UltraPulse® DUO

Carbon Dioxide Laser

Operator's Manual

Lumenis®

Energy to Healthcare

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Use of this Manual.

The UltraPulse DUO laser system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, please contact your Lumenis representative for clarification.

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the UltraPulse DUO CO_2 laser system. Such training should include a review of published literature, seminars, workshops and appropriate preceptorships. Please contact your Lumenis representative for current information on available training.

This manual should always accompany the system, and its location must be known to all personnel operating the system. Additional copies of this manual are available from your Lumenis distributor.

System and accessory specifications are subject to change without notice.

For further information about Lumenis, visit the Lumenis Website: www.Lumenis.com or send email to information@Lumenis.com.

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.

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1 Overview

1.1 Introduction

The Lumenis UltraPulse DUO CO_2 laser system was developed from the UltraPulse® Encore free beam laser (with articulated arm), which is the benchmark carbon dioxide (CO_2) laser for speed, reproducibility, and ease of use. Each UltraPulse laser incorporates Lumenis' patented high-energy, short-pulse CO_2 laser tube technology that has been responsible for consistent proven results in hospitals, surgery centers and offices for over a decade.

Combining the UltraPulse pulsed energy delivery mode with Lumenis' state-of-the-art scanning technology enables the highest level of CO_2 laser precision.

Lumenis offers a complete line of free beam CO_2 laser delivery accessories, most of which are compatible with the SurgiTouch® automated scanner. Additionally, a number of fiber delivery accessories are available to facilitate and simplify transport of the fiber tip to the surgical site.

Lumenis lasers and delivery systems are categorized as 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.

1.2 Scope of This Manual

This manual is intended to provide the surgeon and other personnel who operate or maintain the system with information regarding the operating principles, controls, safety precautions, installation and maintenance of the system. While this manual is intended to provide operational and maintenance information to the user, it does not serve as a substitute for proper training in the clinical applications of medical laser devices.

This operator's manual incorporates the following chapters:

Chapter 1. Overview	Provides a general introduction to the system.
Chapter 2. Safety	Provides explanations and directions concerning safety measures for operating the system. This chapter also includes regulatory information and requirements.
Chapter 3. System Description	Provides a detailed overview of the system and its various components, controls, displays and connections. Includes detailed specifications of all facets of the system.
Chapter 4. Preparing the System for Use	Provides important information prior to the use of the system. It also includes information on connecting various components to the system, moving the system and balancing the articulated arm.
Chapter 5. Normal Operations	Provides general and common instruction in how to operate the system.
Chapter 6. Maintenance & Troubleshooting	Provides a detailed review of how to maintain the system. It also includes a troubleshooting guide and a table of system error messages.
Appendix A. Clinical Guide	Offers information about staff training, indications, contraindications for use and suggested professional reference literature.
Appendix B. EMC Guidance	Describes the electromagnetic environment in which the system may operate.

1.3 Manual Conventions

Throughout this manual, notes, cautions and warnings are used to provide critical information about the use and maintenance of this device. Below, you see how each will appear in the manual and an explanation for each type of information.

Note

A **Note** alerts the operator to particularly important information.

Caution

A **Caution** alerts the operator to the possibility of a problem that can occur as a result of device 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 a problem.

Warning

A **Warning** alerts the operator to the possibility of an adverse event, injury or death as a result of misuse of the device.

1.4 Physician Responsibility

The properly licensed practitioner is responsible for the use and operation of the device and for all user qualifications. Lumenis makes no representations regarding federal, state or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

Caution

Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

No one should use the UltraPulse DUO, or any other medical laser, without specific training in both medical laser use and laser safety.

1.5 Installation and Ongoing Maintenance

The laser is shipped directly from the factory to your site. Your local Lumenis representative initially uncrates, inspects, sets up and installs the laser to ensure that it is ready for use. In addition, Lumenis provides in-service training to ensure that your clinicians are experienced with the operation and safety considerations of the laser.

Thereafter, the clinicians at your facility need to perform the daily maintenance routines associated with the laser and with any delivery systems and/or accessories used during surgery. This includes inspecting and cleaning the laser and delivery systems; sterilizing, connecting, and disconnecting the accessories; and performing laser beam alignment safety checks. These procedures are detailed in this manual and in your delivery system operator manuals.

The UltraPulse DUO is a technical medical device that requires routine service. All service must be performed by a Lumenis technician and all parts must be purchased from Lumenis. Failure to obtain service and parts through Lumenis voids all warranties, express and implied. Please call Lumenis or your local representative for details.

Warning

Do not attempt to open or disassemble the system's covers. Opening the covers exposes personnel to high voltage components, the laser resonator and possibly laser radiation.

Only Lumenis-authorized technical personnel are qualified to service the interior of the system.

1.6 Modification of the Device

Warning

Do not modify the device without explicit approval by the manufacturer. Unauthorized modifications of the device may lead to a serious adverse event, injury or death.

1.7 Resale Inspection

The UltraPulse DUO is a technical medical device. If any Lumenis device is resold by anyone other than an authorized sales representative, Lumenis offers a resale inspection by a Lumenis technician to assure that the device is working in accordance with manufacturer’s specifications.

Warning

Using the device after it has been resold and before it has been inspected is a misuse of the device and may result in injuries.

Lumenis also offers service contracts and extended warranties for its devices. For more information about the services or about the costs of inspections or service calls, please call Lumenis or your local representative.

Caution

In USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner in the state that this product is prescribed.

1.8 Abbreviations and Acronyms

"	Inches
°C	Degrees Celsius
°F	Degrees Fahrenheit
ANSI	American National Standards Institute
CE	European Directives Compliance Marking
cm	Centimeters
CO_2	Carbon Dioxide
CW	Continuous Wave
DC	Direct Current
ENT	Ear, Nose and Throat
EMC	Electromagnetic Compatibility
FDA	Food & Drug Administration (USA)
GUI	Graphic User Interface
GYN	Gynecology
Hz	Hertz
IEC	International Electrotechnical Commission
ISO	International Standards Organization

J/cm²	Joules per square centimeter
kg	Kilogram
lbs.	Pounds
LAM	Laser-Assisted Myringotomy
LAN	Local Area Network
LAUP	Laser-Assisted Uvulopalatoplasty
LCD	Liquid Crystal Display
LED	Light Emitting Diode
m	Meters
mJ	MilliJoules
mm	Millimeters
mW	MilliWatts
nm	Nanometers
OD	Optical Density
UL	Underwriters Laboratories
UP	UltraPulse
USB	Universal Serial Bus
VAC	Volts, Alternating Current
W	Watts
WG	Waveguide

2 Safety

2.1 Introduction

CO_2 surgical lasers bear the following classifications by various regulatory bodies.

- Class IV designation according to the U.S. National Center for Devices and Radiological Health (a division of the Food and Drug Administration)
- Class 4 according to IEC-60825 require controls and measures

These classifications prevent both direct and diffusely reflected exposure of laser energy to eyes and skin, except as a therapeutic application.

Carefully read the information in this section and take the necessary precautions to prevent exposure, fire hazards, electrical injury and pollution

Lumenis does not make recommendations regarding the practice of medicine. The clinician should use laser parameters that will produce the desired tissue effect, based on clinical training and professional experience.

> **Warning**
>
> Read this manual carefully. Use of controls or adjustment, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

This chapter includes:

- Hazards associated with unsafe laser use.
- Safety features of the UltraPulse DUO.
- Notes, precautions, cautions and warnings associated with the UltraPulse DUO.

2.2 CO_2 Laser Beam Characteristics

The wavelength of the CO_2 laser beam is 10,600 nm, placing it in the far-infrared portion of the electromagnetic spectrum. The wavelength is invisible to the human eye. Therefore, to aim the CO_2 beam, the system incorporates a low-power diode laser with a red beam aligned to the CO_2 beam. The red aiming beam serves as a visible pointer, indicating where the treatment beam is directed.

The effect on tissue is instantaneous, and determined by a combination of factors: laser fluence (energy level and spot size), exposure (dwell) time and water content in the tissue. The degree of precision versus thermal build up in tissue is controlled by the operator and is guided by training, observed tissue effect and experience. Provided equipment is in good working order, small adjustments to laser parameters can usually help the clinician to attain desired laser-tissue interaction.

Additional characteristics of the CO_2 laser beam include the following:

- CO_2 laser light is absorbed by most dielectrics, such as water, biological tissue, glass and plastic.
- CO_2 laser energy is instantly absorbed by the first absorbent material it contacts.
- CO_2 laser light can be reflected from smooth materials as metallic surfaces, even if they are blackened (anodized).
- When CO_2 laser light is focused by a lens system, the beam converges to a fine point and then diverges rapidly, causing dissipation of energy density.
- When CO_2 laser light exits the tip of a hollow fiber, the beam diverges. Therefore, the energy is most concentrated at the tip.

2.3 UltraPulse DUO CO_2 Laser System

The UltraPulse DUO is an advanced computer-controlled, user-friendly CO_2 laser system based on a sealed-off CO_2 laser tube providing up to 60 Watts of power. The system incorporates the CO_2 laser tube within the main cabinet, an articulated arm free beam delivery system, a port for connecting a CO_2 fiber and attachable laser accessories. The system is activated for laser emission by a footswitch.

The UltraPulse DUO system is configured to deliver CO_2 laser energy via an articulated arm or through a Lumenis-qualified CO_2 fiber. The following illustrations display how the CO_2 laser energy beam is emitted from a focusing handpiece accessory, connected to the articulated arm and from a CO_2 fiber (hollow waveguide):

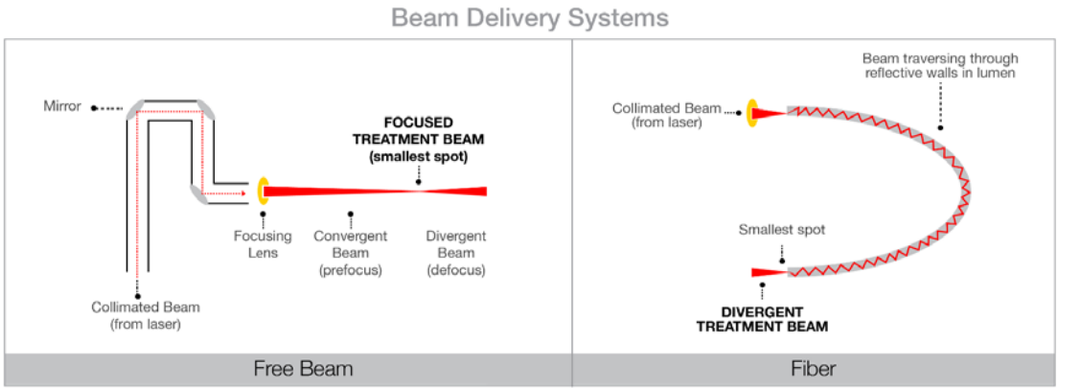


Figure 2-1: CO_2 Laser Beam Divergence from Fiber and Articulated Arm Handpiece

The UltraPulse DUO is a pulsed laser. It can generate a continuous series of short-duration, high-peak-power pulses, where the average power is the set power. Because of its very high peak power, the laser energy brings the water in the tissue to the boiling point so rapidly that the target tissue vaporizes, and only a negligible amount of heat is transferred (by conduction) to adjacent tissue.

UltraPulse DUO can operate in either one of two modes: UP and CW. In both modes, for low pulse energies, the peak power in each pulse increases as the power requested is increased. At a specific power, the pulse peak power reaches its maximum, and further increases in pulse energy is achieved by lengthening the pulse duration.

Three parameters can be controlled to enhance and utilize optimal laser-tissue interaction:

- **E = Pulse Energy**. The energy level within a single pulse. Measured in Joules [J], or milliJoules [mJ].
- **R = Repetition Rate**. The rate at which pulses are emitted from the laser. Measured in Hz (repetitions per second).
- **P_{av} = Average Power**. The average laser power over time. Measured in Watts [W].

These three parameters are related, as indicated in the following formula: **P_{av} = E x R**.

- For example, for pulse energy of 50 mJ and repetition rate of 400 Hz, the average power is 20W.

The UltraPulse DUO has two available Laser Power modes, which differ in repetition rate, as follows:

- **UP Mode** is optimal for incision or ablation where char-free performance is desirable. In this mode, the clinician can define the Average Power or Pulse Energy, and the Repetition Rate is defined as explained above.

- **CW Mode** is optimal for incision or ablation where hemostasis is desirable. The CW mode is similar to the UP mode, but it works at a constant rate of 1kHz. This rapid repetition rate is faster than the tissue relaxation time, so it is effectively a quasi-CW mode of operation.

Laser power affects depth of vaporization and speed. Tissue incision capability is generally enhanced with higher peak power of the laser beam. Thermal damage to surrounding tissue is typically reduced with shorter laser activation durations, whereby the adjacent healthy tissue has more time to cool between pulses.

The UltraPulse DUO has three Timed-Exposure modes, which operate with both UP and CW.

- **Constant** exposure – Continuous lasing while the footswitch is pressed.
- **Single** exposure – A single timed exposure is delivered for each press of the footswitch.
- **Repeat** exposure – Laser beam cycles between defined on and off time intervals while the footswitch is pressed.

Caution

- The power shown on the power display indicates the power delivered to the end of the articulated arm or at the entry point of the fiber, not necessarily the amount delivered to the treatment site. Consult your delivery system operator manual to determine if the delivery system introduces a transmission loss to the final output power.
- Power density is inversely related to spot size. For any constant power setting, power density will decrease as spot size is increased. For this reason, any increase in spot size must be accompanied by a corresponding increase in power if an equivalent power density is desired.

Tissue variability may result in different laser-tissue interaction. During a procedure, clinicians should carefully observe the procedural results. The clinicians should adjust the laser settings according to the desired effect in the targeted area for each specific patient.

SurgiTouch Scanner Operation

The SurgiTouch scanner, required for the Digital AcuBlade scanning micromanipulator and OtoScan Ear Aeration system -- and optional for use with many other Lumenis free beam delivery accessories. The scanner operates by constantly sweeping a focused, high-fluence CO_2 laser beam across the tissue surface, resulting in predictable, reproducible, char-free, layer-by-layer tissue vaporization for incision or ablation. Various scan shapes and sizes are available, depending on the accessory and application. The surgeon selects the three scan parameters, shape, size and depth, which are input into the laser system Control Panel. The number associated with the scan

depth, indicates the number full scan passes. Identical volumes of tissue are removed with each scan pass.

2.4 Ocular Protection

Because CO_2 laser beam is absorbed by water, the cornea and sclera are the predominant ocular structures at risk for injury. They can suffer irreversible damage and scarring as a result of direct or indirect exposure. Severity of an injury depends on how concentrated or diffused the beam is and the exposure time duration.

> **Warning**
>
> All personnel in the treatment room, including patients, must wear protective eyewear when the CO_2 laser is in use.

2.4.1 Laser Safety Eyewear

The following specifications were calculated for this system:

System	Wavelength Used	Maximum Permissible Exposure	Nominal Ocular Hazard Distance
UltraPulse DUO	10. 6µm	1000W/m^2	175m

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

System	Wavelength Used	Minimum Optical Density	Protection level
UltraPulse DUO	10.6 µm	4	D LB4 I LB3

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

Always provide eye protection for the patient. Wet thick cloths or wet gauze 4 x 4s can be used together with the patient protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.

The optics in the surgical microscope serve as sufficient protection for 10,600 nm CO_2 laser energy.

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

- Place a warning sign on the outside of the treatment room door when the laser is in use to alert personnel before they enter the controlled area.
- Close the treatment room door during operation of the laser. Appropriate protective eyewear may be placed outside the room for personnel who may enter.
- External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

2.4.2 Additional Ocular Protection

Warning

- Never look directly into any optical lens, scanner, handpiece, probe, laser articulated arm, fiber or laser system aperture while the laser is energized. Severe eye or skin damage could occur. Turn OFF the laser before inspecting any delivery system or laser components.
- Always verify that all connections between the laser and delivery accessories are properly connected and secure. Stray energy could emit due to an improper connection. Severe eye or tissue damage could occur.
- Never substitute appropriate laser safety eyewear with prescription eyewear for the appropriate laser safety eyewear. 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.
- 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.
- Place a warning sign warning personnel that the laser is in use before they enter the controlled area. To protect passers-by, keep the door closed while the laser is in operation. In addition, appropriate protective eyewear may be placed outside the room for personnel who may enter the treatment room.

2.5 Electrical Hazards

Warning

- Only Lumenis certified service technicians may open the console covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation.
- Do not place fluid-filled containers on top of the laser console or allow fluid of any kind to leak into the laser console.
- Perform the necessary routine inspections and maintenance procedures on your laser, per Lumenis recommendations and institutional standards.
- Grasp the plug to remove it from the electrical outlet; do not pull the cable.
- To avoid risk of electric shock, this equipment must only be connected to the supply mains with protective earth.

2.6 Fire Hazards

Operating room personnel should be aware of the following safety considerations and potential fire hazards when using a CO_2 laser:

- A CO_2 laser beam can ignite most non-metallic materials.
- Use fire-retardant drapes and gowns.
- A UL or CE approved or equivalent fire extinguisher and water should be readily available.

Warning

- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The CO_2 laser beam can ignite most non-metallic materials. Use fire-retardant drapes and gowns. Avoid the use of unnecessary flammable instruments and other flammable items.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
- Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
- When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.

Warning (continued)

- Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
- During airway laser procedures, oxygen concentrations should be as low as clinically permissible. Anesthetic gases should be least-supportive of combustion and use of laser-safe tracheal tubes is advised.
- When choosing endotracheal tubes consider the complications that may result from by-products of tube combustion. The endotracheal tube can be further protected by placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry, as this increases potential fire hazard.
- When choosing endotracheal tubes, consider the complications that may result from by-products of tube combustion. Use endotracheal tubes that are least hazardous to the patient. Laser-resistant, cuffed, and flexible stainless steel endotracheal tubes are commercially available. Red rubber or silicone endotracheal tubes with FDA-approved, laser-resistant wrapping can also be used.

2.7 Pollution Hazards

Warning

- Laser plume may contain viable tissue particulates and can obscure the operative field. The plume presents a possible biologic and pollution hazard and should be effectively evacuated. The use of smoke evacuators is recommended.

Operators are advised to consider the following:

- A commercial smoke evacuator designed for use with surgical lasers may be used. These are usually most effective when the plume is extensive. See Section 3.2.2 and Section 0 for instructions on how to connect and control a smoke evacuator.
- Instruments with built-in features to enhance evacuation of the laser plume (such as speculums and laryngoscopes) should be used whenever possible.
- Smoke evacuators designed for evacuation of the laser plume may be installed. Flow capabilities should be adequate to effectively remove the laser plume.
- The operating surgeon should wear a micron-filtered mask during the procedure to avoid laser plume inhalation.

2.8 Protecting Non-Target Tissues

Warning

- When using the articulated arm, always verify that the diode laser aiming beam and the CO_2 laser treatment beam are aligned. If the beams are not aligned, do not use the laser until the problem is corrected by a Lumenis-authorized service representative.
- When using the fiber and treatment is paused, cover the tip of the fiber with a moist sponge when you lay it down or place the fiber handpiece in its dedicated support arm to prevent injury in case of inadvertent lasing.
- Never operate the laser unless the red aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- When using the fiber, never operate the laser unless the fiber tip is in good condition and it is in full view.
- Never place hands or objects in the direct path of the laser beam. Severe burns could occur.
- 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.
- 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.
- Patient or clinicians may be burned by diffuse reflections from instruments and other surfaces. Mirrors should not be present in the laser treatment room and reflective items such as reflective jewelry should be avoided. Metal surgical instruments, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid laser reflection, so as not to deflect the beam to a non-target tissue.
- The tip of some accessories or backstops used may become hot during lasing and may cause tissue damage to either the clinicians or patient on contact. After lasing has stopped, allow the tip to cool before touching it.
- CO_2 laser energy can be reflected of smooth metallic surfaces.

Non-target tissues may be protected in the following ways:

- Specialized instrumentation such as laparoscopes with laser beam backstops and retractors designed to protect non-target tissues may be used.
- Anodized or ebonized matte-finished titanium rods may be used as backstops for the laser beam.
- Filling a cavity with saline absorbs stray laser energy and protects non-target tissues.
- Patients' lips can be protected by moist gauze. When operating in the oral cavity, care should be taken to protect teeth and bone by using wet gauze or other nonflammable, heat-absorbing protective material.
- When anesthesia or pain medication is not used, the comfort and pain tolerance of the patient must be assessed. Unexpected movement by the patient could result in unintended laser exposure to non-target tissue.

2.9 Additional Safety Considerations

Warning

- During the procedure, if a clinician makes a change to a delivery system that results in a different spot size, the clinician must remember that the energy or power density may change accordingly.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, and power settings that are effective for the intended application should be used until familiarity with the instrument’s capabilities is achieved. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- Incision/excision ideally should be performed with small laser spot sizes and appropriate power/energy densities. At the highest power densities, avoid prolonged exposure to limit depth of incision and thermal spread.
- Tissue variability may result in different laser-tissue interaction. During operation, clinicians should carefully observe the procedural results, and amend laser settings according to the desired effect for the targeted area in each specific patient.

2.10 Safety Features and Indicators

The UltraPulse DUO is equipped with many safety features to provide maximum protection for clinicians and patients.

- **Integrated Safety Features.** Features include an internal safety shutter, various timers, thermal and optical sensors, and identification systems for delivery accessories
- **Key-Switch Entry.** To prevent unauthorized operation, the system can only be operated when the system key is inserted into the key-switch, rotated clockwise and then must remain in place during system operation. When the key is rotated counter-clockwise for removal, the system shuts OFF.
- **Door Interlock System.** For patient and clinician safety, the system may be connected to a door interlock. This automatically disables system lasing if the treatment door is opened.
- **Emergency Stop Button.** In case of emergency, the system can be immediately disabled by pressing the red Emergency Stop Button. To restart the system, turn the key-switch OFF and on again.
- **Internal Power Monitor.** The UltraPulse DUO constantly monitors actual laser emission energies from the console. If a significant discrepancy (>20%) occurs, laser emission immediately stops and a fault message is displayed.
- **Fault Detection and Error Message System.** The UltraPulse DUO has a closed loop monitoring system. If a system fault is detected, an error message appears on the control display. If the error can be corrected by the user, the error message includes the corrective action. If the error cannot be corrected by the user, lasing is disabled until the fault is corrected by a Lumenis-authorized service representative. See Chapter 6, Maintenance and Troubleshooting for a more information on system faults.

- **Illuminated Indicators for Laser Delivery.** The system has two illuminated indicators for laser output.

Active Port Indicators. These indicators show which delivery mode is active (see Figure 2-2).

Figure 2-1.1: Indicator for Active Free Beam Port

When the system is set and ready to emit laser energy from the articulated arm, the indicator which encircles the articulated arm will illuminate blue.

- **Indicator for Active Fiber Port**. When the system is set and ready to emit laser energy from the fiber port, the indicator which appears as a bar on the side of the port will illuminate blue.
- **Laser Delivery Indicator.** This is a yellow LED located on top of the console, just above the control panel. The behavior of the light signals the system status (see Figure 2-2):
  - **Yellow Indicator Off.** The system is in Standby mode and no energy will emit if the footswitch is depressed.
  - **Yellow Indicator Flashing.** The system is in Ready mode and laser emission will begin when the footswitch is pressed.
  - **Yellow Indicator Continuously Illuminated.** The footswitch is pressed and the system is now emitting laser energy.

Figure 2-2: CO_2 Laser Output Port Indicators

- **Audible Indicators.** The system also has audible tones which emit different tones.
  - **Single Tone.** Once the READY button has been pressed, a single tone indicates the system is ready for emission and the footswitch can now be pressed (the yellow LED will also flash).
  - **Intermittent Tone.** An intermittent tone indicates the laser is emitting energy (footswitch is pressed).

2.11 Labeling

As required by national and international regulatory agencies, appropriate warning labels are mounted in the specified locations. The figures below are for illustration purposes only.

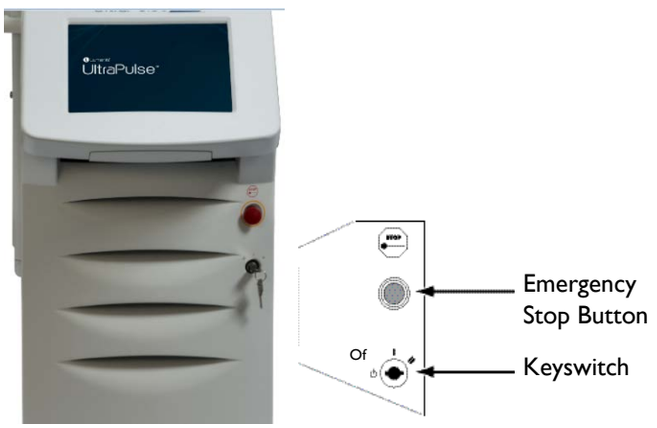


Figure 2-3: Location of Regulatory Compliance Labels – Front

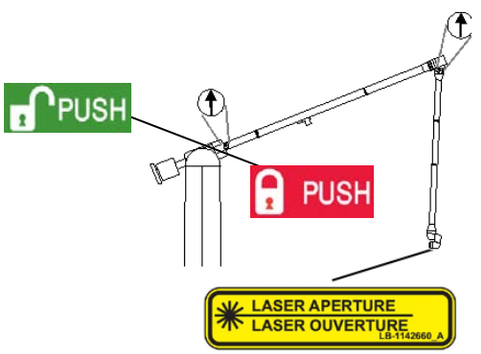


Figure 2-4: Location of Regulatory Compliance Labels – Arm

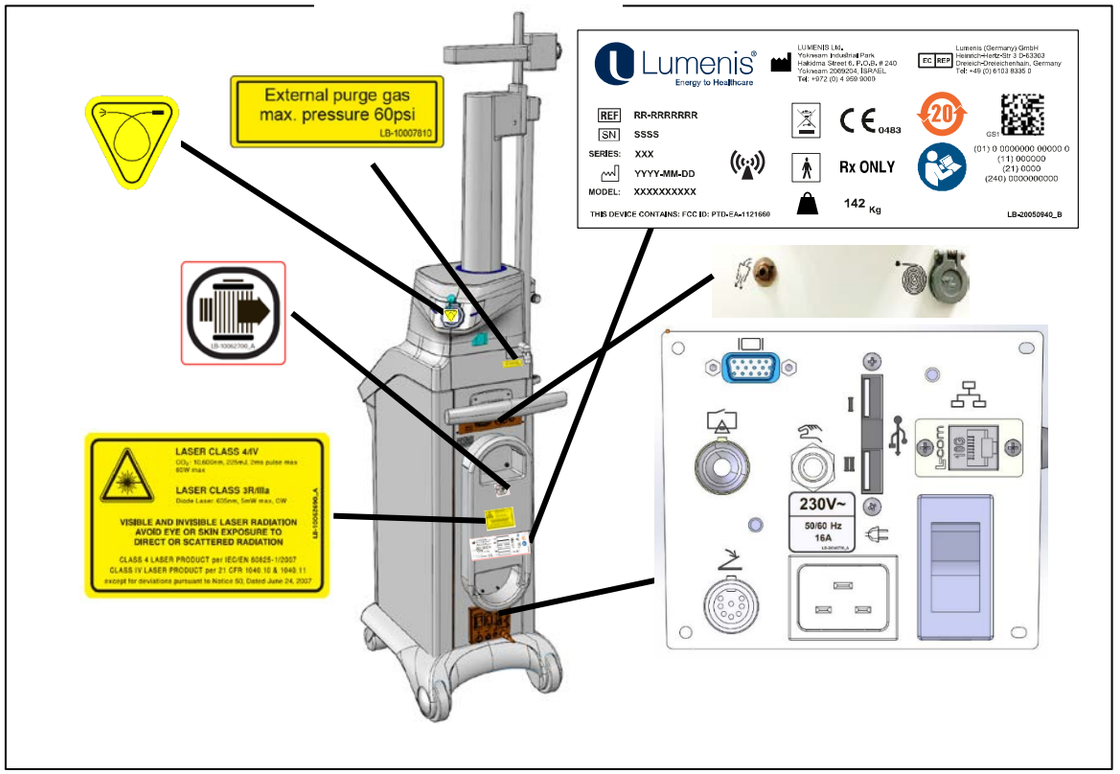
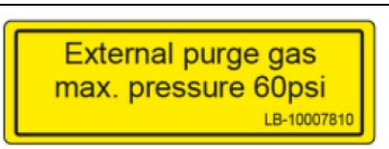
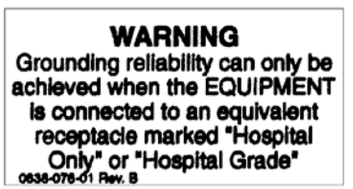
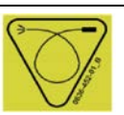
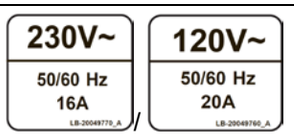
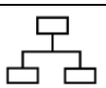


Figure 2-5: Location of Regulatory Compliance Labels – Rear

Table 2-1: Regulatory Compliance and Identification Labels and Symbols

Description and Text	*Symbol/Label*
Lumenis, Energy to Healthcare	Lumenis® Energy to Healthcare
CE Compliance	CE 0483
Manufacturer	
Date of Manufacture	
Catalogue Number (Part Number)	REF
Serial Number	SN
Laser Class IV Label: **LASER CLASS 4/IV** CO_2: 10,600nm, 225mJ, 2ms pulse max, 60W max **LASER CLASS 3R/IIIa** Diode Laser: 635nm, 5mW max, CW **VISIBLE AND INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION** CLASS 4 LASER PRODUCT per IEC/EN 60825-1/2007 CLASS IV LASER PRODUCT per 21 CFR 1040.10 & 1040.11 Except for deviations pursuant to Notice 50, Dated June 24, 2007	
Articulated Arm Aperture Label: LASER APERTURE	
Max External Air Pressure Label: External purge gas max pressure 60psi	

Description and Text	*Symbol/Label*
Power Cable Label: **WARNING** Grounding reliability can only be achieved when the EQUIPMENT is connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade”	
Fiber Aperture	
Emergency Button	
Refer to Instruction Manual	
This Device Contains: **FCC ID: PTD-EA-1121660**	This Device Contains: FCC ID: PTD-EA-1121660
Product Includes RF Transmitter	
Type BF Equipment	
Interlock Connection	
Waste of Electrical and Electronic Equipment (WEEE) compliance	
ETL Compliance	
Articulated Arm Release/Lock	
In the USA: Federal law restricts this device to sale by or on the order of a physician	**Rx Only**
RoHS Compliance (China)	

Description and Text	*Symbol/Label*
Air Filter	
Air Flow Direction	
Purge air connector towards articulated arm accessory	
Scanner connector	
Model	**Model**
Series	**Series**
Mains Connection	
Electrical Requirements	
Ethernet Connection	
USB Connection	
Video Graphics Array (VGA) Port	
Footswitch Connection	
Smoke Evacuator Connection	
Articulated Arm Direction	
Keyswitch ON/OFF	

Description and Text	*Symbol/Label*
Unique Device Identifier (UDI) Code, Type GS1	
Machine Weight	
Temperature Limitation	
Humidity Limitation	
Atmospheric Pressure Limitation	

3 System Description

3.1 Overview

The UltraPulse DUO laser system includes the following:

- Laser console with an Articulated Arm, Fiber Port and a Control Display
- Footswitch

A variety of accessories are available for use with the free beam articulated arm or fiber. The system is supplied with the following basic accessories:

- **Fiber Handpiece Support Arm**. This can be mounted on the rear handle of the console. It can be used to store the fiber handpiece during a procedure, when not in use.
- **Thread Adapters**. These are sometimes necessary for connecting delivery accessories to the arm.
- **Focused Incisional Handpieces**. The spot sizes are 0.2 mm and 1.0 mm.

Refer to the operator manuals included with the delivery accessories for specific descriptions and operating instructions.

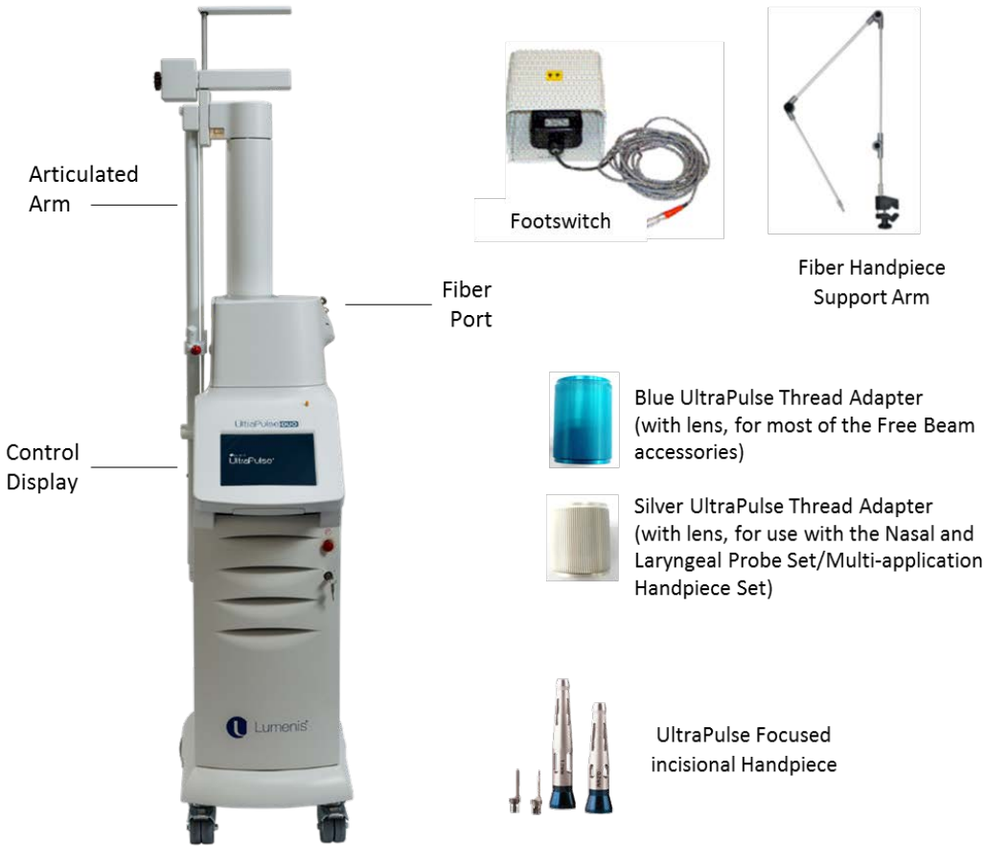


Figure 3-1: UltraPulse DUO Laser Console and Components

3.2 Laser Console

The laser console houses the CO_2 laser tube, laser excitation source and sealed- cooling system; articulated arm; fiber connection port; control panel for application driven user-interface; SurgiTouch software for scanner operation; purge air system; and various connection ports, controls and indicators. The Control Display is an LCD touch screen situated on top of the laser console. It allows full system control, including selecting laser output port and setting treatment parameters.

3.2.1 Indicators and Connections: Front of Console

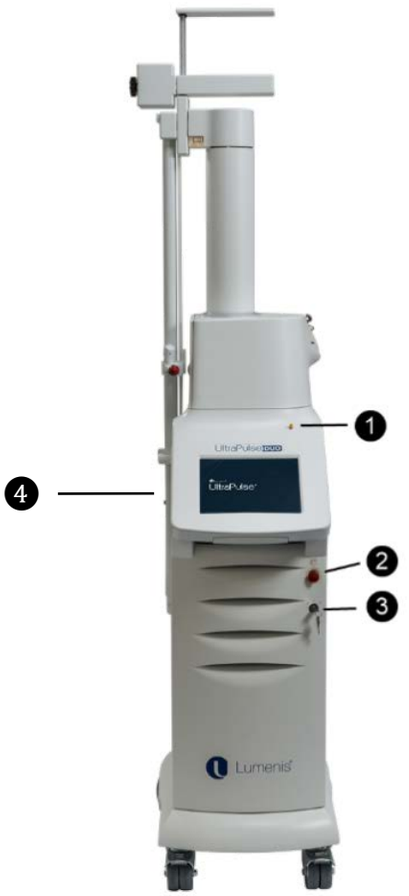


Figure 3-2: UltraPulse DUO Console – FRONT view

Laser Emission Indicator ❶. This is a yellow LED, located on top of the console, just above the control panel and it shows the emission status (see Figure 2-2):

- **Yellow Indicator Off**. When the yellow indicator is not illuminated, the system is in Standby mode and no energy will emit if the footswitch is depressed.
- **Flashing Yellow Indicator**. When the yellow indicator is flashing, the system is in Ready mode and laser emission will begin when the footswitch is pressed.
- **Continuous Yellow Indicator**. **When the yellow** indicator **is continuously illuminated, this indicates that the footswitch is pressed and the system is emitting laser energy.**

Laser Emergency Stop Button ❷. When this red button is pushed the system is immediately shut down. To restart the system, turn OFF and ON the system with the keyswitch.

ON/OFF KeySwitch ❸. The key is rotated clockwise in the keyswitch to turn the system. It can only be removed from the console when the switch is in the OFF position.

Control Panel for Application-Guided User Interface ❹. An LCD touch screen is situated on the top front of the laser console.

Note

The laser emergency stop button should be activated **only** in case of an emergency and not used to routinely turn OFF the laser system.

3.2.2 Rear of UltraPulse DUO Console

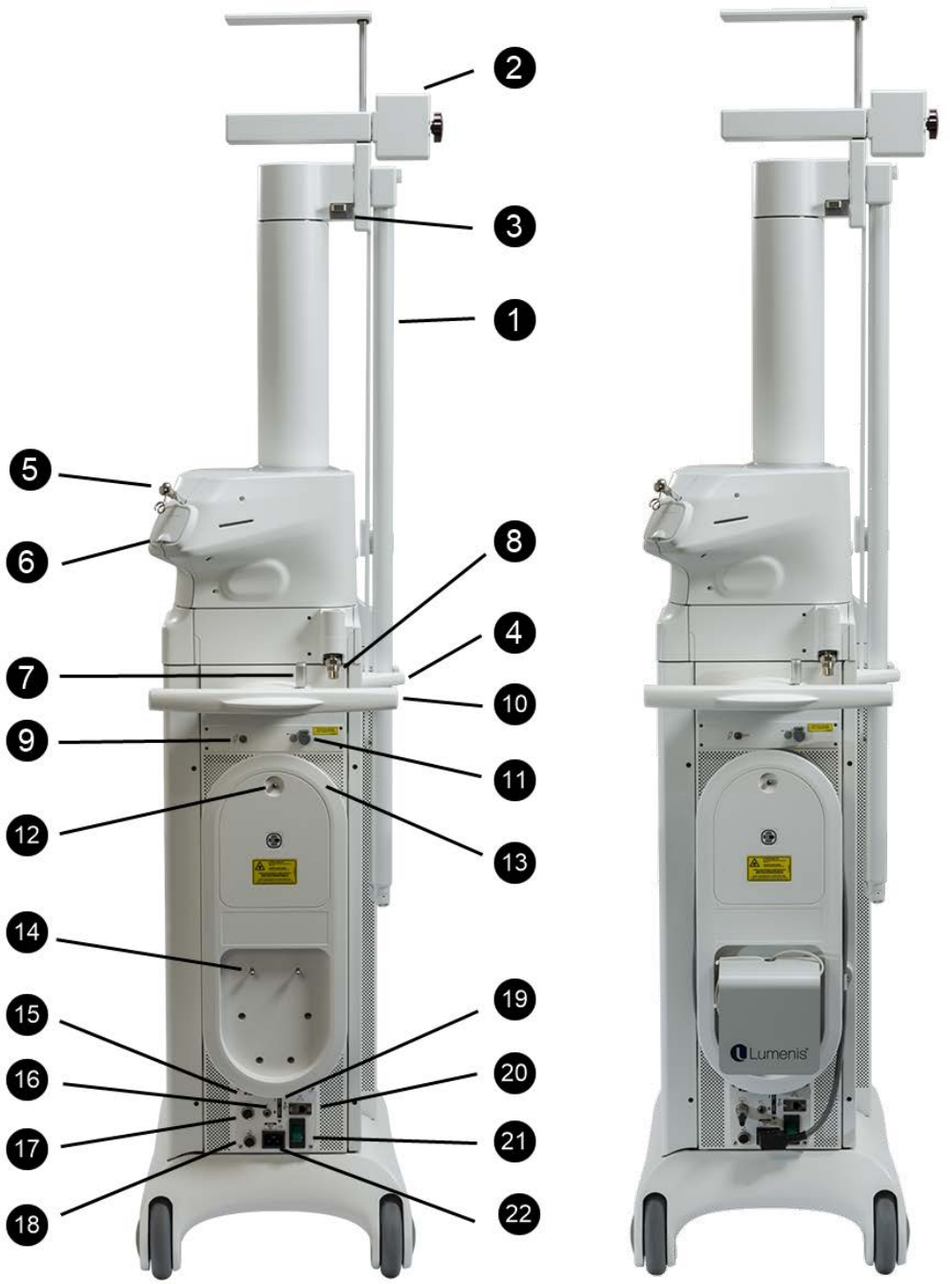


Figure 3-3: Rear of Console

Articulated Arm (1) with Counterweight (2), Locking Mechanism (3) and Storage Bay (4). Used for "Free Beam" transmission of laser energy. The height, length and 360° rotation of the arm, combined with the counterweight, permit near weightless and effortless positioning and maneuverability. The perfectly aligned mirrors imbedded in the articulating joints transmit the CO_2 laser beam down the center of the arm and then it exits the opening at the distal end. A Free Beam laser delivery accessory with mirrors and/or a focusing lens connects to the articulated arm and is used by the operating surgeon to direct beam delivery to the surgical site. For most Free Beam accessories, a blue or silver thread adapter, supplied with the system, is required to connect the accessory to the arm.

Fiber Support Arm (5) and Fiber Connection Port (6). The hinged cover is raised to reveal the connection port for the FiberLase flexible CO_2 fiber. Once connected, the Fiber Support Arm is extended and the fiber is inserted into the distal loop, so that the first 30 cm/1 foot remain straight during use. The fiber extension permits the laser power to ramp up inside the fiber, while preventing overheating and non-repairable damage to the fiber. The Fiber Support Arm is critical to the proper function of the fiber. Care should be exercised to prevent damage to it, particularly when storing the laser. In the unlikely event the Fiber Support Arm breaks, contact your Lumenis representative immediately for repair.

Holder for Arm for Handpiece Receptacle (7). The arm (not shown) is used to hold the FiberLase Handpiece with the loaded fiber. The arm simply slides into and out of the holder.

DISS Connector for Compressed Air from External Source (8). DISS stands for Diameter Index Safety System. DISS connectors for gasses are standardized for each type of gas. The connector on the UltraPulse DUO is for medical-grade compressed air. The external source supplies air under greater pressure and is only used when the fiber is used with a robot or when higher laser powers and fiber bends are anticipated.

> **Caution**
>
> To prevent damage to the system, the external source pressure must never exceed 60psi.

Connector for Purge Air Tubing for Free Beam Accessories (9). One end of the tubing attaches to this connector. Then the tubing is extended along the articulated arm and secured with clamps. Most free beam accessories have a port for connection of the tubing. The purge air is used to keep smoke from damaging the focusing lens on the accessory.

Handle (10). The handle should be used to move the system.

Socket for Connecting the Scanner Cable (11). Before pushing the connector into the socket, hold the connector perpendicular to the socket and line up the small red dot and pins.

Door for Air Filter Compartment (12). The door to the compartment is easily opened and secured using the thumb screw. Inside is a bacterial filter that filters the air from the internal compressor.

The arrow on the filter indicates the direction the air should flow through the filter – it should always point left. This filter must be changed periodically (See full instructions in Chapter 6 – Maintenance and Troubleshooting).

Cord Wrap (13). For storage, the power cord and cable for the footswitch can be wrapped around this mount.

Storage Bay for Footswitch (14). When not in use, the footswitch hangs onto the pegs in the storage bay.

Female Socket for VGA Cable (15). A VGA cable can be extended from this socket to a monitor. Then the laser parameters will display on the monitor.

Socket for Smoke Evacuator Cable (16). Smoke evacuation can be synchronized to laser activation by connecting a cable between this socket and a compatible smoke evacuator.

Socket for Door Interlock Cable (17). The door interlock system is a safety feature that disables the laser when a treatment room door is opened.

Socket for Footswitch Cable (18). To make the connection, line up the male pins to the socket and insert. Secure the connection by threading the cap onto the socket.

Sockets for USB Connectors (19). A mouse and keyboard can connect to the system using these sockets. This feature is used by Lumenis-authorized service representatives.

Socket for LAN Cable (20). Lumenis authorized service representatives use this socket.

Circuit Breaker (21). The circuit breaker should be turned OFF when the system is not used for an extended time.

Power-In Socket (22). The power cable connects to this socket. Ensure that the power cable and plug are designated for this system and your electrical supply. Connect and disconnect the power cable by grasping and pulling the connectors, not the cable. Do not use the power cable if it is frayed or internal wires are visible.

3.2.3 System Specifications

3.2.3.1 Laser Outputs

Treatment Beam Operation Specifications	
CDRH classification	Class IV
European Laser classification	Class 4
Wavelength	10.6 µm (invisible, infrared, TEM_{00})
Type	Sealed carbon dioxide, radio frequency (RF) excited
Pulse duration	Up to 2 ms
Laser Mode	Pulsed, CW (high frequency pulsed)
Energy-per-pulse	2 - 225 mJ
Repetition rate pulse frequency	1–1,000 pulses-per-second (Hz), adjustable
Average power	Articulated arm: 1 - 60 watts, adjustable Fiber: 1 - 40 watts, adjustable
Timed exposure	1 ms - 1.0 second
Repeat delay	0.1 - 5.0 seconds
Aiming beam	
CDRH classification	Class IIIa
International (IEC-60825) laser classification	3R/IIIA
Wavelength	635 nm
Type	Diode
Intensity	6 settings (up to 5mW maximum)
Laser Mode	CW
Operational modes	Continuous or blinking

3.2.3.2 Electrical Requirements

100–120 VAC input power	
Voltage	120 VAC ±10%
Frequency	50/60 Hz, Single phase
Wall outlet	20 A, Dedicated service
200–240 VAC input power	
Voltage	230 ±10%
Frequency	50/60 Hz, Single phase
Wall outlet	16 A, Dedicated service
Purge Air	
Air Filtration	Up to 0.45 microns

3.2.3.3 Physical Specifications

Height	100 cm (40 inches) to top of console; 195 cm (77 inches) to top of vertical folded stored arm
Width	34 cm (13.6 inches) front; 27 cm (10.8 inches) rear
Depth	51 cm (20 inches)
Weight	142 kg (312lbs.)
Power cable length	8 meters (26.3 feet)
Footswitch cable length	4.8 meters (15.7 feet)
Scanner communication cable length	3.3 meters (10.8 feet)

3.2.3.4 Environmental Specifications

Ambient Temperature	
Operating	5 to 30°C (41 to 86°F)
Storage	(-20) to 70°C [(-4) to 158°F]
Relative Humidity	
Operating	5% to 85% relative humidity, non-condensing
Storage and Transportation	10% to 95% relative humidity, non-condensing
Atmospheric Pressure	
Operating	80 - 106 kPa
Storage and Transportation	70 - 106 kPa

3.2.3.5 System Electrical Classifications

Type of Protection against Electric Shock	Class I
Degree of Protection against Electric Shock for Applied Parts	BF
Suitability for use in Presence of Flammable Mixture	Not suitable
Protection against Ingress of Water (Console)	IPX0
Protection against Ingress of Water (Footswitch)	IPX8

3.3 Accessories

Accessory Family	Accessory
Fiber	**FiberLase™ Handpieces**
	FiberLase Robotic Drop-In Guide (DIG)
	FiberLase CO_2 Fiber
	FiberLase ENDURE CO_2 Fiber
	FiberLase ENDURE Endoscope Protection Sheath
Free Beam	**BeamAlign™ Laparoscope Set**
	Nezhat™ Couplers
	Thread Adapter Set
	Nasal and Laryngeal Probes
	Multi-Application Handpiece Set
	TrueSpot™ 2.0 mm
	UltraPulse Incisional Handpiece Set
	AcuSpot™ 712, 712-L, 712-Z Micromanipulators
	OtoScan™ Ear Aeration System
	SurgiTouch™ Scanner

4 Preparing the System for Use

4.1 Introduction

Each day, prior to procedures, the laser should be checked for damage to the console, missing parts and proper function.

- The cord for the footswitch should not be frayed and should be connected to the console.
- The cord for the power should not be frayed and should be connected to the console.
- The Fiber Handpiece Support Arm should be attached.
- The Air Filter should be clear and the arrow should be pointing to the left.
- The cover for the Fiber Port should be intact.
- The telescoping Fiber Support Arm should be intact, including the pigtail.
- The articulated arm should be properly stored in the storage bay, with no visible damage. The red cap should be attached to the distal end.
- The laser should be turned ON and the articulated arm should be checked for beam alignment.

Warning

Beam alignment checks are extremely important for the safe operation of your laser equipment. If aiming and treatment beams are not coincident do not operate the laser or delivery system; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.

Use caution when performing the laser beam alignment check: follow the procedure as described in this manual. Take care to ensure that the beam alignment procedure is performed when the patient, operating room personnel and flammable materials are not in the beam path.

To check the alignment of the beams through the articulated arm, a non-sterile incisional handpiece can be used. Performing this check prior to scheduled cases, will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care. The Beam Alignment Check should be again performed, each time a free beam accessory is attached. Regardless of the accessory, the steps for the Beam Alignment Check are always the same. (see Section 6.3)

Warning

In Canada this instrument must be installed and operated according to CAN/CSA-Z386-14: Laser Safety in Health Care Facilities.

4.2 Moving the Laser Console

Caution

Never use the articulated arm to move the laser. Moving the laser by the articulated arm may cause irreparable damage.

Warning

Use care when rolling the console in tight spaces and over uneven surfaces and slopes. Any large shock to the system can cause damage to the system, including beam misalignment and/or someone can be injured

To move the laser console:

1. Before moving the system, ensure that the articulated arm is folded and stowed, the footswitch is stowed and the cables are wrapped or secure.
2. Use the handle on the rear of the console to push it, or pull by grasping the ledge under the front control panel
3. Position the laser console with no less than 50 centimeters (20 inches) of free space around it to ensure proper air circulation.
4. Lock the laser console wheels by pressing down the wheel locks.

Warning

Once the console is in place, verify that the wheels are locked. If the console moves unexpectedly, the system can be damaged and/or someone can be injured.

4.3 Room Preparation and General Laser Safety

The Laser Treatment Controlled Area (LTCA) must be made laser safe during procedure setup.

Prior to the procedure, do the following:

- Take appropriate steps to minimize ocular hazards
  - Post an appropriate laser warning sign on all doors for entry to the LTCA.
  - Post appropriate laser safety eyewear at all entry doors
  - Ensure adequate laser safety eyewear for all treatment room personnel
  - Ensure proper eye protection for the patient
- Take appropriate steps to minimize electrical hazards
- Take appropriate steps to minimize fire hazards, including special precautions for laser surgery in the airway
- Take appropriate steps to protect non-target tissues
- Take appropriate steps to minimize hazards associated with the laser plume

4.4 Pre-Procedure Preparation

Perform the following preoperative checks and procedures before every operation:

1. Place the laser console in the location from where the procedure will be performed. Using the laser console handle, move the laser console to the desired site. Position the laser console no less than 50 centimeters (20 inches) from walls, furniture, or other equipment. Adequate space around the laser console ensures proper air circulation.
2. Lock the laser console wheels by pressing down the wheel locks.
3. Verify that the laser and delivery accessories are properly set up, including the following:
   - Power connection (see Section 4.5.3)
   - Footswitch (see Section 4.5.1)
   - Door interlock (see Section 4.5.2)
   - Relevant delivery accessory, such as arm orientation (see Sections 4.5.5.1 and 4.5.5.2)
   - Relevant support arms (see Section 4.5.5)
   - Relevant purge air connection (see Sections 4.5.4.2 and 4.5.5.2)
4. Verify that the delivery system is properly connected and sterile drape the arm if necessary, as instructed in the delivery system operator manual.

5. Ensuring that all safety procedures have been met, including the following:

- Post the “Laser in Use” warning sign outside the treatment room door.
- Ensure that all people in the treatment room are wearing the appropriate laser safety eyewear. See Section 2.4.1 for detailed laser safety eyewear information.
- Ensure that all surgical accessories are clean and sterilized. Refer to the instruction of the relevant accessory for the complete cleaning and sterilization instructions.

6. Turn ON the laser, as instructed in Section 5.2.
7. Perform the beam alignment check, as instructed in your delivery system user manual.

Warning

- Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the 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.
- Before beginning an operative procedure, always verify that the laser aiming and treatment beams are aligned, as instructed in the delivery system operator manual. If the aiming and treatment beams are not aligned, do not use the laser until alignment is corrected by a Lumenis-certified service technician. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.

4.5 Connection Instructions

Before connecting the system components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Check all electrical cables to ensure that they are not frayed or split. Inspect all delivery systems, as instructed in the appropriate delivery system operator manual.

Most connections can be made once and then checked for security prior to each procedure.

Warning

Always disconnect delivery system components from the laser articulated arm before inspection. Never look directly into a delivery system while it is connected to the laser articulated arm. Never look directly into the laser articulated arm while the laser is energized. Accidental laser exposure can cause severe eye damage.

Caution

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

Figure 4-1: UltraPulse DUO Connections

4.5.1 Connecting the Footswitch

The connector for the footswitch cable should be fully inserted into the footswitch port on the rear panel of the console and threaded securely. If the connection is not adequate when the laser is turned On, an Attach Footswitch message will appear on the control display and it will not be possible to place the laser in Ready mode.

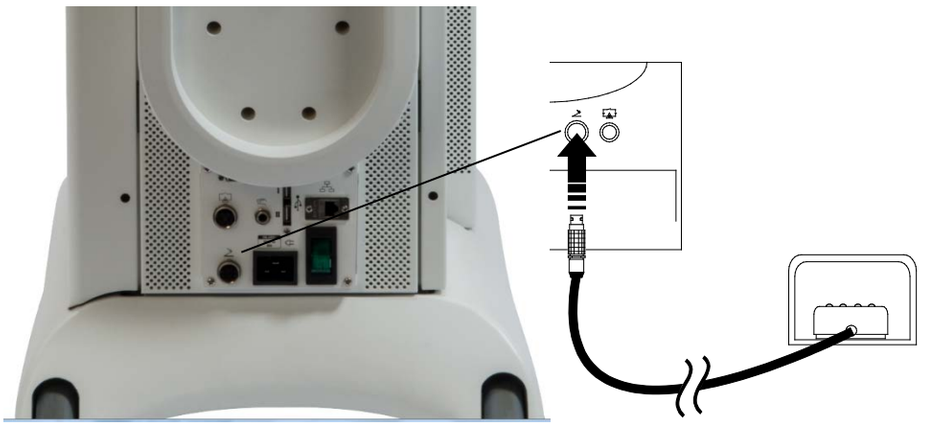


Figure 4-2: Connecting the Footswitch

4.5.2 Connecting the Door Interlock

The external door interlock is a safety feature that disables the laser when the treatment room doors are opened. Before turning the laser system ON, be sure the cable for the external door interlock is securely connected.

When an external door interlock system is utilized, opening the treatment room door causes the laser to automatically disable, activates Standby mode and an error message appears on the control display. To resume treatment, close the treatment room door and then press Ready to resume normal treatment.

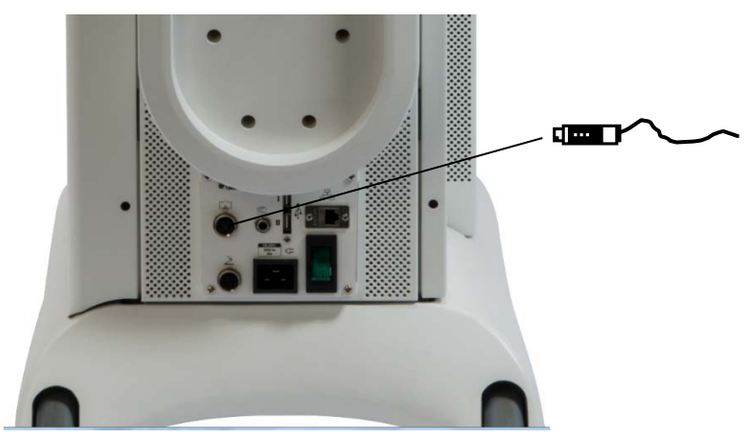


Figure 4-3: Inserting the External Door Interlock

4.5.3 Connecting the Main Power Cable

1. Ensure that the laser main power circuit breaker is OFF (down) and that the laser keyswitch is in the ⏻ (OFF) position.
2. Unwrap the power cable from the power cable wrap.
3. Insert the UltraPulse main power plug into the wall socket, and ensure that the plug is secure in the socket.

Warning

Only use the power cable that was provided with the UltraPulse DUO system when connecting the system.

Figure 4-4: Connecting the Main Power Cable

4.5.4 Preparing for Fiber Use

4.5.4.1 Fiber Handpiece Support Arm

The Handpiece Support Arm with the sterilizable Handpiece Receptacle is designed to be a convenient place to rest the handpiece and protect the fiber tip between uses during the surgical procedure. The handpiece can be inserted with the fiber tip pointing up or down. The arm length and articulations permit flexible positioning for surgical procedures.

To insert the Handpiece Receptacle into the arm, loosen the adaptor, mount the support arm into the adaptor on the system's handle, and firmly tighten the adaptor.

To adjust the arm, loosen the three black knobs, position the arm, as desired, then retighten the knobs. When sterility of the handpiece or the possibility of cross-contamination is a concern, the arm should be covered with a sterile or non-sterile equipment drape. Refer to the Processing Instructions for Lumenis Surgical CO_2 Laser Accessories for the complete cleaning and sterilization instructions of the Fiber Handpiece Support Arm and Handpiece Receptacle.

Figure 4-5: Handpiece Support Arm

4.5.4.2 Connecting to an External Purge Air Source

These instructions are for connecting the purge flow system to an external air source via a pressurized tank or central supply wall outlet.

> **Note**
>
> Use of an external air source requires advance preparation. See the Maintenance Section in this manual for full information about the necessary equipment.

Connecting External purge air from an in-line wall source.

1. Turn OFF the laser system.
2. Connect the yellow air hose to the air connector on the rear side of the console (see section 3.2.2). The hose should be adequately long to reach from the wall outlet and to where the rear of the console will be positioned for the procedure. Position the hose so that it will not pose a safety hazard to room personnel.
3. If the hose is not fitted with Quick Connect/Disconnect hardware, there will be nothing to prevent air from bleeding into the room when the hose is attached to the air outlet. Therefore, the hose should first be connected to the laser; then to the wall outlet. The air is under pressure, so it will take some exertion to make the wall connection.

Connecting External purge air from a medical-grade gas cylinder.

1. Turn OFF the laser system.
2. Attach the hose from the cylinder nozzle to the barb on the rear of the console; apply a tie wrap so that the tubing does not automatically pop of when the cylinder is opened.
3. Use a wrench to open the valve about a fourth turn on the compressed air tank. You will see the tank volume register on the air gauge for the tank. It should be at least half full.
4. Use the dial on the tank regulator to set the pressure regulator to between 50 psi (3.45 bar) and 60 psi (4.14 bar).

Once the connections are made and secure, the laser can be turned ON for use.

Figure 4-6: Connection to External Purge Air Source

5. Turn ON the external purge air source.
6. Ensure that the air flows freely out of the CO_2 fiber.

4.5.4.3 Fiber Connection

Before connecting the fiber to the laser, read and comprehend the Directions for Use for the fiber and fiber accessories.

Warning

Damaged fibers may lead to inadvertent laser radiation, therefore verify fiber integrity prior to and during treatment.

Cautions

- To prevent unintended laser discharge, always turn OFF the laser before connecting a delivery system.
- The UltraPulse DUO system only works with Lumenis-qualified CO_2 fibers. If a non-qualified fiber is connected the laser emission is blocked and a red icon appears on the control display. Any attempt to use incompatible delivery systems may result in unpredictable or unsafe laser operation.
- Prior to operating with the CO_2 Laser fibers, thoroughly read its complete Instruction for Use document (provided separately with reach fiber).

1. Connect the fiber to the Fiber Port according to the Instructions for Use for the fiber. Verify that the fiber connector is properly seated and securely attached into the Fiber Port. If not, the system will not recognize the fiber and will not allow switching to Ready mode.
2. Extend the fiber support arm to its full length and thread the fiber through the loop at the end of the arm. This arm is designed to support the first 30 cm (1 foot) of the fiber to ensure optimal performance of the fiber (see Figure 4-7).
3. After the system is turned ON, observe the fiber status in the top-right corner of the screen. Verify that the fiber connected is a valid fiber.

4. Prior to using the fiber, insert the tip into a sterile solution or water. Verify that a constant stream of air is flowing out of the fiber tip by observing the constant stream of bubbles in the solution.

Figure 4-7: Connecting the Fiber

Note

Fiber length, actual positioning and bending radius can affect the quality of energy transmission. Therefore, when choosing treatment parameters, be aware that the actual level of laser power delivered at the distal tip of the fiber will be less than the level displayed on the system's control display.

4.5.5 Preparing for Free Beam Use

4.5.5.1 Releasing and Orienting the Articulated Arm

Warning

The articulated arm is a precision component; carefully handle and position the arm. Avoid arm collision with other objects or the ceiling in order to reduce risk of misalignment. An improperly oriented or misaligned articulated arm can reduce the quality or intensity of the laser beam and may result in unintended tissue effect.

When the laser is not in use, the articulated arm should be stored in the articulated arm storage compartment, with the red protective cap in place.

To release the articulated arm:

Slide the articulated arm pivot lock to the  (unlocked) position (see Figure 4-8).

1. To release the articulated arm, open the side panel lock, open the articulated arm latch and carefully remove the arm so that it rotates toward the front of the laser console. Monitor the direction of the arrows on the arm. If they are not pointing up, replace the arm into the storage receptacle and remove it again.

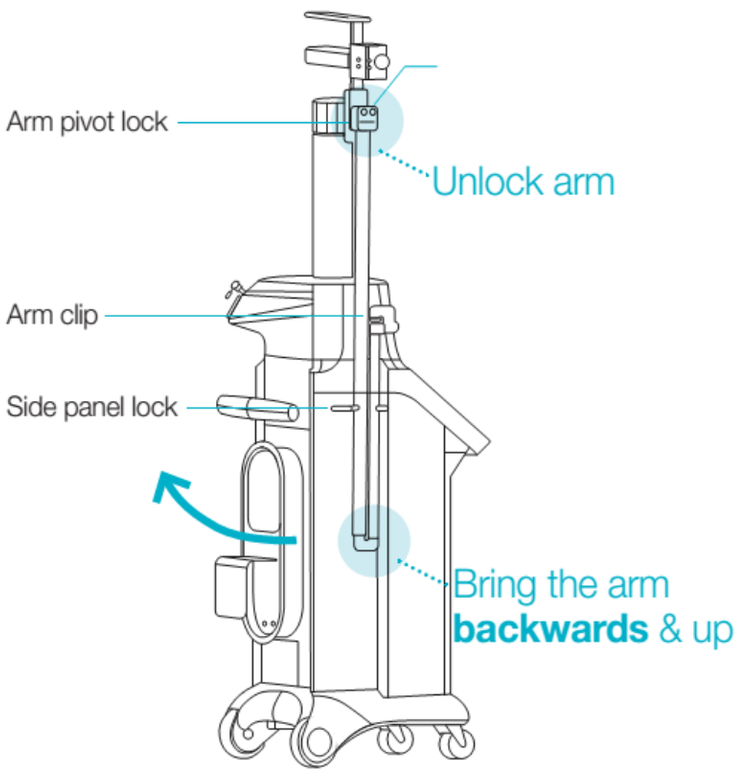


Figure 4-8: Releasing the Articulated Arm

Note

The arrows must point up in order to ensure proper arm orientation. An improperly oriented articulated arm can reduce the quality or intensity of the laser beam.

3. Remove the red protective cap from the distal end of the arm. Store the cap in the holder on the mast.
4. Hold the articulated arm in place until you have connected a delivery system.

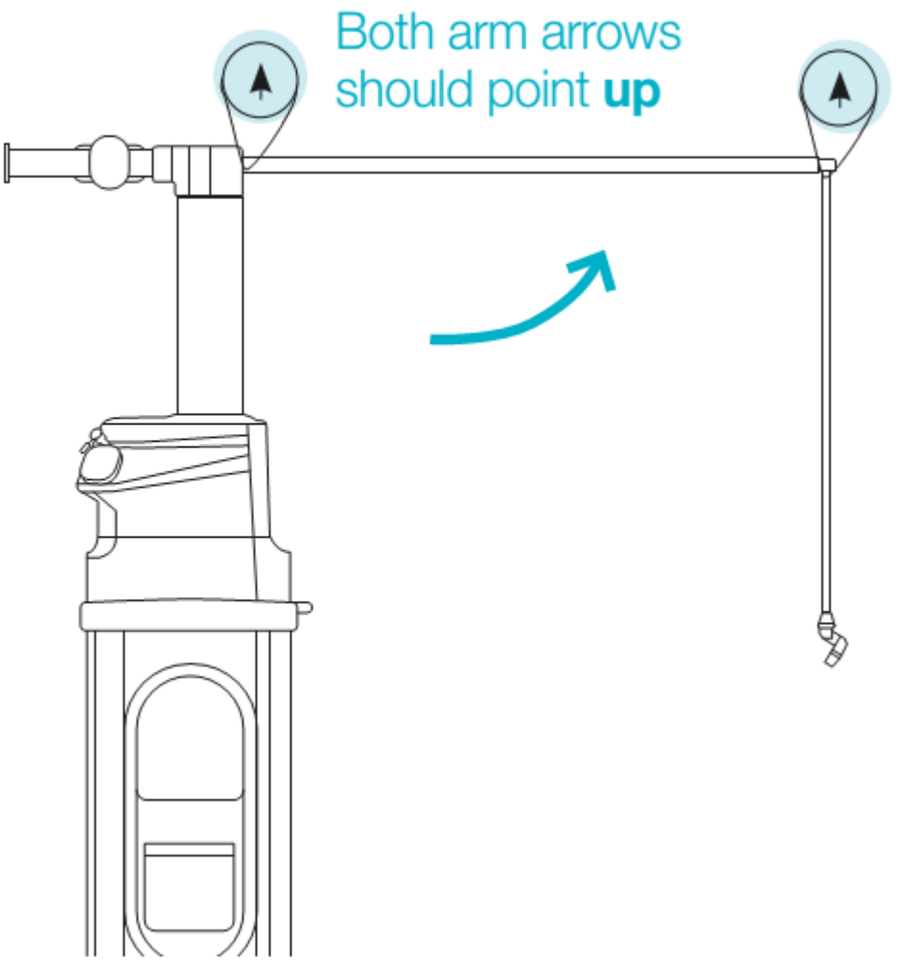


Figure 4-9: Orienting the Articulated Arm

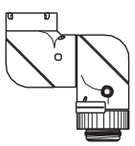
4.5.5.2 Connecting the Free Beam Delivery Accessory

After unfolding the articulated arm, connect the appropriate delivery accessory as instructed in your delivery accessory operator manual.

When using a delivery accessory with a smoke evacuation tip, connect the smoke evacuator as instructed in your delivery accessory operator manual.

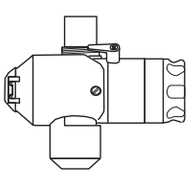
When using a delivery accessory with a purge air connector, connect the free end of the purge air tube to the delivery accessory as instructed in your delivery accessory operator manual.

For most Free Beam accessories, a blue thread adapter, supplied with the system, is required to connect the accessory to the arm.



Laser articulated arm

Blue UltraPulse thread adapter (with lens)



UltraPulse SurgiTouch Scanner

Warning

- To avoid possible damage to the optical system, use only qualified, compatible Lumenis delivery systems with this laser. Use of incompatible delivery systems may result in unpredictable or unsafe laser operation and will nullify your Lumenis warranty or service contract.
- The quality of the mirrors and focusing lenses need to be inspected and cleaned if necessary. Otherwise the performance will be degraded to prevent unintended laser discharge, always turn OFF the laser before connecting a delivery system.

4.5.5.3 Connecting the Scanner Communication Cable

Scanners are controlled by the laser system software. The communication cable provides constant communication between the laser and the scanning device. To connect the scanner communication cable:

1. Verify that the laser keyswitch is in the ⏻ (OFF) position, or if the system is turned ON – that it is in the Home Screen, before connecting the scanner communication cable to the laser.
2. Insert the communication cable plug into the communication cable connector on the rear of laser console, under the handle.

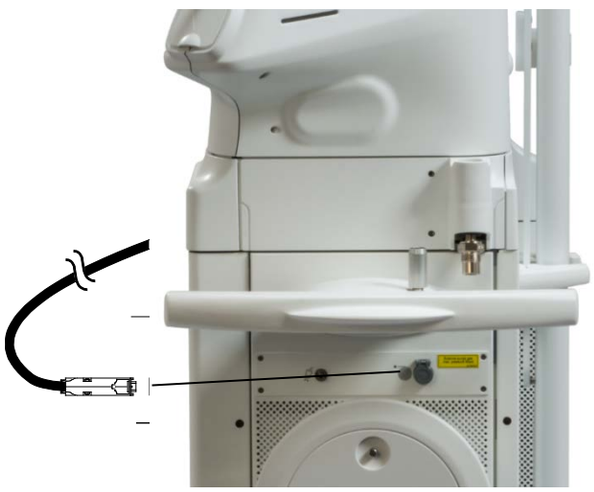


Figure 4-10: Connecting the Scanner Communication Cable to the Laser Console

Warning

To avoid potential damage to the scanner, always connect or disconnect the scanner cable while the laser system is turned OFF, or that it is in the Home Screen if turned ON.

3. Secure the communication cable along the length of the articulated arm with the appropriately sized cable clips, as shown in Figure 4-11.
4. When securing the cable, leave enough slack at articulated arm joints to allow free movement and proper positioning of the articulated arm and to avoid damaging the cable.
5. Insert the communication cable plug into the cable socket on the scanning device.

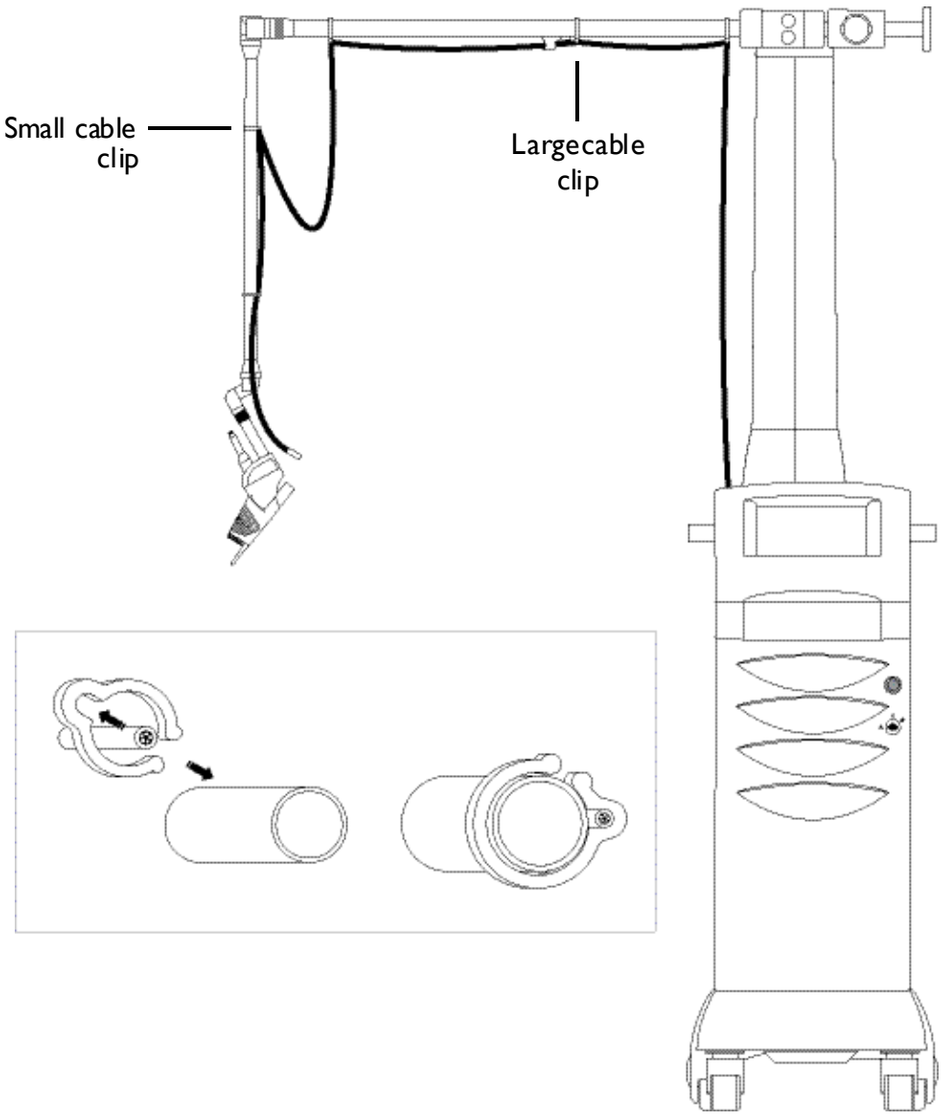


Figure 4-11: Securing the Communication Cable to the Articulated Arm

4.5.5.4 Balancing the Articulated Arm

After connecting the delivery accessory, adjust the weight bar so that it counterbalances the weight of the delivery system. To adjust the weight bar:

1. Loosen the control knob by rotating it counterclockwise.
2. Adjust the weight bar forward or backward along the articulated arm, as needed.
3. Retighten the knob until the weight bar is secure.

Figure 4-12: Adjusting the Weight Bar

5 Control Panel Operation

5.1 Before Turning ON the System

Before you turn the system ON, perform the following:

- Verify that the laser emergency stop button is not engaged.
- Verify that the door interlock is connected.
- Verify that the system is plugged into an appropriate power outlet.
- Verify that the power circuit breaker on the rear panel is in the **ON** position.
- Verify that the footswitch is connected to the rear panel.
- Verify that the purged air tubing is clean and properly connected. This includes all visible tubing and connections from the laser console to the delivery accessory.

> **Caution**
>
> Prior to using the system, verify that the purge air is operational. Specifically when using the fiber, place the fiber tip in a glass of liquid and activate the purge air flow on the laser system. You should see bubbles that indicate that air is flowing properly through the fiber.

- Verify that the wheel brakes are locked.

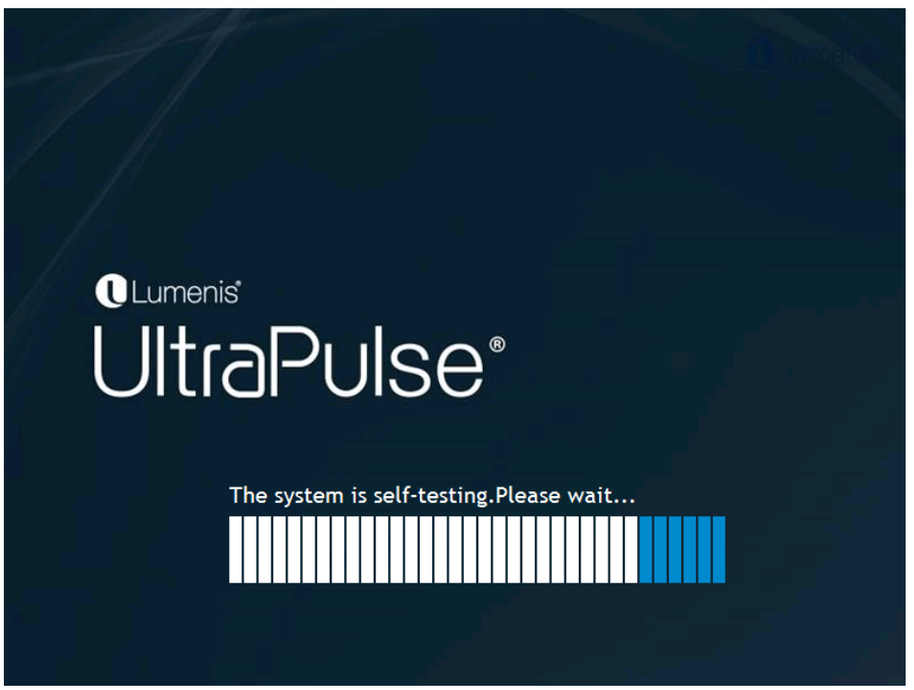
> **Warning**
>
> Once the console is placed, verify that the wheels are locked. If the console moves unexpectedly, the system can be damaged and/or someone can be injured.

- Verify that a delivery system accessory is connected to the articulated arm's end joint and/or a fiber is connected to the Fiber Port.
- Verify that the patient and clinicians in the room are wearing adequate safety eyewear.

5.2 Turning ON the Laser

To turn ON the laser:

1. Place the laser console power circuit breaker to the **ON** (up) position.
2. Insert the key into the keyswitch, and rotate the key to the II (start) position. Hold for one full second, and release the key. Upon release, the key automatically springs back to the I (ON) position.
3. The laser will perform a self-test that will be completed in less the 2 minutes.



*The Home screen appears, and the laser goes into **Standby** mode.*

5.3 Home Screen

The Home screen presents the available treatment types the laser system is provided with. The system may support the following treatment types:

- **Basic** – for directly navigating to the **Treatment** screen, without additional selection of specialty or handpiece.
- **Surgical – navigates the** user to a smart selection of specialty, application and handpiece for easier use.

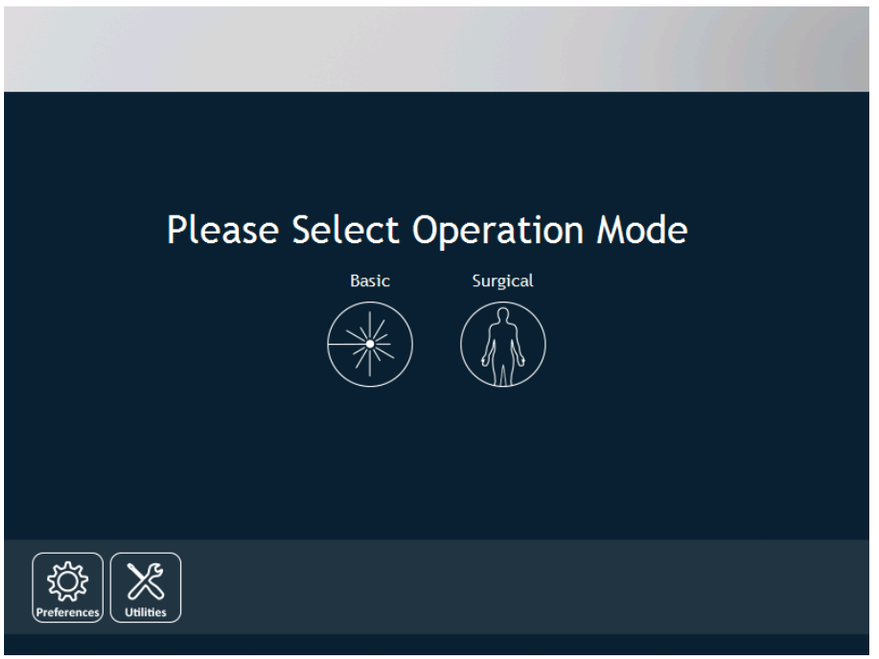


Figure 5-1: Home Screen

5.4 Select Specialty Screen

The Surgical treatment type is followed by the Select **Specialty** screen, which prompts the user to select one of the optionally available specialties:

- ENT
- GYN
- NEURO
- General

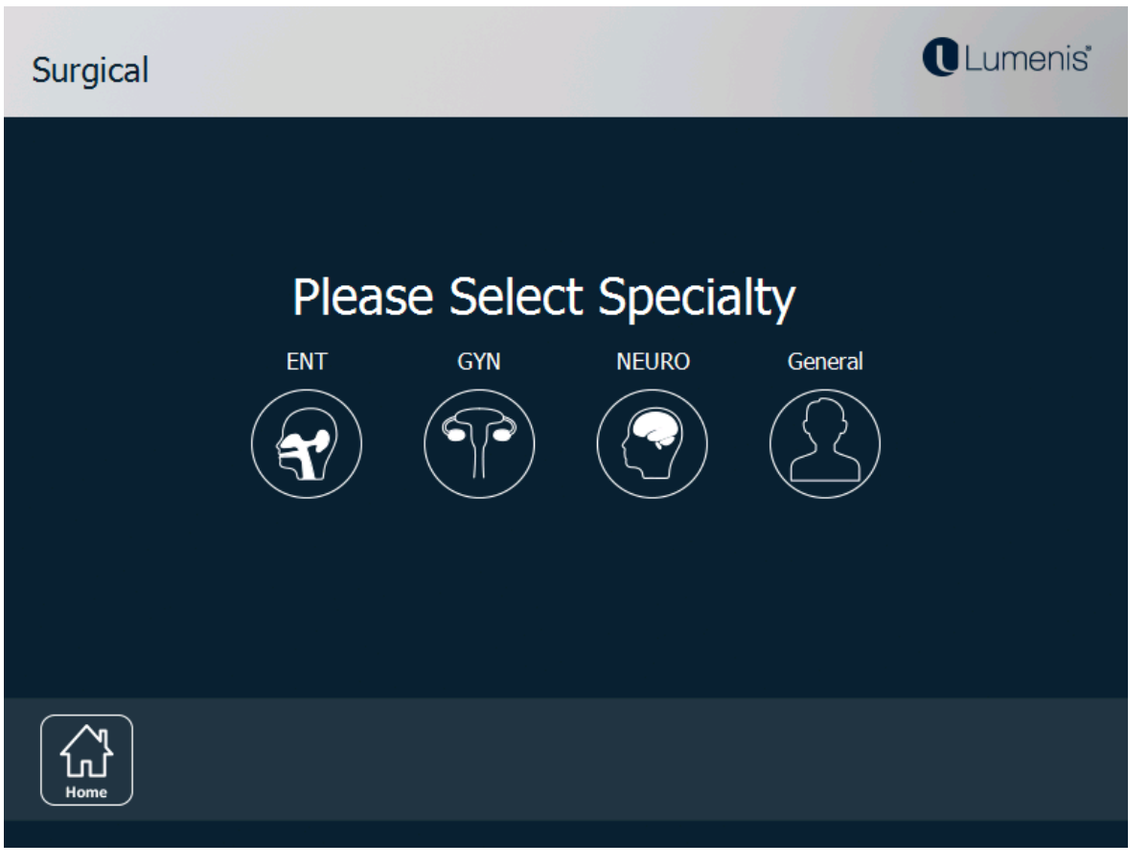


Figure 5-2: Select Specialty Screen

5.5 Select Application and Accessory Screen

Following the selection of the Application, the user selects the application and appropriate accessory to work with. The figure below shows a selection of Larynx and AcuBlade 400mm accessory. Upon selection and pressing "Treatment" at the bottom right corner, the user is navigated to the Treatment Screen.

Warning

Make sure to select in the graphical user interface, the same accessory that is connected to the articulated arm. Selecting a different accessory may result in unsafe laser operation and danger the patient and staff.

Figure 5-3: Select Application and Handpiece Screen

5.6 Treatment Screen

The **Treatment** screens define the parameters for the laser emissions for each of the treatment modalities. All **Treatment** screens are similar in layout and function. Based on the type of treatment modality, different elements are displayed in the screen. The system supports the following treatment screens:

- Basic Mode (not application driven)
- Surgical Mode (application driven)
- Free Beam (Articulated Arm with or without a scanner; application driven)
- Fiber

Figure 5-4: Treatment Screen – Basic Mode, Free Beam (not application driven)

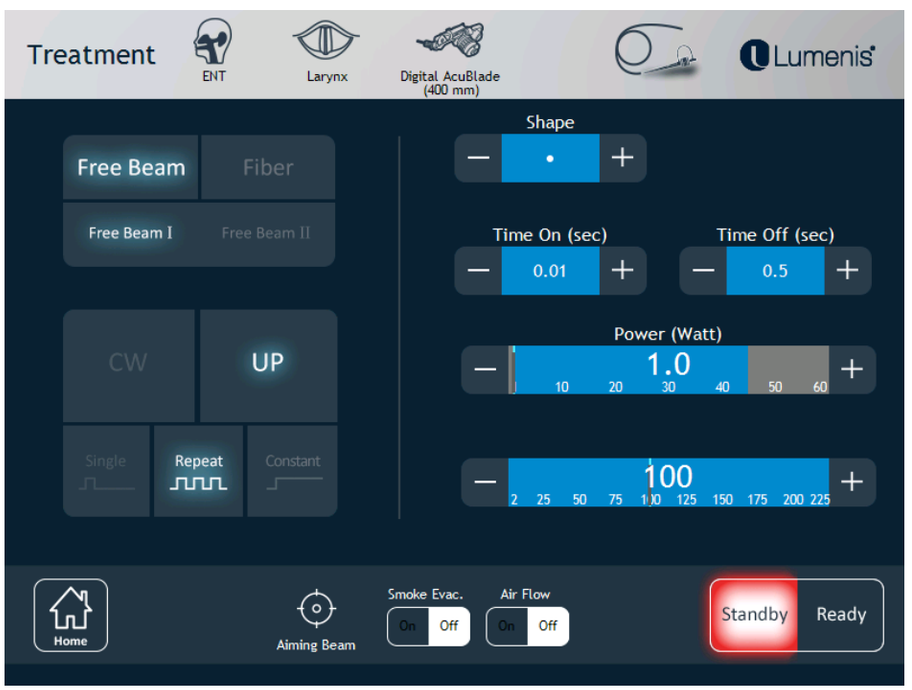


Figure 5-5: Treatment Screen – Surgical Mode, Free Beam (application driven)

Figure 5-6: Elements of a Treatment Screen

The elements of a typical **Treatment** screen (see Figure 5-7) are as follows:

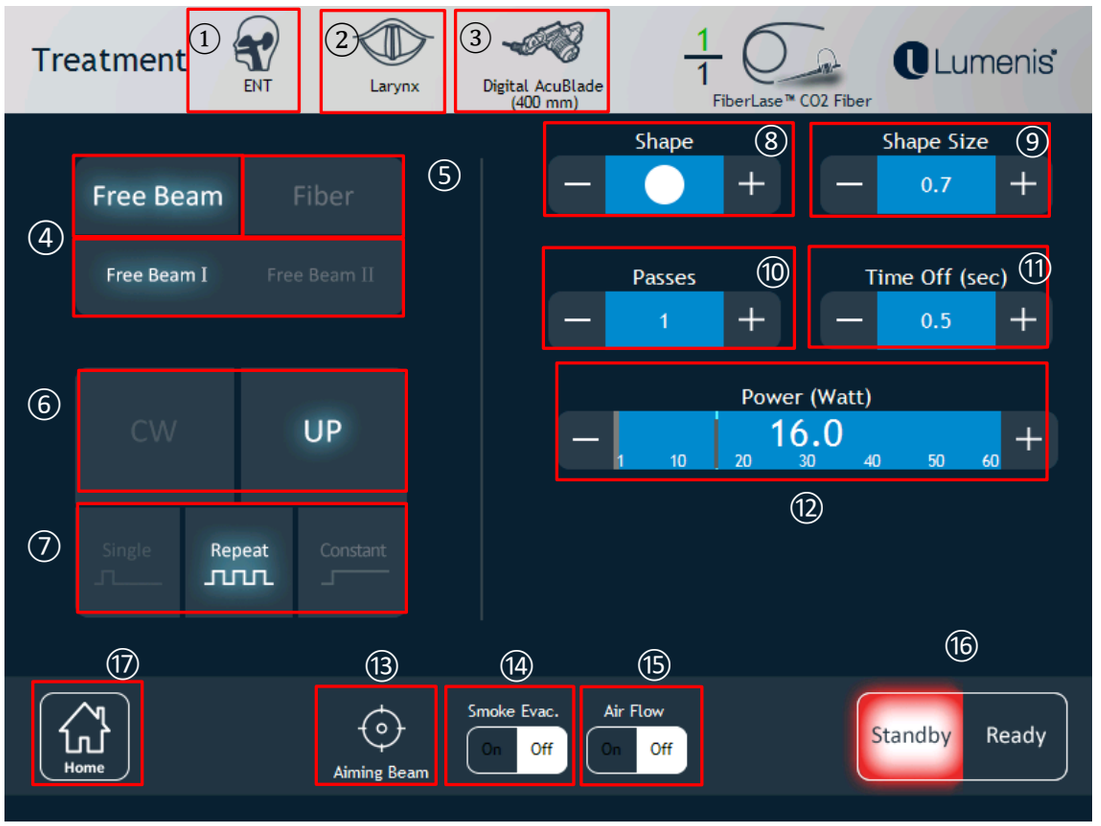


Figure 5-7: Typical Treatment Screen

1	**Specialty**	Shows the selected **Specialty**, and allows quick navigation to the **Select Specialty** Screen.
2	**Application**	Shows the selected **Application**, and allows quick navigation to the **Select Application and Handpiece** Screen.
3	**Accessory**	Shows the selected **Handpiece**, and allows quick navigation to the **Select Handpiece** Screen.

4 **Free Beam**

Select this tab to use the system in **Free Beam** (Arm) mode, when you work with the articulated arm instead of the CO_2 fiber.

Setting I/II

Setting I and II (either Free Beam or Fiber) enable the user to define 2 different laser settings to be used during the treatment.

These parameters are valid as long as the user has not left the Treatment Screen.

5 **Fiber**

Select this tab to use the system in **Fiber** mode, when you work with the CO_2 fiber instead of the articulated arm. The Fiber Status Icon at the upper bar of the screen shall be green if a fiber is properly connected to the system, shall be displayed red if a fiber is not validated and shall be displayed grey if a fiber is not connected.

Unsupported fiber

Connected fiber

Disconnected fiber

Note

If a new CO_2 fiber has been connected to the system and the status is not as expected, the fiber may be defective, or not connected properly to the system.

Disconnect and reconnect the fiber, and ensure that it is tightly secured to the connection port. If the problem persists, return the fiber to Lumenis for replacement.

6 **Laser Emission Mode**

Selects the emission mode. Set the mode to **CW** (**C**ontinuous **W**ave) or **UP** (**U**ltra**P**ulse**)**. This option is available for applications that do not use a scanner, in Basic and Fiber treatments only.

7 **Exposure Types**

Selects the type of laser beam exposure. Set the exposure to **Single**, **Repeat** or **Constant**.

8 Scan Shape Selector

Selects the scan shape. Scroll through the shapes with the + or — buttons to select the shape. Note that not all shapes are available for all accessories. Select “dot” to eliminate the scanning mode.

> **Note**
>
> When set to Scan treatment (i.e. scan shape is not a dot, and the shape size is not present), the system always operates in UP mode.

9 Shape Size (mm)

Selects the size of the scanned shape. Scroll through the sizes with the + or — buttons to select the shape size.

10 Passes

Sets the number of sequential scans or pulses emitted while the footswitch is pressed. When that number of scans or pulses has been emitted, the system stops. To continue lasing, release and re-press the footswitch.

11 Time Off (sec)

Selects the delay time interval of laser beam emission. Scroll through the + or — buttons to define the Off-time. This is not available in **Single** or **Constant** modes.

> **Note**
>
> - The system's operational design is based on a train of consistent pulse cycles, comprised of laser-emission and laser-paused periods.
> - The user-selected Off-time (displayed on the screen) determines the number of pulse cycles that will be blocked during the continuity of laser beam emission.

12 Power (W)

Sets the laser power, measured in Watts:

- Press the + or — buttons to raise or lower the power setting.
- Press anywhere on the power bar to immediately set that power setting.

13 Aiming Beam

This button opens the aiming beam sub screen, which allows setting the intensity of the aiming beam, to select whether the aiming beam blinks or not, and to set the Beam Offset relative to the scanner zero position. See further details in Figure 5-8.

Warning

Never deliver the treatment beam to the target tissue if the aiming beam integrity has not been verified.

14 Smoke Evacuator

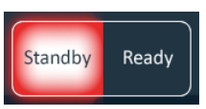
Selects whether the smoke evacuator (when connected to the system's rear panel) is ON or OFF, if defined in the preferences

15 Air Flow

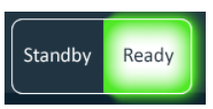
Selects whether the purge air is ON or OFF.

16 Ready/Standby

Sets the system to a **Ready** or **Standby** mode.



Standby mode



Ready mode

Warning

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

Note

Changing parameters during lasing will cause a warning message

17 Home

This button navigates back to the **Home Screen**.

The following figure is another typical Treatment screen (Basic Fiber mode) and it contains elements that are not included in Figure 5-7.

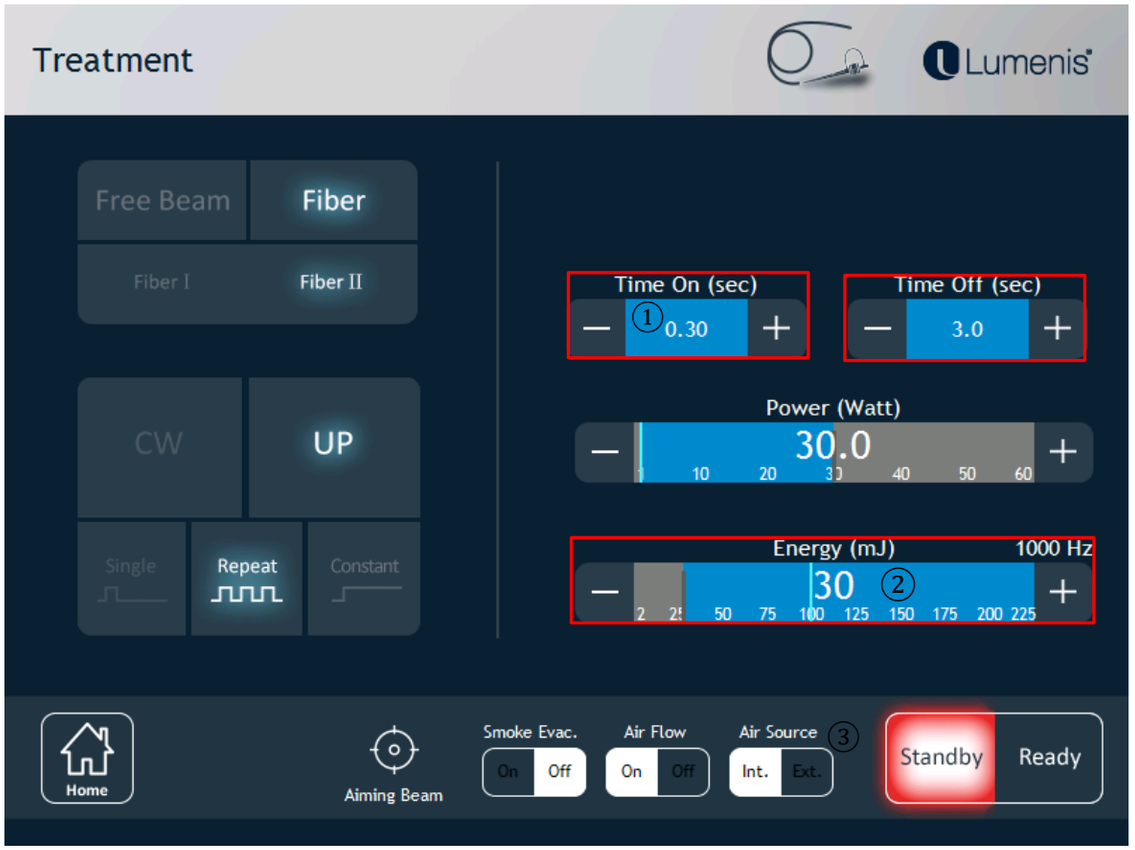


Figure 5-8: Treatment Screen – Fiber UP Repeat Mode

The following are descriptions for the elements not described above or displayed in Figure 5-7.

1	**Time On**	Selects the On-time of laser beam emission. Scroll through the **+** or **—** buttons to define the On-time. This is not available in **Constant** mode.
2	**Energy**	Sets the energy per pulse of the laser emission. Press the **+** or **—** buttons to raise or lower the energy level in milliJoules. This is only available in **UP** mode when in a **Basic** Treatment Type.

3 Air Source

Selects whether the source of the purge air for the fiber is internal or external air. The UltraPulse DUO requires the use of air flow through the fiber, whenever fiber is used. The system includes a compressor that can supply filtered internal purge air supply. As an option, an external purge air supply can be connected to the system (see Section 4.5.3).

- The fiber is designed to be used in a non-contact mode. Keep inadvertent contact with the tissue and fiber tip to a minimum.
- Always use the recommended laser power setting for a given procedure. Minimize the amount of bending of the fiber to avoid damage to the fiber or handpiece.

Caution

Fiber damage can occur when using a laser at a high-power level or at an extreme bending radius for long lasing time periods.

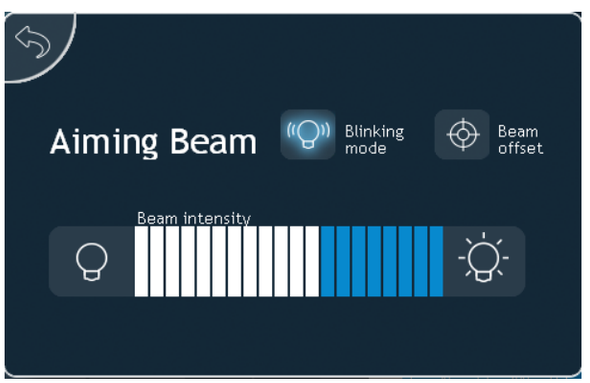
To avoid damage to the fiber and delivery accessory, an external pressurized purge air supply must be connected to the system when working with a fiber at a power level greater than 20 watts. The external pressure must be set between 50 psi (3.45 bar) and 60 psi (4.14 bar).

4 Aiming Beam

This button opens the aiming beam sub screen. Press the bulb to the left of the bar to reduce aiming beam intensity, or the bulb to its right to increase it. Use the toggle Blinking mode button to select whether the aiming beam blinks or not, and press Beam offset to open the Beam Offset sub screen.

Caution

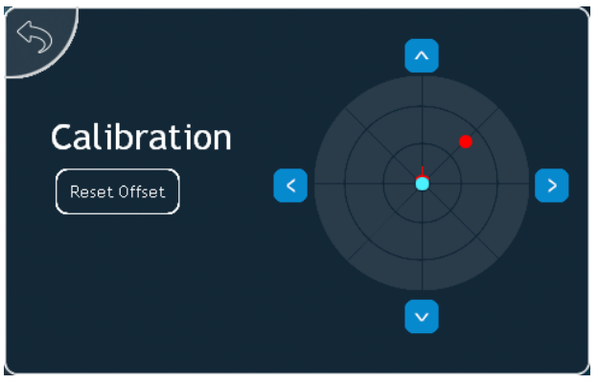
In Fiber mode when the aiming beam is in its minimum level/value/ intensity, is turned OFF. In Free Beam mode when the aiming beam is in its minimum setting it has minimal light.



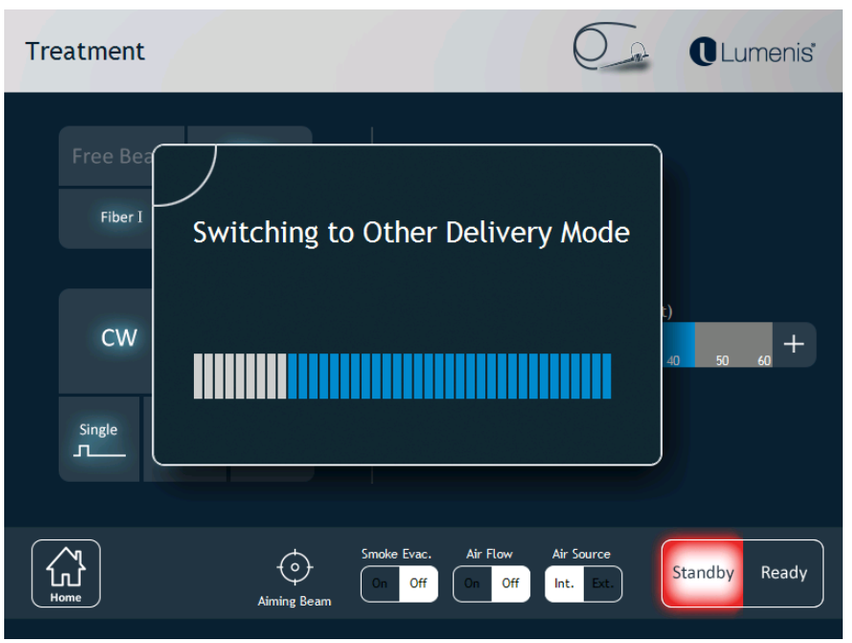
Not blinking

Blinking

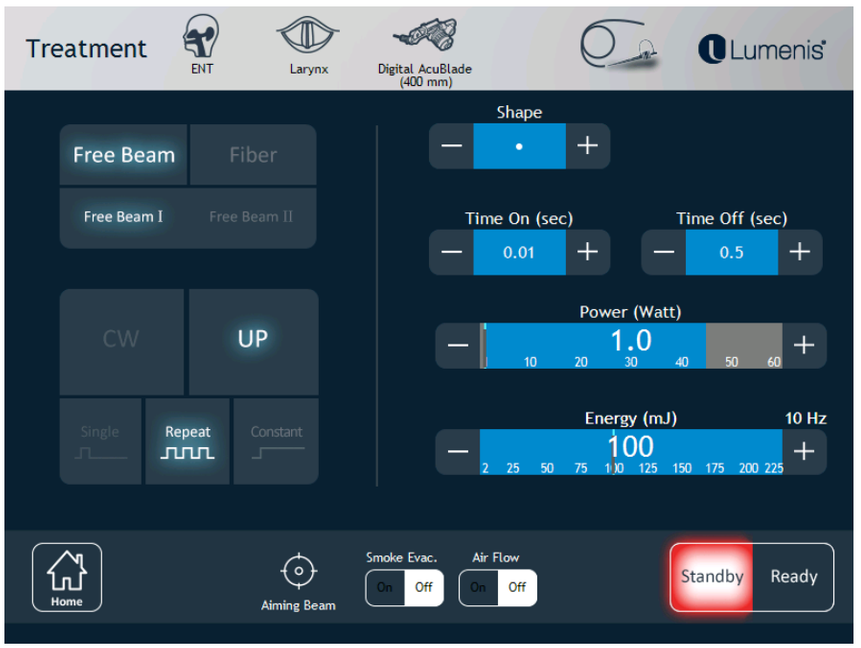
Press the up\down\right\left arrows to offset the scanner relative to its zero position. Use "*Reset Offset*" to return to no offset.



At any time, press the arrow in the upper left corner to return to the previous screen.

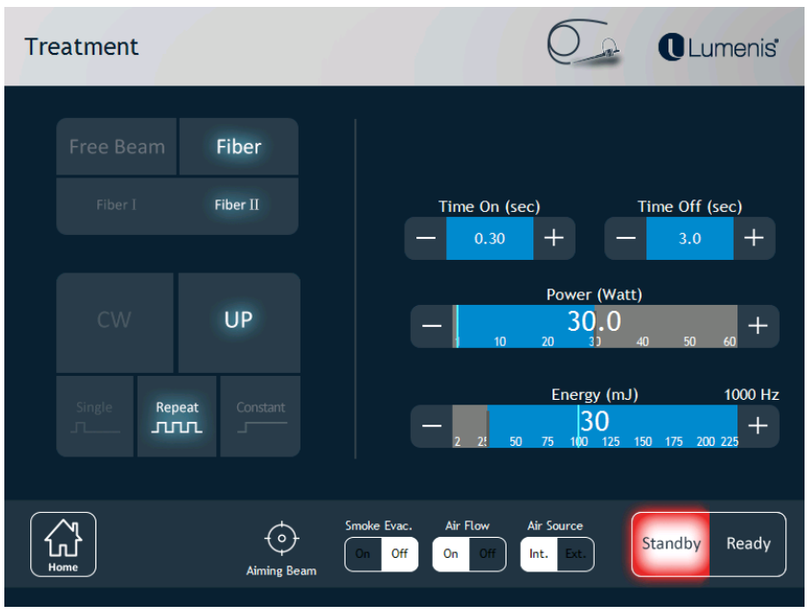


When switching from Free Beam to Fiber mode or from Fiber to Free beam mode a message will be shown on the screen. The message will disappear after a few seconds.



Free Beam I and II enables to user to define different laser settings to be used during the treatment.
For each setting, Free Beam **I/II** the user can change each of the lasing parameters: power, energy, CW/UP, ON/OFF time, single/constant/repeat, and shape.
Other settings as Aiming beam, air flow and smoke evacuator, use the last used setting for both Free Beam **I/II**.
The same behavior exists also in Fiber mode for Fiber **I/II**.

Fiber 1 settings



Fiber 2 settings

Fiber status

Fiber is not connected

Endure Fiber is connected with 5 sessions

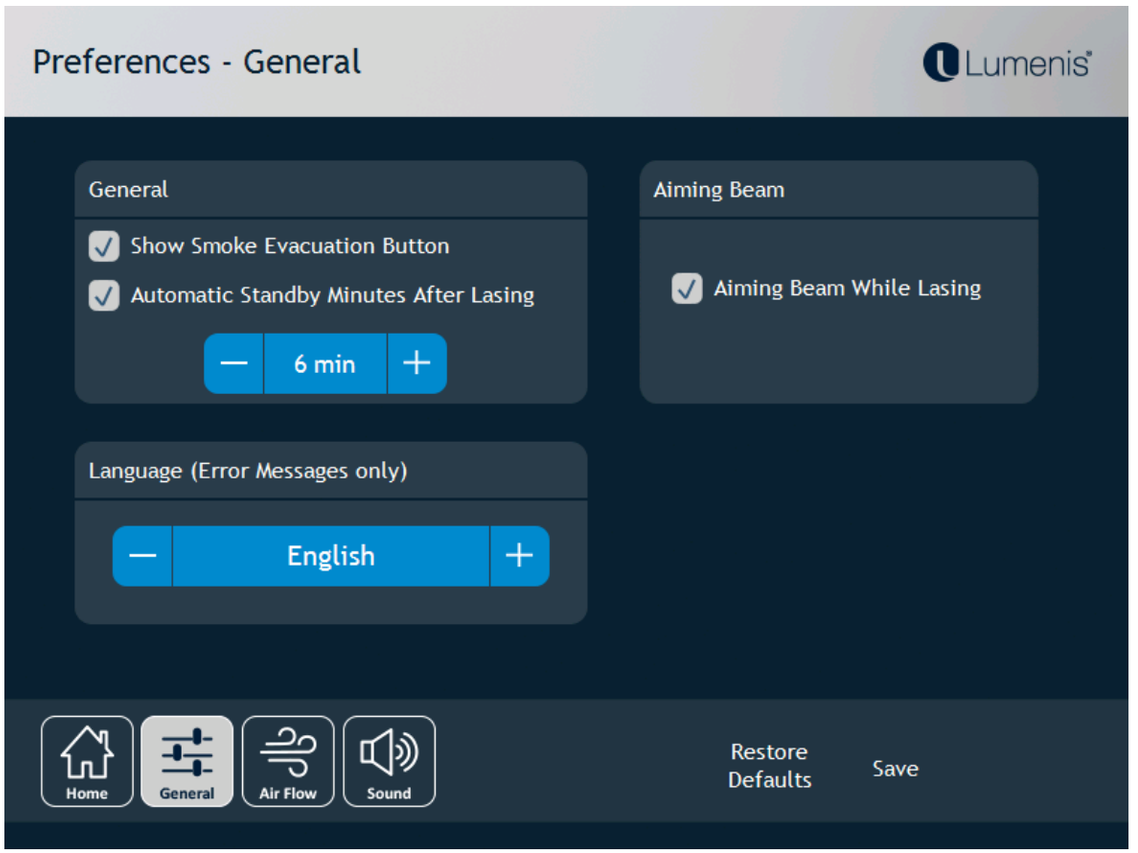
Endure Fiber is connected with 1 session

Endure Fiber is connected without sessions

FiberLase is connected with 1 session

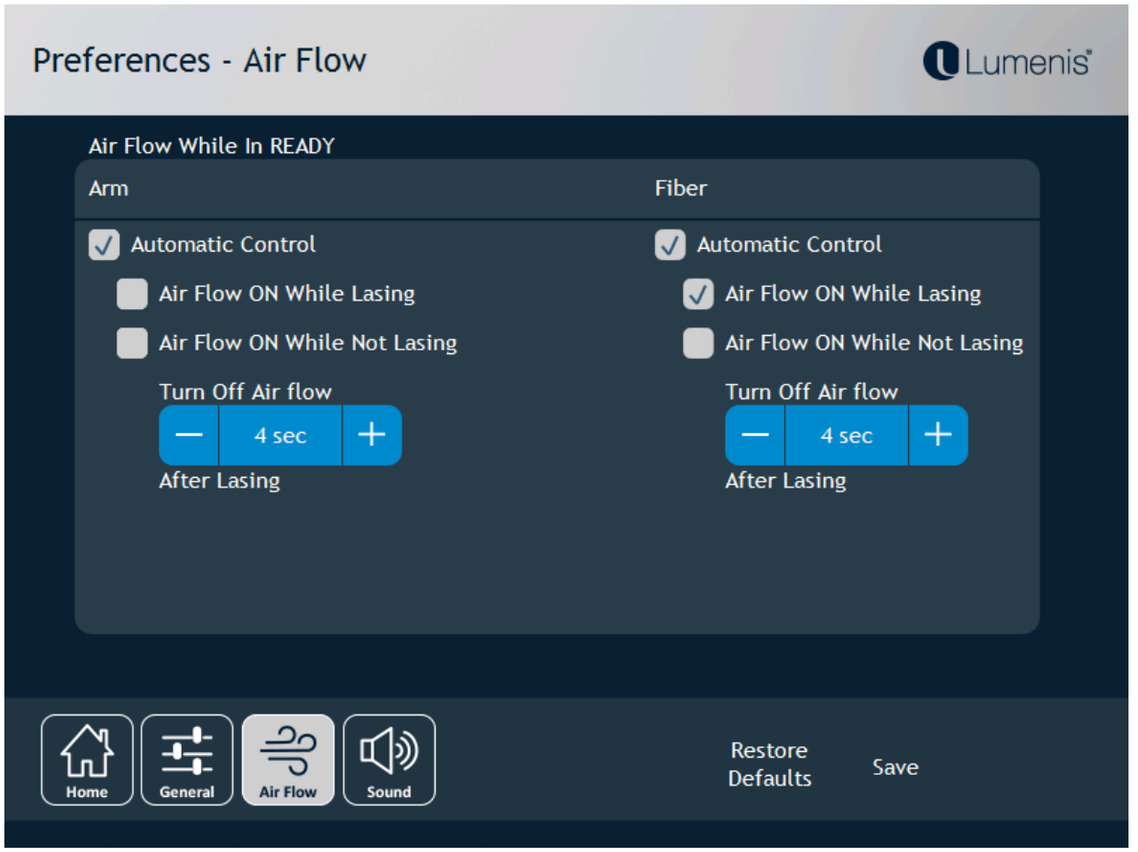
FiberLase is connected without sessions

5.6.1 Preferences



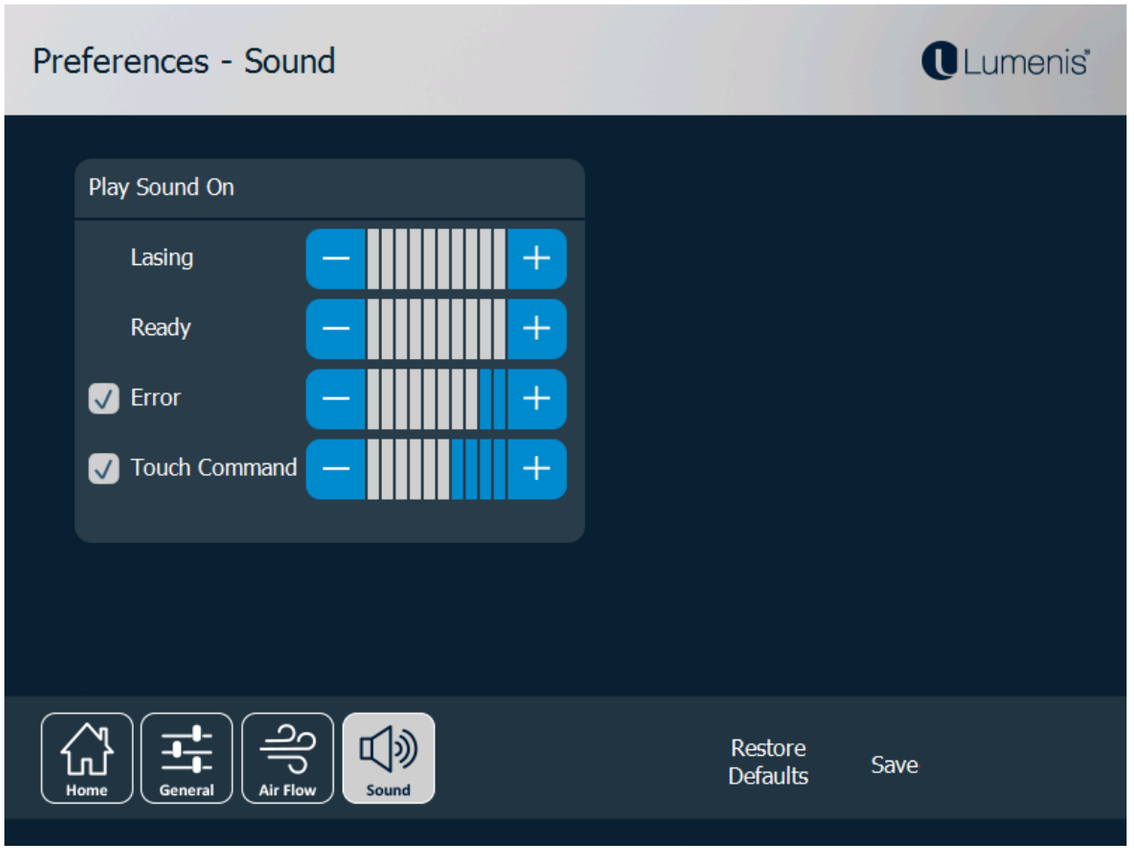
Preferences screen - General:

- Show smoke Evacuation button in Treatment screen or not
- Going to standby x minutes after lasing – if the system if left in Ready mode and the set time is passed, the system automatically goes to standby
- Language selection – changes the error/warning messages only
- Aiming beam while lasing – turns the aiming beam OFF during lasing.



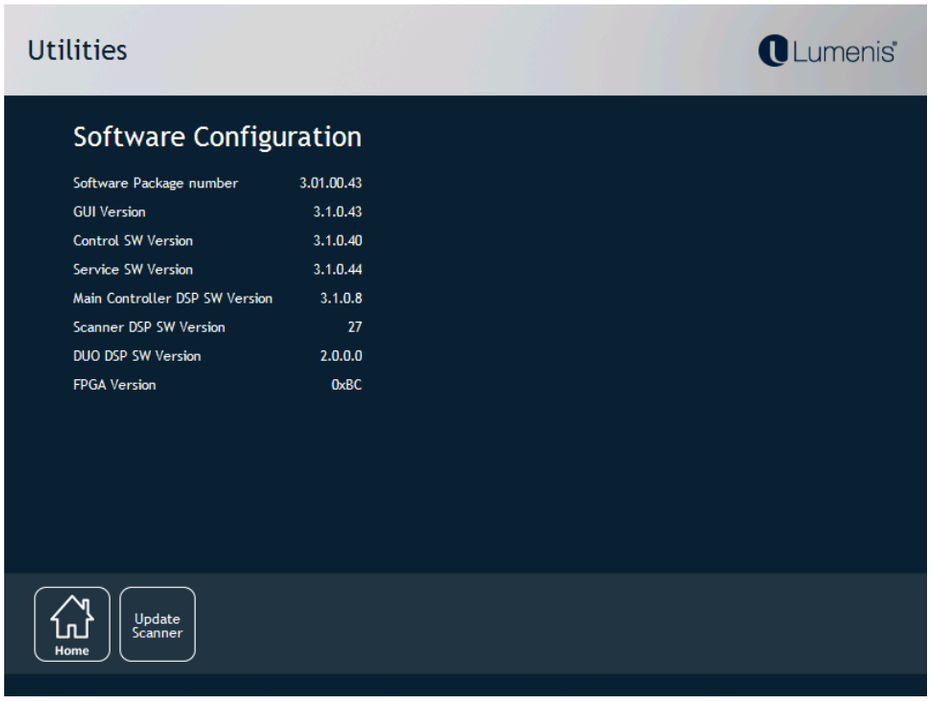
Air flow preferences:

- Defines whether working in automatic air flow mode during Ready mode and when the air is stopped after lasing for both Arm and Fiber.
- Automatic control – enable automatic control of the air flow during Ready mode
- Air flow ON while lasing
- Air flow ON while not lasing – enables air flow in Ready while not lasing
- Turn OFF air flow 0-15 seconds time after lasing – When “Air flow ON while not lasing” is checked, the “Turn OFF air flow 0-15 seconds time after lasing” is hidden and when “Air flow ON while not lasing” is unchecked, the user can stop the air flow x seconds after laser is stopped.

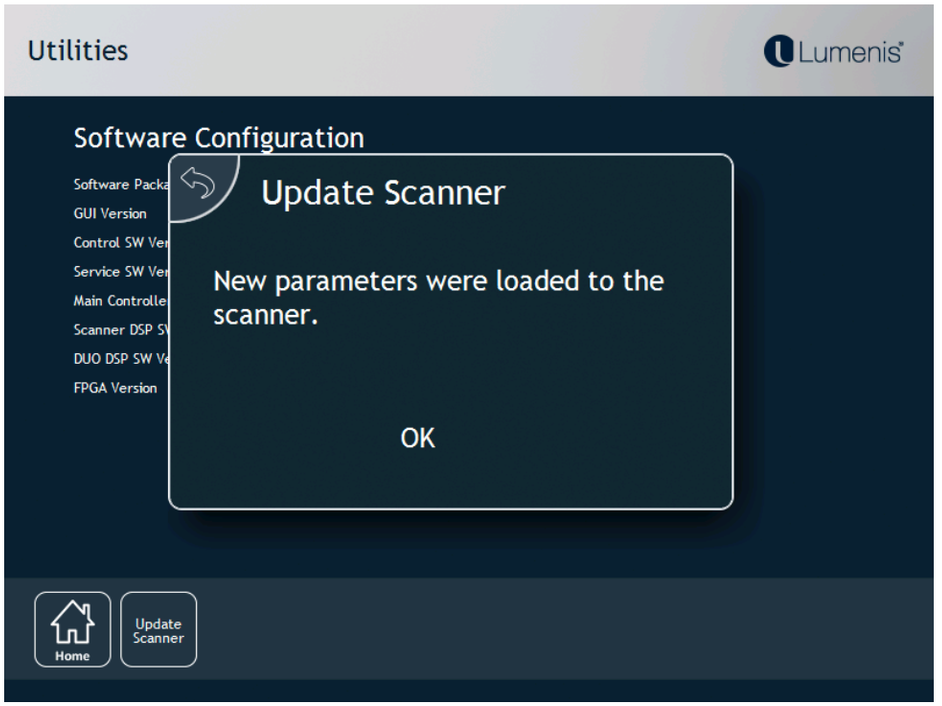


Sound preferences

- Lasing – Defines the volume of the lasing sound
- Ready – Defines the volume of the Ready Button
- Error – enables errors/warnings sound and its volume level.
- Touch command – enables/disables touch screen command sound and its volume level.

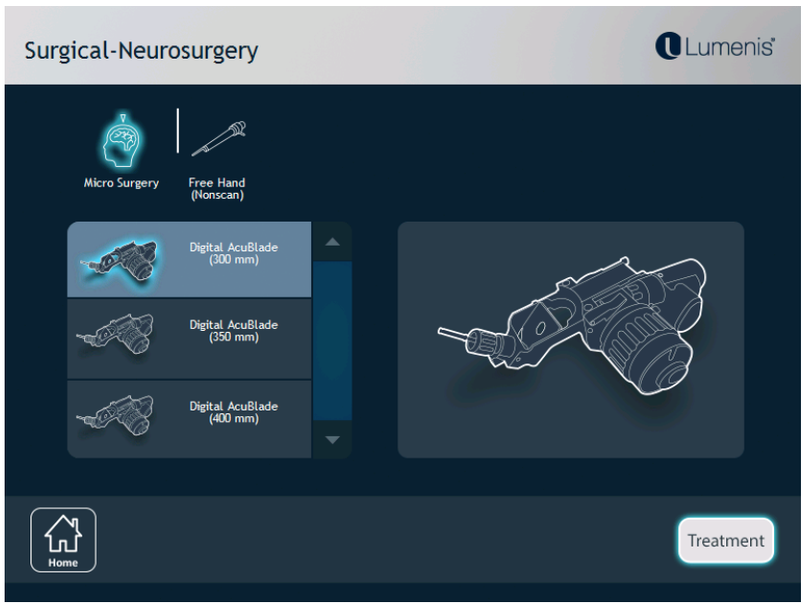


Software configuration screen – displays the current software versions that are installed in the machine.

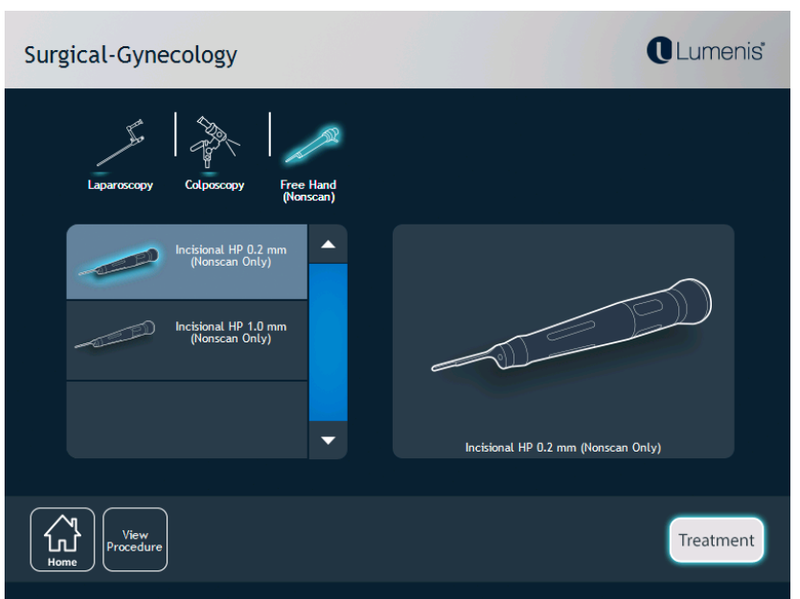


Update scanner – when using a new scanner in the UPD, insert the scanner parameters disk on key DOK and press the “Update Scanner” button on the screen. The new parameters will be downloaded to the machine and an appropriate message will appear.

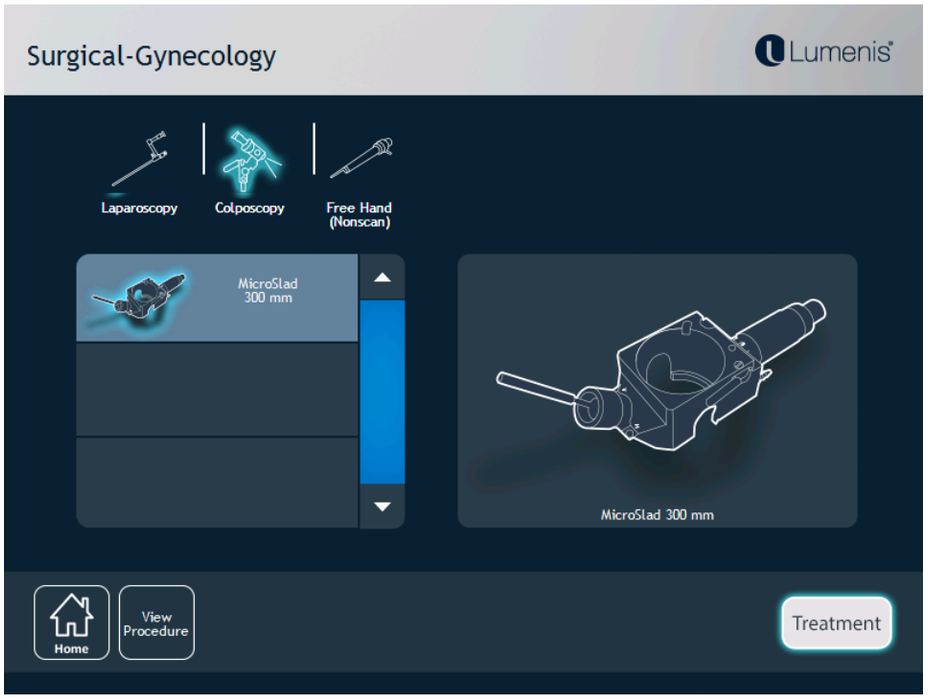
5.6.2 The following screens show the menus in each of the specialties: ENT, Gynecology and Neurosurgery and the selectable tools in each of the Specialties.



Surgical – Neurosurgery Micro Surgery

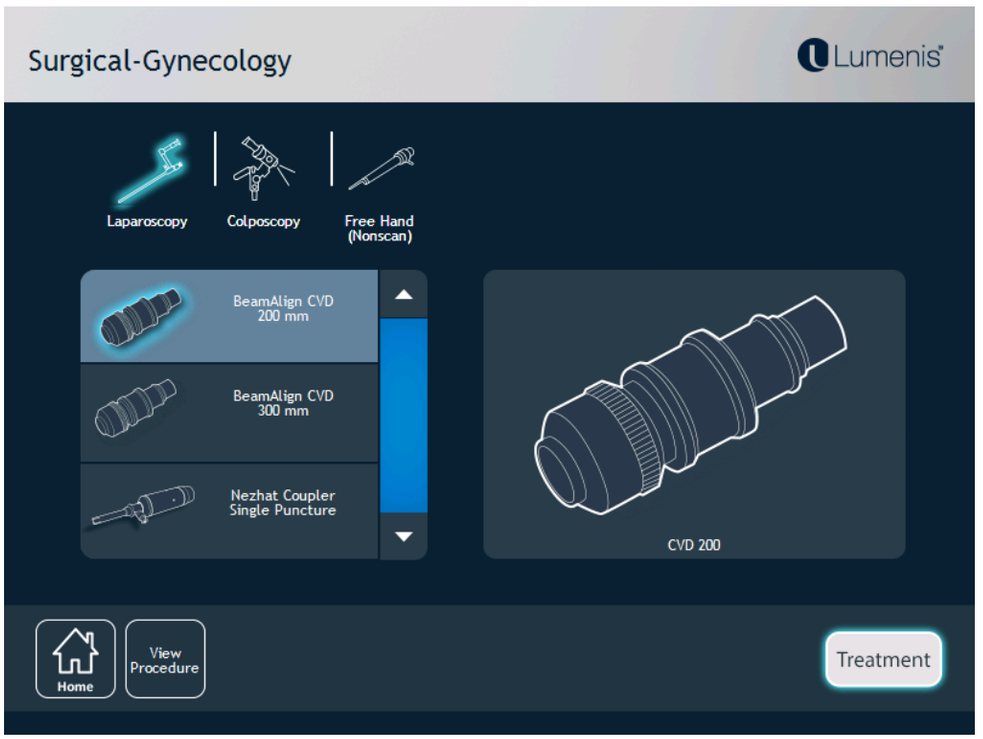


Surgical – Gynecology Free hand

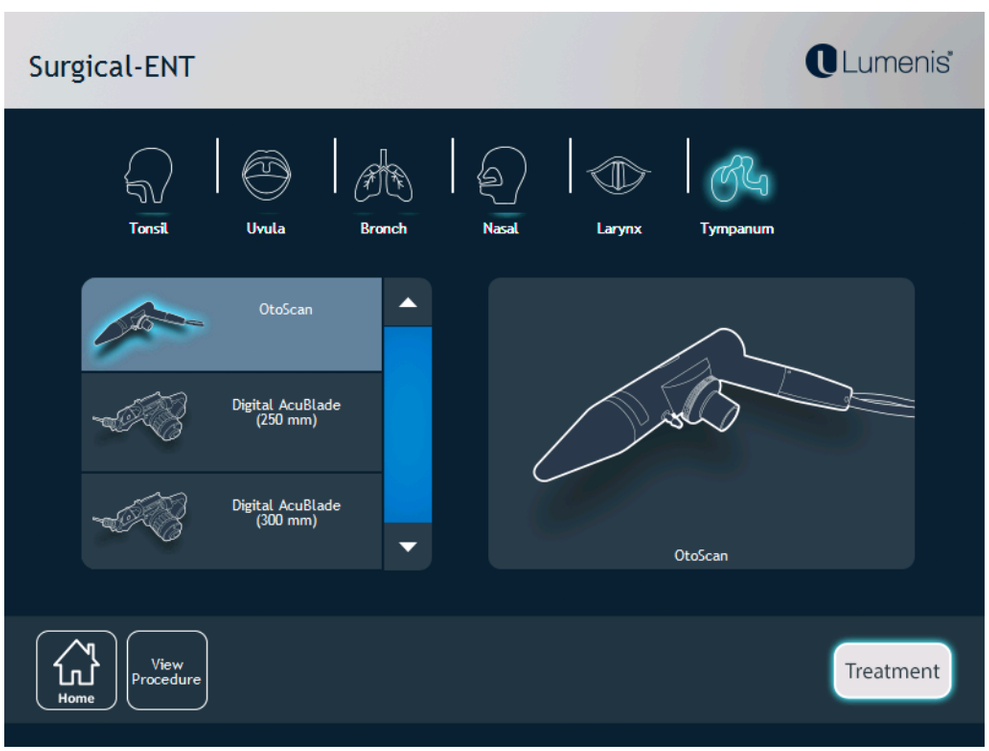


Surgical – Gynecology Colposcopy

When a View Procedure button is displayed a video is available

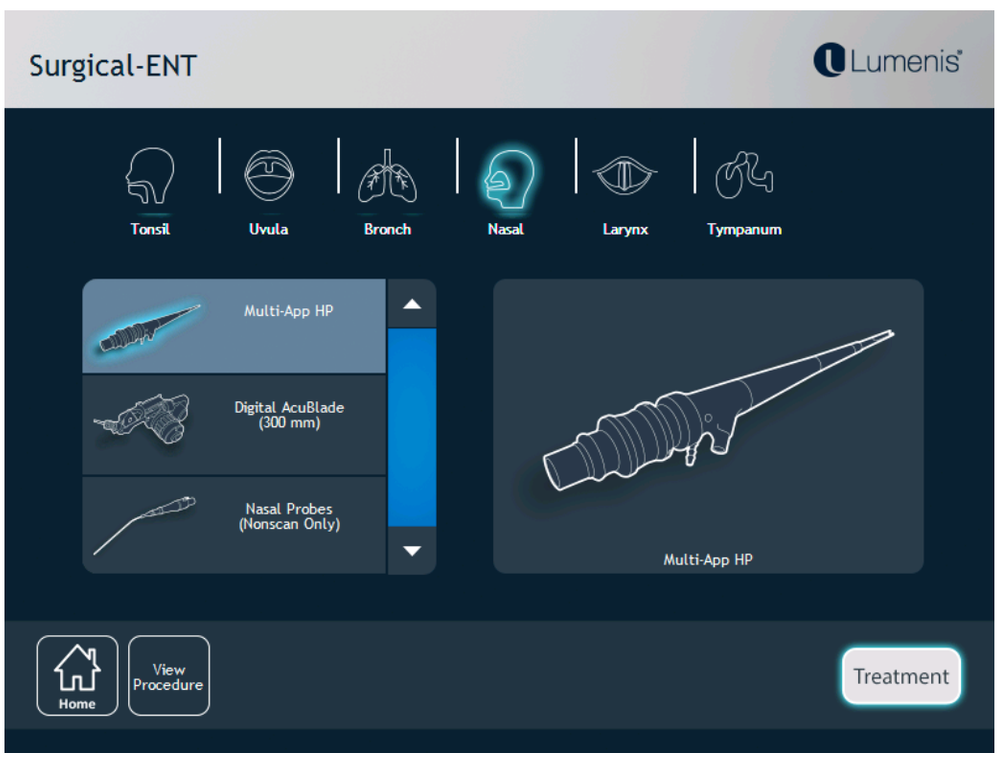


Surgical – Gynecology Laparoscopy

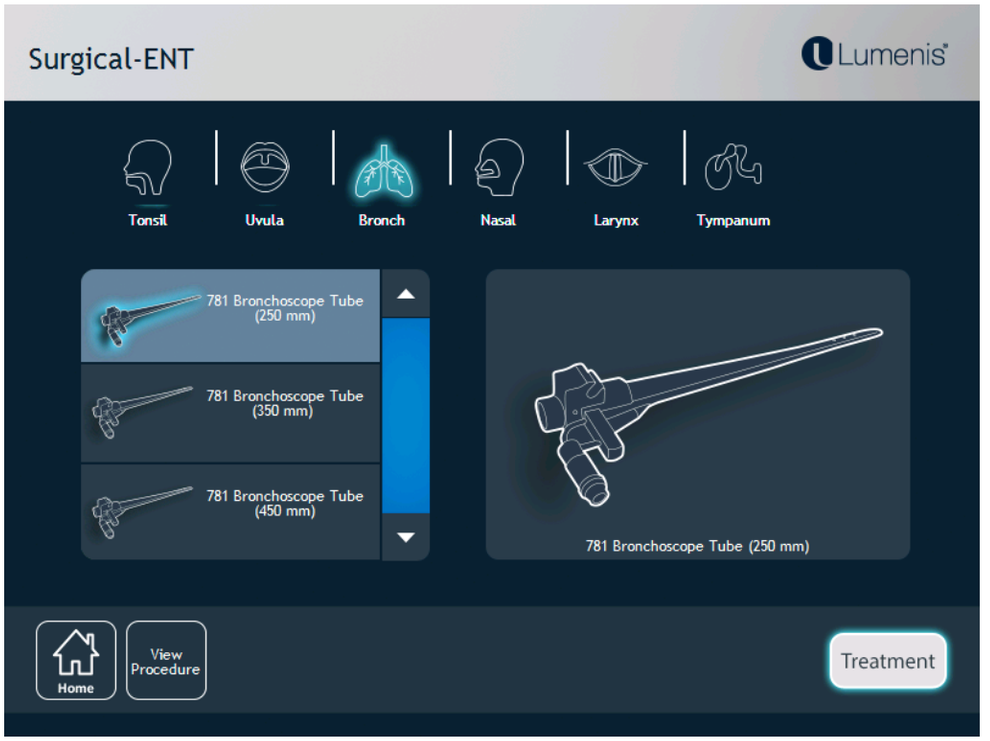


Surgical – ENT Tympanum

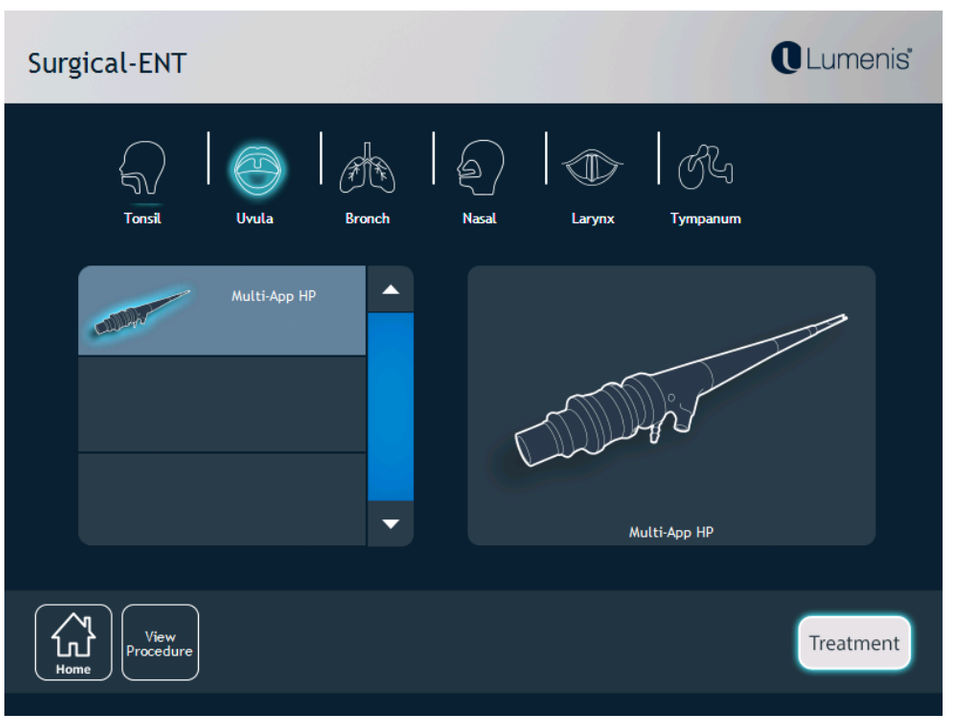
Surgical – ENT Larynx



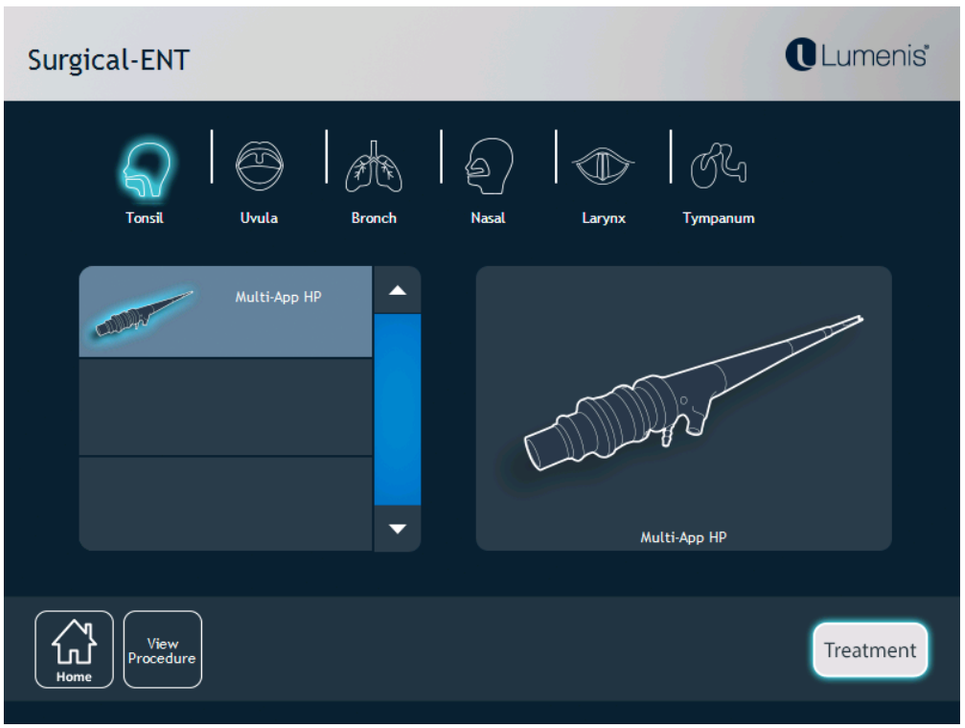
Surgical – ENT Nasal



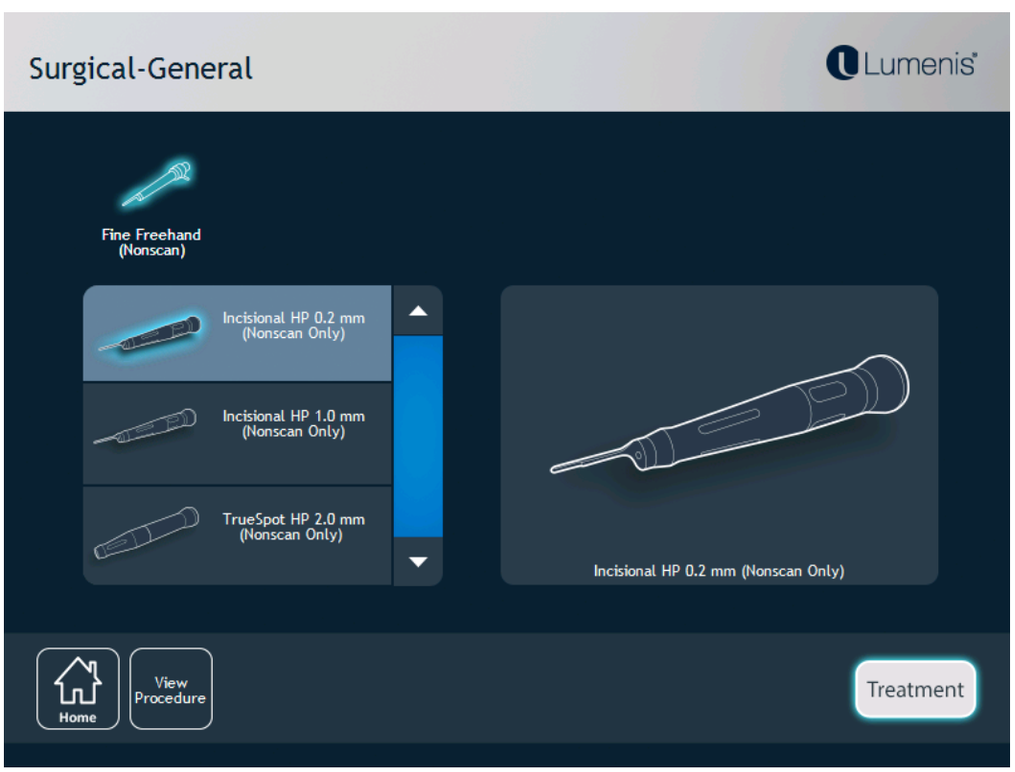
Surgical – ENT Bronchoscope



Surgical – ENT Uvula



Surgical – ENT Tonsil



Surgical General fine free hand

5.7 Post Procedure Disassembly

1. Turn the keyswitch to the ⏻ (OFF) position.
2. Turn the power circuit breaker switch (on the rear panel) to the **OFF** position.

> **Note**
>
> When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all of the internal circuits, place the laser main power circuit breaker in the OFF position.

3. Clean/sterilize the surgical accessories. Refer to the instruction of the relevant accessory for the complete cleaning and sterilization instructions.
4. Disconnect the delivery system, including all adapters and couplers. Clean the delivery system and store in the appropriate storage container, as instructed in the **Processing Instructions for Lumenis CO_2 Laser Accessories**.

> **Note**
>
> See the appropriate delivery system operator manual for a list of additional postoperative instructions that are specific to the delivery system.

5. Clean the exterior surfaces of the laser, as instructed in Section 6.6.2.
6. Close the red protective cap on the distal end of the laser articulated arm.
7. Fold and secure the articulated arm at the side of the console.
8. Remove the power plug from the electrical outlet and wrap the power cable around the cable wrap.
9. Place the footswitch on the footswitch storage mounts.
10. If used, turn OFF the external Purge Air Compressor. Disconnect its air tube from the console.

6 Maintenance and Troubleshooting

6.1 Introduction

This chapter contains the maintenance and troubleshooting instructions for the UltraPulse DUO laser system.

Routine maintenance may be performed by clinicians unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by Lumenis-authorized technical personnel.

The UltraPulse DUO laser system is equipped with self-testing software that continuously monitors system operation. If a system malfunction is detected, an error message appears on the display screen. Should a malfunction occur, consult the troubleshooting guides in Section 6.7.

Warning

Do not attempt to open or disassemble the system's covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation.

Only Lumenis-authorized technical personnel are qualified to service the interior of the system.

Warning

In Canada this instrument must be installed and operated according to CAN/CSA-Z386-14: Laser Safety in Health Care Facilities.

6.2 Daily Laser Check Before Procedures Begin

Each day, prior to procedures, the laser should be checked for damage to the console, missing parts and proper function.

- The cord for the footswitch should not be frayed and should be connected to the console.
- The cord for the power should not be frayed and should be connected to the console.
- The Fiber Handpiece Support Arm should be attached.
- The Air Filter should be clear and the arrow should be pointing to the left.
- The cover for the Fiber Port should be intact.
- The Fiber Support Arm should be intact, including the pigtail.
- The articulated arm should be properly stored in the storage bay, with no visible damage. The red cap should be attached to the distal end.
- The laser should be turned ON and the articulated arm should be checked for beam alignment.

6.3 Laser Beam Alignment Check

Beam alignment checks serve two purposes: to verify that the laser treatment beam is of an acceptable quality, and to verify that the aiming and treatment beams are coincident.

To check the alignment of the beams through the articulated arm, a non-sterile incisional handpiece can be used. Performing this check prior to scheduled cases, will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care. The Beam Alignment Check should be again performed, each time a free beam accessory is attached. Regardless of the accessory, the steps for the Beam Alignment Check are always the same.

Warning

Beam alignment checks are extremely important for the safe operation of your laser equipment. If aiming and treatment beams are not coincident do not operate the laser or delivery system; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.

Use caution when performing the laser beam alignment check: follow the procedure as described in this manual. Take care to ensure that the beam alignment procedure is performed when the patient, operating room personnel and flammable materials are not in the beam path. It may be desirable to place energy-absorbing material behind a target area.

1. Verify that all persons in the treatment room are wearing laser safety eyewear.
2. Using a knife or fine pencil, mark an “X” on a wooden tongue depressor and moisten with a nonflammable solution.

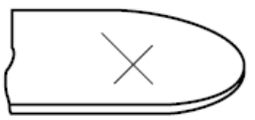


Figure 6-1 Mark an “X” on a tongue depressor

3. Input the following parameters into the treatment screen: CW power mode, 10 Watts power, single timed exposure for 10ms or 0.01 seconds
4. Position the handpiece so the visible aiming beam is centered at the intersection of the “X”. To steady the handpiece and ensure the correct spot size, ensure that the tip of the spatula touches the tongue depressor. Adjust the aiming beam intensity on the laser until the aiming beam is bright enough to be viewed under normal ambient light.

NOTE

Use a spatula tip when performing the beam alignment check; do not use an angled mirror tip.

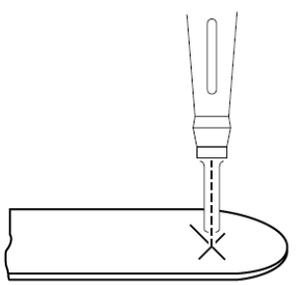


Figure 6-2 Position the handpiece and aiming beam

5. Place the laser in ready mode.
6. Direct the aiming beam at the center of the “X” and depress the laser footswitch. Observe the burn and check for the appropriate spot size; a round, evenly distributed spot should appear on the tongue depressor, as shown.

Figure 6-3 Acceptable and unacceptable test burns

7. Reposition the aiming beam at the center of the “X” and verify that the burn lies within the area of the aiming beam, as shown.

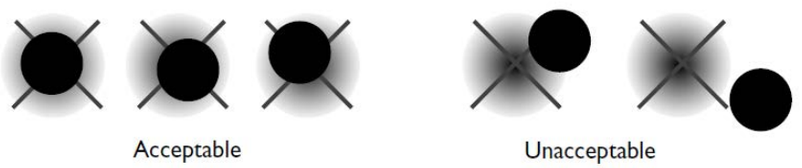


Figure 6-4 Acceptable and unacceptable beam alignment.

If the burn is not within the aiming beam, if the burn is unacceptable, or if the aiming beam is not visible, check the following:

- Verify that the delivery system connections are secure.
- Verify that any “up arrows” on the articulated arm are pointing toward the ceiling.
- It may be helpful to move the articulated arm or rotate the articulated arm knuckles closest to the handpiece. Sometimes changing the orientation of the articulated arm knuckles can affect aiming beam transmission, particularly if the articulated arm is extended or moved during a procedure.
- Remove the handpiece from the articulated arm, hold it toward a light source and look through it. The lens should appear translucent, smooth, bright, and free of any cracks, spots, debris, or obvious damage. If the lens appears dirty, clean as described in this chapter.
- If the brightness of the aiming beam fluctuates greatly or if the aiming beam is not visible, the optical lens may be damaged or the laser articulated arm may be out of alignment.
- If you cannot remedy the problem, if possible, substitute the optical coupler or handpiece with a different, compatible delivery accessory and repeat the alignment check. If the beam alignment is still unacceptable, call your local Lumenis service representative.

8. After successfully completing the beam alignment check, place the laser in standby mode until ready for use.

6.4 Routine Periodic Maintenance

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

A recommended routine inspection and maintenance schedule is provided in Table 6-1:

Table 6-1: Recommended Routine Inspection and Maintenance Schedule

Inspection / Service	Frequency	Performed By	Remarks
Relevant accessories disinfection / sterilization	Before each procedure	Clinician	As instructed in the relevant accessory instructions
Accessories cleaning and maintenance	After each procedure	Clinician	As instructed in the relevant accessory instructions
System routine exterior cleaning	After each procedure	Clinician	
Inspect accessories for damage	Before each procedure	Clinician	If damage is found, call Lumenis Service
Purge air flow check	Before each procedure	Clinician	If no air flow, replace air filter. If problem is not resolved, contact Lumenis Service
Replace air filter	Every 6 months or as required	Clinician	See Section 6.6.6
Inspect cables and all external surfaces for damage	Before each procedure	Clinician	If damage is found, call Lumenis Service
Inspect electrical connections	Weekly	Clinician	If damage is found, call Lumenis Service
Check door interlock and laser emergency stop button	Weekly	Clinician	If interlock and button do not perform as required, call Lumenis Service
Laser Beam Alignment	Every 6 months or as required	Clinician	If beam alignment fails, try to align it by using the Beam Offset feature (see Section 0) or call Lumenis Service
Electrical safety checks	Annually (or as required by institutional procedures)	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel

Inspection / Service	Frequency	Performed By	Remarks
Check and perform power meter calibration procedures	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

6.5 Lumenis Service

Customer-performed maintenance is limited to the procedures contained in Section 6.6 – Clinician Maintenance.

Lumenis Service should also be contacted when service is required for correction of any problem or system fault listed in the troubleshooting tables.

If the UltraPulse DUO must be shipped for service, call service to get packaging instructions. Always repackage the system using the original packaging materials.

Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repackaging instructions are needed.

6.6 Clinician Maintenance

6.6.1 Visual Inspection

The exterior of the system should be inspected before each procedure to ensure that there are no loose cable connections and that there is no damage to the system.

6.6.2 Routine Exterior Cleaning

The external surfaces of the system (console, LCD panel and articulated arm) and the footswitch should be cleaned when the system is received, and after each procedure.

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

- Clean the outer surfaces of the system with alcohol only when system is turned OFF. Verify that the alcohol has evaporated prior to turning system ON.
- Do not spray or pour cleaning agents directly on the laser console or control display. This can damage the console, display and laser system electronics.

6.6.3 Door Interlock System Check

Laser beam emission is disabled when the door interlock is not connected or is improperly connected to the rear panel. The door interlock must be checked weekly, as follows:

1. Set the system to **Standby** mode.
2. Unplug the door interlock or open the door interlock.
3. Try to select **Ready** mode. The system should display the following error message: **Remote Interlock Fault**, **Please verify Treatment Room door is closed**.
4. If the system does not display the error message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

6.6.4 Emergency Stop Button Check

The **Emergency Stop Button** is designed to disable the laser when pressed. The emergency stop button must be checked weekly, as follows:

1. With the system **ON**, press down on the laser emergency stop button. The system shuts down.

   If this is not the situation, discontinue use and contact Lumenis Service.
2. To turn the system on after shutting down use the keyswitch.

6.6.5 Air Filter Inspection and Purge Air Flow Check

Check the internal purge air flow as follows:

1. Use the keyswitch to turn the system ON (see section5.2).
2. Select **Basic** treatment. The **Free Beam** modality is selected by default.
3. Press **Start Air Flow** at the bottom of the screen for constant internal purge air. The air pump turns ON.
4. Check that air comes from the end of the flexible tube that leads along the length of the articulated arm.
5. Select the **Fiber** tab.
6. Check that air is coming from the fiber connection aperture.
7. Examine the filter. It should white. Replace the filter if it seems discolored or if air flow seems insufficient or cannot be detected (See Section 6.6.6).
8. When using an external source of air, connect the hose directly from the regulator to the connection port's nipple, or quick-connect system (on the rear side of the UltraPulse DUO laser system) and check for air flow.
9. If after replacing the air filter the air flow is insufficient or not present, discontinue use and contact Lumenis Service.

Warning

Lack of adequate air flow can damage the fiber and/or the delivery accessory, thus creating laser radiation and/or other injury hazards to the clinicians or patient.

Note

- The internal air flow or external air source must always be used with the Lumenis CO_2 fiber.
- The air filter should be replaced periodically. Lumenis recommends that the filter be changed every 6 months.

6.6.6 Air Filter Replacement

The air filter should be replaced periodically. Lumenis recommends that the filter be changed every 6 months.

To replace the air filter:

1. Turn the keyswitch to the ⏻ (OFF) position.
2. Open the access panel in the back of the laser console (see Figure 3-3).
3. Look at the installed air filter. The filter has an arrow that indicates the direction of air flow. The air flow direction is also indicated by the label inside the access panel. The new filter must be installed in the same direction.

4. Remove the air filter hoses from the two barb nipples.
5. Attach the new air filter hoses to the two barb nipples. Verify that the filter is installed in the same direction as the old filter.

6.7 Troubleshooting

Notifications and errors appear as popup messages.

Follow the instructions for the error message or notification. If a safety-related error occurred, the error message shall prompt the user to turn the system OFF. The user may turn the system back ON. If the error persists, call for service. If not, the error has been resolved and it is safe to work with the system. A full list of errors is presented in Table 6-2.

Table 6-2: Displayed System Errors

#	Error message	Description
1	01: Open shutter error. Please restart the system. If error persists, please contact service.	Safety shutter not open (so it is stopping the laser) when it is supposed to.
2	02: Closed Shutter error. Please restart the system. If error persists, please contact service.	Safety shutter not closed when it is supposed to.
3	03: Shutter driver error. Please restart the system. If error persists, please contact service.	Shutter Driver Fail (SHUT_ALARM pin GPIOA13)
4	04: Footswitch error. Please connect the footswitch. If connected please contact service.	Footswitch error (NO & NC statuses are same) or footswitch is not connected
5	05: FPGA integrity error. Please contact service.	FPGA signature is not UPD (not correct version or FPGA malfunctioned). Need to change a bit in the FPGA or use AP FPGA image
7	07: Footswitch engaged. Please disengage to proceed.	Footswitch pressed before ready mode
10	10: Unexpected light detected. Please restart system. If error persists, please contact service.	FPGA error: Unexpected light detected
11	11: 48V power supply error. Please restart the system. If error persists, please contact service.	48 Volt power supply is OFF when should be ON.
12	12: Water system pressure switch error. Please restart the system. If error persists, please contact service.	Water system pressure switch error
13	13: Main ADC error. Please restart system. If error persists, please contact service.	Test main ADC data read accuracy within 10% tolerance when setting ADC main channel
14	14: Safety ADC error. Please restart the system. If error persists, please contact service.	Test safety ADC data read accuracy within 10% tolerance when setting ADC safety channel
15	15: Attenuator is out of 6-16 % transmission range or not calibrated.	Test Attenuator transmission range within 6-16%
16	16: Water overheating warning. Please allow 5 minutes for system cool down.	Water system overheating warning ($47\ ^{O}C < T < 56^{O}C$) ± 10%
17	17: Water system overheating error. Please restart the system and allow 20 minutes for the	Water system overheating error ($T \geq 56\ ^{O}C$)

	system to cool down. If error persists, please contact service.	
19	19: System overheating warning. Please allow 5 minutes for system cool down.	Ambient System overheating warning. (47 ^{O}C < T <56 ^{O}C) ± 10%
20	20: System overheating error. Please allow 20 minutes for system to cool down.	Ambient System overheating error (T≥56 ^{O}C)
23	23: Remote Interlock error. Please verify that the Treatment Room door is closed.	Door is open error
24	24: GUI communication error.	GUI ping error from Main DSP to GUI during ready and lasing. "ring busy tone" will be played in buzzer of main DSP
26	26: Attenuator driver error. Please restart the system. If error persists, please contact service.	Attenuator Driver Fail (ATTEN_ALARM pin GPIOA15)
28	28: FPGA Safety pyro energy over 20% error. Please restart system. If error persists, please contact service.	FPGA: safety pyro energy over 20% error, FPGA reg 7, bit 8
29	29: FPGA Safety pyro energy less 20% error. Please restart system. If error persists, please contact service.	FPGA: safety pyro energy less in 20% than expected error, FPGA reg 7, bit 9
30	30: FPGA Main comparator error. Please restart system. If error persists, please contact service.	FPGA: main comparator error, reg 7 bit 10
31	31: FPGA Gate driver error. Please restart system. If error persists, please contact service.	FPGA: gate driver error, reg7 bit 11
32	32: FPGA Safety comparator error. Please restart system. If error persists, please contact service.	FPGA: safety comparator error, reg 7 bit 13
33	33: FPGA Shutter error. Please restart system. If error persists, please contact service.	FPGA: shutter error. Reg 7 bit 14
34	34: Invalid parameters error. Please restart the system. If error persists, please contact service.	Invalid parameters error
35	35: GUI PC: DSP Communication error. Please restart the system. If error persists, please contact service.	GUI PC - DSP Communication error from GUI
37	37: +24V error. Please restart the system. If error persists, please contact service.	24 V error, 24V power supply tolerance level exceeds 10%
38	38: +3.3V error. Please restart system. If error persists, please contact service.	3.3 V error, 3.3V power supply tolerance level exceeds 10%
39	39: +15V error. Please restart system. If error persists, please contact service.	15 V error, +15V power supply tolerance level exceeds 10%
40	40: -15V error. Please restart system. If error persists, please contact service.	-15 V error, -15V ~~volt~~ power supply tolerance level exceeds 10%
41	41: +5V error. Please restart the system. If error persists, please contact service.	5V error, 5V power supply tolerance level exceeds 10%

42	42: +12V error. Please restart the system. If error persists, please contact service.	12 V error, +12V power supply tolerance level exceeds 10%
43	43: -12V error. Please restart the system. If error persists, please contact service.	-12 V error, -12V power supply tolerance level exceeds 10%
44	44: Attenuator open error. Please restart the system. If error persists, please contact service.	Attenuator open error.
45	45: Attenuator close error. Please restart the system. If error persists, please contact service.	Attenuator close error.
46	46: Could not detect Optical Bench. Please restart system. If error persists, please contact service.	Optic bench isn't present (FPGA, reg4 bit 6)
47	47: Laser Tube overheating error. Please restart the system. If error persists, please contact service.	Tube overheat error from optic bench to FPGA (FPGA reg 4bit 8)
48	48: Treatment parameters changed during lasing.	New state update from DSP to GUI fail
49	49: No acknowledgment from FPGA. Please restart the system. If error persists, please contact service.	No FPGA interrupt detected every lasing period, or the interrupt isn't acknowledged before the next FPGA interrupt
50	50: RF error. Please restart the system. If error persists, please contact service.	RF disabled when it should be enabled. FPGA reg 3 bit 2
51	51: FPGA Timing Error. Please restart the system. If error persists, please contact service.	FPGA Timing error
52	52: Trying to enter ready while mirror is in transition. Please restart the system. If error persists, please contact service.	Trying to enter ready while mirror is in transition
53	53: Fiber is disconnected (due ready/firing) or due trying to enter ready when WG is active	Fiber is disconnected in Fire/RDY state
54	54: Fiber is not connected due trying to enter ready when WG is active	Fiber is disconnected when entering RDY state
56	56: Laser pulse longer than 2 msec. Please restart the system. If error persists, please contact service.	Length of laser pulse is more than 2ms (must be less 2ms). System should be recalibrated
57	57: Footswitch is disconnected, please connect the Footswitch	No Footswitch is attached
65	65: Scanner synchronization error. Please restart the system. If error persists, please contact service.	Scanner synchronization error.
66	66: Scanner communication error. Please restart the system. If error persists, please contact service.	Scanner communication error.
69	69: Scanner position error. Please restart the system. If error persists, please contact service.	Scanner position error.

70	70: Scanner is disconnected. Please connect and resume.	Scanner is disconnected.
71	71: No scanner board detected error. Please restart the system. If error persists, please contact service.	Scanner board present error.
74	74: Scanner position (X) error. Please restart the system. If error persists, please contact service.	Scanner position (X) error.
75	75: Scanner position (Y) error. Please restart the system. If error persists, please contact service.	Scanner position (Y) error.
85	85: Configuration error (no calibration table is created). Please restart the system. If error persists, please contact service.	No calibration table was created duo to configuration error.
86	86: Configuration is corrupted. Please restart the system. If error persists, please contact service.	Configuration is corrupted.
100	100: DUO Mirror position error. Please restart the system. If error persists, please contact service.	DUO Mirror position error.
101	101: DUO communication error. Please restart the system. If error persists, please contact service.	DUO communication error.
102	102: DUO Hardware failure. Please restart the system. If error persists, please contact service.	DUO Hardware failure.

Table 6-3 lists some possible system symptoms that indicate malfunctions that do not appear on the display screen. If the corrective action listed in the table does not solve the problem, contact Lumenis Service.

The troubleshooting table does not attempt to list all possible system failures. Any fault not listed should be referred to Lumenis Service.

Table 6-3: Undisplayed System Malfunctions Troubleshooting Guide

Symptom	Probable Cause	Action
System does not turn ON when plugged in and the keyswitch is turned	No AC power from wall outlet	Check if AC power is available from wall outlet, and power cable is properly plugged into AC outlet
	Tripped main circuit breaker (clinic power supply)	Reset main circuit breaker
	Emergency button pressed	Release Emergency button.
System will not switch to **Ready** mode	1. Footswitch not connected properly	1. Check footswitch connection
	2. Footswitch malfunction	2. Contact Lumenis Service
	3. Scanner not connected when in a scanning application	3. Check scanner connection
	4. Fiber not connected when in Fiber mode	4. Check fiber connection
	5. Interlock not connected	5. Check interlock connection
	6. System malfunction	6. Contact Lumenis Service
Laser emission does not occur when footswitch is pressed	1. System is not in **Ready** mode	1. Set system to **Ready** mode
	2. Damaged accessory or CO_2 fiber	2. Replace accessory or CO_2 fiber
	3. Footswitch malfunction	3. Contact Lumenis Service
	4. System malfunction	4. Contact Lumenis Service
System not responding to touch-screen commands	Control panel's touch-screen is out of calibration	Contact Lumenis Service
Laser emission indicator does not flash in **Ready** mode	Burnt LED	Contact Lumenis Service after completing the procedure
System changes from **Ready** to **Standby** mode without input command	Inadvertent, light pressure on the footswitch (for more than 3 seconds) may have activated 1 of the 2 internal microswitches, causing the system to change mode for safety purposes	Press the **Ready** key and resume normal operation

Appendix A. Clinical Guide

A.1. Introduction

This section is provided to aid professionals in the use of the UltraPulse DUO laser system for soft tissue applications in surgery. It adds to or reinforces information presented in the operator's manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operators must read the entire operator's manual before reviewing this section and before operating the system.

A.2. Indications for Use

The UltraPulse DUO CO_2 laser system is intended for use in surgical applications requiring the ablation, vaporization, excision, incision and coagulation of soft tissue in medical specialties including:

- Aesthetic (Dermatology and plastic surgery)
- Podiatry
- Otolaryngology (ENT)
- Gynecology (including laparoscopy)
- Neurosurgery
- Orthopedics (soft tissue, including arthroscopy)
- General and thoracic surgery (including open and endoscopic)
- Dental and oral surgery
- Genitourinary surgery

The UltraPulse DUO CO_2 system is indicated for use in specific surgical applications, as detailed in this chapter. Read and comprehend all of the following contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for the appropriate specialties.

The physician is also advised to consult medical publications for clinical parameters, techniques, and other current information on CO_2 laser treatment in a specialty.

Warning

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating room 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.

Note

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

A.3. Contraindications

- Do not use the UltraPulse DUO on hard tissues, such as bone or teeth.
- Do not use the UltraPulse DUO for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the UltraPulse DUO on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective and ensure the immediate availability of other surgical instruments for coagulation (i.e., electrocautery, graspers, sutures, etc.) to control hemostasis is strongly recommended.
- Do not use the UltraPulse DUO where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.

A.4. General Laser Warnings and Precautions

Warnings

- There are risks of excessive thermal injury, ulceration, scarring, edema, excessive bleeding, and infection - associated with any CO_2 laser surgical procedure. These risks may affect the tissue's structure and functionality. Therefore appropriate use of the CO_2 laser, as well as appropriate pre-and post-surgical care should always be practiced.
- Purge gases used with CO_2 delivery accessories and fibers may increase the risk of gas embolism where large, open vessels are present. Monitor all patients for gas embolism, which may occur even without the use of the laser.

A.5. General Laser Warnings and Precautions

Warnings

Serious tissue damage can occur as a result of incorrect energy settings when using a different accessory than the one selected in the treatment screen.

A.6. General Laser Recommendations

- The surgeon must employ appropriate patient selection and pre- and post-operative management.
- Select the appropriate delivery accessory for the intended application after consulting with surgical experts, reviewing the published literature, and attending procedure-specific training programs.
- See the UltraPulse DUO Delivery Accessory Connection Diagram in the General Operation section of this manual for a list of compatible delivery accessories.
- For char-free superficial ablation, pulsed laser modes or a scanner accessory are recommended.
- As with conventional non-laser surgery, there is no guarantee that treatment with the CO_2 laser will entirely eliminate any disease entity. Repeat treatment or alternative therapies subsequently may be required.

A.7. Aesthetic (Dermatology/Plastic Surgery)

A.7.1. Indications

The UltraPulse DUO laser is indicated for use in dermatology and plastic surgery for the following applications:

- Ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of:
  - laser skin resurfacing
  - laser dermabrasion
  - laser burn debridement
- Laser skin resurfacing (ablation and/or vaporization) for the treatment of:
  - wrinkles, rhytids, and furrows (including fine lines and texture irregularities)
- Laser skin resurfacing (ablation, and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
  - Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart and verruca seborrheica
  - Vermillionectomy of the lip
  - Cutaneous horns
  - Solar/actinic elastosis
  - Cheilitis, including actinic cheilitis
  - Lentigines, including lentigo maligna or Hutchinson’s malignant freckle
  - Uneven pigmentation/dyschromia
  - Acne scars
  - Surgical scars
  - Keloids including acne keloidalis nuchae
  - Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
  - Tattoos
  - Telangiectasia
  - Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
  - Superficial pigmented lesions
  - Adenosebaceous hypertrophy or sebaceous hyperplasia

  - Rhinophyma reduction
  - Cutaneous papilloma (skin tags)
  - Milia
  - Debridement of eczematous or infected skin
  - Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
  - Nevi, including spider, epidermal and protruding
  - Neurofibromas
  - Laser de-epithelialization
  - Tricoepitheliomas
  - Xanthelasma palpebrarum
  - Syringoma
- Laser ablation, vaporization, and/or excision for complete and partial nail matrixectomy
- Vaporization/coagulation of:
  - Benign/malignant vascular/avascular skin lesions
  - Moh's surgery
  - Lipectomy
  - Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts
- Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty
- Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

A.7.2. Contraindications

Patients should not be considered for laser skin resurfacing procedures if they:

- Have taken isotretinoin (e.g. Accutane®) within the past 12 months
- Have a history of keloid formation
- Have a history of poor wound healing
- Demonstrate excessive or unusually prolonged erythema, hyperpigmentation, or hypopigmentation upon laser test patching

A.7.3. Complications and Expected Sequelae

General dermatology and plastic surgery

Complications include:

- Scarring
- Ulceration
- Persistent edema
- Infection
- Persistent erythema

Expected Sequelae include:

- Erythema that resolves over time
- Swelling/edema that resolves over time

In addition to these general complications and sequelae, note the following procedure-specific complications and sequelae:

Rhinophyma

Complications include:

- Transient pustule formation
- Alar lift

Laser Matrixectomy

Complications include:

- Sterile inflammatory condition

Blepharoplasty

Complications include:

- Ectropion
- Asymmetry of eyelids

- Fold release (Asian eyelids)
- Wound dehiscence
- Postoperative bleeding
- Hematoma
- Keratoconjunctivitis sicca (dry eyes)
- Suture abscesses that resolve without treatment
- Allergic reaction to surgical suture material

Expected sequelae include:

- Minimal bruising and swelling (as compared to cold steel)
- Minimal ecchymosis (as compared to cold steel)
- Reduced intraoperative and/or postoperative pain (as compared to cold steel)
- Slightly reduced healing time (as compared to cold steel)
- Conjunctivitis (usually transient)
- Ptosis (usually transient)

Laser Hair Transplantation

Complications include:

- Hypopigmentation at laser-created sites
- Grafts that do not take (fall out)

Expected sequelae include:

- More crusting (some with de-epithelialization) at laser-created operative sites, as compared to recipient sites created using cold steel
- Delayed healing of laser-created recipient sites, as compared to recipient sites created using cold steel
- Removal of hair in laser-created slits in areas bearing hair

Skin Resurfacing

Note

- The medical management of resurfacing patients is an evolving field. In addition to studying current literature regarding the latest techniques, physicians are advised to obtain training by attending professional workshops and one-on-one training conducted by specialists in resurfacing.
- Because clinical outcome is dependent on a variety of factors, such as patient skin type, wrinkle severity, pre- and postoperative patient care, and physician technique, specific parameters are not recommended by Lumenis.
- Throughout the preoperative, operative, and postoperative time-period, antibiotic and/or antiviral medications may be prescribed prophylactically and/or as needed, at the discretion of the physician.

Warning

- The incidence and duration of postoperative hyperpigmentation and postoperative pain may be higher in subjects with darker skin types (III-VI) than in subjects with lighter skin types (I-II). Therefore, careful assessment of the patient skin type and laser test patching is recommended prior to commencement of treatment. Preoperative preparation of skin such as use of sunscreen or retinoic acid may be considered to reduce the likelihood of hyperpigmentation.
- Temperature increase due to laser treatment in patients with previous history of herpes simplex virus (HSV) may increase the like hood of HSV recurrence. Assess the patient' history for HSV and take the necessary preoperative measures such as antiviral therapy to avoid HVS recurrence.
- High energy densities may result in excessive tissue vaporization. Laser test patching should be considered prior to treatment to avoid unexpected results.
- Avoid overlapping of treatment spots as this will cause increased energy density and thermal effect to the treatment area
- To ensure proper healing of the treated area and the likelihood of hyperpigmentation, subjects should avoid unprotected exposure to sunlight. It is recommended to continue the use of sunscreen during the postoperative period.

Complications include:

- Hypopigmentation
- Scarring that generally resolves over time with steroid treatment
- Induration that generally resolves over time with steroid treatment
- Formation of fibrotic tissue that generally resolves over time with steroid treatment
- Reactivation of herpes simplex
- Acne flare-up that generally resolves over time by itself or with antiacneic medication if persistent

Expected sequelae include:

- Hyperpigmentation that resolves over time
- Transient pain that is observed immediately postoperatively and generally resolves quickly
- Transient burning sensation that is observed immediately postoperatively and generally resolves quickly
- Crusting that is observed immediately postoperatively through 2 weeks postoperatively
- Itching that generally resolves within the first 2 weeks postoperatively
- Textural change that is generally observed between 2 and 12 weeks postoperatively and resolves over time
- Sensation of tightness that resolves over time
- Formation of milia that resolves over time
- Contact irritant dermatitis to postoperative topical agents (primarily antibiotics)
- Postauricular skin slough/loss

Note

The use of a barrier coating improves patient comfort, and reduces the sensation of pain and burning by preventing air from contacting the treated region. The occlusive dressing should be maintained or changed as needed until crusting of the serous exudate is diminished, usually between 5 and 10 days postoperatively.

Subjects may apply cool water to the treated area to relieve discomfort, making sure to reapply the occlusive ointment or dressing between soaks.

A.8. Podiatry

The UltraPulse DUO laser is indicated for use in podiatry for the following applications:

A.8.1. Podiatry Indications

- Laser ablation, vaporization and/or excision of soft tissue for the reduction, removal, and/or treatment of:
  - Verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts.
  - Fungal nail treatment*
  - Porokeratoma ablation.
  - Ingrown nail treatment.
  - Neuromas/fibromas, including Morton's neuroma.
  - Debridement of ulcers.
  - Other soft tissue lesions.
- Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy.

General podiatry complications include:

- Infection
- Ulceration of tissue.

*** Restriction**

Fungal nail treatment indication is not cleared in the USA.

Laser matrixectomy complications also include:

- Sterile inflammatory condition.

A.9. Otolaryngology (ENT)

The UltraPulse DUO laser is indicated for laser incision, excision, ablation, and/or vaporization of soft tissue in otolaryngology for the treatment of:

A.9.1. ENT Indications

- Choanal atresia.
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue.
- Nasal obstruction.
- Adult and juvenile papillomatosis polyps.
- Polypectomy of nose and nasal passages.
- Lymphangioma removal.
- Removal of vocal cord/fold nodules, polyps and cysts.
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue.
- Zenker's Diverticulum/ pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodivertuculostomy (ELAED)].
- Stenosis, including subglottic stenosis.
- Tonsillectomy (including tonsillar cryptolysis and neoplasma) and tonsil ablation/tonsillotomy.
- Pulmonary bronchial and tracheal lesion removal.
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial).
- Benign and malignant lesions and fibromas (nose and nasal passages).
- Benign and malignant tumors and fibromas (oral).
- Acoustic neuroma in the ear.
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease.
- Telangiectasia/hemangioma of larynx, pharynx, and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue).
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx, and trachea.
- Myringotomy/tympanostomy (tympanic membrane fenestration).
- Uvulopalatoplasty (LAUP, laser UPPP).

- Turbinectomy and turbinate reduction/ablation.
- Septal spur ablation/reduction and septoplasty.
- Partial glossectomy.
- Tumor resection of oral, subfacial and neck tissues.
- Rhinophyma
- Verrucae vulgares (warts).
- Gingivoplasty/gingivectomy.

A.9.2. ENT Contraindications

- LAUP for palatal snoring is contraindicated without demonstrated obstruction by uvulopalatal tissue.
- LAUP for palatal snoring is contraindicated in pediatric patients (less than 16 years) because the upper airway is not fully developed.
- When used as the only form of treatment for palatal snoring, LAUP may not be effective in obese patients, patients with severe tonsillar hyperplasia, patients with macroglossia or patients with disproportionably short necks. Therefore the physician is advised to consult current relevant published medical information.

Warning

- To prevent airway fires and severe injury to the patient, protect endotracheal tubes from exposure to the CO_2 wavelength, or use CO_2 laser-resistant endotracheal tubes.
- To prevent airway fires and severe injury to the patient, do not direct the CO_2 laser at any tracheal tube in any oxygen-enriched environment, or any other environment that supports combustion.
- To prevent airway fires and severe injury to the patient, consideration of the type of anesthesia and ventilation are important.
- To prevent severe injury to the patient, middle ear surgery should be performed with appropriate parameters, considering acoustic and thermal effects.
- Avoid placing the tip of the nasal or laryngeal probe or fiber in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.

ENT Complications and Expected Sequelae

General ENT complications include:

- Excessive bleeding
- Infection
- Edema
- Hearing loss

Zenker's Diverticulum

- Transient soft tissue emphysema
- Mediastinitis

Tonsil Ablation/Tonsillotomy

- Transient dysphagia
- Mucosa lesions

Cordotomy

- Formation of granuloma

Turbinate Reduction/Ablation

- Transient nasal obstruction associated with postoperative edema and limited nasal crusts

LAUP

- Excessive bleeding
- Infection
- Edema
- Rhinophonia
- Nasopharyngeal stenosis
- Velopharyngeal incompetence

Myringotomy/Tympanostomy

- Scarring
- Transient otorrhea
- Infection
- Recurrence of otitis media

Note

Following laser-assisted myringotomy/tympanostomy, a pressure- equalizing tube may be used in situations when long-term ventilation has been determined to be necessary.

Warning

- Clinical studies have shown that patency time is directly related to the diameter of the laser fenestration. The average diameter used is 2.0mm. Therefore, clinical judgment and caution should be used when exceeding this diameter.
- Uncooperative pediatric patients should be appropriately restrained during office OtoLAM myringotomy/tympanostomy procedures in order to avoid unexpected movement and risk of affecting non-target tissue. Use appropriate measures to avoid unexpected movement such as local or topical anesthesia.

A.10. Gynecology and GYN Laparoscopy

The UltraPulse DUO laser is indicated for use in gynecology for the following applications.

A.10.1. Gynecology and GYN Laparoscopy Indications

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
  - Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN).
  - Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP) lesions.
  - Leukoplakia (vulvar dystrophies).
  - Incision and drainage (I&D) of Bartholin’s and Nabothian cysts.
  - Herpes vaporization.
  - Urethral caruncle vaporization.
  - Cervical dysplasia.
  - Benign and malignant tumors.
  - Hemangiomas.

- Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
  - Endometrial lesions, including ablation of endometriosis.
  - Excision/lysis of adhesions.
  - Salpingostomy
  - Oophorectomy
  - Fimbrioplasty
  - Metroplasty
  - Microsurgery (tubal).
  - Uterine myomas and fibroids.
  - Ovarian fibromas and follicle cysts.
  - Uterosacral ligament ablation.
  - Hysterectomy

A.10.2. Gynecology and GYN Laparoscopy Contraindications

- The UltraPulse DUO is contraindicated for patients who are not candidates for general surgery, where local or spinal epidural anesthesia is inappropriate.
- The UltraPulse DUO is contraindicated for laparoscopic applications where laparoscopy is contraindicated.
- The UltraPulse DUO is contraindicated for uterus laparoscopy or hysteroscopy surgery for pregnant women.

Warning

- When using a laser laparoscope, maintain an adequate flow of purge gas through the delivery accessory in order to prevent the fiber from over-heating.
- High purge flows require a specialized purge system or recirculating insufflator/ smoke evacuator to prevent over-pressurization and over-distention of the pneumoperitoneum and resultant complications.
- Ensure that the laser laparoscope is properly aligned and a clear, round aim beam is visible at all times.
- Avoid placing the tip of the fiber in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.

A.10.3. Gynecology and GYN Laparoscopy Complications

Gynecology and laparoscopic surgery complications include:

- Excessive bleeding
- Infection
- Excessive thermal injury or vaporization of tissue
- Gas embolism
- Subcutaneous emphysema

A.11. Neurosurgery

The UltraPulse DUO laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of the following indications (note Restriction below*):

A.11.1. Neurosurgery Indications

- **Cranial ***
  - Posterior fossa tumors
  - Peripheral neurectomy
  - Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
  - Arteriovenous malformation
  - Pituitary gland tumors (transphenoidal approach)
- **Spinal Cord ***
  - Incision/excision and vaporization of benign and malignant tumors and cysts
  - Intra- and extradural lesions
  - Laminectomy/laminotomy/microdiscectomy

*** Restriction**

Neurological indications for treatment of the central nervous system are only for USA.

A.11.2. Neurosurgery Contraindications

Do not use the laser on tumors that are inoperable or inaccessible with the laser beam.

A.11.3. Neurosurgery Complications

Warning

- Purge air used with CO_2 delivery accessories and fibers may increase the risk of gas embolism where large, open vessels are present. Monitor all patients for gas embolism, which may occur even without the use of the laser.
- Using the laser to open the dura causes shrinkage that may make closure difficult or impossible.

A.12. Orthopedics

The UltraPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in orthopedic surgery.

A.12.1. Orthopedics Indications

Applications include the following:

- Arthroscopy
  - Meniscectomy
  - Chondromalacia
  - Chondroplasty
  - Ligament release (lateral and other)
  - Excision of plica
  - Partial synovectomy
- General
  - Debridement of traumatic wounds
  - Debridement of decubitus and diabetic ulcers
  - Microsurgery
  - Artificial joint revision
  - PMMA removal

Warning

- When performing arthroscopic surgery with fibers where purge air is required, control the purge air with a tourniquet to prevent pressurization of an enclosed space (for example, shoulder), which can result in gas embolism or systemic subcutaneous emphysema.
- Residual carbon by-products of tissue vaporization are believed to increase the risk of postoperative synovitis and other complications. Mechanically scrape observed char from lased tissue surfaces following use of the laser.

A.12.2. Orthopedics Complications

Orthopedics complications include:

- Subcutaneous emphysema.
- Synovitis

A.13. General and Thoracic Surgery

The UltraPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures.

A.13.1. General and Thoracic Surgery Indications

Applications include the following:

- Debridement of decubitus ulcers, stasis, diabetic, and other ulcers
- Mastectomy
- Debridement of burns.
- Rectal and anal hemorrhoidectomy
- Breast biopsy
- Reduction mammoplasty
- Cytoreduction for metastatic disease
- Laparotomy and laparoscopic applications
- Mediastinal and thoracic lesions and abnormalities
- Skin tag vaporization
- Atheroma

- Cysts, including sebaceous cysts, pillar cysts, and mucous cysts of the lips
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

A.13.2. General and Thoracic Surgery Complications

General and thoracic surgery complications include:

- Excessive bleeding
- Infection
- Excessive thermal injury or vaporization of tissue

A.14. Dental and Oral Surgery

The UltraPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in dentistry and oral surgery.

A.14.1. Dental and Oral Surgery Indications

Applications include the following:

- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts, and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

A.14.2. Contraindications for Dental and Oral Surgery

The UltraPulse DUO is contraindicated for hard tissue such as bone or teeth.

Warning

While directing the laser beam near the tooth, shield the tooth from laser energy using either nonreflecting metal or an instrument inserted between the tooth and gum, being careful to prevent laser reflection.

A.14.3. Complications of Dental and Oral Surgery

Dental and oral surgery complications include:

- Laser damage to teeth through inappropriate use.
- Infection

A.15. Genitourinary

The UltraPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in genitourinary procedures.

A.15.1. Genitourinary Indications

Applications include the following:

- Benign and malignant lesions of external genitalia
- Condyloma
- Phimosis
- Erythroplasia

Appendix B. EMC Guidance and Manufacturer's Declaration

B.1. Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
UltraPulse DUO is intended for use in the electromagnetic environment specified below. The customer or the user of UltraPulse DUO should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	UltraPulse DUO 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	UltraPulse DUO 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	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Note

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radiofrequency energy. If not installed and used in accordance with the instruction manual, it may cause harmful interference to radio communications.

B.2. Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
UltraPulse DUO is intended for use in the electromagnetic environment specified below. The customer or the user of UltraPulse DUO should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±2,4,6kV contact ±2,4,8kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV line to ground ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±0.5, 1kV differential mode ±0.5, 1, 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of UltraPulse DUO requires continued operation during power mains interruptions, it is recommended that UltraPulse DUO be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)			
UltraPulse DUO is intended for use in the electromagnetic environment specified below. The customer or the user of UltraPulse DUO should ensure that it is used in such an environment.			
			Portable and mobile RF communications equipment should be used no closer to any part of the UltraPulse DUO system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vm	d = 1.17√P 80 MHz to 800 MHz d = 2.33√P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UltraPulse DUO is used exceeds the applicable RF compliance level above, the UltraPulse DUO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UltraPulse DUO. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

B.3. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the UltraPulse DUO

The UltraPulse DUO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UltraPulse DUO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UltraPulse DUO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.