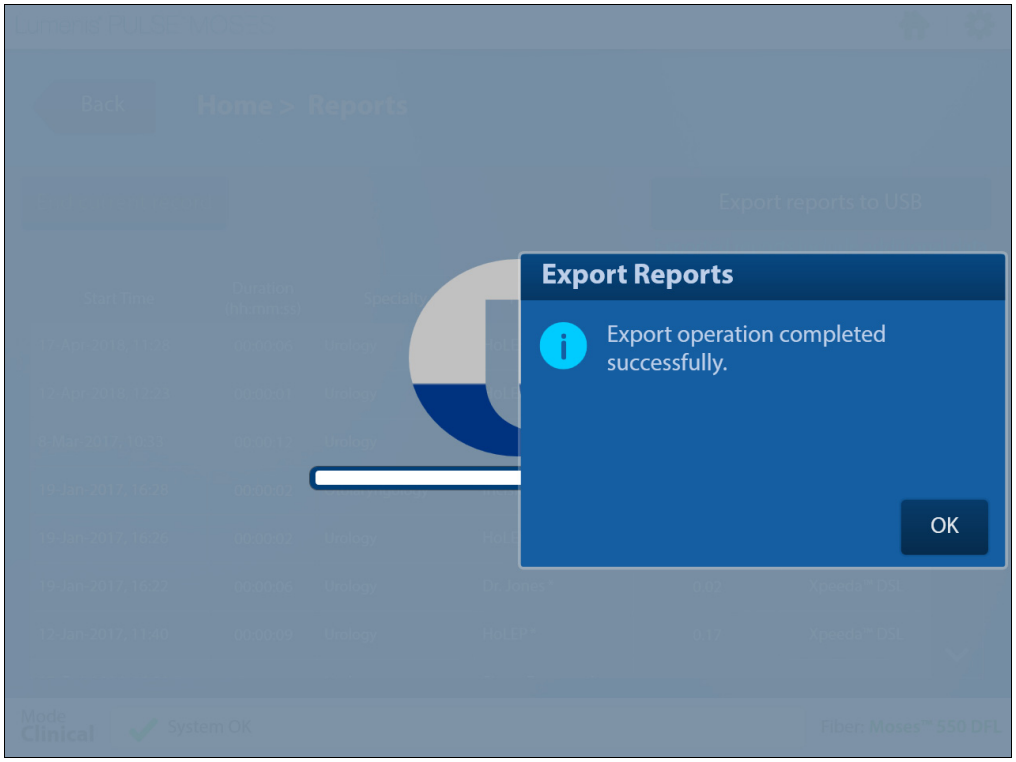


Figure 56: Reports Export Operation Completed

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.

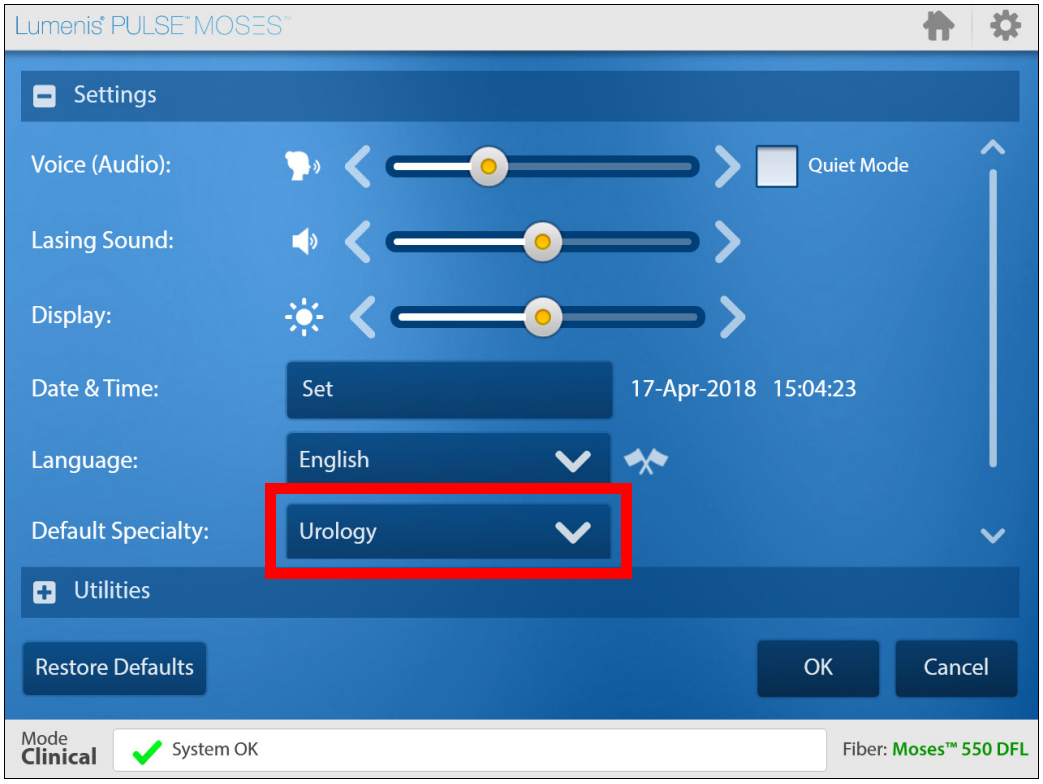


Figure 57: Default Specialty Button

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

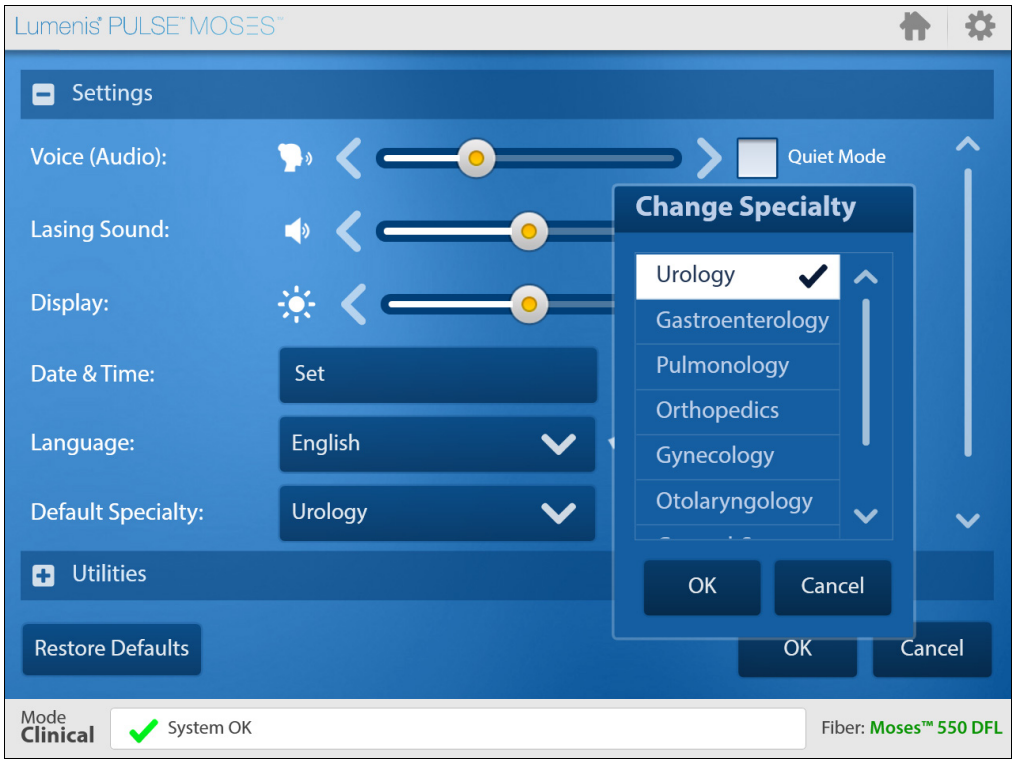


Figure 58: Default Specialty Selection Popup

4. In the **Change Specialty** pop-up, press **OK**.

5. In the **Settings & Utilities** screen, press **OK**.

NOTE:

The specialty name highlighted in the pop-up with the ✓ symbol is the system's default specialty.

Other Operations

Turning Off the Aiming Beam

Turn off the aiming beam by following the instructions on page 56 (Treatment Screen Description).

WARNING:

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

CAUTION:

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

Changing Screen Settings

1. Press the cogwheel (upper-right corner).
2. Select **Quick Settings**.

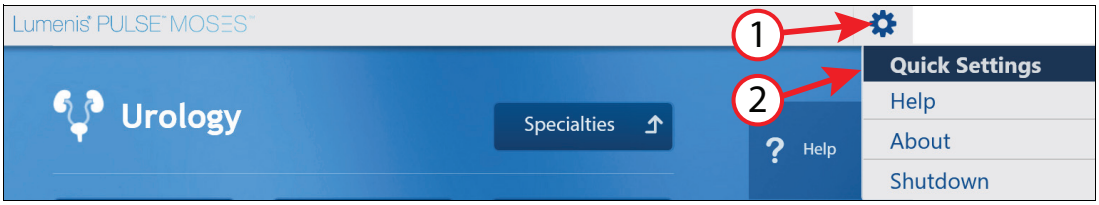


Figure 59: Select Quick Settings

3. 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.

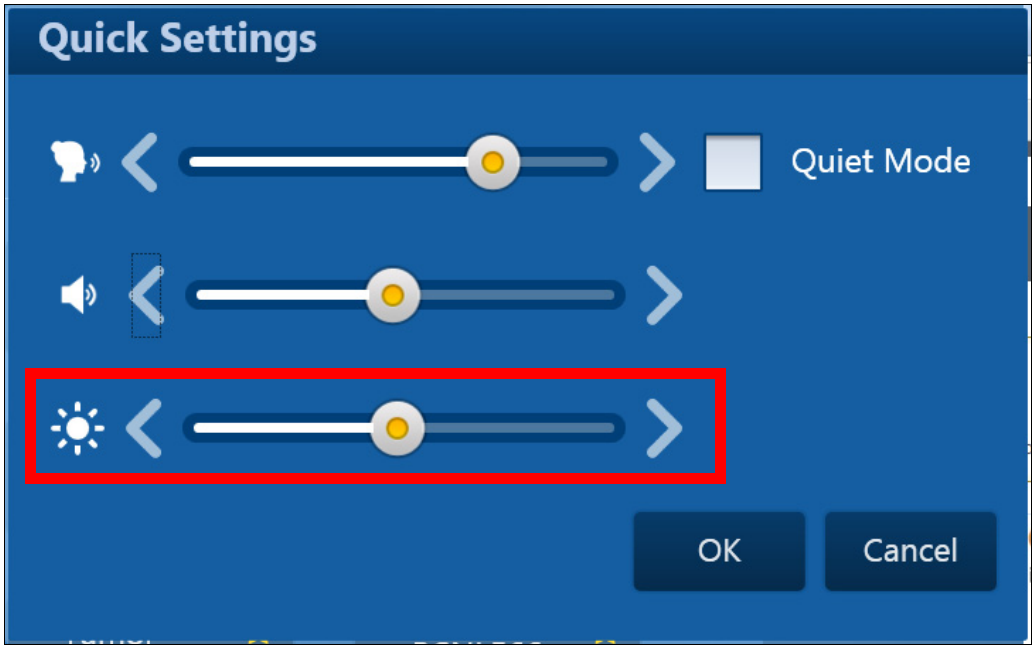


Figure 60: Quick Settings Pop-up Screen

4. Press **OK**.

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

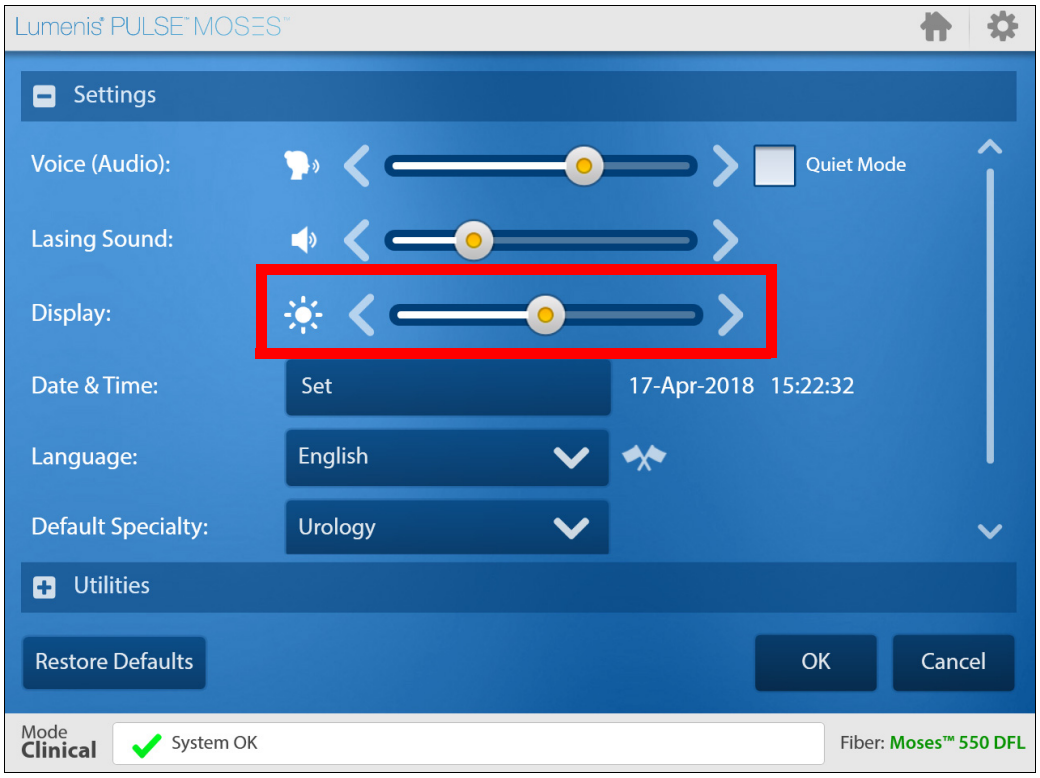


Figure 61: Settings & Utilities > Display Adjustment

Adjusting Volume and Sound Indications

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

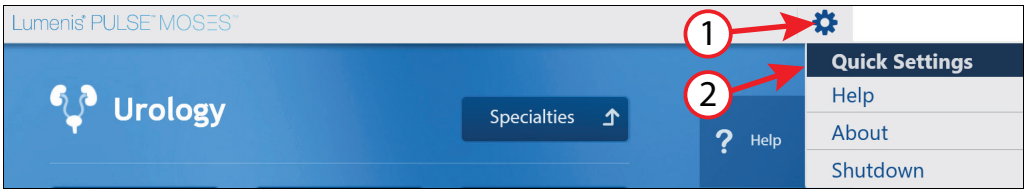


Figure 62: Select Quick Settings

2. **Sound Indications:**

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

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

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

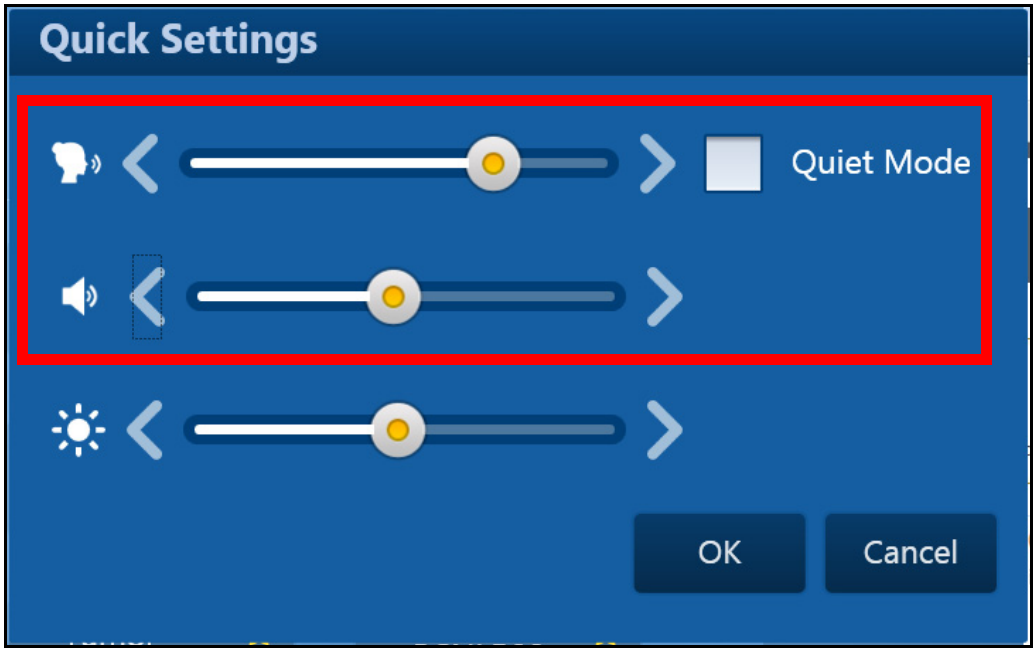


Figure 63: Quick Settings Pop-up Screen

NOTE:

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

4. Press **OK**.

NOTE:

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

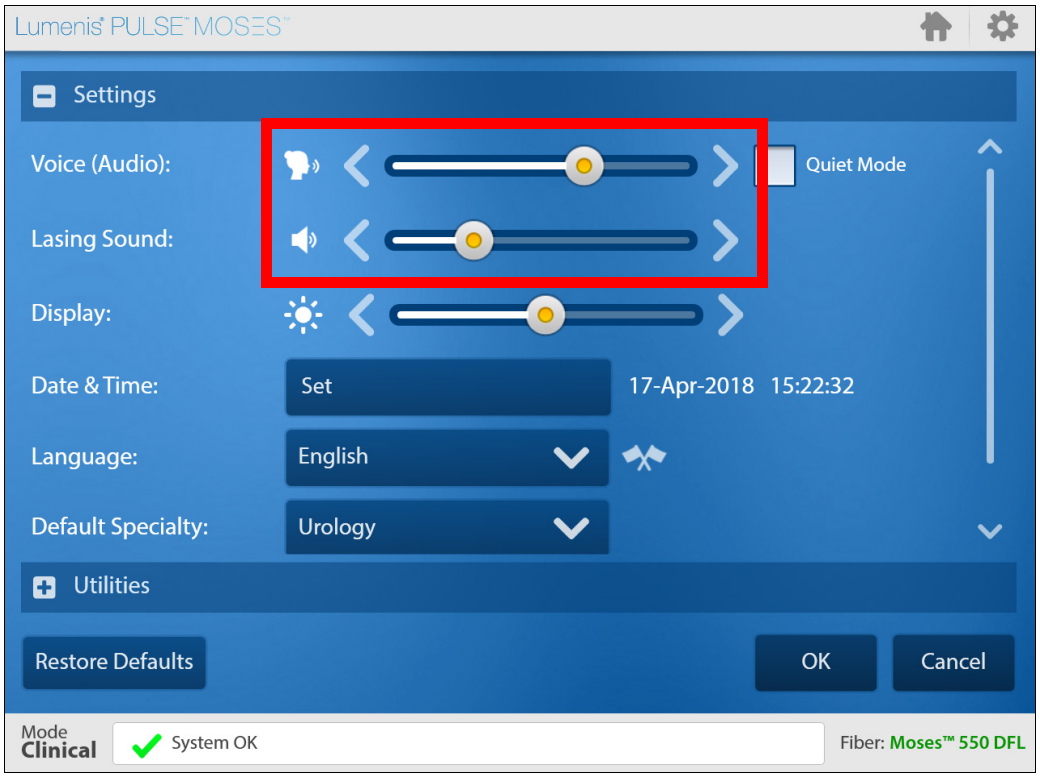


Figure 64: Settings & Utilities > Sound Indications Level Adjustments

Changing Date and Time

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

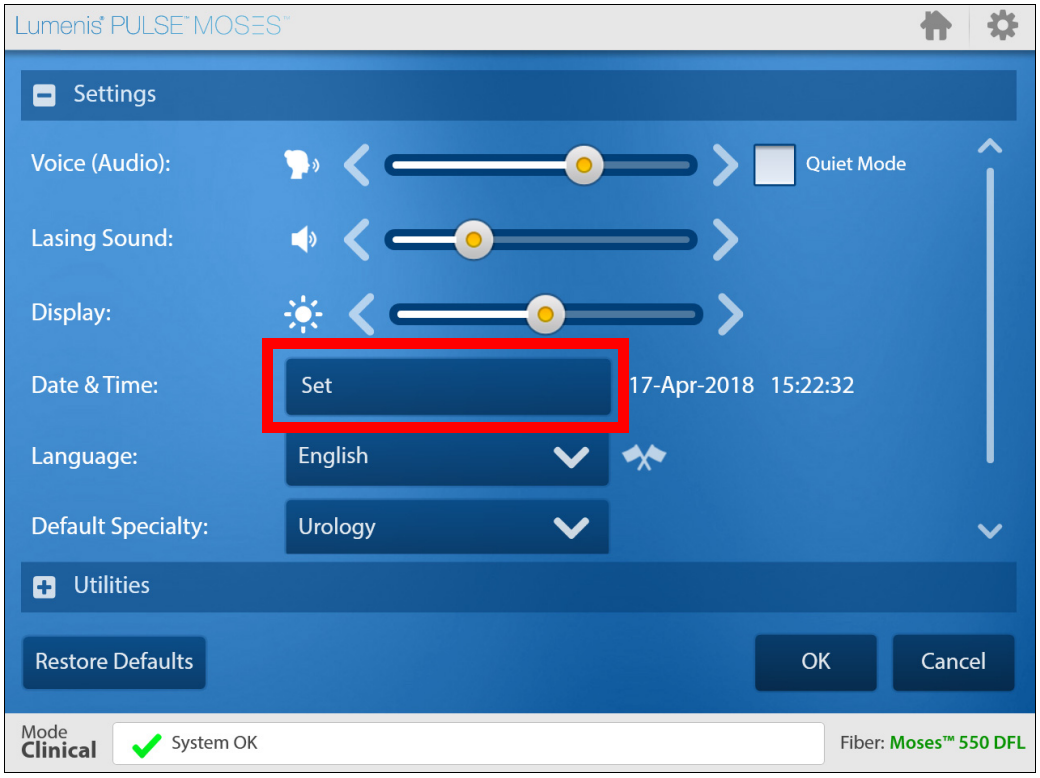


Figure 65: Set Date & Time Button

3. In the **Set** screen that opens, press the up and down arrows to set the date and time.
4. If you prefer a 12/24 hour clock, mark or clear the **24H** check box.
5. In the **Set** menu, press **OK**.
6. In the **Settings & Utilities** menu, press **OK**.

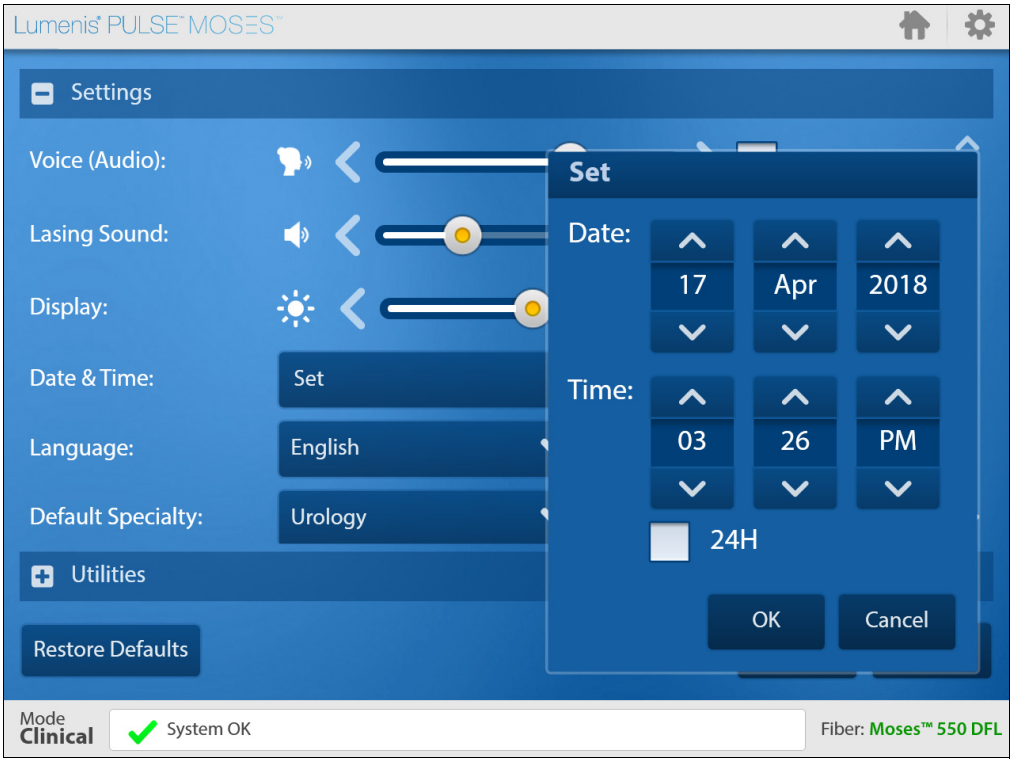


Figure 66: Settings & Utilities > Set Date and Time

Changing Language

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

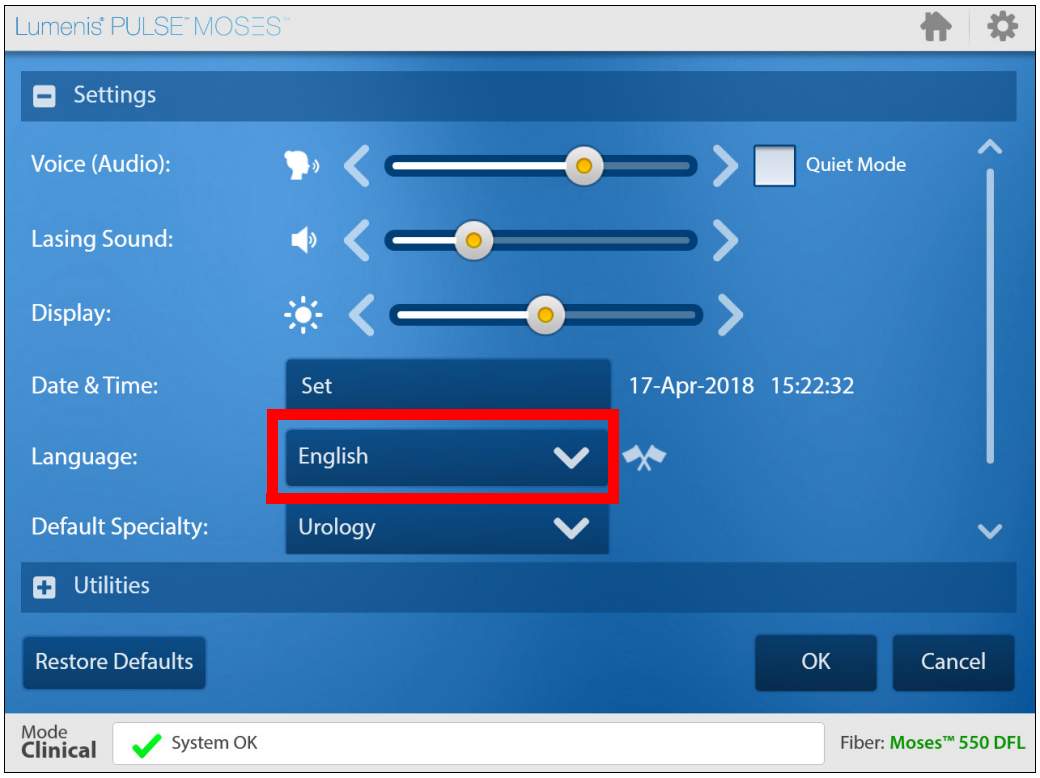


Figure 67: Language Button

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

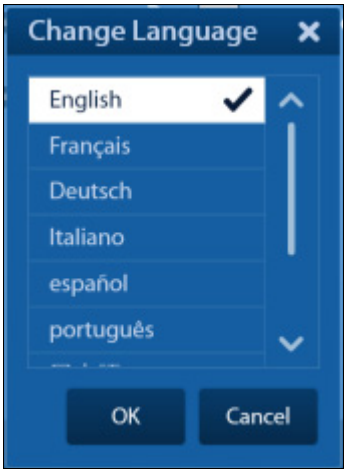


Figure 68: Settings & Utilities > Change Language

4. On the **Change Language** menu press the **OK** button (see Figure 68).
5. On the **Settings** screen press the **OK** button (see Figure 69).
6. Press the **Cancel** or **Home** button to return to the **Main Menu** screen without changing the language.

NOTE:

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

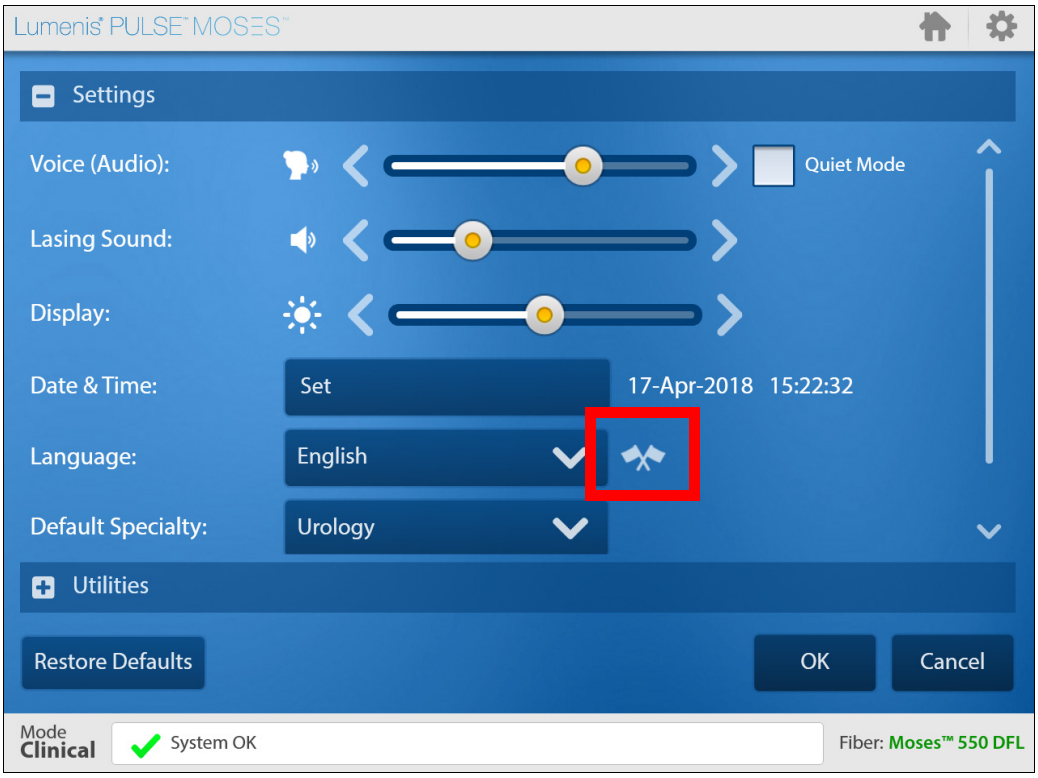


Figure 69: Settings & Utilities > Language Reset Flag

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.

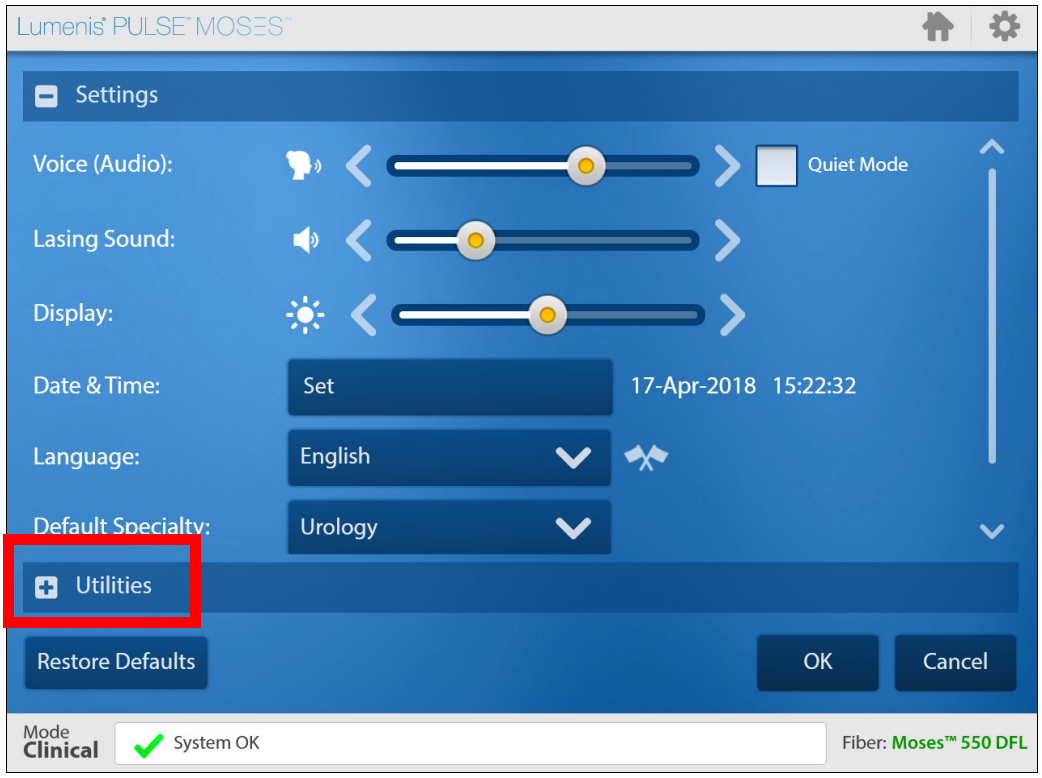


Figure 70: Set Date & Time Button

4. Insert a USB device.
5. Press the **Export data to USB** button.

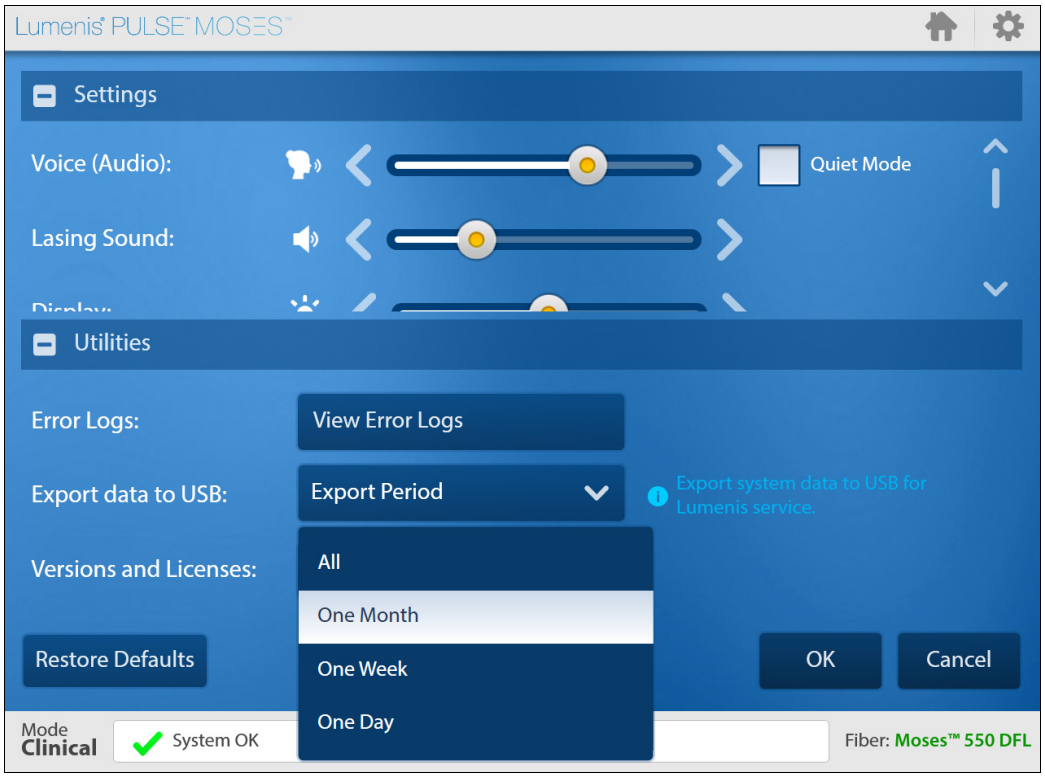


Figure 71: Export Data to USB Button

6. In the **Export data to USB** pop-up menu press one of the following:
   - **All**
   - **One Month**
   - **One Week**
   - **One Day**
7. Press **OK**.

8. Wait until the export operation is completed successfully.

9. Press the **OK** button to return to the **Home** screen.

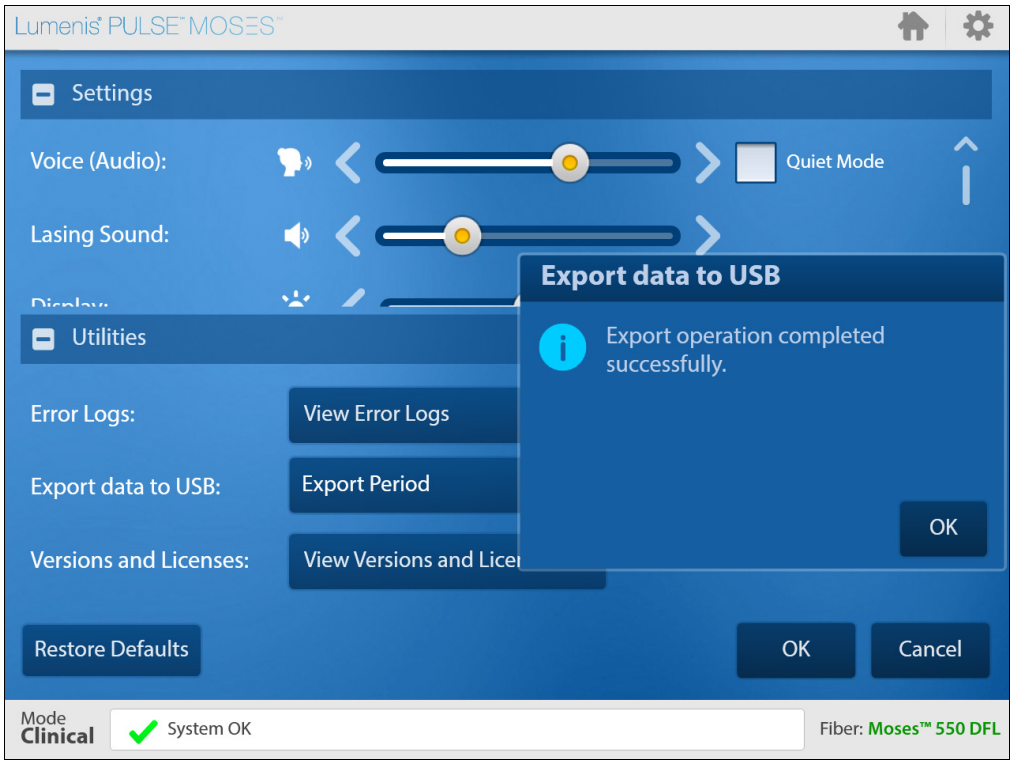


Figure 72: Export Operation Completed

Restoring Default Settings

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

1. From the **Main Menu** screen, press the **Settings & Utilities** button.
2. Press the **Restore Defaults** button.

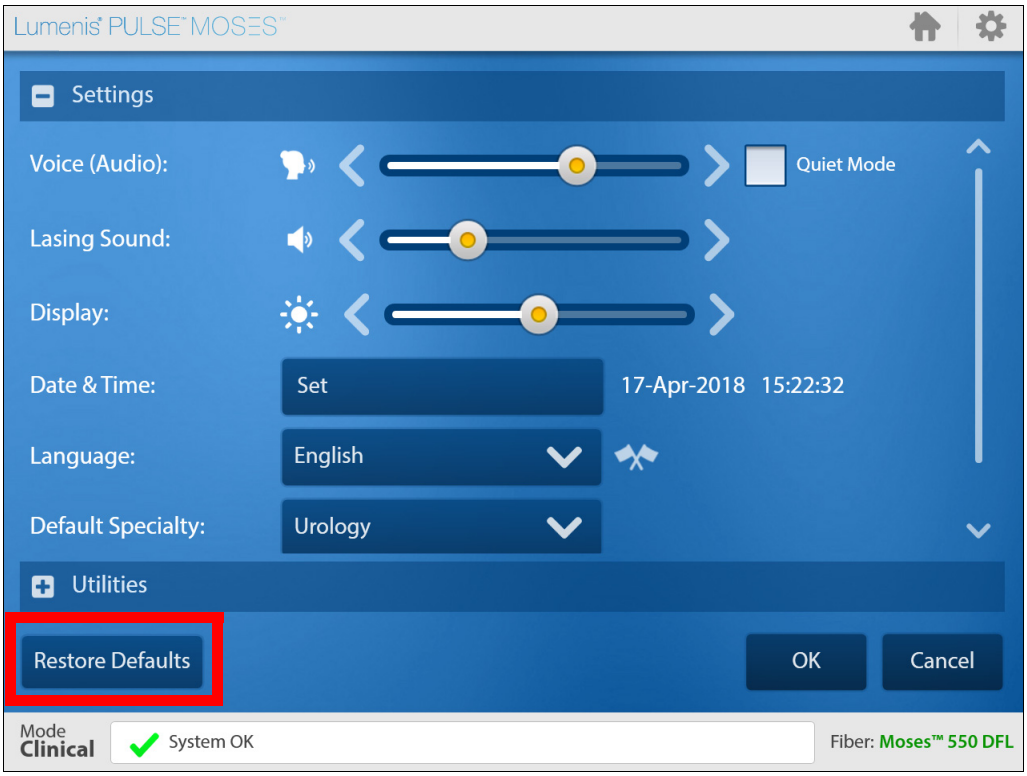


Figure 73: Set Date & Time Button

Remote Connection

Lumenis Pulse 120H system[1] includes a cellular modem which enables cellular connection. The cellular connection is intended to be used for Service Remote Connection by Lumenis-certified service technicians only. The cellular connection is not active during treatment. The remote connection to the system is initiated upon the user's request only, and starts when the service technician approves the request.

The Cellular modem specifications are:

- Model: **Telit LM940**
  Telit LM940 data card delivers data via Advanced LTE, a secured, data encrypted network connection.
- FCC ID: **RI7LM940**

In order to initiate a Service Remote Connection, perform the following steps:

1. Enter the **Settings & Utilities** screen.
2. Press the + next to **Utilities** to expand it.

1. The cellular modem is available in certain Lumenis Pulse 120H configurations, and may be enabled/disabled as needed per regulatory approvals in the relevant regions.

3. Press the **Request Remote Connection** button.

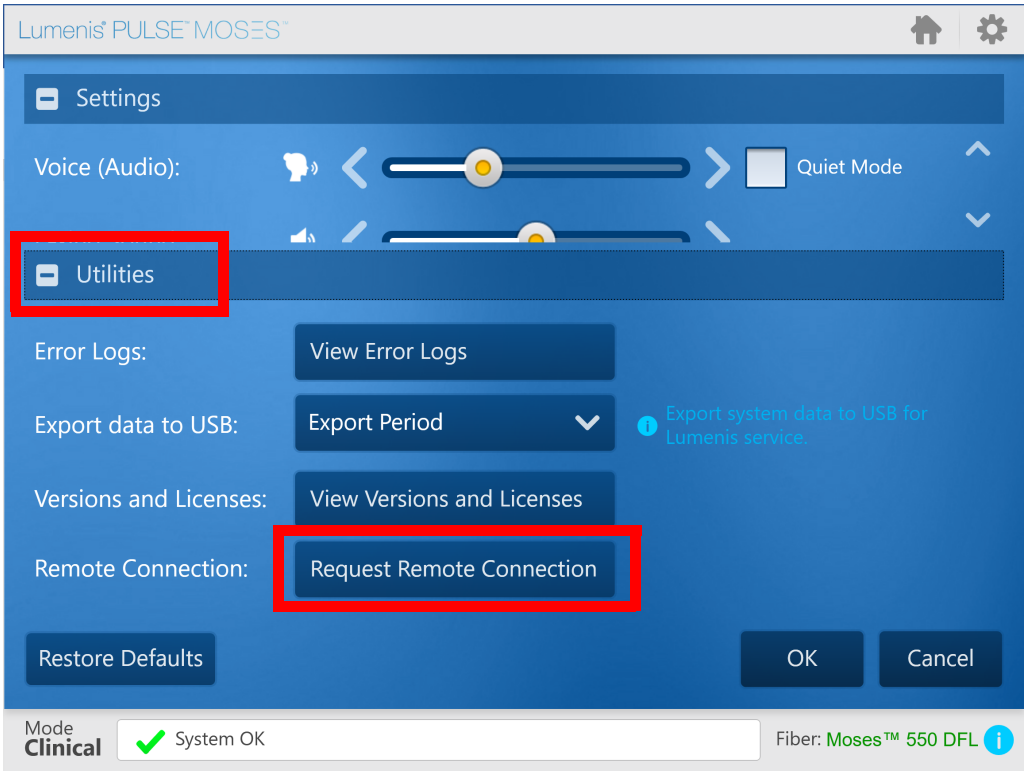


Figure 74: Settings & Utilities > Utilities

The Remote Connection session will be initiated. To cancel connection, press the **Cancel** button.

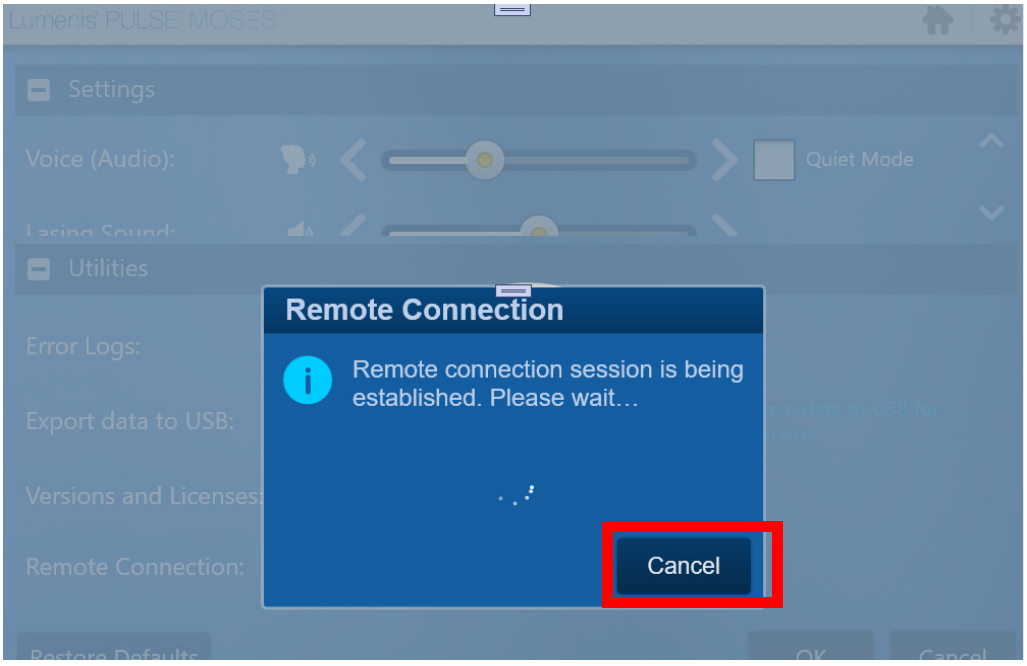


Figure 75: Remote connection initiation

Once the Remote connection session is established, the service technician controls the system. The service technician can terminate the Remote connection session and turn off the laser system, or alternatively you can terminate the Remote connection session by turning off the laser system.

Case Saver Mode

The **Case Saver Mode** is a system state that enables the user to continue using the system safely, however with reduced power capability in instances where:

1. There is a technical limitation. In such cases the system will require the user to acknowledge working with reduced power capability.
2. The current environmental conditions are not optimal. In such cases the system will work with reduced power capability or offer the user to lower the room temperature and humidity in order to return to maximum power capability.

Help

To access the **Help**, do the following:

1. Press the **Help** button.

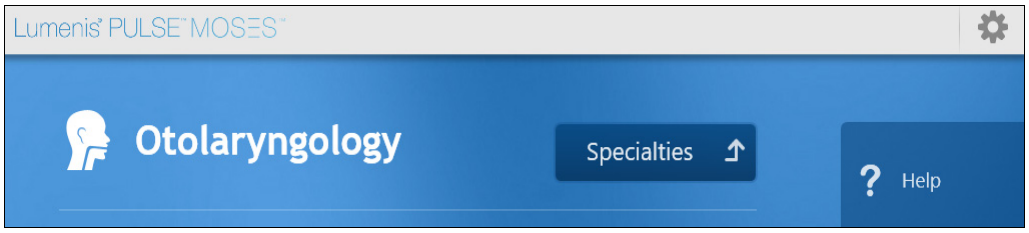


Figure 76: Select Help

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 displays in the main pane on the right.

NOTE:

When a help topic contains more information than can fit on the screen, a scroll bar displays 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 77: Location of the Back Button

Troubleshooting and Maintenance

Handling Error Messages and Notifications

Notifications and error messages display in the **Notification bar** at the bottom of the screen. If you press **READY** while there is an error, it opens the **Notification** screen. You can also open it from the notification bar as a pop-up by pressing the **Show Notifications** button. Refer to Figure 78.

1. Follow the instructions for the error message or notification.
2. For notifications, press the **Acknowledge all** button.
   - A check mark will display to show that you have acknowledged the message and the notification will fade.
   - If the notification is ignored, it will remain in the list.
   - If it is an error message, depending on the severity of the error, the system may require a restart or to be shut down and not operated until serviced professionally.
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 display 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 **Notification** screen.

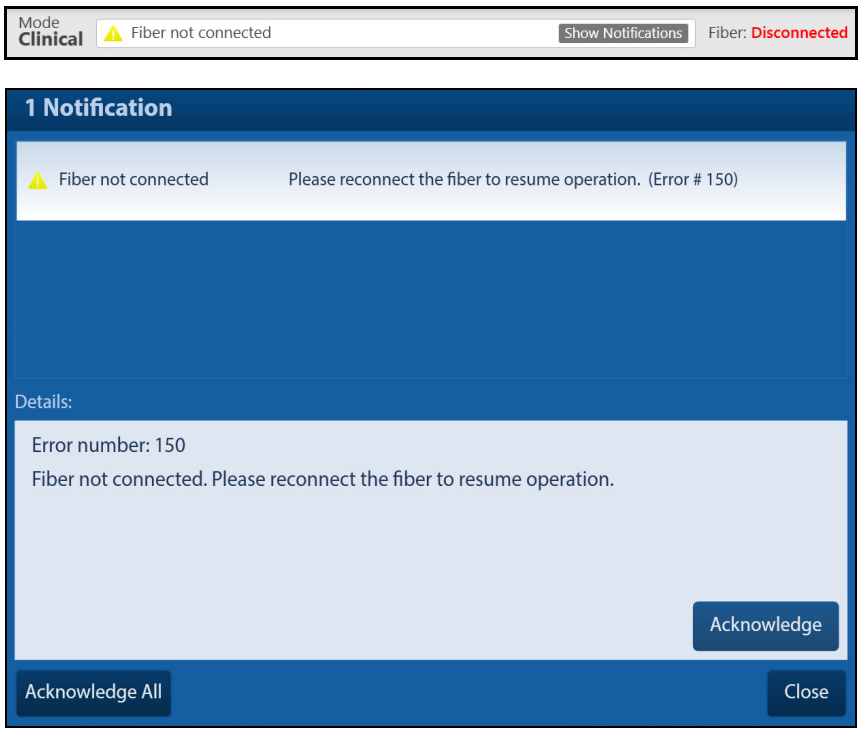


Figure 78: Example of Error Notification Area and Pop-Up Window

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 displays on the Control Screen

1. Clear the message by pressing the **Acknowledge** button and follow the suggested steps intended to clear the fault.
2. Resume normal operation; if the same notification displays again, turn off the laser system for one minute and restart it. Resume normal operation.
3. If the same notification displays again, record the error number and contact your local Lumenis service representative.

Cooling System Notification

The following notification displays on the control screen: **System overheated**.

1. Press the **Show Notifications** icon to open a pop-up window that displays the nature of the notification.
2. Clear the message by pressing the **Acknowledge** button and pause operation for one minute to allow the system to cool.
3. Resume normal operation; if the same notification displays again, turn off the laser system for five minutes and restart it. Resume normal operation.
4. If the same notification displays again, 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. Replace the optical fiber with a new one.

“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 Limited

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

1. Select 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 fail-safe mechanisms.

A recommended routine inspection and maintenance schedule is provided below.

Inspection/Service	Frequency	Performed By	Remarks
Routine exterior cleaning.	As required by hospital/clinic protocol.	Hospital/Clinic Staff	
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's internal components will be powered down and laser emission will be disabled. This should be verified by trying to access **Ready** mode and noting that **Ready** mode is not available.
2. Turn the button clockwise to release it and restart the system.
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 79: 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.

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.

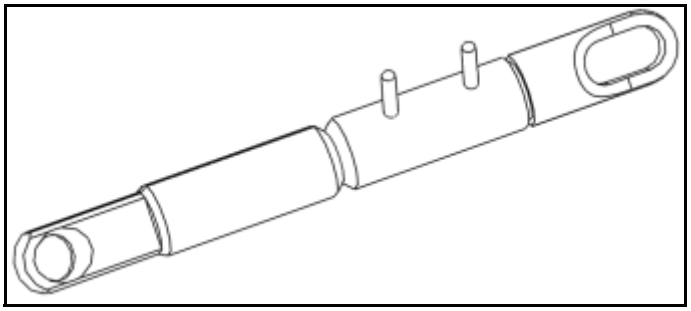


Figure 80: Inspect the Debris Shield Optic

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.

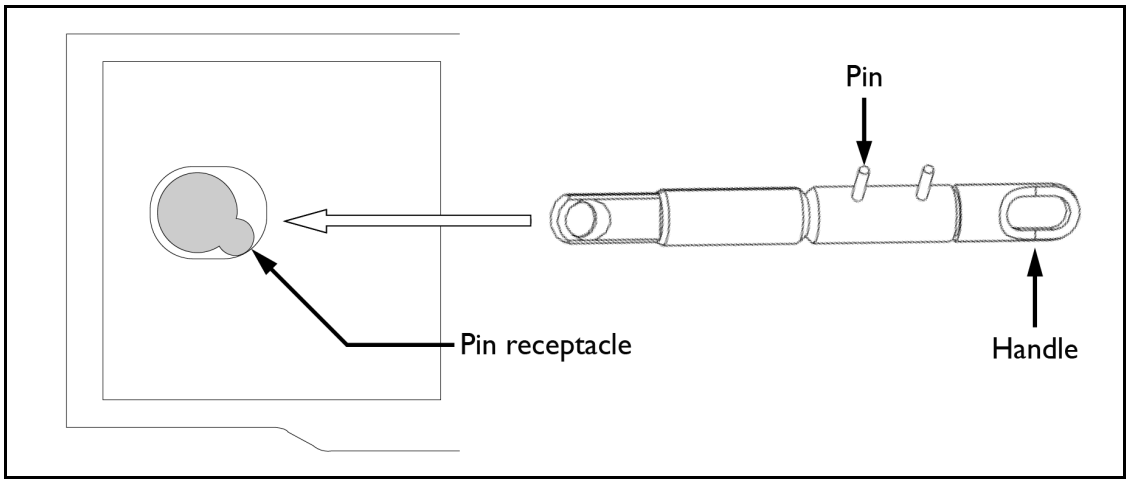


Figure 81: Reinsert the Debris Shield

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

NOTE:

Lumenis strongly recommends that at least one spare debris shield be kept on hand with the P120H system, such as to avoid delays or interruptions of surgical procedures.

Professional Maintenance

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

CAUTION:

The Lumenis Pulse 120H laser system may be serviced by Lumenis-certified field service engineers using an approved service manual.

WARNING:

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

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-Z386-14: Laser safety in health care facilities.

Accessories

Delivery Devices and Accessories

- SlimLine SIS 200, 365, 550, 1000
- SlimLine EZ / SlimLine EZ SIS 200, 365, 550
- SlimLine GI SIS 365
- Xpeeda D/S/L
- Slimline 200 D/F/L
- Moses D/F/L 200, 365, 550
- Sterile aspiration tubing
- Non-sterile drainage tubing
- Collection container
- Suction handpiece

Additional Accessories

- Fiber cutting scissors
- Optical fiber strippers
- Cleaving tool
- SlimLine steam sterilization tray
- Safety eyewear

Electrical Requirements

Electrical Utilities

The Lumenis Pulse 120H holmium laser is available in two electrical configurations:

- Single-phase (200-240 VAC, <46A, 50 or 60 Hz)
- Three-phase (380-415 VAC, <18A per phase, 50 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.

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.

When installed with a removable or lockable wall plug, the socket and wall plug connection must be rated for higher than the electrical requirements of the specific configuration. In most instances, customers must purchase a suitable electrical connection kit locally.

Compliance With International Standards

In accordance with regulations 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 displays 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 switches 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.

WARNING:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Specifications

Specifications are subject to change without notice.

Treatment Beam

Laser Medium/Energy Source	Holmium:YAG crystal rod
Wavelength	2.1 µm
Laser Mode	Pulsed
Maximum Average Power	120 W
Pulse Energy	0.2 – 6 J (Japan: 0.2 – 3.5 J)
Pulse Frequency	5 - 120 Hz
Max Pulse Duration	1300 µs

NOTE:

When using a 30A or 32A configuration, system performance will be limited in order to meet the maximum current limits. 30A configuration: up to 80 Watts; 70 Hz. 32A configuration: 112.5 Watts.

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

System Classifications

IEC 60601-1 classification	Class I, type BF applied part
IEC 60601-1-2 classification	Class A
IEC 60825-1 laser classification	Class 4
US FDA CDRH laser classification	Class IV

System Electrical Specifications

Operation	Continuous
Type of Protection against Electric Shock	Class I
Degree of Protection against Electric Shock for Applied Parts	BF
Protection against Ingress of Water: System	IP20
Protection against Ingress of Water: footswitch	IP68

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	260 kg. / 573 lbs.
Power Cable Length	5 meters (16.4 feet)[a]
Footswitch Cable Length	7 meters (23 feet)
Door Interlock Cable Length	Up to 3 meters (9.8 feet)
Potential Equalization Conductor	Up to 3 meters (9.8 feet)

a. Power cable length for 30A systems: 7 meters (23 feet).

Environmental Requirements (Operating)

Temperature range:	16 – 24°C / 60.8 – 75°F
Maximum humidity:	75% non-condensing
Atmospheric pressure:	77 – 106 kPa

NOTE:

The combination of environmental temperature and relative humidity should be such that the dew point is below 16°C.

NOTE:

In certain conditions of high temperature and relative humidity, system performance will be limited in order to prevent condensation within the system.

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
Transportation pressure:	50 – 106 kPa
Storage pressure:	77 – 106 kPa

Laser Safety Eyewear

The following laser safety eyewear complies with DIN EN 207 and ANSI Z136.1 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:

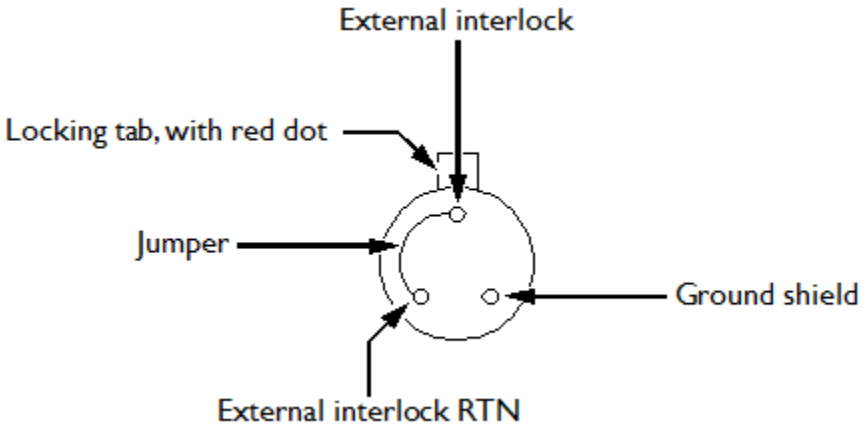


Figure 82: External Door Interlock Pin Assignments (solder side of plug shown)

Customer Service

Warranty

Lumenis warrants the Lumenis Pulse 120H system and its accessories to be free from defects in materials and workmanship, and to perform in the manner and under the conditions specified in the operator manual.
A defective device must be returned to Lumenis or an authorized Lumenis representative. Refer to the next section for information about returning equipment to Lumenis. For specific and detailed warranty information for this instrument, refer to the first page of your purchase "Agreement" and the last page of the "Terms and Conditions of Sale".

Returning Equipment

Before sending equipment to Lumenis, call your local Lumenis representative or the closest Customer Service Center (http://www.Lumenis.com/contact) to obtain a Return Material Authorization (RMA) tracking number.

To comply with postal and transportation laws, used equipment shipped to Lumenis or authorized representatives for return or repair must be properly decontaminated according to the cleaning and sterilization instructions. To document that all equipment has been properly decontaminated, a signed Certificate of Decontamination must be enclosed in the package. Failure to enclose the certificate will cause the supplier to assume that the product is contaminated and will assess the customer with cleaning costs. Any decontamination inquiries should be directed to your closest Lumenis Service Center.

Customer Feedback

Contact the closest Customer Service Center (http://www.Lumenis.com/contact) with any feedback or to report any adverse events.

Appendix A: EMC Compliance

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	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.
Harmonic emissions IEC 61000-3-2	Not applicable	The system consumes more than 16A momentary current per phase, and therefore is exempt from these requirements.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The system consumes more than 16A momentary current per phase, and therefore is exempt from these requirements.

NOTE:

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity The Lumenis Pulse 120H system is intended for use in the electromagnetic environment specified below. The customer or the user of the Lumenis Pulse 120H system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD), IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 SIP/SOP lines	±2 kV for power supply lines ±1 kV for SIP/SOP lines	Mains power quality should be that of a typical commercial or hospital environment
Surge, IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptable power supply or a battery.
	0% U_T for 250/300 cycles	0% U_T for 250/300 cycles	
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 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 AC mains voltage prior to application of the test level.			

Immunity test	**IEC 60601 level**	**Compliance level**
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz)	[V] = 3 Vrms [V] = 6 Vrms
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.7 GHz	[E] = 3 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	

Appendix B: Intentional RF Radiation

The system uses an RFID module, FCC ID: Z97-1149466.

RF receiver:

Frequency of Reception	125 KHz
Preferred Frequency or Frequency Band	125 KHz
Bandwidth of the receiving section	±1 KHz

RF transmitter:

Frequency of Transmitter	125 KHz
Type and Frequency of the modulation	Amplitude-Shift Keying (ASK) / 125 KHz
Effective radiated power (ERP)	70 dB (µV/m) @ 3m

The system uses a Cellular module, FCC ID: RI7LM940.

WCDMA Band I	Frequencies of Transmitter and Reception	1922.4-1977.6 MHz
	Type of the modulation	WCDMA
	Effective radiated power (ERP)	0.171 W
WCDMA Band VIII	Frequencies of Transmitter and Reception	882.4-912.6 MHz
	Type of the modulation	WCDMA
	Effective radiated power (ERP)	0.185 W
LTE Band 1	Frequencies of Transmitter and Reception	1922.5-1977.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.171 W
LTE Band 2	Frequencies of Transmitter and Reception	1852.4-1907.6 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.186 W
LTE Band 2	Frequencies of Transmitter and Reception	1855-1905 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.164 W

LTE Band 2	Frequencies of Transmitter and Reception	1860-1900 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.196 W
LTE Band 3	Frequencies of Transmitter and Reception	1710.7-1784.3 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.182 W
LTE Band 4	Frequencies of Transmitter and Reception	1712.4-1752.6 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.177 W
LTE Band 4	Frequencies of Transmitter and Reception	1715-1750 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.185 W
LTE Band 4	Frequencies of Transmitter and Reception	1720-1745 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.185 W
LTE Band 5	Frequencies of Transmitter and Reception	826.4-846.6MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.182 W
LTE Band 5	Frequencies of Transmitter and Reception	829-844 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.190 W
LTE Band 7	Frequencies of Transmitter and Reception	2502.5-2567.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.156 W
LTE Band 7	Frequencies of Transmitter and Reception	2505-2565 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.135 W
LTE Band 7	Frequencies of Transmitter and Reception	2510-2560 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.161 W
LTE Band 8	Frequencies of Transmitter and Reception	880.7-914.3 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.181 W
LTE Band 12	Frequencies of Transmitter and Reception	699.7-715.3 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.162 W

LTE Band 12	Frequencies of Transmitter and Reception	701.5-713.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.140 W
LTE Band 12	Frequencies of Transmitter and Reception	704-711 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.162 W
LTE Band 13	Frequencies of Transmitter and Reception	779.5-784.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.158 W
LTE Band 13	Frequencies of Transmitter and Reception	782 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.179 W
LTE Band 17	Frequencies of Transmitter and Reception	706.5-713.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.139 W
LTE Band 17	Frequencies of Transmitter and Reception	709-711 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.161 W
LTE Band 20	Frequencies of Transmitter and Reception	834.5-859.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.185 W
LTE Band 25	Frequencies of Transmitter and Reception	1855-1910 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.173 W
LTE Band 25	Frequencies of Transmitter and Reception	1857.5-1907.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.202 W
LTE Band 25	Frequencies of Transmitter and Reception	1860-1905 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.156 W
LTE Band 26	Frequencies of Transmitter and Reception	826.5-846.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.169 W
LTE Band 26	Frequencies of Transmitter and Reception	829-844 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.210 W

LTE Band 26	Frequencies of Transmitter and Reception	831.5-841.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.210 W
LTE Band 28	Frequencies of Transmitter and Reception	704.5-746.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.180 W
LTE Band 30	Frequencies of Transmitter and Reception	2310 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.14 W
LTE Band 38	Frequencies of Transmitter and Reception	2572.5-2617.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.167 W
LTE Band 38	Frequencies of Transmitter and Reception	2580-2610 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.161 W
LTE Band 40	Frequencies of Transmitter and Reception	2302.5-2397.5 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.175 W
LTE Band 41	Frequencies of Transmitter and Reception	2506-2680 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.191 W
LTE Band 66	Frequencies of Transmitter and Reception	1720-1770 MHz
	Type of the modulation	QPSK, 16QAM, 64QAM
	Effective radiated power (ERP)	0.2 W