

UltraPulse[®]

Carbon Dioxide Laser **Operator Manual**

for Encore™ and SurgiTouch™ Models



This manual is copyrighted with all rights reserved. Under copyright laws, this manual may not be copied in whole or in part or reproduced in any other media without the express written permission of Lumenis. Permitted copies must carry the same proprietary and copyright notices as were affixed to the original. Under the law, copying includes translation into another language.

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

Lumenis, the Lumenis logo, UltraPulse, UltraPulse SurgiTouch, SurgiTouch+, Encore, UltraScan CPG, PigmentFX, ActiveFX, ActiveFX gentle, MaxFX, DeepFX, SCAAR FX, PreciseFX, IncisionFX, BrowFX, CoolScan, CO₂ Lite, TrueSpot, ClearSpot, UltraFlex, Lumenis/Nezhat, AcuSpot, OtoScan, OtoLAM, AcuBlade, BeamAlign, MicroSlad, and FiberLase are trademarks or registered trademarks of Lumenis.

Retin-A and Renova are registered trademarks of Ortho Pharmaceuticals Corporation, Dermatological Division. Melanex is a registered trademark of Neutrogena Dermatologics. Valtrex is a registered trademark of Glaxo Wellcome, Inc. Famvir is a registered trademark of SmithKline Beecham Pharmaceuticals. Cipro is a registered trademark of Bayer Corporation. Coppertone and Shade are trademarks, distributed by Schering-Plough HealthCare Products, Inc. Vaseline is a registered trademark of Chesebrough-Pond's USA, Co. Acutane is a registered trademark of Roche Laboratories, Inc.



Copyright© Lumenis Ltd.

May 2012
0637-129-01
Revision G

Authorized Representative:

Lumenis GmbH Germany
Heinrich-Hertz-Strasse 3
D-63303 Dreieich-Dreieichenhain
Germany

Manufactured by Lumenis Ltd.

P.O.B. 240
Yokneam 20692
Israel

Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)

In accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheellie 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 wheellie bin. Please visit www.lumenis.com/recycling to understand what arrangements Lumenis has made in each EU Member State.



Contents

General Operation	Overview	9
	Introduction: The UltraPulse Laser Systems	11
	Characteristics of the carbon dioxide laser beam	12
	Laser Preparation	13
	UltraPulse Components	14
	Laser console	15
	Footswitch	15
	External door interlock plug	15
	Delivery devices.....	15
	Purge air compressor	15
	Connection Instructions	16
	Connecting the footswitch	18
	Inserting the external door interlock plug	19
	Releasing and orienting the articulated arm	20
	Connecting the delivery device	22
	UltraPulse Delivery Device Connection Diagram.....	23
	Balancing the articulated arm	26
	Connecting the scanner communication cable.....	27
	Connecting the main power cable	29
	Laser Console Basics	31
	Turning on the laser	31
Restarting the laser	31	
Laser beam alignment check	33	
Turning off the laser	33	
Emergency off.....	33	
Disconnecting the laser	35	
Moving the laser console	35	

	Control Screen Basics	37
	Control screen tabs	37
	Overview of operating modes and treatment screens	38
	Changing the control screen mode: English or icon	39
	Laser status: ready or standby	41
	Advisory messages	43
	Setting the aiming beam characteristics	45
	Adjusting the system volume	48
	Adjusting the Exposure On / Off	49
	Sleep Mode	50
	Replacing the Scanner (Scanner Pause)	51
	Saving and retrieving treatment settings	52
	UltraScan Encore CPG functions	56
	Beam offset	57
	Preoperative Instructions	58
	Intraoperative Instructions	59
	Postoperative Instructions	60
SurgiTouch+	Overview	61
	Introduction: The SurgiTouch+ User Interface	63
	Selecting a Specialty, Application, and Delivery Device	64
	Recalling the last setup	67
	Setting Treatment Values	68
	Selecting the scan mode: Non-scan or Scan	68
	Adjusting the power	70
	Adjusting the UltraPulse SurgiTouch Scanner settings	72
	Timed exposure and repeat delay in SurgiTouch+	75
	Setting timed exposure	76
	Setting repeat delay	77
UltraPulse	Overview	79
	Setting Treatment Values	81
	Setting the energy or fluence	81
	Setting the repetition rate or average power	84
	Timed exposure and repeat delay in UltraPulse mode	86
	Setting timed exposure	87
	Setting repeat delay	88
CW	Overview	89
	Setting Treatment Values	91
	Setting the power	91
	Timed exposure and repeat delay in CW mode	93
	Setting timed exposure	94
	Setting repeat delay	95

Maintenance	Overview	97
	Troubleshooting Guide	99
	User Maintenance	105
	Annual laser maintenance.....	106
	Laser repair.....	106
	Clean the external surfaces of the laser console.....	106
	Clean the laser control screen.....	106
	Water utilities.....	106
	Electrical Utilities	107
	Systems designed for use outside of Europe.....	107
	Systems designed for use in the European Community under MDD.....	107
	Hard-wired configurations.....	108
	Removable or lockable wall socket and plug configurations.....	108
	Specifications	109
	External Door Interlock Pin Assignments	112
Calibration Procedure	113	
Calibration instructions.....	114	
Warranty Information	115	
Decontamination of Returned Equipment	115	
Safety and Regulatory	Overview	117
	Introduction	119
	Laser Safety Eyewear	120
	Additional Ocular Protection	123
	Additional Safety Considerations	124
	Fire hazards.....	125
	Airway precautions.....	126
	Smoke evacuation—laser plume pollution hazards.....	127
	Protecting nontarget tissues.....	128
	Electrical Safety.....	130
	Regulatory Compliance	131
	Emergency off pushbutton.....	131
	Key lock switch.....	131
	Location of controls.....	131
	Protective housing.....	131
External door interlock.....	131	
Safety interlocks.....	131	
Manual reset.....	132	
Electronic fault detection circuitry.....	132	
Safety shutter.....	132	
Laser emission indicators.....	132	
Location of regulatory and system labels.....	133	

Indications for Use	Overview	139
	General Indications	141
	General laser contraindications	142
	General laser warnings and precautions	142
	General laser recommendations	143
	Aesthetic (Dermatology/Plastic Surgery) Indications	144
	Safety considerations for dermatology and plastic surgery	146
	Safety considerations for laser skin resurfacing	148
	Podiatry Indications	154
	Safety considerations for podiatry	154
	Otolaryngology (ENT) Indications	155
	Safety considerations for ENT	157
	Safety considerations for LAUP	159
	Safety considerations for myringotomy/tympanostomy (tympanic membrane fenestration)	160
	Gynecology and GYN Laparoscopy Indications	161
	Safety considerations for gynecology and GYN laparoscopy	162
	Neurosurgery Indications	163
	Safety considerations for neurosurgery	163
	Orthopedics Indications	164
	Safety considerations for orthopedics	164
	General and Thoracic Surgery Indications	165
Safety considerations for general and thoracic surgery	165	
Dental and Oral Surgery Indications	166	
Safety considerations for dental and oral surgery	167	
Genitourinary Indications	168	
Safety considerations for genitourinary procedures	168	
Clinical Studies Referenced	169	

General Operation

Overview

- Introduction: The UltraPulse Laser Systems 9
- Laser Preparation 11
- UltraPulse Components 12
- Connection Instructions 14
- UltraPulse Delivery Device Connection Diagram 21
- Laser Console Basics 29
- Control Screen Basics 35
- Preoperative Instructions 56
- Intraoperative Instructions 57
- Postoperative Instructions 58

Introduction: The UltraPulse Laser Systems

The Lumenis UltraPulse® SurgiTouch™ and the UltraPulse Encore™ CO₂ lasers are the benchmark for speed, reproducibility, and ease of treatment for a wide variety of aesthetic and surgical procedures. Each system incorporates our patented high-energy, short-pulse CO₂ technology that has delivered proven results in hospitals and surgery centers for over a decade. Extensive experience with CO₂ laser skin resurfacing has broadened not only the merits of the technology, but also its utility for a full range of surgical treatments.

With the addition of the SurgiTouch automation system, Lumenis combines state-of-the-art scanning technology with the best in pulsed laser technology. The optional SurgiTouch+ interface offers predetermined application settings that make the UltraPulse Encore even more adaptable and easy-to-use in a variety of specialties, including aesthetics, ENT, gynecology, neurosurgery, and general surgery. Our complete line of delivery systems and accessories, including the optional UltraPulse SurgiTouch Scanner, further extends the versatility of the UltraPulse laser system.

UltraPulse is now available in two models: The SurgiTouch model includes the SurgiTouch scanning system and application-specific SurgiTouch+ user interface. The Encore model is fully upgradeable to SurgiTouch to support the future needs of your practice. And, of course, both models deliver the proven benefits of UltraPulse technology.

Lumenis lasers and delivery systems are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser or delivery system, contact your local Lumenis representative.



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.

Characteristics of the Carbon Dioxide Laser Beam

The carbon dioxide laser wavelength falls in the mid-infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye; therefore, a low-power, visible aiming beam that is coaxial with the invisible treatment beam is used to target tissue.

Carbon dioxide laser energy is readily absorbed by water in tissue. Since soft tissue is comprised primarily of water, carbon dioxide laser energy can be used effectively for the excision, incision, ablation, vaporization, and coagulation of soft tissue.

Laser Preparation

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 surgical staff is experienced with the operation and safety considerations of the laser.

Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser and with any delivery systems used during surgery, including inspecting and cleaning the laser and delivery systems; sterilizing, connecting, and disconnecting the delivery systems; and performing laser beam alignment safety checks. These procedures are detailed in this manual and in your delivery system operator manuals.

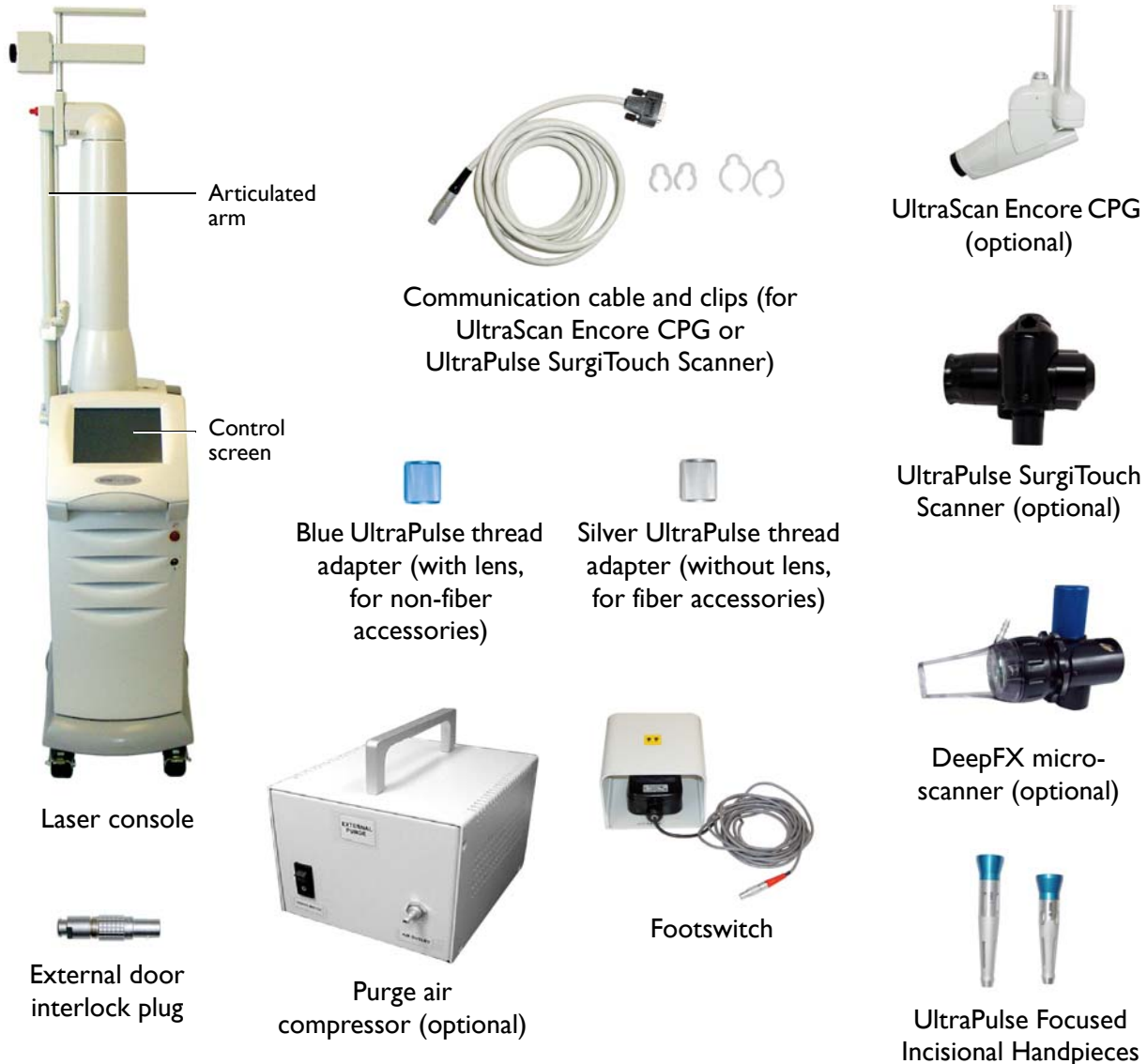
Most nursing staff prefer to inspect delivery systems and perform a laser beam alignment check daily, usually prior to scheduled cases and before patients are premedicated. Doing so will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care. These routine surgical tasks may be performed outside of the sterile field; in this case, ensure enough time to sterilize any components, as necessary, before scheduled cases.

UltraPulse Components

The UltraPulse laser system comprises:

- A laser console with articulated arm and control screen
- A footswitch
- An external door interlock plug
- All electrical cables necessary for operation
- Thread adapters for connecting delivery devices
- A purge air compressor

An UltraScan Encore CPG, an UltraPulse SurgiTouch Scanner, a DeepFX microscanner or additional delivery systems, if ordered, may also be shipped with your laser system.



UltraPulse Laser Console and Components

Laser Console

The laser console houses the control screen, articulated arm, main power keyswitch, emergency off button, control electronics, laser source and associated optics, and power supply.

Footswitch

The footswitch activates the laser treatment beam.

External Door Interlock Plug

The external door interlock plug must be inserted into the proper receptacle on the back of the laser console in order for the laser to operate. It can be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

Delivery Devices

Delivery devices for a variety of applications may have been shipped with your UltraPulse laser. Refer to the operator manuals included with those delivery devices for specific descriptions and operating instructions. In addition to the UltraScan Encore CPG and Focused Incisional Handpieces, compatible delivery devices include the UltraPulse SurgiTouch Scanner; the AcuBlade™ Micromanipulator; the DeepFX™ Microscanner; the OtoScan™ Ear Aeration Delivery System; and a wide range of other handpieces. For a complete list of compatible delivery devices, refer to the UltraPulse Delivery Device Connection Diagram in this chapter.

Refer to the operator manuals of the above delivery devices for complete operating instructions.

Purge Air Compressor

An optional external purge air compressor should be connected to and used with delivery devices that require internal air-cooling and smoke evacuation. These include:

- The nasal and laryngeal probes
- Multi-Application (Oral Pharyngeal) and Nasal Handpiece
- AcuSpot 712 Micromanipulator
- AcuBlade Micromanipulator
- DeepFX Microscanner (with connected disposable tip)
- OtoScan Ear Aeration Delivery System

Connection Instructions

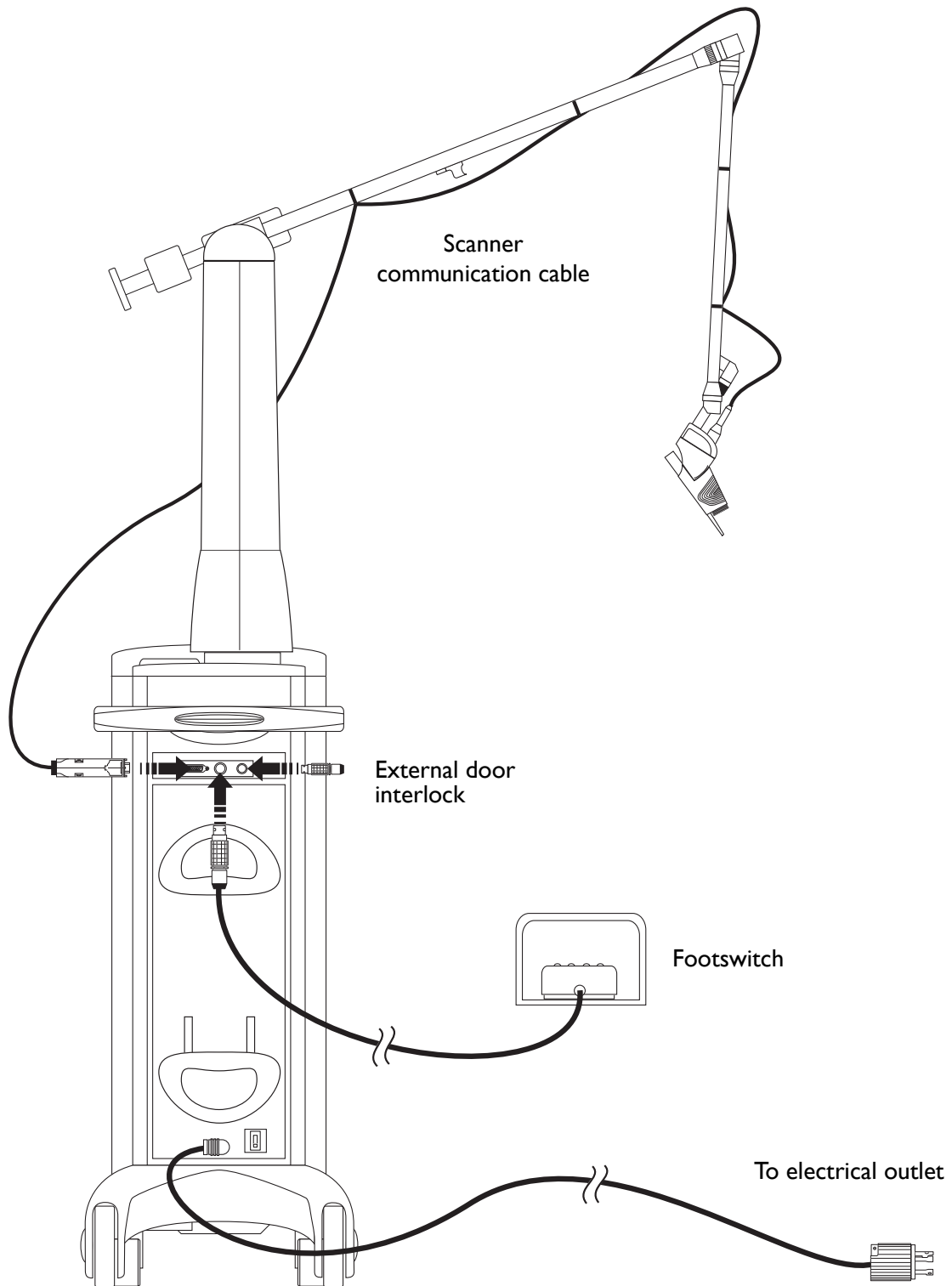
Before connecting the system components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Check all electrical cables to ensure that they are not frayed or split. Inspect all delivery systems, as instructed in the appropriate delivery system operator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



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.




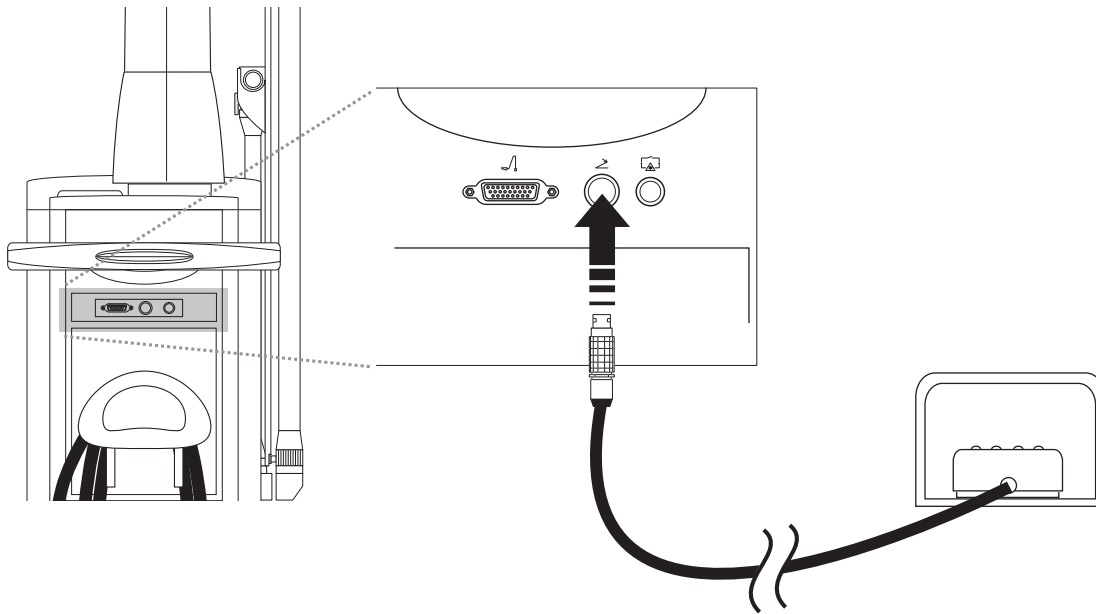
CAUTION - Do not touch any optical lens; finger oils may damage the delicate coatings.



UltraPulse Connections

Connecting the Footswitch


Plug the footswitch cable into the  (footswitch) receptacle. If the footswitch is not properly connected when the laser is turned on, "Attach Footswitch" displays in the advisory text bar on the control screen, and the laser cannot be placed in ready mode.




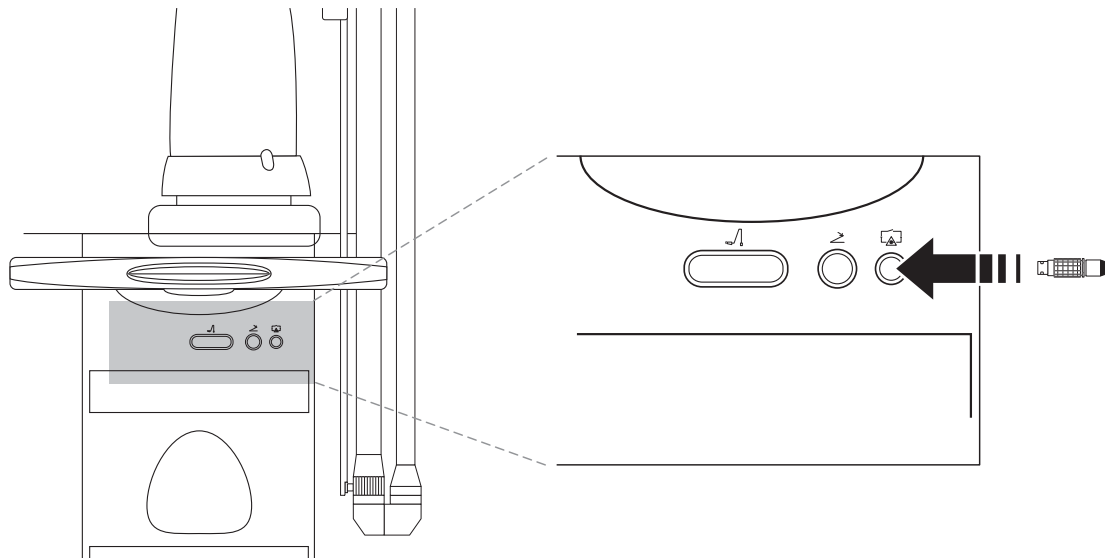
Connecting the Footswitch

Inserting the External Door Interlock Plug

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

Use of an external door interlock is optional; however, you must insert the interlock plug into the  (external interlock) receptacle whether or not you are using an external door interlock. The laser remains inoperative until the plug is inserted into the receptacle.

When an external door interlock is in use, the laser is automatically disabled and returns to standby mode if the treatment door is opened or the interlock plug is removed; “Remote Interlock” displays in the advisory text bar on the control screen. To resume treatment, close the treatment room door or reinsert the interlock plug, and press the  button on the advisory text bar.




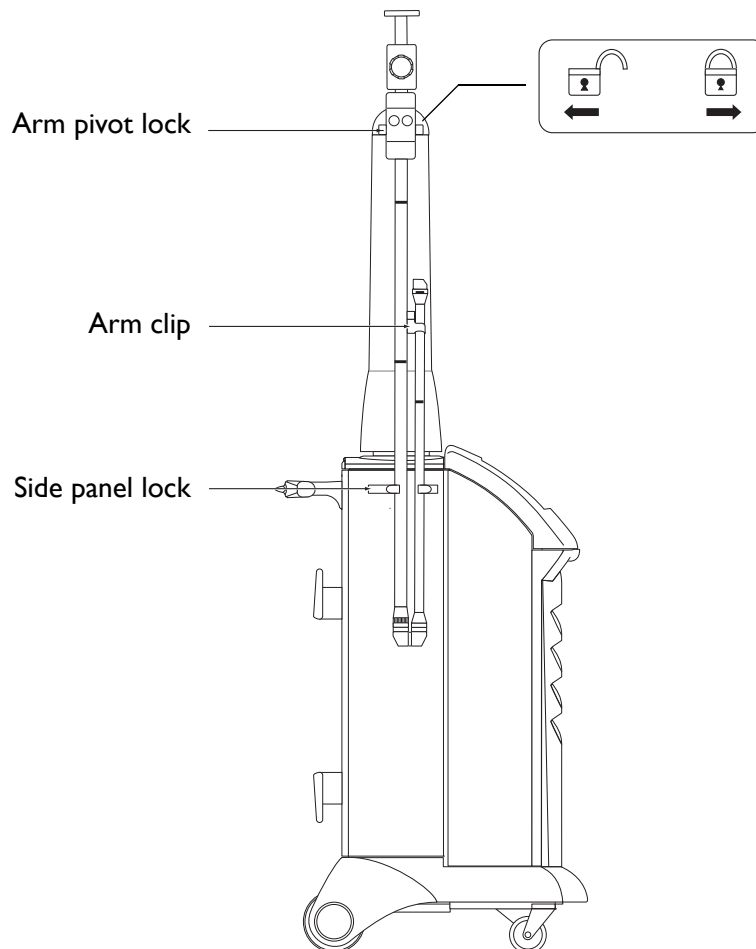
Inserting the External Door Interlock Plug

Releasing and Orienting the Articulated Arm


⚠ CAUTION - The articulated arm is a precision component; carefully handle and position the arm. An improperly oriented 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. Two latches secure the arm in the compartment.

- 1 Slide the arm pivot lock to the  (unlocked) position.
- 2 Turn the latch on the side panel lock to the vertical position, and carefully swing the articulated arm up and out of the storage compartment.



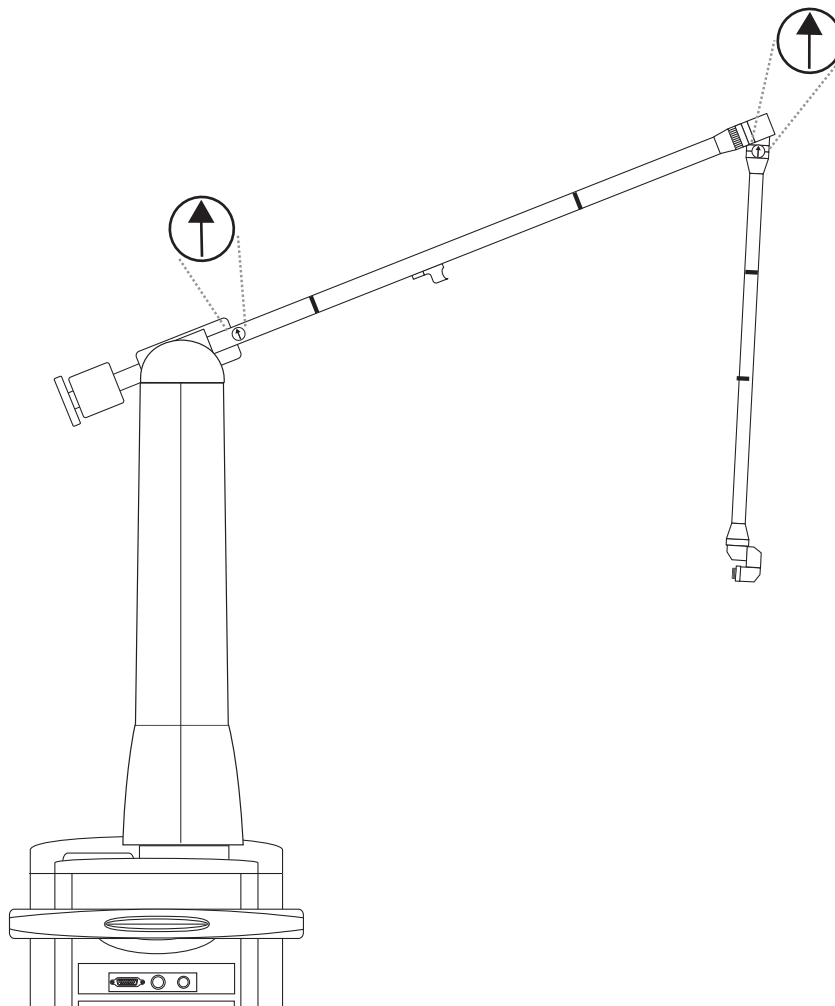
Releasing the Articulated Arm

- 3 Release the lower part of the articulated arm from the arm clip, and unfold the arm toward you. As you unfold, ensure that the  labels on the articulated arm point toward the ceiling.



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.

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



Orienting the Articulated Arm

Connecting the Delivery Device

After unfolding the articulated arm, connect the appropriate delivery device as instructed in your delivery device operator manual. Some devices attach directly to the articulated arm, while some require adapters or couplers. Refer to the UltraPulse Delivery Device Connection Diagram on the following pages for an illustrated overview of delivery device connections.

If using the UltraPulse SurgiTouch Scanner, connect the scanner to the articulated arm as shown, then connect the appropriate delivery device to the scanner. If using a delivery device with a smoke evacuation tip, connect the smoke evacuator as instructed in your delivery device operator manual.

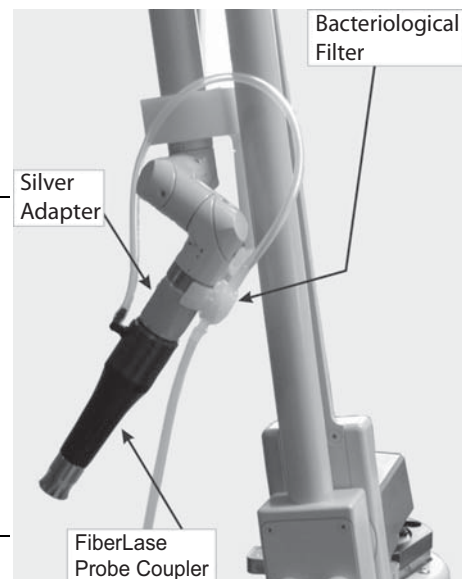
If using the Nasal or Laryngeal Probes, connect the external Purge Air Compressor to the FiberLase Probe Coupler as follows:

- 1 Situate the compressor on a stable surface, in close proximity to the base of the articulated arm.
- 2 Connect one end of the power cable to the compressor's power cable receptacle and the other end to a normal electrical outlet.
- 3 Unpack the air tube with the bacteriological filter and connect one end of the tube to the spigot on the compressor labeled **Air Outlet**.
- 4 Ensure that the Silver UltraPulse Thread Adapter and the FiberLase Probe Coupler are attached to the articulated arm's endjoint.
- 5 Attach the bacteriological filter's clamp to the silver thread adapter.
- 6 Connect the free end of the air tube to the FiberLase Probe Coupler's intake nipple.

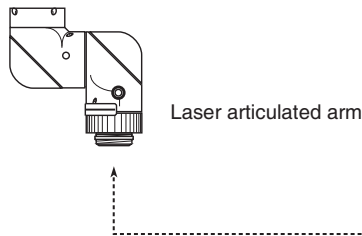
If using the Multi-Application (Oral Pharyngeal) OtoScan, AcuBlade or 712 Acuspot delivery devices, connect the free end of the air tube to the appropriate purge air port on the delivery device.

⚠ 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.

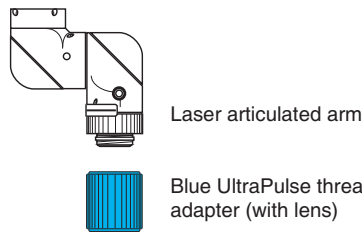
⚠ WARNING - Carefully inspect any delivery system sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system.



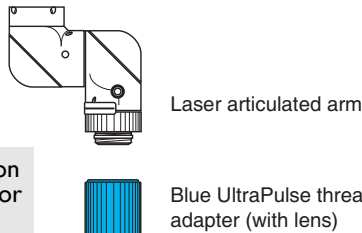
UltraPulse Delivery Device Connection Diagram



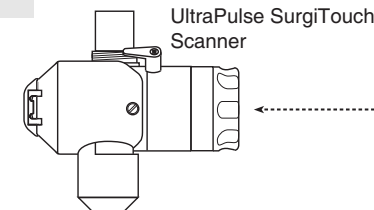
- 0.2mm Focused Incisional Handpiece
- 1.0mm Focused Incisional Handpiece
- ClearSpot 160 Micromanipulator
(in UltraPulse or CW mode only)
- ClearSpot 350 Micromanipulator
- UltraScan Encore CPG*
(Computer Pattern Generator)
- Nezhat Laparoscopic Coupler
- Second Puncture Laparoscopic Coupler
- Variable Spot Laparoscopic Coupler
- TrueSpot 2.0mm Collimated Handpiece
- UltraFlex Waveguide



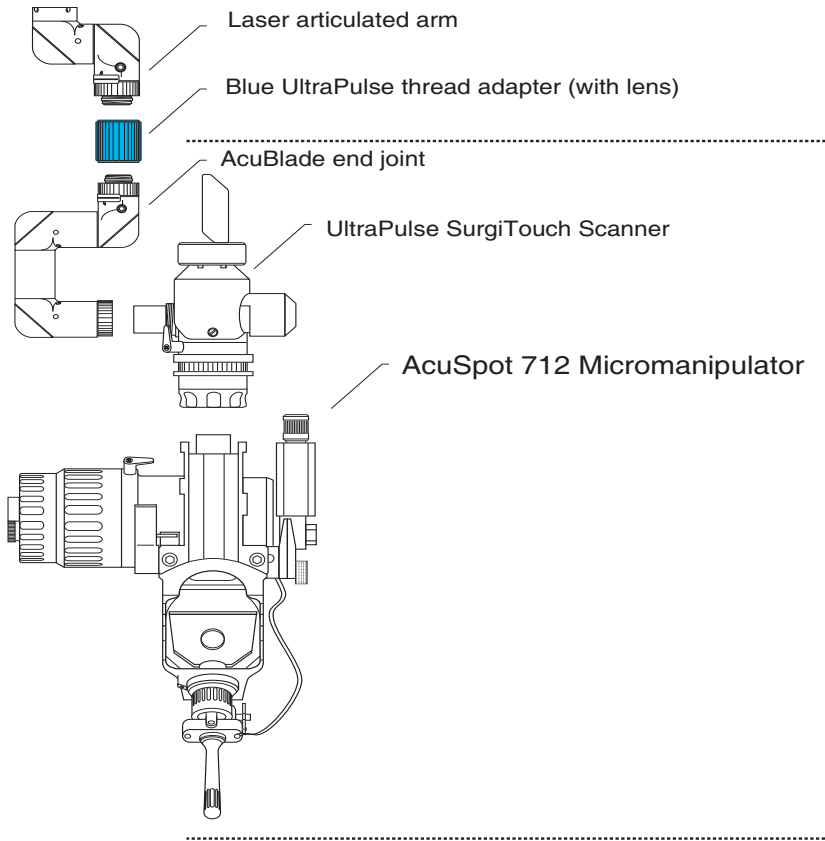
- Bronchoscope 781
- MicroSlad 715, 717, 718, 719 Micromanipulators
- AcuSpot 712 Micromanipulator
- Multi-Application (Oral Pharyngeal) Variable Spot Handpiece
- BeamAlign Laparoscopic Direct Coupler
- Single Puncture Laparoscopic Coupler
- Second Puncture Laparoscopic Coupler



This configuration is only suitable for the UltraPulse SurgiTouch laser model.

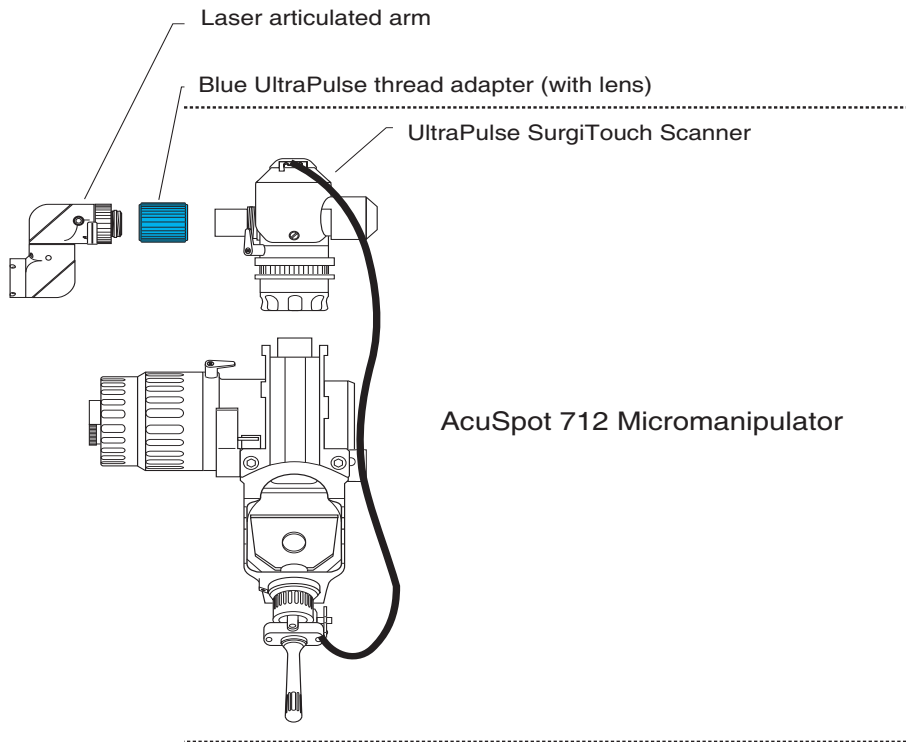


- OtoScan Ear Aeration Delivery System 15300
- Bronchoscope 781
- MicroSlad 715, 717, 718, 719 Micromanipulators
- AcuSpot 712 Micromanipulator
- Multi-Application (Oral Pharyngeal) Variable Spot Handpiece
- Single Puncture Laparoscopic Coupler
- Second Puncture Laparoscopic Coupler

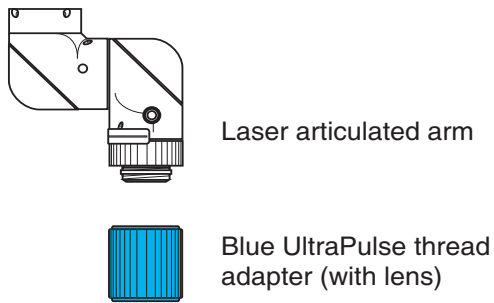
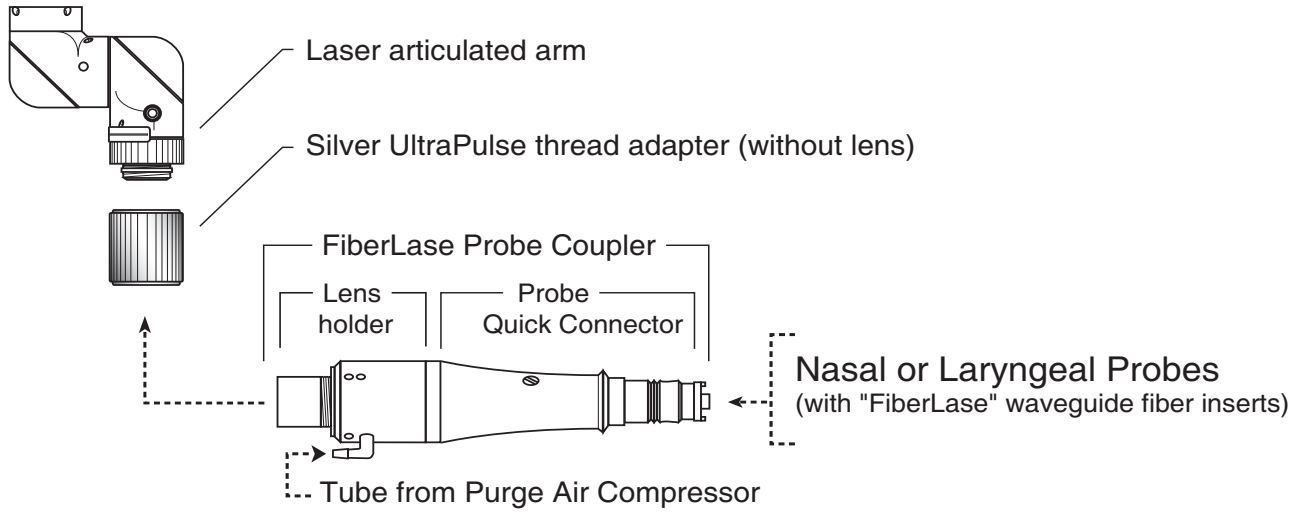


This configuration is only suitable for the UltraPulse SurgiTouch laser model.

AcuBlade™
Microsurgery
System

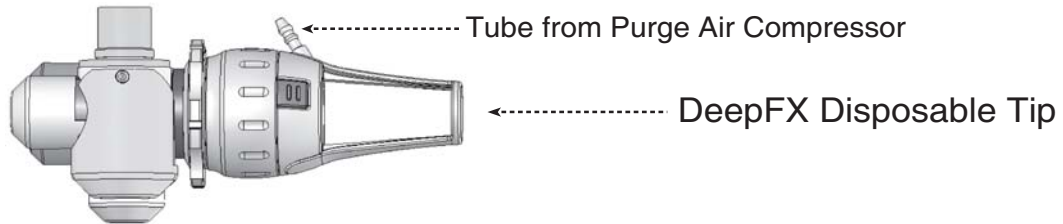


Digital AcuBlade™
Microsurgery
System



DeepFX Microscanner

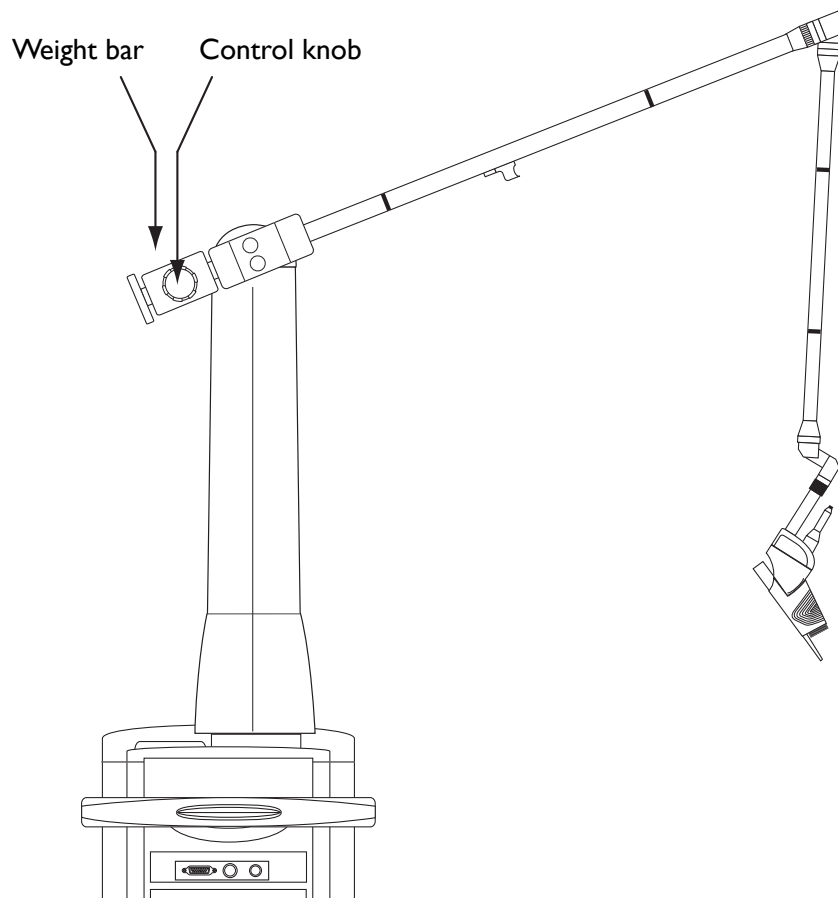
This configuration is only suitable for the UltraPulse SurgiTouch laser model.



Balancing the Articulated Arm

After connecting the delivery device, balance the articulated arm by adjusting 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.




Adjusting the Weight Bar

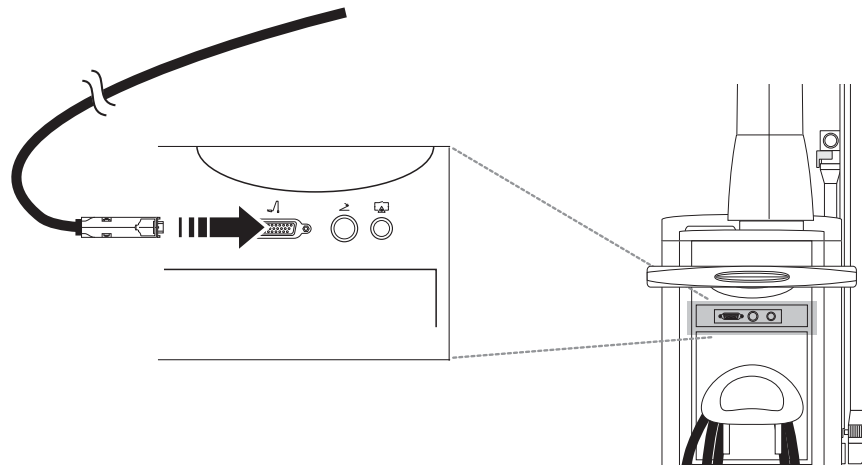
Connecting the Scanner Communication Cable

(for the UltraPulse SurgiTouch Scanner and the UltraScan Encore CPG)

▶ Verify that the laser keyswitch is in the  (off) position before connecting the scanner communication cable to the laser.

The UltraPulse SurgiTouch Scanner and the UltraScan Encore CPG scanning devices are controlled by laser system software. The communication cable provides constant communication between the laser and the scanning device. To connect the scanner communication cable:

- 1 Insert the communication cable plug into the  (communication cable) receptacle on the laser console.



Connecting the Scanner Communication Cable to the Laser Console

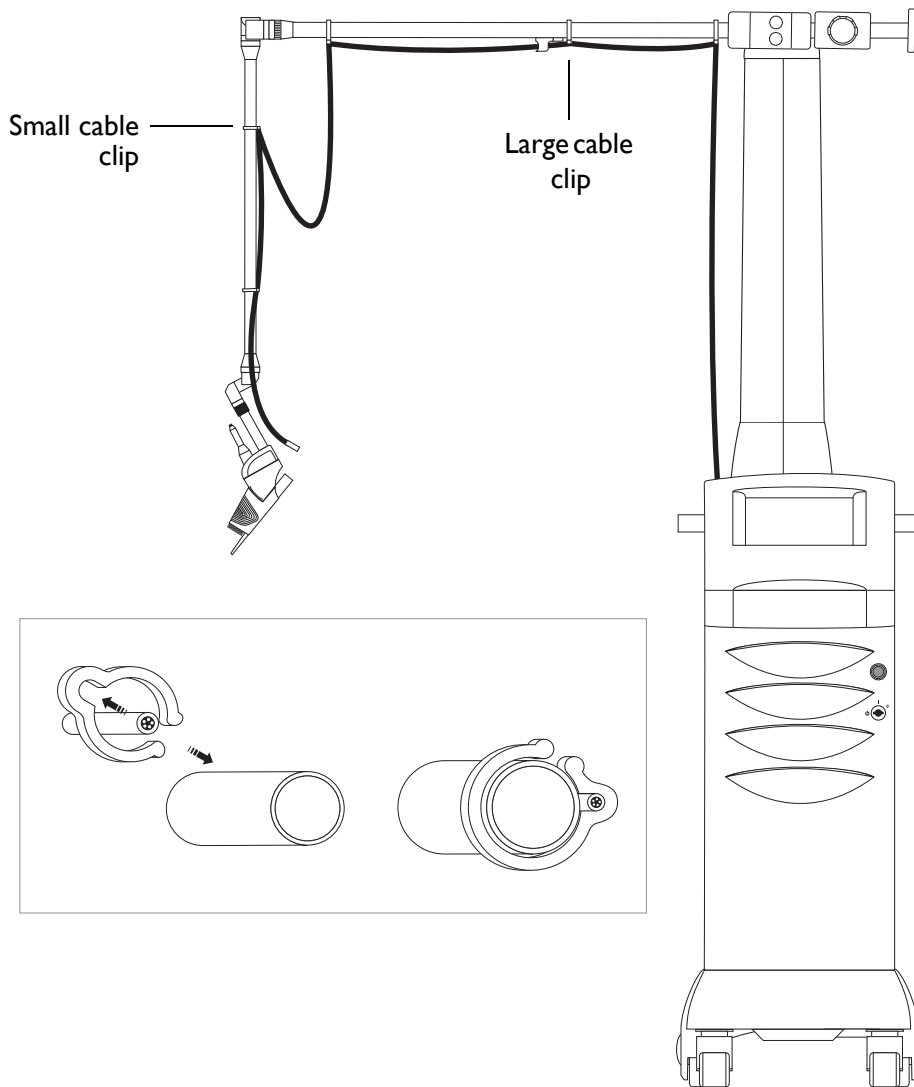


WARNING - Never connect or disconnect the scanner cable (CPG or SurgiTouch) while the laser system is turned on without pausing the scanner mode - refer to page 49.

- 2 Secure the communication cable along the length of the articulated arm with the appropriately sized cable clips, as shown.

▶ 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.


- 3 Insert the communication cable plug into the cable receptacle on the scanning device.

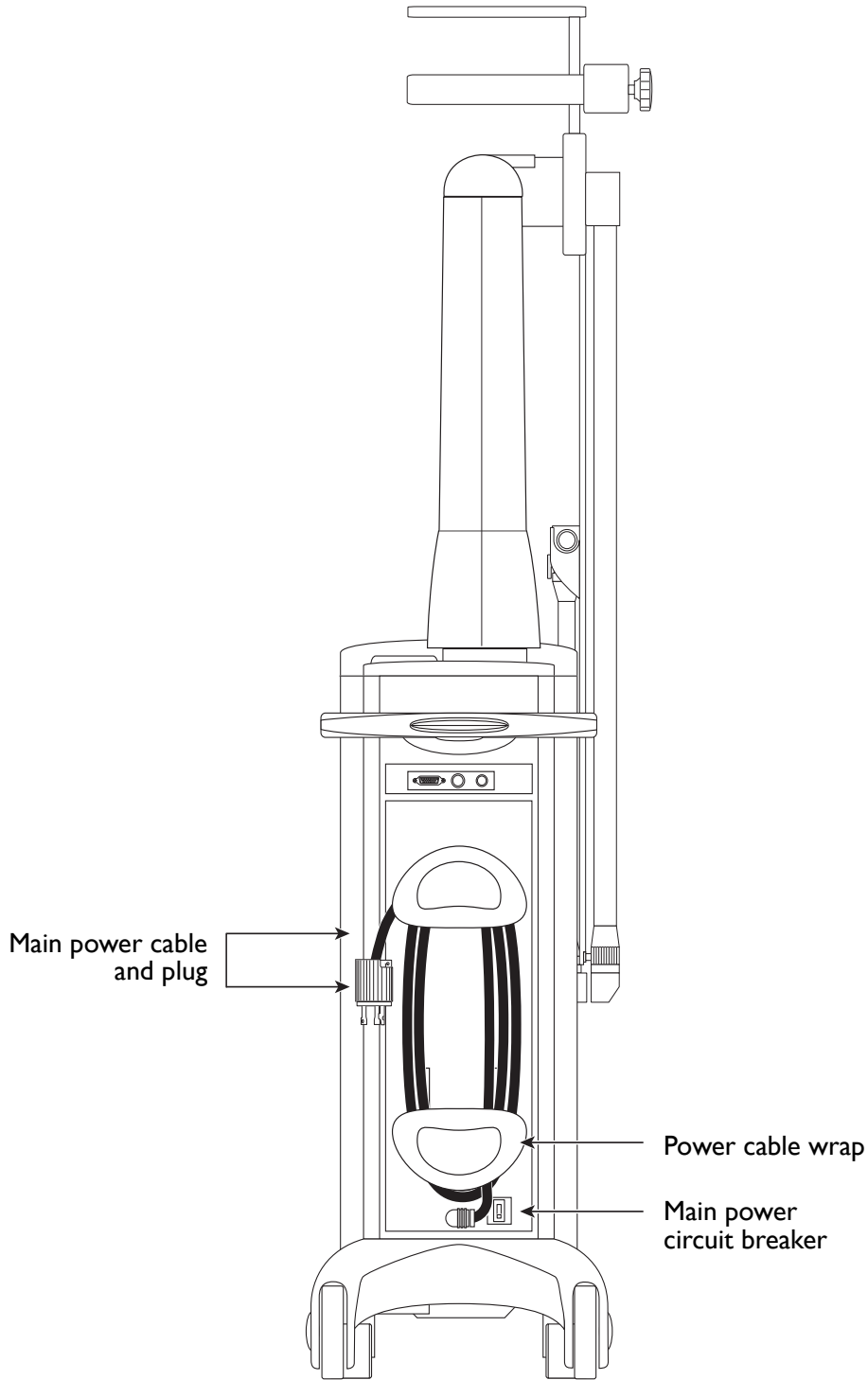


Securing the Communication Cable to the Articulated Arm

Connecting the Main Power Cable

(for UltraPulse systems with a removable wall plug)

- 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.



Connecting the main Power Cable

Laser Console Basics

Turning On the Laser

- 1 Place the laser main power circuit breaker in the on (up) position.
- 2 Insert the key into the keyswitch, and rotate the key to the **||** (start) position; hold for one full second, and release the key. Upon release, the key automatically springs back to the **|** (on) position.

The start-up screen appears, and the laser begins a self-test and warm-up. When the self-test is successfully completed, the system beeps and the self-test message disappears. The control screen appears, and the laser goes into standby mode.



WARNING - Do not touch the control screen during system self-test. Touching the screen during system self-test may interfere with the system's response to those controls, resulting in incorrect power levels.



Do not depress the footswitch during system turn-on or self-test. Depressing the footswitch during system turn-on or self-test will disable the footswitch.

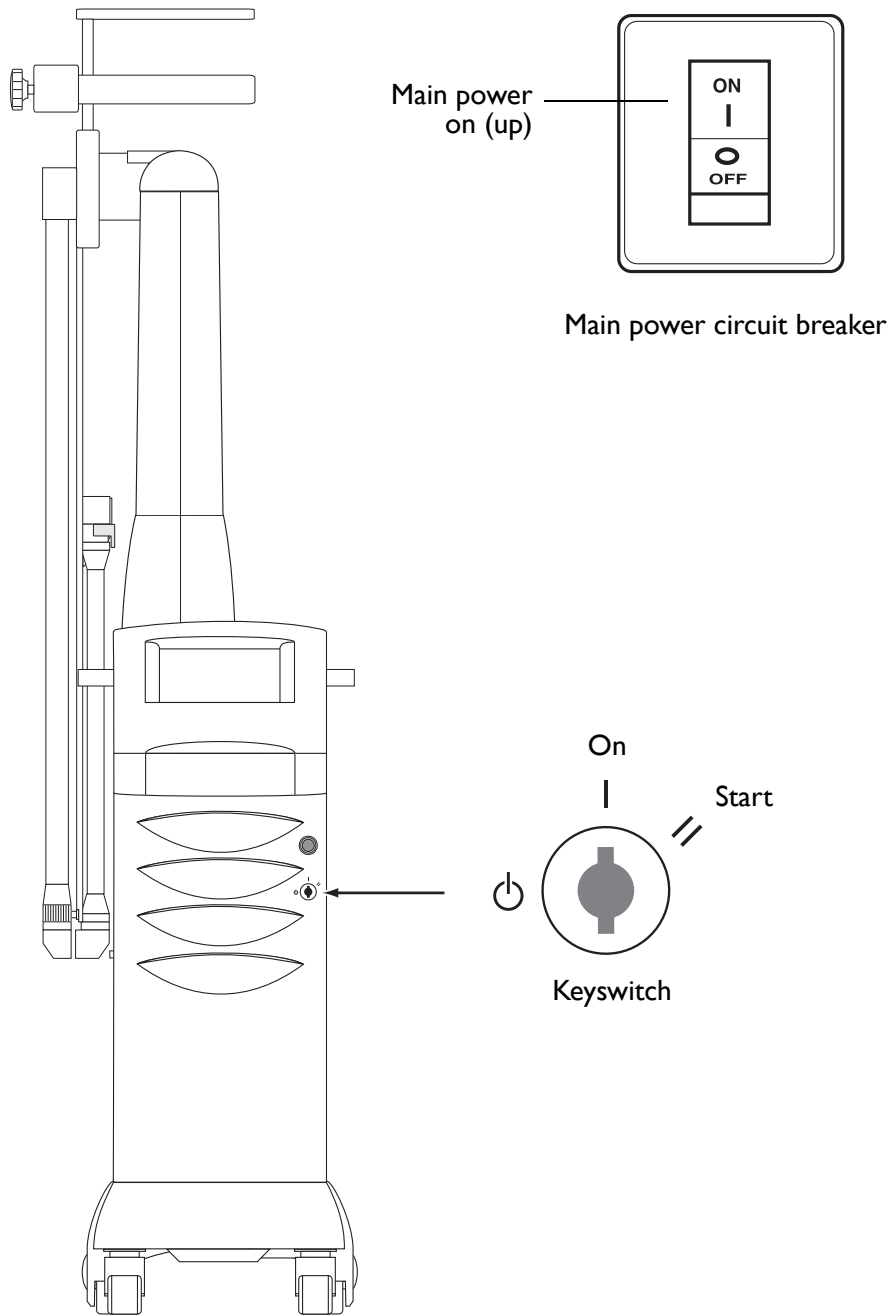


If any fault conditions, advisory messages, or error codes appear in the message display during the self-test, refer to the Troubleshooting Guide in the Maintenance section of this manual. Record error codes in case service is required.

Restarting the Laser

In most cases you will not need to restart the laser. If a condition occurs that requires you to restart the laser:

- 1 Turn the keyswitch to the **⊖** (off) position.
- 2 Wait five seconds before turning the keyswitch to the **||** (start) position. Release the key. The system goes through the standard start-up sequence.



Controls for Turning On and Restarting the Laser


Laser Beam Alignment Check

Perform the beam alignment check as described in your delivery system operator manual or Quick Reference Guide.



WARNING - Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.


Turning Off the Laser

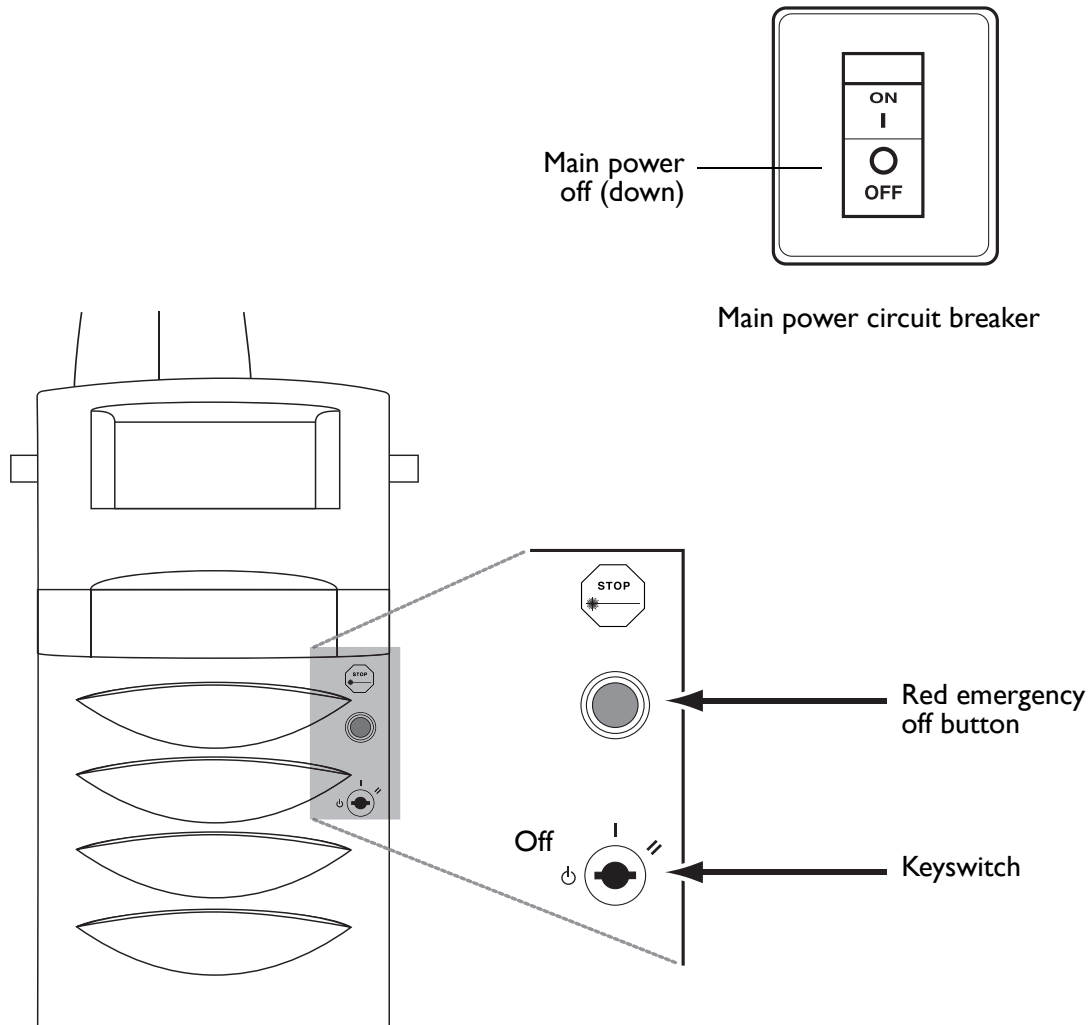
Under normal operating conditions, turn the keyswitch to the  (off) position.



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 (down) position and turn off the main electrical service (wall circuit breaker).

Emergency Off


In an emergency, press the red  (emergency off) button to immediately turn off the laser.



Controls for Turning Off the Laser

Disconnecting the Laser

(for UltraPulse systems with a removable wall plug)

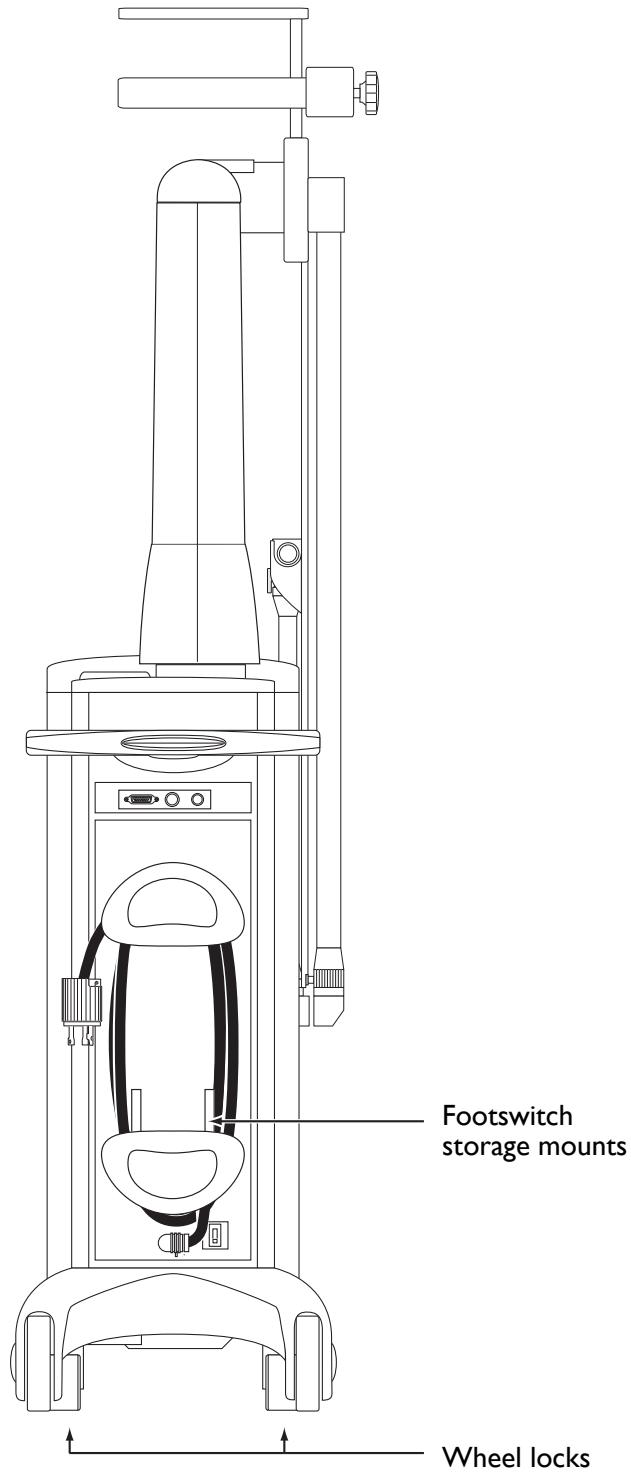
- 1 Turn the keyswitch to the  (off) position.
- 2 Place the laser main power circuit breaker in the off (down) position.
- 3 Remove the power plug from the electrical outlet and wrap the power cable around the cable wrap.
- 4 Place the footswitch on the footswitch storage mounts on the rear of the laser console. Coil the footswitch cable and store it inside the footswitch housing. Do not wrap the footswitch cable around the power cable wrap.
- 5 Disconnect any delivery systems, including all adapters and couplers, and unplug all cables from the articulated arm and laser console.
- 6 Place the red protective cap securely onto the end of the articulated arm.
- 7 Fold and store the articulated arm in the articulated arm storage compartment.

Moving the Laser Console



CAUTION - Never use the articulated arm to move the laser. Moving the laser with the articulated arm may irreparably damage the articulated arm.

- 1 Disconnect the laser.
- 2 Unlock the laser console wheels by pulling up on the wheel locks.
- 3 Using the laser console handle, move the laser 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.
- 4 Lock the laser console wheels by stepping on the wheel locks.

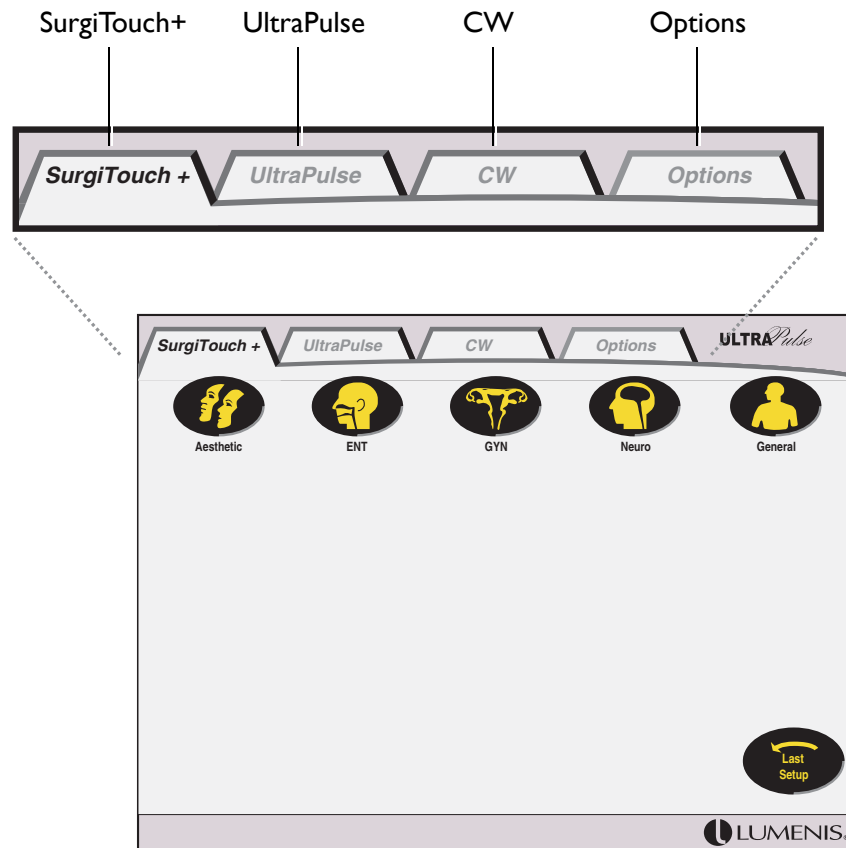


Moving the Laser Console

Control Screen Basics

Control Screen Tabs

The tabs at the top of the control screen allow you to select one of three treatment control screens: SurgiTouch+, UltraPulse, or CW (continuous wave). You can also select the Options screen, from which you can adjust system preferences. To select a screen, press the appropriate tab.



Control Screen Tabs

Overview of Operating Modes and Treatment Screens

The UltraPulse laser has three treatment control screens, allowing you to operate using the SurgiTouch+ interface, UltraPulse mode, or CW (continuous wave) mode. For detailed instructions on using the treatment control screens, refer to the SurgiTouch+, UltraPulse, and CW sections of this manual.

SurgiTouch+

The SurgiTouch+ interface allows you to select a specialty and application. The laser then automatically displays the recommended delivery device and default treatment settings. You do not need to specify UltraPulse or CW mode.



The UltraPulse SurgiTouch model includes the application-specific SurgiTouch+ interface. The UltraPulse Encore model is fully upgradeable to SurgiTouch; contact your local Lumenis representative for upgrade information.

UltraPulse

UltraPulse mode produces short-duration, high-energy pulses and is particularly useful for applications that require minimal thermal damage and layer-by-layer ablation, such as skin resurfacing.

UltraPulse mode incorporates dedicated operation modules for the following aesthetic specialties: PigmentFX, CO₂ Lite, ActiveFX Gentle, ActiveFX and MaxFX.

CW

CW mode produces a continuous laser beam and is useful for applications in which some thermal effect is desired, such as blepharoplasty.

Changing the Control Screen Mode: English or Icon

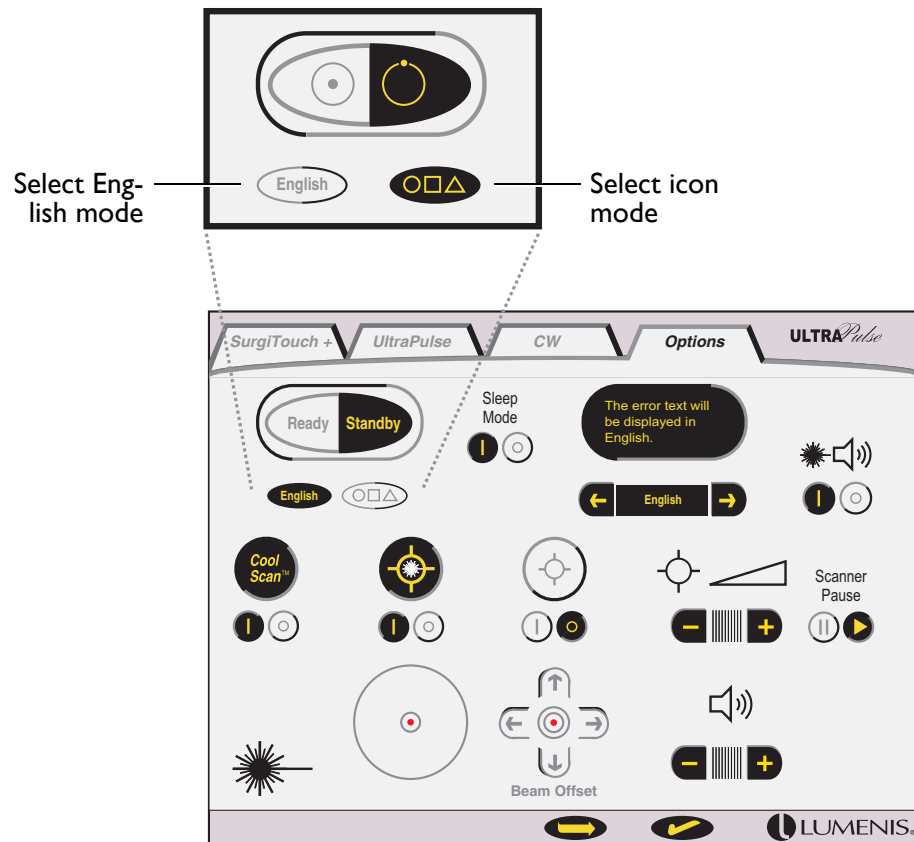
You can view the treatment screens in either English or icon mode. In English mode, the treatment setting buttons are labeled in English. In icon mode, the buttons are labeled using symbols.



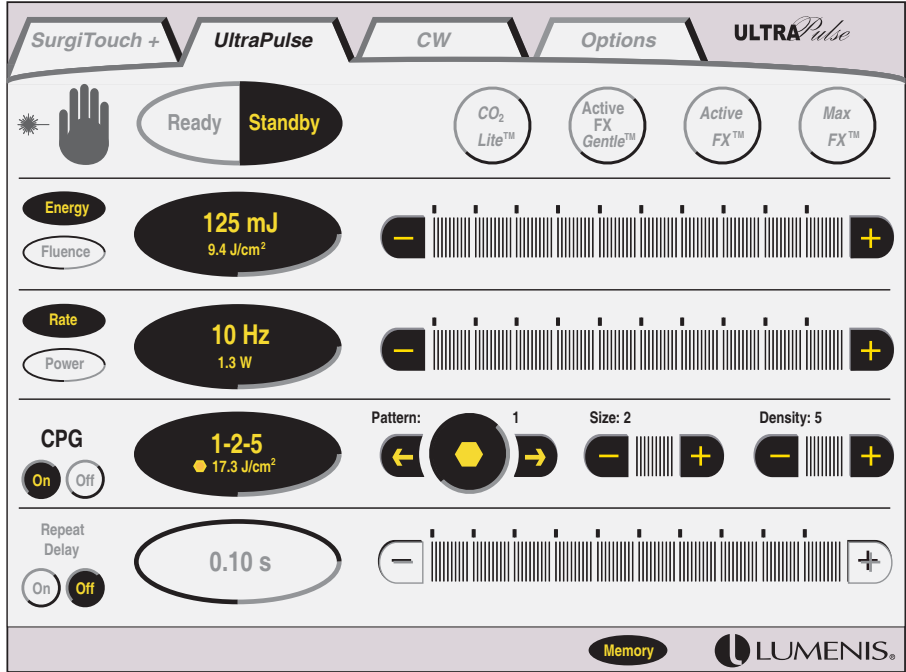
The SurgiTouch+ Specialty, Application, and Delivery Device buttons display English and icons simultaneously.

To change the control screen mode:

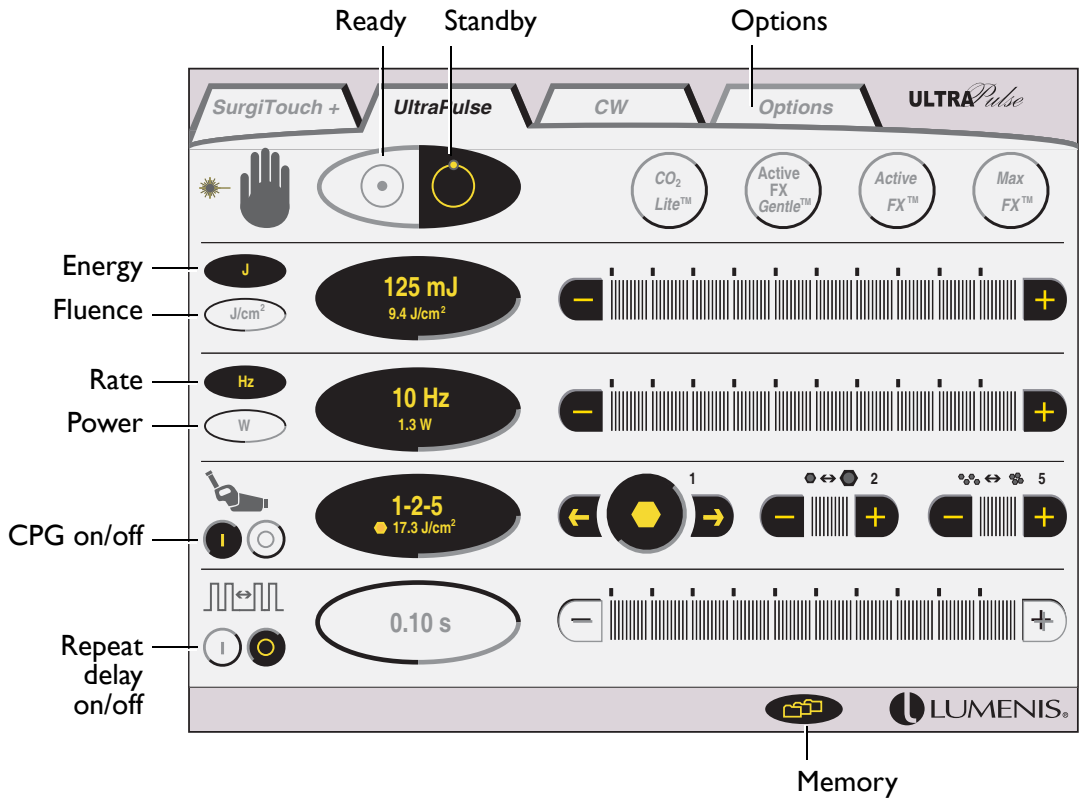
- 1 Press the **Options** tab to view the Options screen.
- 2 Press the **English** button to select English mode; press the **Icon** button to select icon mode.



Changing the Control Screen Mode





UltraPulse Treatment Screen—English Mode





UltraPulse Treatment Screen—Icon Mode

Laser Status: Ready or Standby


 **WARNING** - Except during actual treatment, the system must always be in standby mode. Maintaining the system in standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

 **WARNING** - Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in ready mode.


The laser status display at the upper left of each treatment screen shows the laser status: ready or standby. Press the  (ready) button to place the laser in ready mode; press the  (standby) button to place the laser in standby mode.

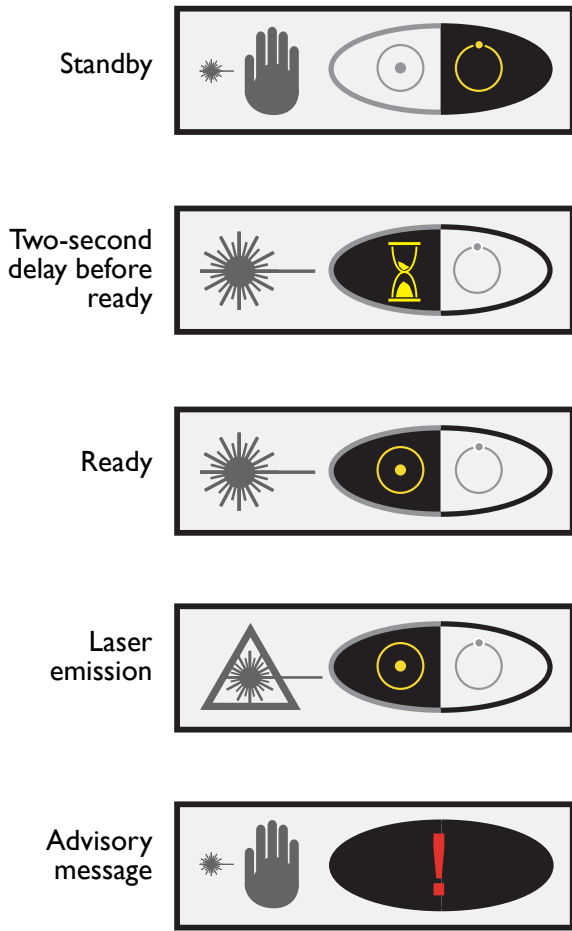
In standby mode, the footswitch is disabled and the safety shutter is closed; no treatment beam is available. At system startup, the laser automatically goes into standby mode.

When you select ready mode, the system emits a low-pitched tone to indicate the start of a two-second delay, and the hourglass icon appears in the laser status display. After two seconds, the system emits a high-pitched tone, and the ready icon appears in the laser status display. In ready mode, the footswitch is enabled and the treatment beam is available.

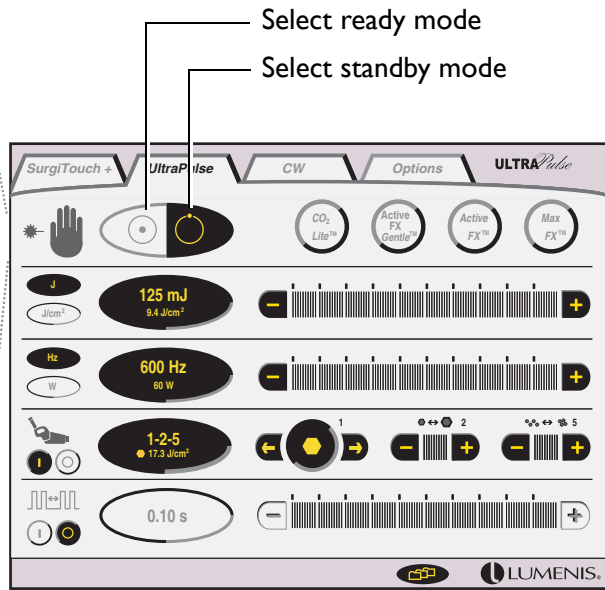
 If the laser system is not used for five minutes, it automatically defaults to **Standby** mode (see page 48).

The laser status display changes, as shown, to indicate the following conditions:

- The laser is in ready or standby mode.
- There is a two-second delay before ready.
- Laser emission  is occurring.
- An advisory message appears in the advisory text bar; you must read and acknowledge the message before you can place the laser in ready mode.







Laser status display

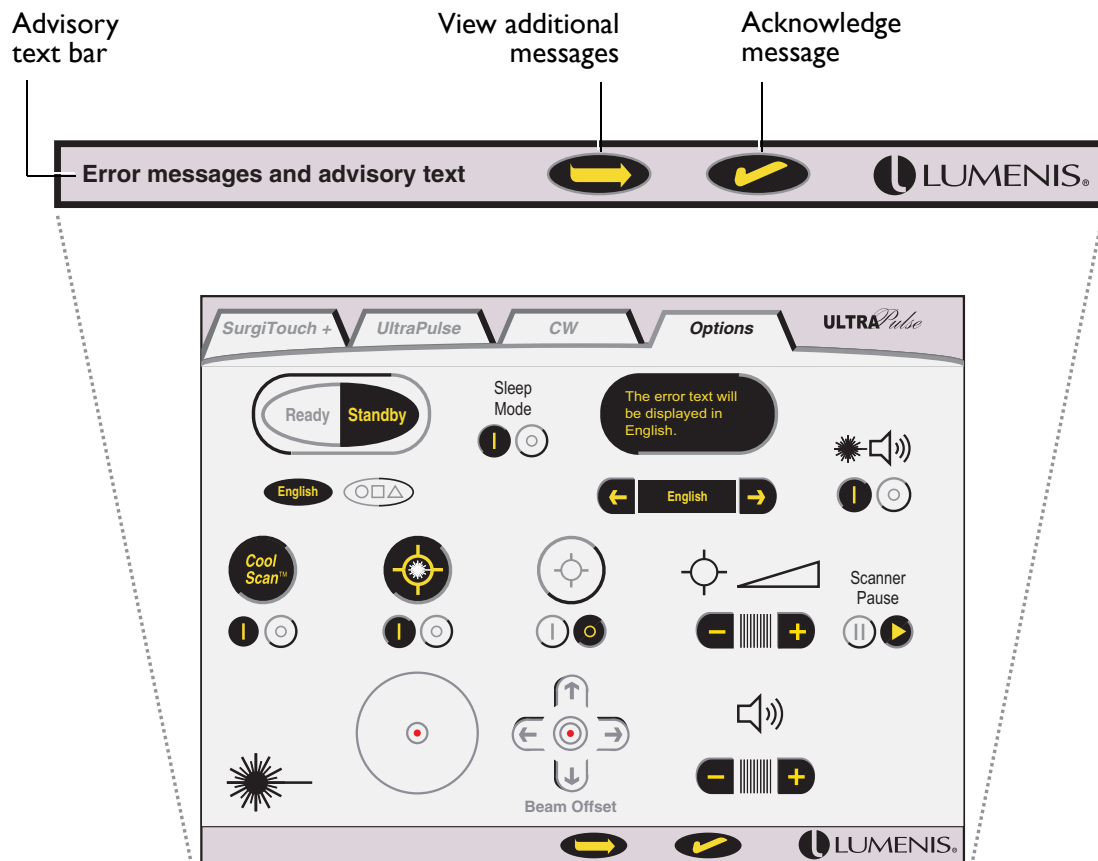


Laser Status

Advisory Messages

Advisory and system error messages appear in the advisory text bar at the bottom of the control screen. Two buttons display in the advisory text bar: the  button and the  button.

- 1 When the  button displays, press it to view additional messages.
- 2 Press the  button to acknowledge that you have read and understood the advisory message, and are ready to proceed.



Advisory Messages

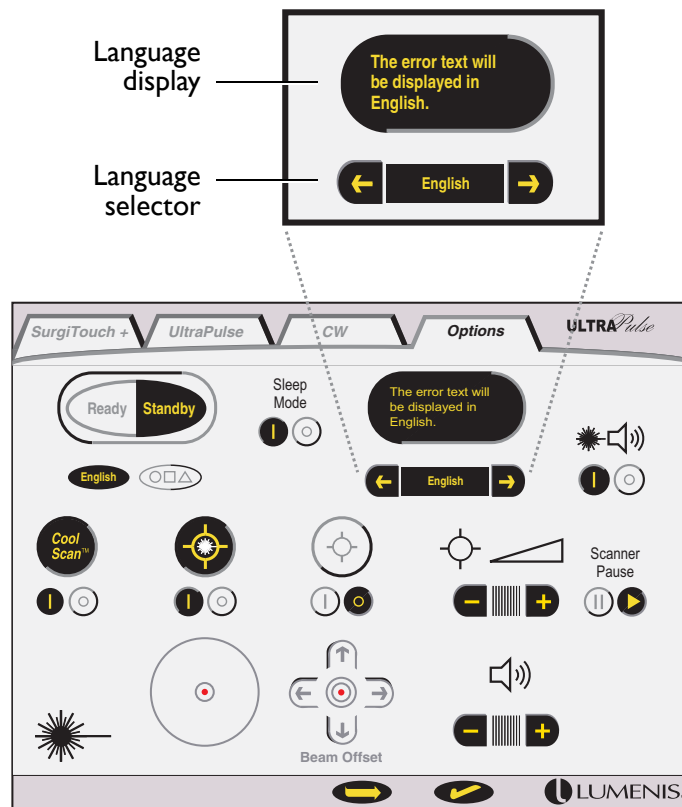
Selecting the Advisory Text Language

The messages that display in the advisory text bar can be displayed in any of the following languages:

- Danish
- Dutch
- English
- Finnish
- French
- German
- Greek
- Italian
- Portuguese
- Spanish
- Swedish

To select the advisory text language:

- 1 Press the **Options** tab to view the Options screen.
- 2 Press the ← and → buttons on the language selector to scroll through the available languages. The selected language appears in the language display.





Selecting the Advisory Text Language



Setting the Aiming Beam Characteristics

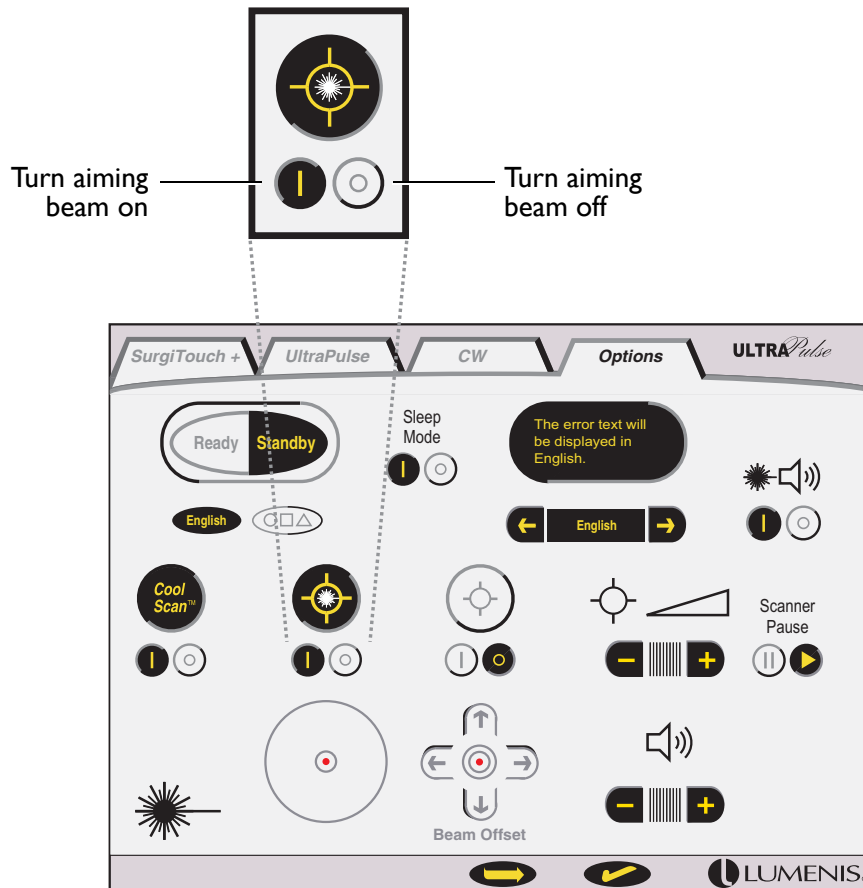
All aiming beam functions are controlled from the Options screen. Press the **Options** tab to view the Options screen.

Turning the Aiming Beam On or Off

During some procedures, especially in aesthetic and ENT applications, the aiming beam may obstruct the view of the treatment site while lasing. The aiming beam can be either on or off while lasing.

To turn on the aiming beam, press the  (on) button on the  (aiming beam on/off) control.



To turn off the aiming beam, press the  (off) button on the  (aiming beam on/off) control.





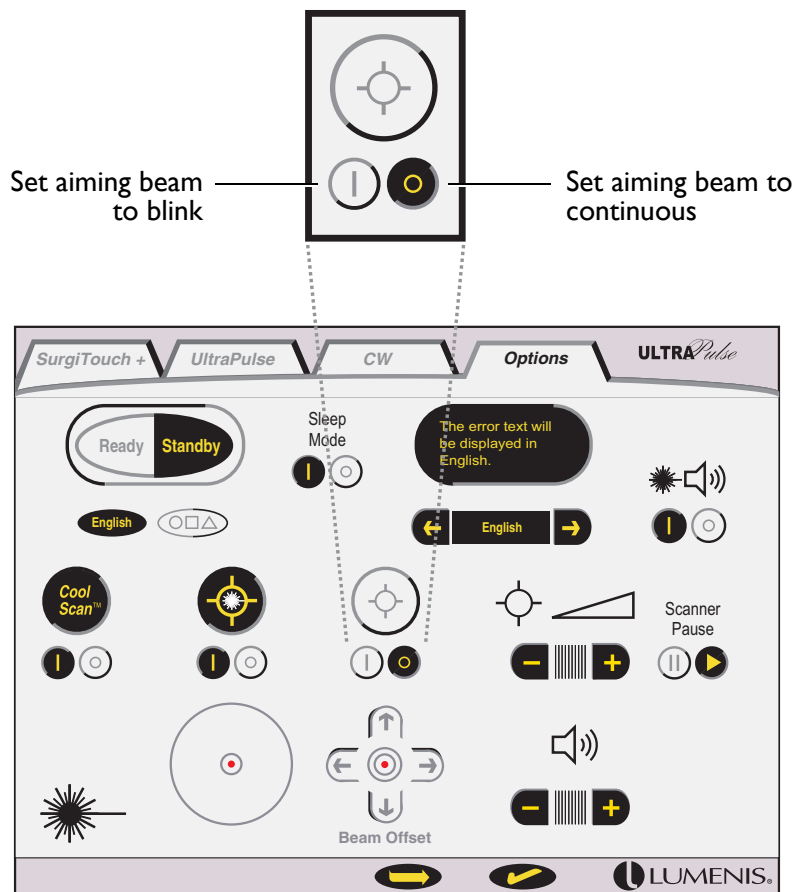
Turning the Aiming Beam On or Off

Selecting a Blinking or Continuous Aiming Beam

You can select a blinking or continuous aiming beam. When the blink option is on, the aiming beam pulses on and off. When the blink option is off, the aiming beam is continuous.


To set the aiming beam to blink, press the  (on) button on the  (blink) control.

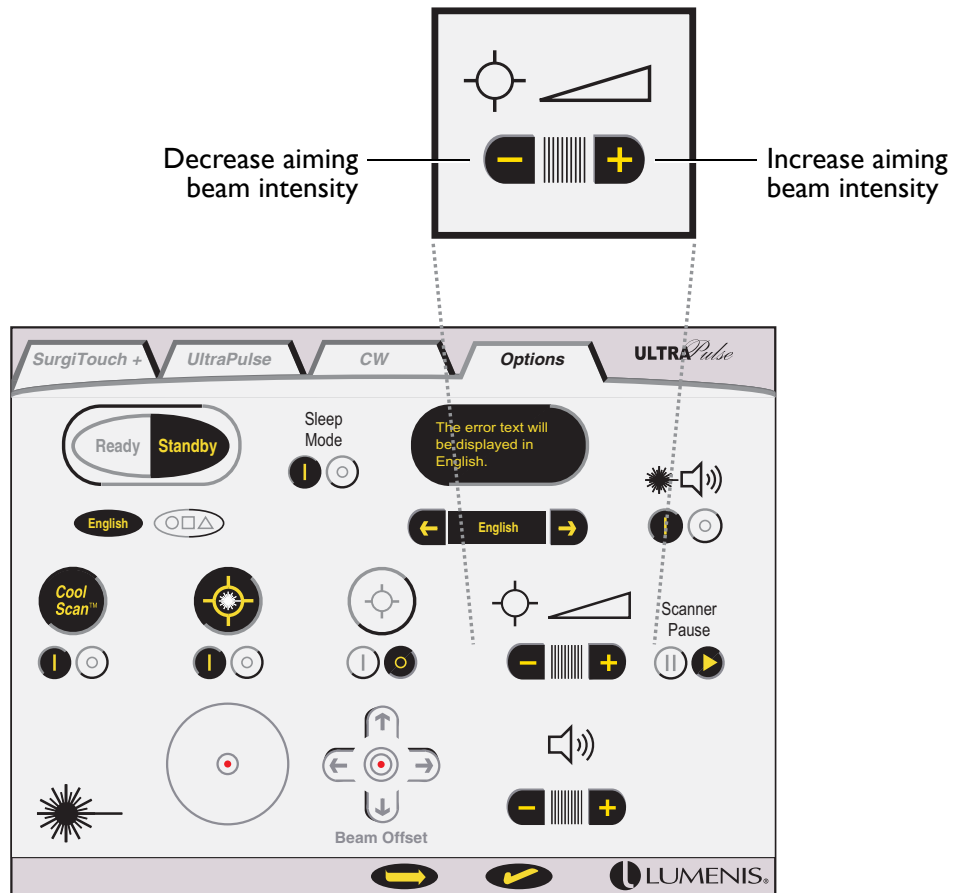
To set the aiming beam to continuous, press the  (off) button on the  (blink) control.



Selecting a Blinking or Continuous Aiming Beam

Adjusting the Aiming Beam Intensity


To adjust the aiming beam intensity, press the **-** and **+** buttons on the  (aiming beam intensity) control.

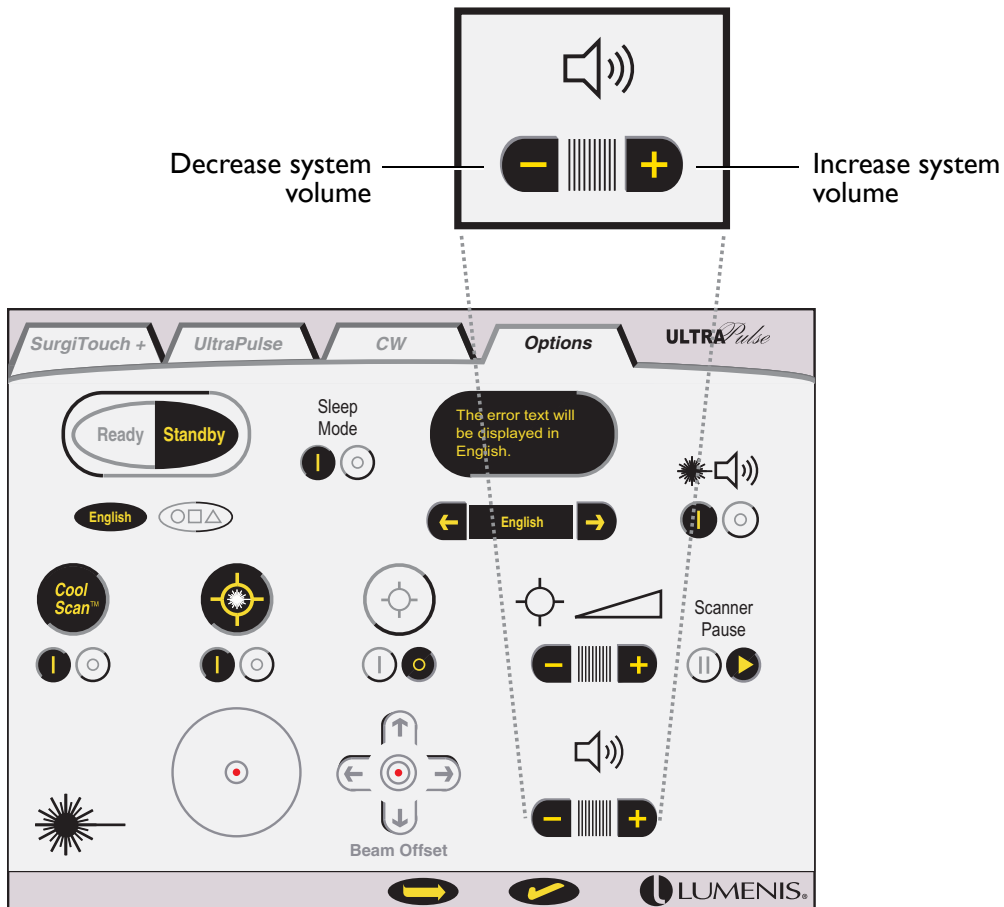


Adjusting the Aiming Beam Intensity

Adjusting the System Volume

The laser system emits a single tone with every control screen selection. The laser system emits a long, low tone when a minimum or maximum setting is reached or when an error has occurred.


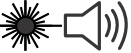


- 1 Press the **Option** tab to view the Options screen.
- 2 Press the **-** and **+** buttons on the  (volume) control.

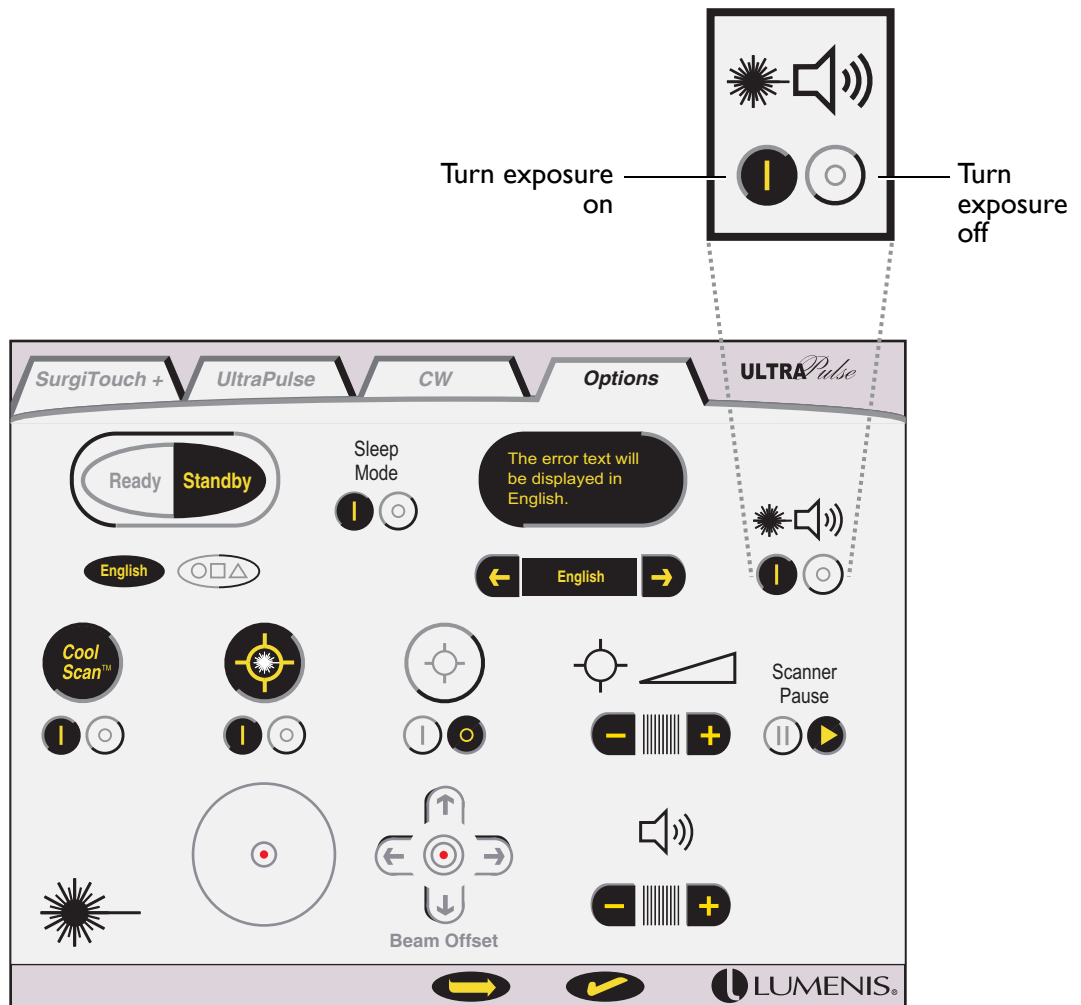


Adjusting the System Volume

Adjusting the Exposure ON / OFF

You can select an exposure tone during treatment. If the exposure tone is on, an audible tone is heard during treatment. If the exposure tone is off, no tone is heard during treatment.

- 1 To turn on the exposure tone, press the  (on) button on the  (exposure) control.
- 2 To turn off the exposure tone, press the  (off) button on the  (exposure) control.

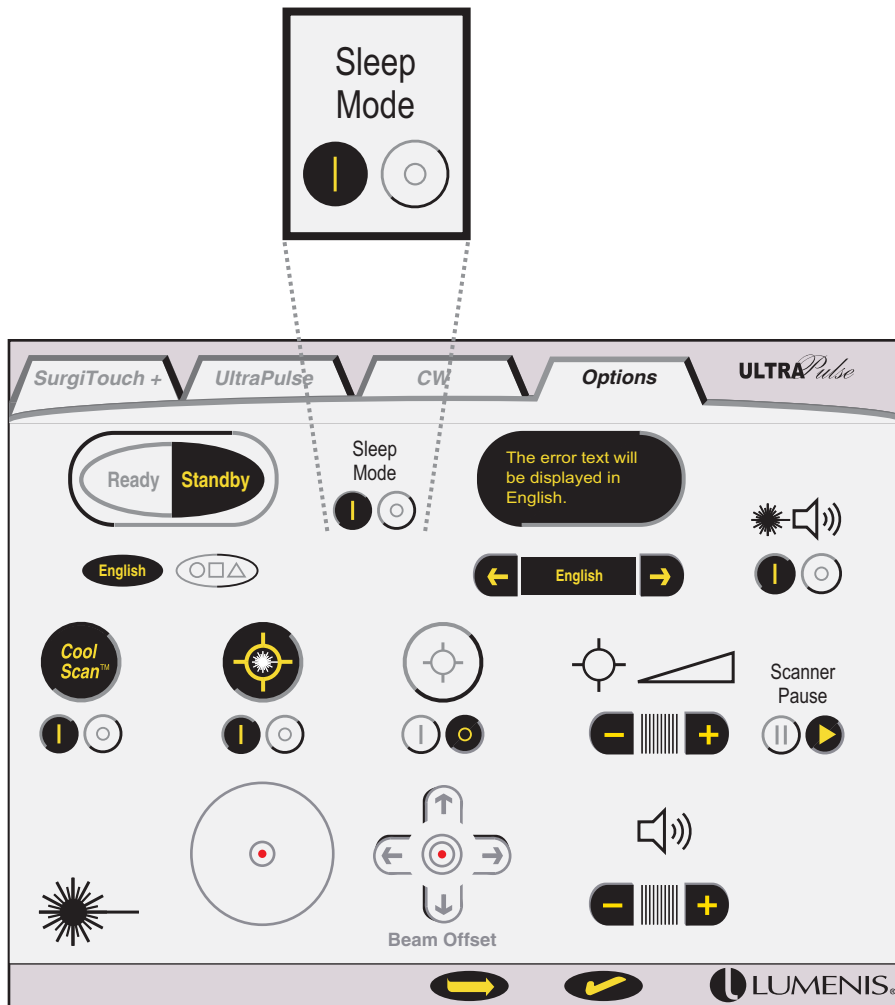


Adjusting the Exposure Tone

Sleep Mode

When **Sleep Mode** is configured to **On** (I), the UltraPulse system will automatically leave **Ready** mode and set itself to **Standby** after a 5-minute period of non-use. When configured to **Off** (O), the system will switch to **Standby** after two hours.



- 1 To configure **Sleep Mode** to **On**, press the (I) (on) button on the Options screen.
- 2 To configure **Sleep Mode** to **Off**, press the (O) (off) button on the Options screen.

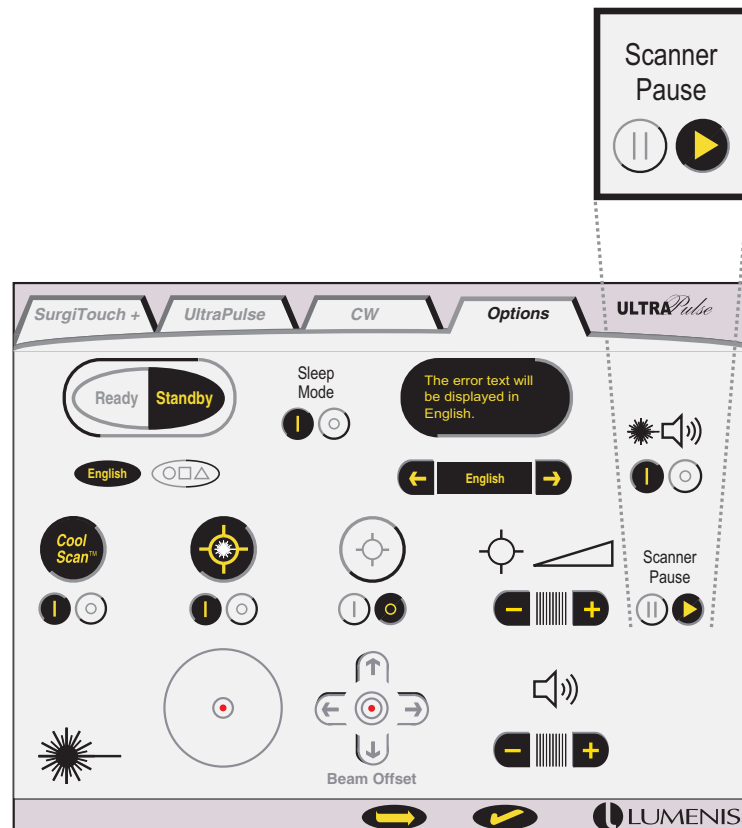


Configuring Sleep Mode On / Off

Replacing the Scanner (Scanner Pause)

Before replacing any scanning accessory at the endjoint of the articulated arm (DeepFX, Encore CPG, etc.), the scanner software module needs to be paused in order to prevent possible damage to the system.

- 1 Pause the scanner software module by pressing the  (pause) button on the Options screen.
- 2 Disconnect the communication cable from the scanning accessory and disconnect the accessory from the articulated arm.
- 3 Connect the desired scanning accessory to the articulated arm, and connect the communication cable to the accessory.
- 4 To restart the scanner software module after you have connected the new scanning accessory to the endjoint, press the  (restart) button on the Options screen.



Scanner Pause



Saving and Retrieving Treatment Settings

Default treatment settings are active upon startup. Although default settings cannot be changed, you can use the memory function to save and retrieve your own frequently-used treatment settings.



For each treatment screen, the UltraPulse laser has three memory locations: 1, 2, and 3. Treatment settings that you store in these memory locations are saved even when the laser is turned off and restarted.

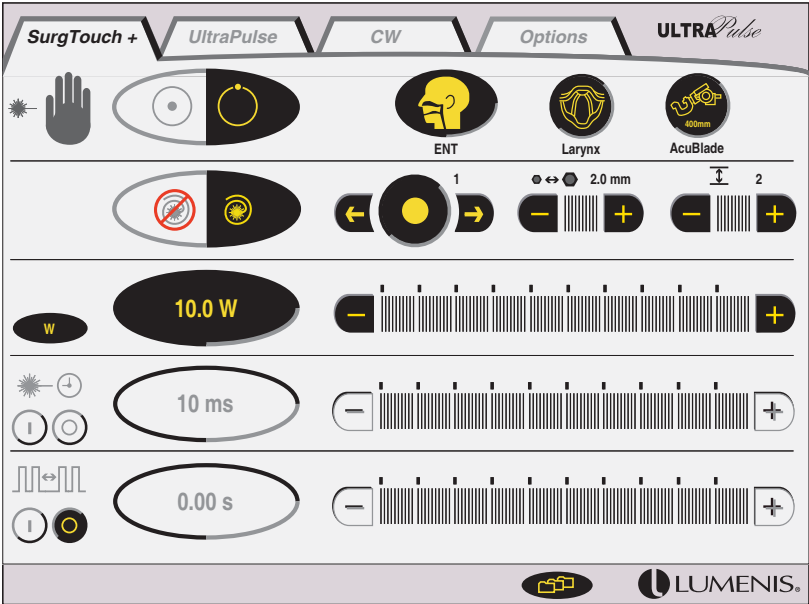
The three memory locations apply to the active treatment screen. In SurgiTouch+, there are three memory locations for each delivery device within an application and specialty.

To save treatment settings:

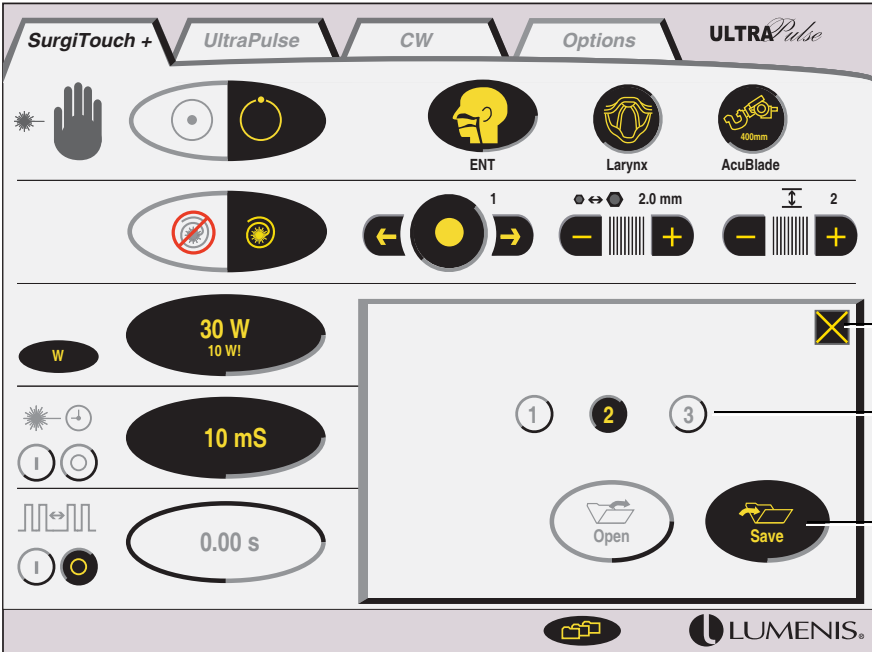
- 1 On the appropriate treatment screen, set the treatment values that you would like to save.
- 2 Press the  (memory) button at the lower right of the treatment screen. A pop-up memory window appears.
- 3 Press the  (save) button in the memory window, then press the desired memory location 1, 2, or 3, until the system emits a tone.

The selected button highlights to indicate the location where your settings have been saved.

- 4 Press the  at the upper right corner of the memory window to close the window and return to the active treatment screen.
- 5 The system automatically defaults to standby mode whenever you use the memory function. Press the  (ready) button on the laser status bar to enable the footswitch.



Open memory window



Close memory window

Memory locations


Save treatment settings

Saving Treatment Settings

To retrieve treatment settings:


- 1 Select the appropriate treatment screen: SurgiTouch+, UltraPulse, or CW.

In SurgiTouch+, you must select the specialty, application, and delivery device for which to retrieve treatment settings. Refer to the SurgiTouch+ section of this manual for detailed instructions on using SurgiTouch+.


- 2 Press the  (memory) button at the lower right of the treatment screen. A pop-up memory window appears.




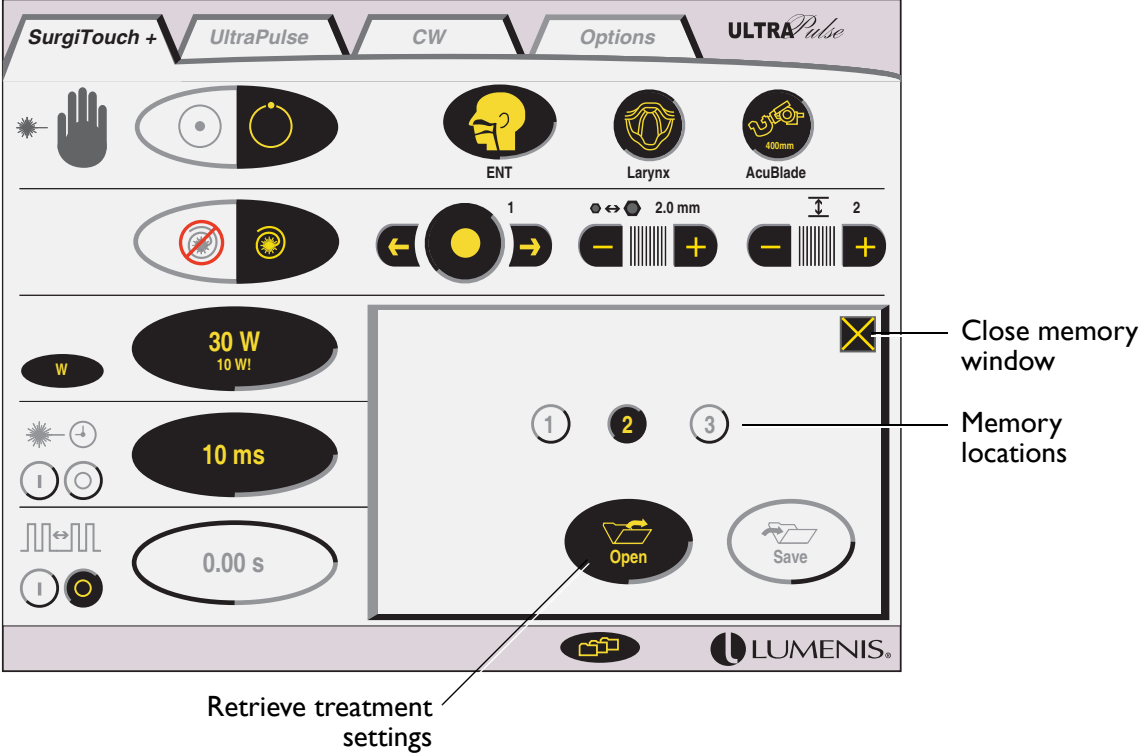
The numbered buttons represent the memory locations for the active treatment screen. In SurgiTouch+, the memory locations apply to the selected delivery device within an application and specialty.

- 3 Press the  (open) button in the memory window, then press the desired memory location 1, 2, or 3, until the system emits a short tone.

The selected button highlights to indicate the active memory location.

- 4 Press the  at the upper right corner of the memory window to close the window and return to the active treatment screen.


- 5 The system automatically defaults to standby mode whenever you use the memory function. Press the  (ready) button on the laser status bar to enable the footswitch.



Retrieving Treatment Settings

UltraScan Encore CPG functions

CPG On/Off

The CPG controls displays on the UltraPulse treatment screen when the UltraScan Encore CPG handpiece is attached. Pressing the CPG  (on) button on activates the CPG controls. For detailed instructions on using the CPG controls, refer to the UltraScan Encore CPG operator manual.

CoolScan Button

The CoolScan button displays on the Options screen when the UltraScan Encore CPG handpiece is attached. CoolScan is a non-linear scanning mode that is only available with the UltraScan CPG. For detailed instructions on using CoolScan mode, refer to the UltraScan Encore CPG operator manual.

PigmentFX Button

PigmentFX mode is used with the UltraScan CPG handpiece to deliver very low sub-ablative energy for use on dyschromia. These low energies induce zero to very-low downtime, but may require multiple treatments. PigmentFX mode is available only when the CPG is connected to the UltraPulse laser

CO₂ Lite Button

The CO₂ Lite button displays on the UltraPulse treatment screen when the UltraScan Encore CPG handpiece is attached. CO₂ Lite mode is used with the UltraScan CPG handpiece to perform light skin resurfacing. For detailed instructions on using CO₂ Lite mode, refer to the UltraScan Encore CPG operator manual.

ActiveFX Gentle Button

ActiveFX Gentle mode is used with the CPG handpiece for darker skin and off-face areas. ActiveFX Gentle mode is available only when the CPG is connected to the UltraPulse laser.

ActiveFX Button

ActiveFX mode is used with the CPG handpiece for moderate effects on tone, texture and wrinkle reduction with low downtime. ActiveFX mode is available only when the CPG is connected to the UltraPulse laser.

MaxFX Button

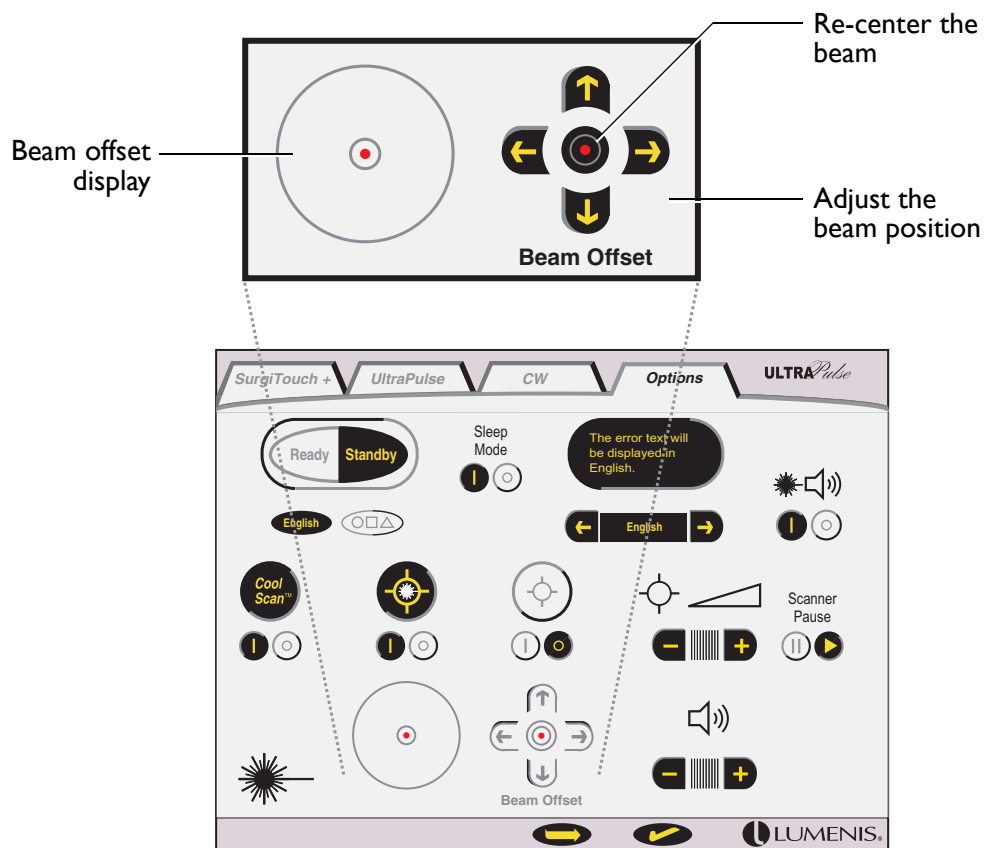
MaxFX mode is used with the CPG handpiece for traditional resurfacing with aggressive removal of wrinkles, dyschromia, acne scars, and skin wrinkle reduction. MaxFX mode is available only when the CPG is connected to the UltraPulse laser.

Beam Offset

The beam offset controls display on the Options screen when the UltraPulse SurgiTouch Scanner is attached to the laser. Beam offset is a fine-tuning adjustment for centering the laser beam in the exit aperture of some narrow-diameter delivery devices that are used with the UltraPulse SurgiTouch Scanner, such as the OtoScan Ear Aeration Delivery System.

The beam position is shown by the red circle in the beam offset display. Press the **↑** and **↓** buttons to adjust the vertical position of the beam; press the **←** and **→** buttons to adjust the horizontal position of the beam. Press the **⊙** (reset) button to re-center the beam.

⚠ WARNING - Laser beam alignment checks are extremely important for the safe use of your laser equipment. Beam offset is not intended, and should not be used, to replace this important safety test. Prior to any procedure, perform the laser beam alignment check as described in your delivery system operator manual.



Beam Offset Controls

Preoperative Instructions

- 1 Verify that the laser is properly connected, as instructed in “Connection Instructions” in this manual.
- 2 Verify that the delivery system is properly connected, and sterile drape the arm if necessary, as instructed in the delivery system operator manual.
- 3 Post the “Laser in Use” warning sign outside the treatment room door.
- 4 If necessary, turn on the main electrical service (wall circuit breaker).
- 5 Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See “Laser Safety Eyewear” in this manual for detailed laser safety eyewear information.
- 6 If using the OtoScan, Acuspot, AcuBlade, Multi-Application (Oral Pharyngeal) handpiece, or the Nasal or Laryngeal Probes, connect the external Purge Air Compressor, as instructed in “Connection Instructions” in this manual.
- 7 Turn on the laser, as instructed in “Laser Console Basics” in this manual.
- 8 Perform the beam alignment check, as instructed in your delivery system operator 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.




WARNING - 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 nontarget tissues and possible injury.


Intraoperative Instructions

- 1 Set the treatment values, as instructed in the SurgiTouch+, UltraPulse, and CW sections of this manual.
- 2 If any of the “OtoScan”, “Tympanic Membrane”, “Nasal” or “Nasal Probes” ENT applications have been selected, a message will appear in the advisory text bar requesting you to turn on the external Purge Air Compressor (see below). Turn on the compressor and press the  button.

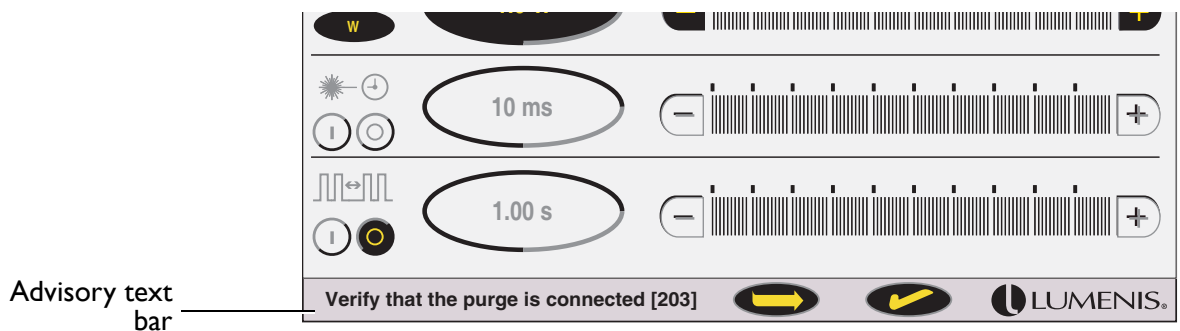
 **CAUTION** - Operating the laser with the FiberLase delivery systems without turning on the external Purge Air Compressor can cause severe damage to the FiberLase fibers.

- 3 Place the laser in ready mode.
- 4 Ensure that the aiming beam is visible. If using the UltraScan Encore CPG or the SurgiTouch scanner or the DeepFX microscanner, preview the pattern as described in the UltraScan Encore CPG operator manual.

 **CAUTION** - Before beginning a procedure with the UltraScan Encore CPG or the SurgiTouch scanner or the DeepFX microscanner, always preview the pattern. Repeat the pattern preview instructions during treatment if the pattern is changed, if single exposure is changed to timed exposure, or if the time delay between patterns is adjusted. Delivering the treatment beam to the target tissue before previewing the pattern may result in unintended laser-tissue interaction.

- 5 Position the aiming beam on the target tissue.
- 6 Press the footswitch to deliver the treatment beam to the tissue. The  (laser emission) icon appears in the laser status display on the control screen.

If surgery must be interrupted, place the laser in standby mode to disable the footswitch.



External Purge Air Compressor Message

Postoperative Instructions

- 1 Place the laser in the standby mode.
- 2 Turn off the laser, as instructed in “Laser Console Basics” in this manual.
- 3 Turn off the main power circuit breaker.
- 4 Place the footswitch on the footswitch storage mounts. Coil the footswitch cable and store it inside the footswitch housing. Do not wrap the footswitch cable around the power cable wrap.
- 5 If used, turn off the external Purge Air Compressor. Disconnect its air tube from the delivery device.
- 6 Disconnect the delivery system, including all adapters and couplers. Clean the delivery system and store in the appropriate storage container, as instructed in the delivery system operator manual.



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

- 7 Clean the exterior surfaces of the laser, as instructed in the Maintenance section of this manual.
- 8 Replace the red protective cap on the distal end of the laser articulated arm.
- 9 Fold and secure the articulated arm, as instructed in “Connection Instructions” in this manual.

SurgiTouch+

Enabling application-specific settings

Overview

- Introduction: The SurgiTouch+ User Interface 61
- Selecting a Specialty, Application, and Delivery Device 62
- Setting Treatment Values 66

Introduction: The SurgiTouch+ User Interface

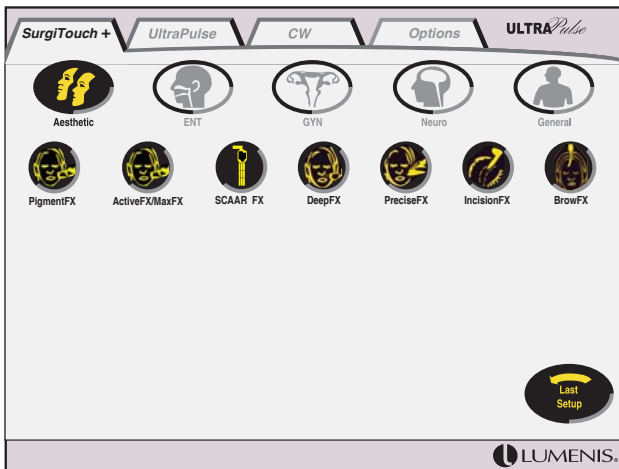
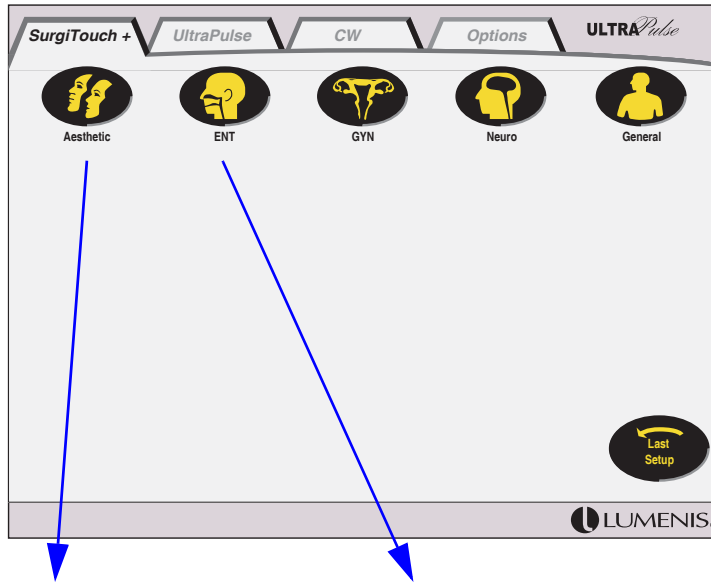
The SurgiTouch+ user interface allows you to select a specialty and application; the laser then automatically displays the treatment screen with the recommended delivery device and treatment settings. You can also select from a group of delivery devices within each application. The following table shows the available applications and delivery devices within each specialty.

Specialty	Application	Delivery Device
Aesthetic	PigmentFX	UltraScan Encore CPG
	CO ₂ Lite	UltraScan Encore CPG
	ActiveFX Gentle	UltraScan Encore CPG
	ActiveFX/MaxFX	UltraScan Encore CPG
	DeepFX	DeepFX Microscanner
	SCAAR FX	DeepFX Microscanner
	BrowFX	UltraFlex Waveguide Delivery System
	IncisionFX	0.2mm Focused Incisional Handpiece
	PreciseFX	TrueSpot 2.0mm Collimated Handpiece
ENT (Otolaryngology)	Tonsil	Multi-Application (Oral Pharyngeal) & Nasal Delivery System
	Uvula	Multi-Application (Oral Pharyngeal) & Nasal Delivery System
	Bronchi	781 Laser Bronchoscope
	Tympanic Membrane	OtoScan Ear Aeration Delivery System AcuSpot 712 Micromanipulator
	Larynx	AcuBlade Micromanipulators AcuSpot 712 Micromanipulator Laryngeal Probes
	Nasal	Multi-Application (Oral Pharyngeal) & Nasal Delivery System AcuSpot 712 Micromanipulator Nasal Probes
GYN (Gynecology)	Laparoscopy	Lumenis/Nezhat Laparoscopic Coupler Variable Spot Laparoscopic Coupler Second Puncture Probe Coupler BeamAlign CVD 200 BeamAlign CVD 300
	Colposcopy	MicroSlad Micromanipulator ClearSpot 350 Micromanipulator
	Freehand	1.0mm Focused Incisional Handpiece 0.2mm Focused Incisional Handpiece
Neurosurgery	Microsurgery	AcuSpot 712 Micromanipulator
	Freehand	1.0mm Focused Incisional Handpiece 0.2mm Focused Incisional Handpiece
General Surgery	Freehand	1.0mm Focused Incisional Handpiece 0.2mm Focused Incisional Handpiece

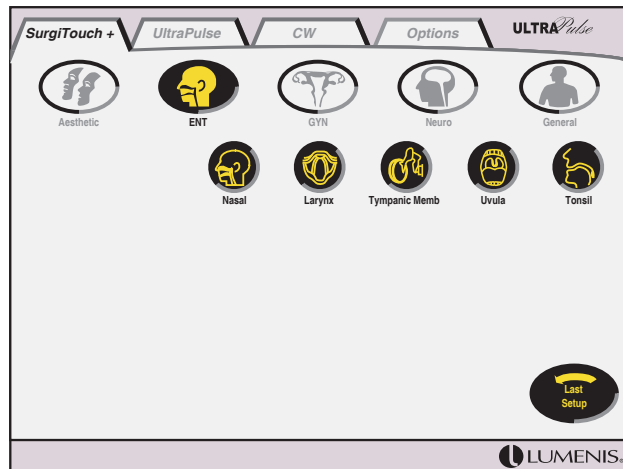
Selecting a Specialty, Application, and Delivery Device

- 1 Press the SurgiTouch+ tab to view the Specialties screen.
- 2 Press the button for the desired specialty; the available applications for each specialty will appear as shown in the following Aesthetic and ENT example screens.

Select ENT or Aesthetic specialty



Available Aesthetic Applications



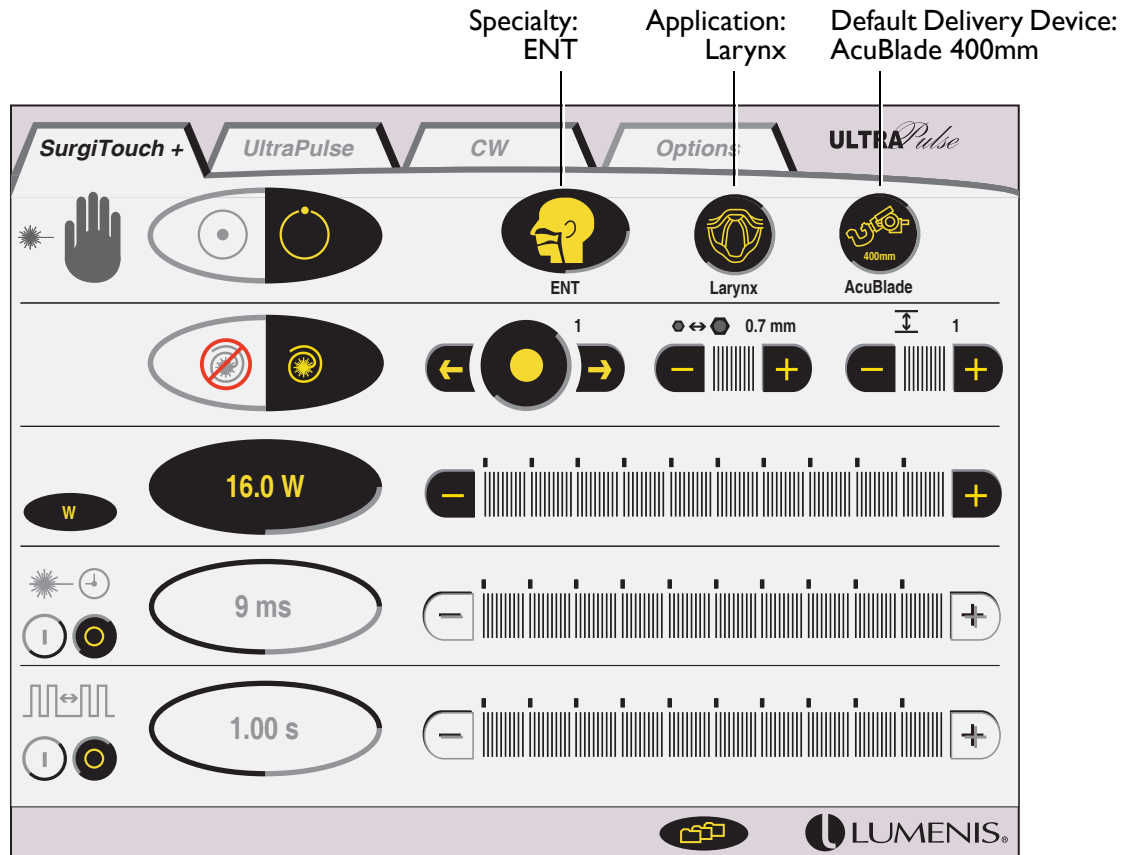
Available ENT Applications

SurgiTouch+; Selecting a Specialty and Application


- ▶ For complete operating instructions of these modules, refer to the UltraScan CPG operator's manual or the DeepFX operator's manual.
- ▶ From this point forward, the operating instructions narrative will discuss the ENT applications.

- 3 Press the button for the desired application. The SurgiTouch+ treatment screen displays the default delivery device and recommended treatment settings.

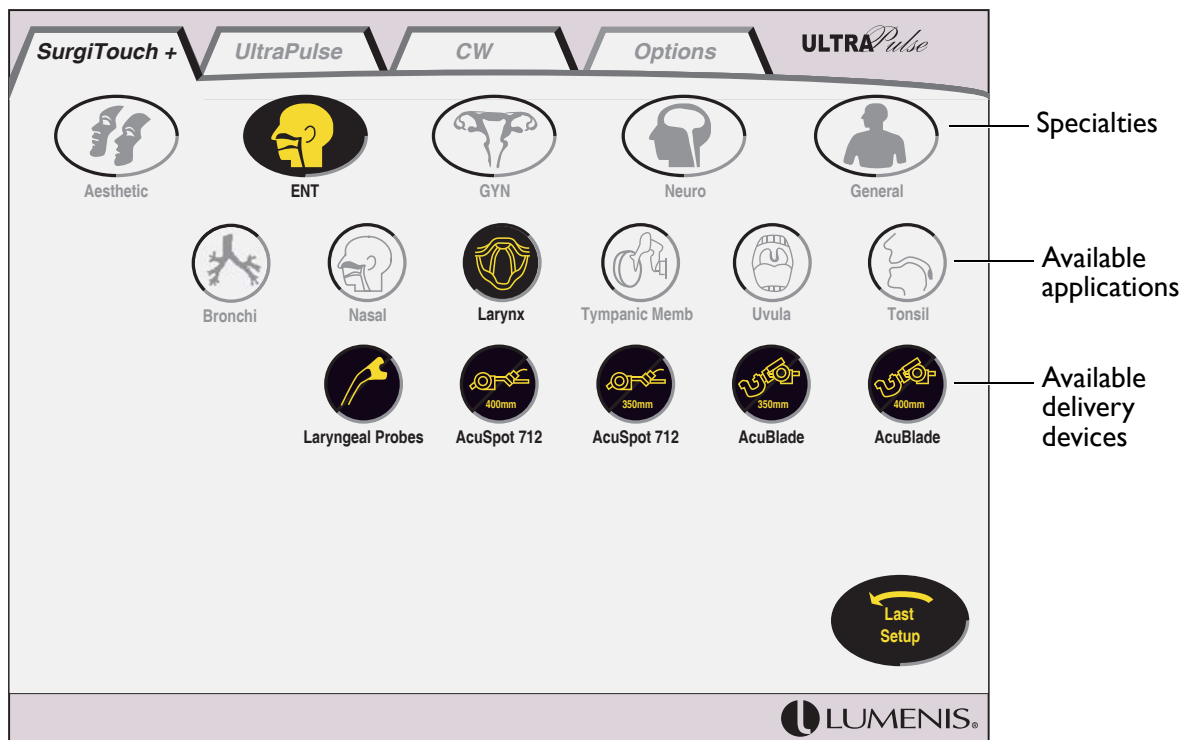
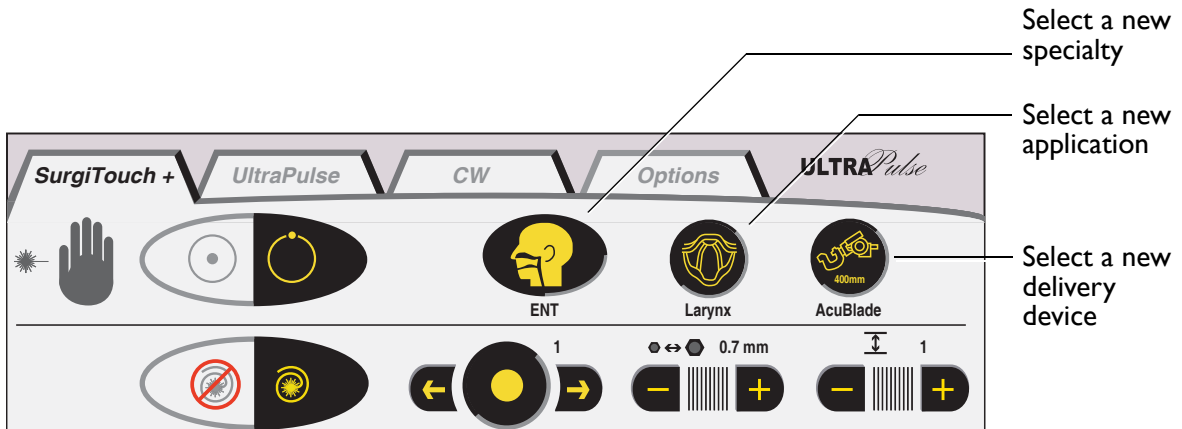
For example, when you select the Larynx application, the treatment screen displays the default treatment settings for the AcuBlade at a 400 mm working distance, as shown.



SurgiTouch+ Treatment Screen Showing Default Delivery Device and Treatment Settings for ENT: Larynx

- 4 A message appears in the advisory text bar, reminding you to verify that the correct delivery device is attached to the laser. Verify that the correct delivery device is attached, then press the  button to continue.


- 5 To select a different specialty, application, or delivery device, press the appropriate button at the upper right of the SurgiTouch+ treatment screen, as shown. The Specialty, Application, or Delivery Device screen appears.
- 6 Press the button for the desired specialty, application, or delivery device.




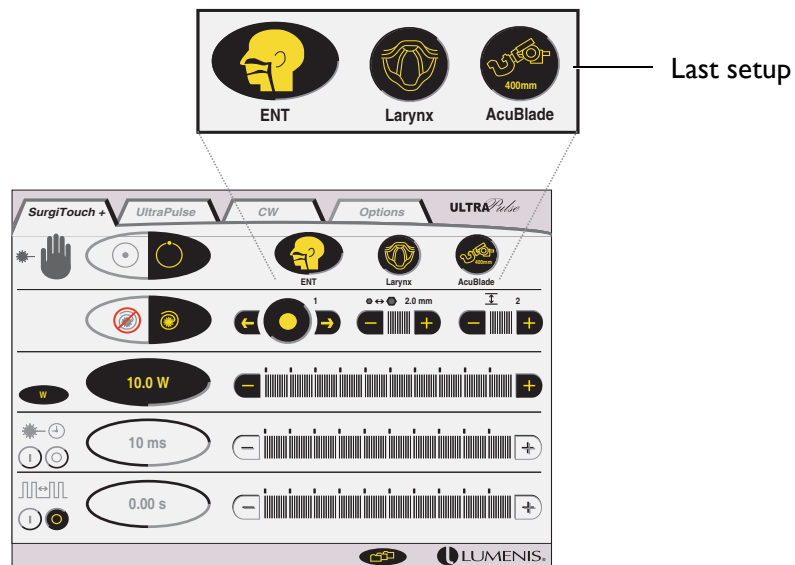
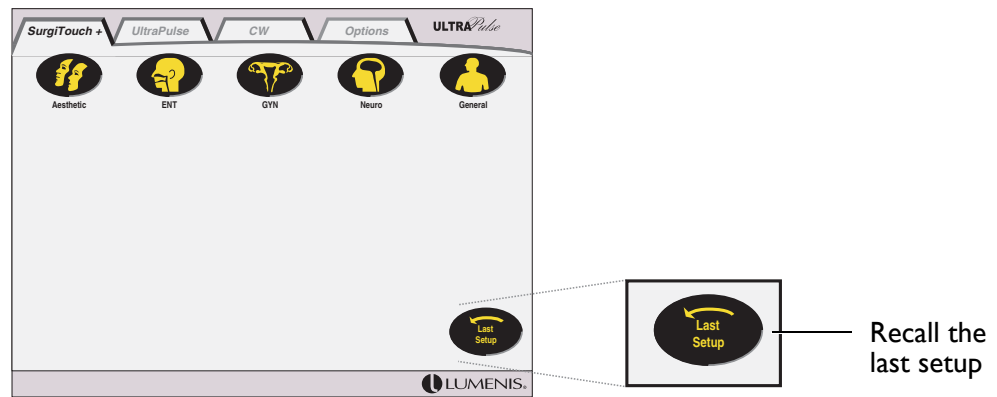
**SurgiTouch+; Selecting a New Specialty, Application, or Delivery Device
(Delivery Device Screen Shown)**

Recalling the Last Setup

The last setup function recalls the last selected specialty, application, and delivery device, even if the laser has been turned off and restarted. To recall the last setup:

Press the  (last setup) button at the lower right of the SurgiTouch+ control screen. The SurgiTouch+ treatment screen automatically displays the default treatment settings for the last setup.

▶ Verify that the correct delivery device is attached, then press the  button in the advisory text bar to continue.





SurgiTouch+; Recalling the Last Setup

Setting Treatment Values

All available delivery devices have default treatment settings, including power, timed exposure, repeat delay, scan mode, and UltraPulse SurgiTouch Scanner settings (where applicable). Available treatment settings vary depending on the selected application and delivery device. You can adjust treatment settings from the default values, as needed.

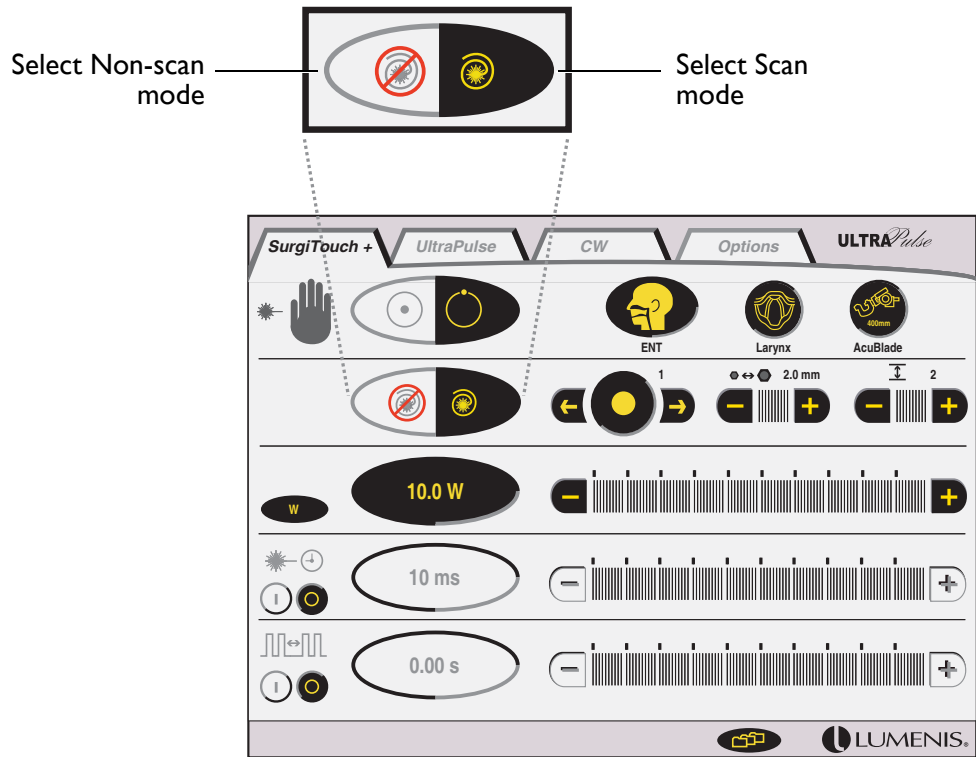
Selecting the Scan Mode: Non-Scan or Scan

The laser supplies a default scan mode: Non-scan or Scan. The default mode depends on the selected operating parameters. For some delivery devices, only Non-scan mode is available. In Non-scan mode, the laser can be used for incising or excising tissue. In Scan mode, the laser can be used for char-free, superficial ablation of tissue.

Press the  (non-scan) and  (scan) buttons on the treatment screen to select a scan mode, or to toggle between Non-scan and Scan modes while operating.



CAUTION - To avoid unintended tissue effect, pay attention to differences in power when toggling between scan modes while operating.



SurgiTouch+; Selecting the Scan Mode

Adjusting the Power

The default power automatically displays on the treatment screen. Energy and repetition rate (where applicable) are controlled by adjusting the power.



Read “Power density” in the CW section of this manual for a full explanation of power density and a table showing power density values at various spot sizes and power settings.

Adjust the power by pressing the **–** and **+** buttons on the power bar. The average power, in watts, displays on the control screen.



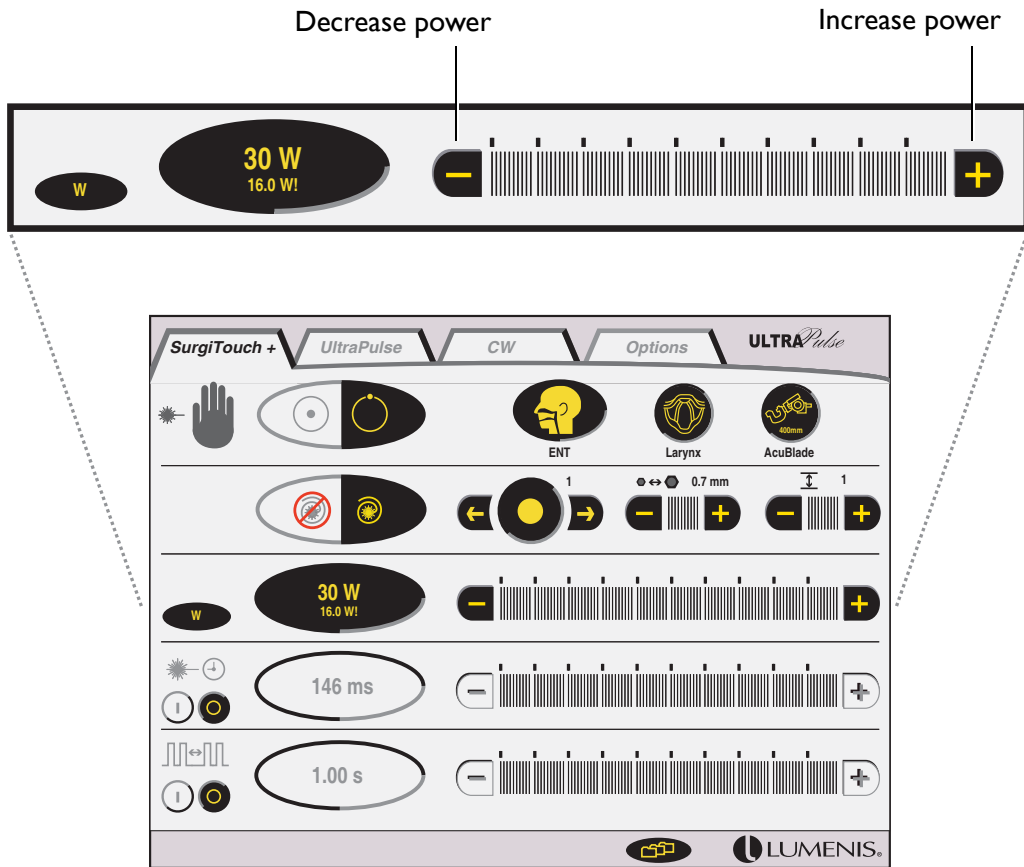
WARNING - Serious tissue damage can occur as a result of incorrect power settings. Use the lowest acceptable settings until you understand the biological interaction between the laser power and tissue.



CAUTION - The power shown on the power display indicates the power delivered to the end of the articulated arm, 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.



CAUTION - 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.



SurgiTouch+; Adjusting the Power

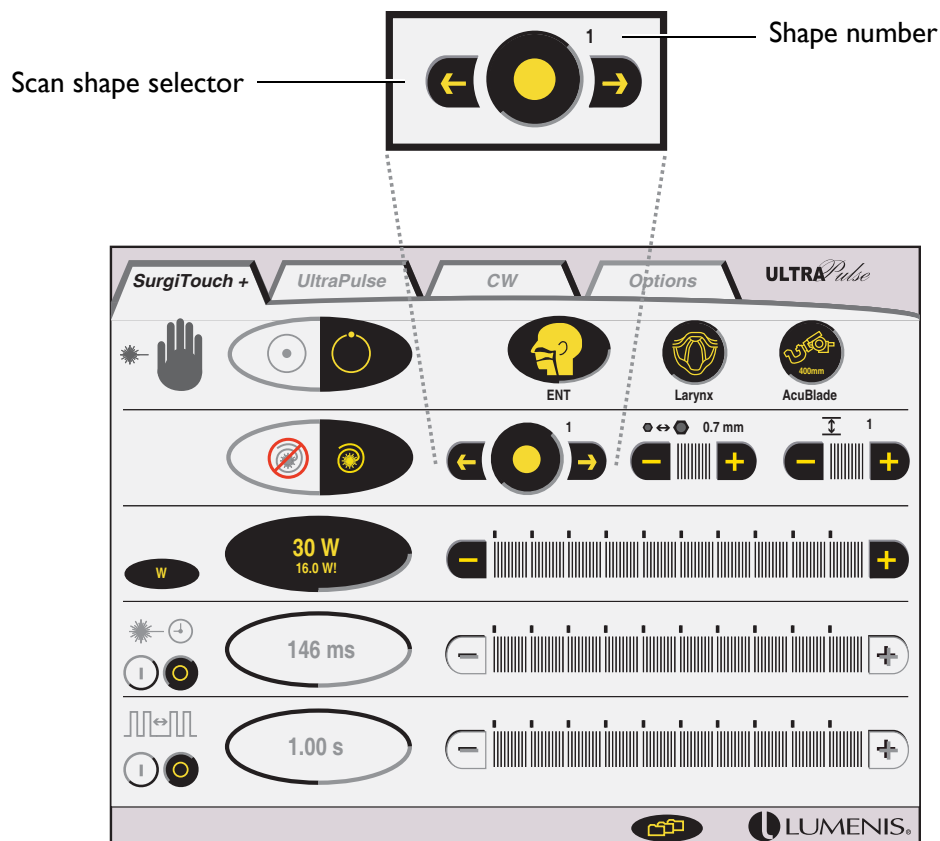
▶ When the power is adjusted from the default setting, the default power appears below the selected setting in the power display, as shown, indicating that the power is set outside of recommended parameters.

Adjusting the UltraPulse SurgiTouch Scanner Settings

When the SurgiTouch Scanner and communication cable are connected to the laser, default scanner settings automatically display on the treatment screen. Scanner settings, including shape, size, and depth, are active when Scan mode is selected.

Setting the Scan Shape

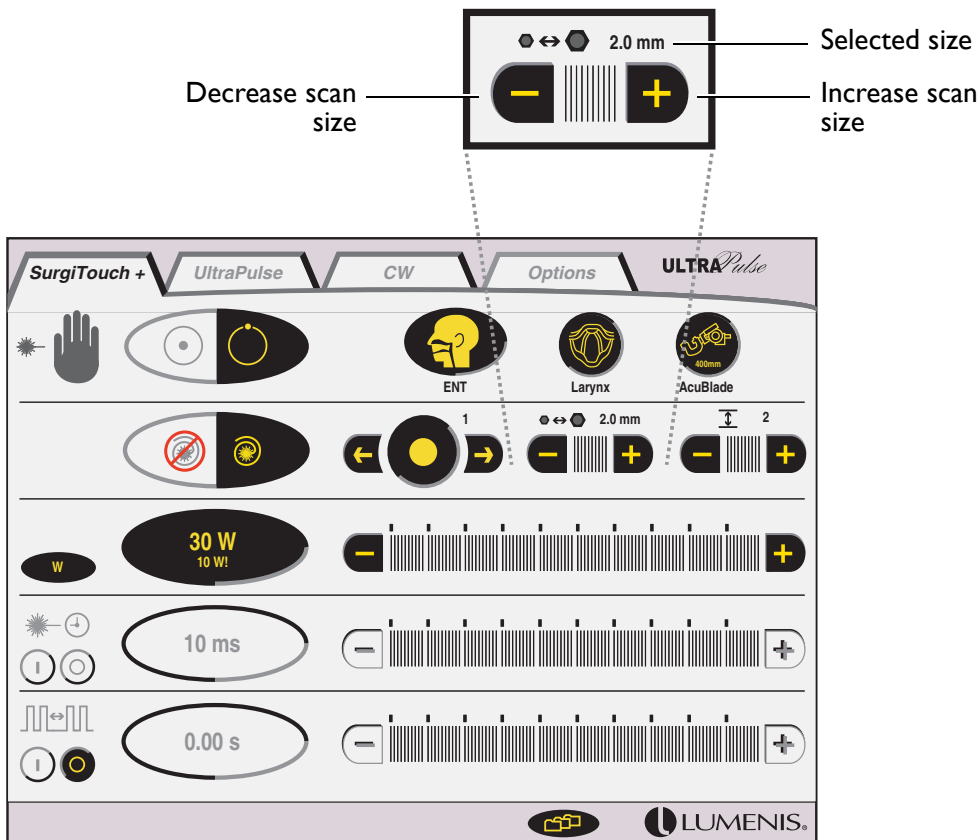
Press the ← and → buttons on the scan shape selector to scroll through the available shapes. The shape number and an outline of the selected shape display on the control screen.



SurgiTouch+; Setting the Scan Shape

Setting the Scan Size

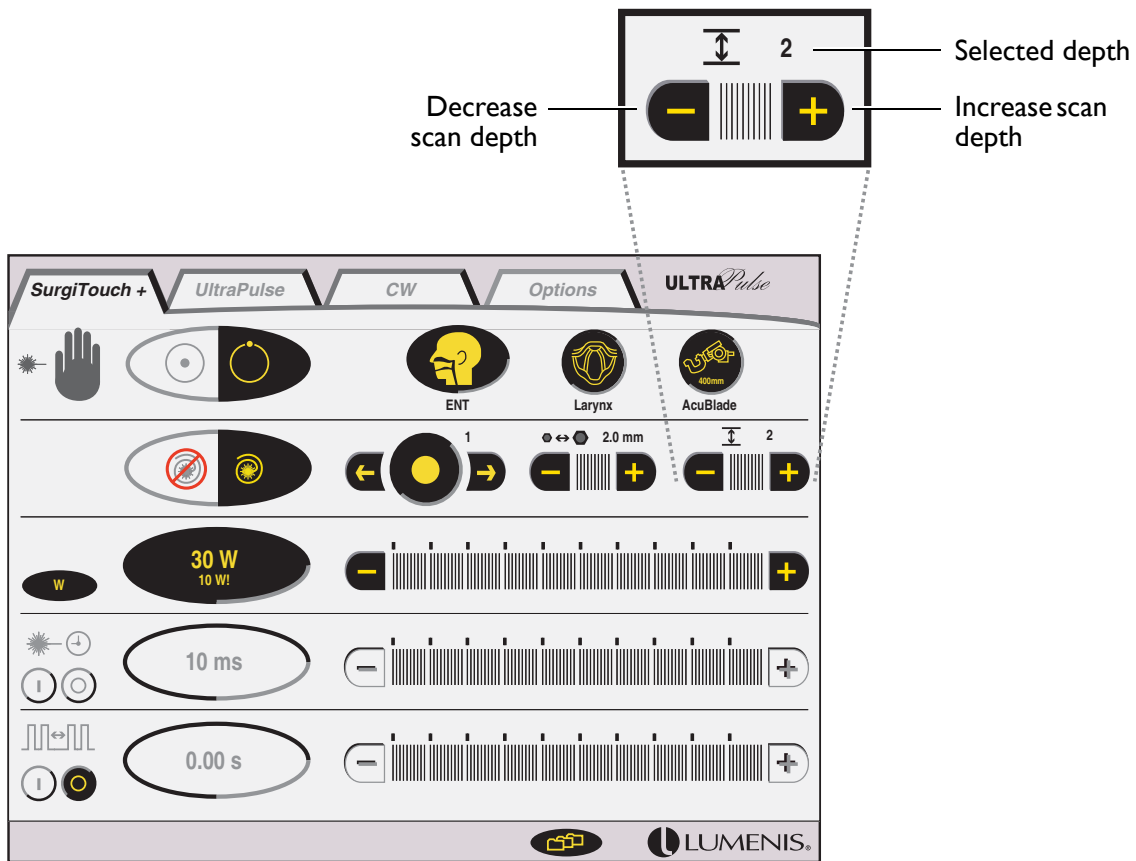
Press the **-** and **+** buttons on the scan size selector. The selected scan size displays on the control screen.



SurgiTouch+; Setting the Scan Size

Setting the Scan Depth

Press the **-** and **+** buttons on the scan depth selector. The selected depth displays on the control screen. The scan depth represents the number of times that the selected pattern is scanned.



SurgiTouch+; Setting the Scan Depth

Timed Exposure and Repeat Delay in SurgiTouch+

In SurgiTouch+, exposure time is adjustable only when the laser is in Non-scan mode. When the laser is in Scan mode, timed exposure is on but is not adjustable - it is determined by the scan settings.

Procedures requiring extremely brief treatment durations are difficult to control with a footswitch. Timed exposure allows a level of precision that is unavailable with the footswitch alone.

With timed exposure off (in Non-scan mode), treatment duration is controlled entirely by depressing and releasing the footswitch; treatment duration is continuous until the footswitch is released.

With timed exposure on (in Non-scan mode), treatment energy is delivered only for a specified duration, after which treatment stops. Treatment also stops if the footswitch is released before the specified duration is complete. To deliver additional timed exposures, you must release the footswitch and depress it again.






Repeat delay allows you to repeatedly deliver timed exposures to the target tissue, with a set interval between each exposure. For example, if repeat delay is set to 1.5 s, the laser delivers treatment, delays 1.5 seconds, delivers treatment again, delays again, and so on, until the footswitch is released.

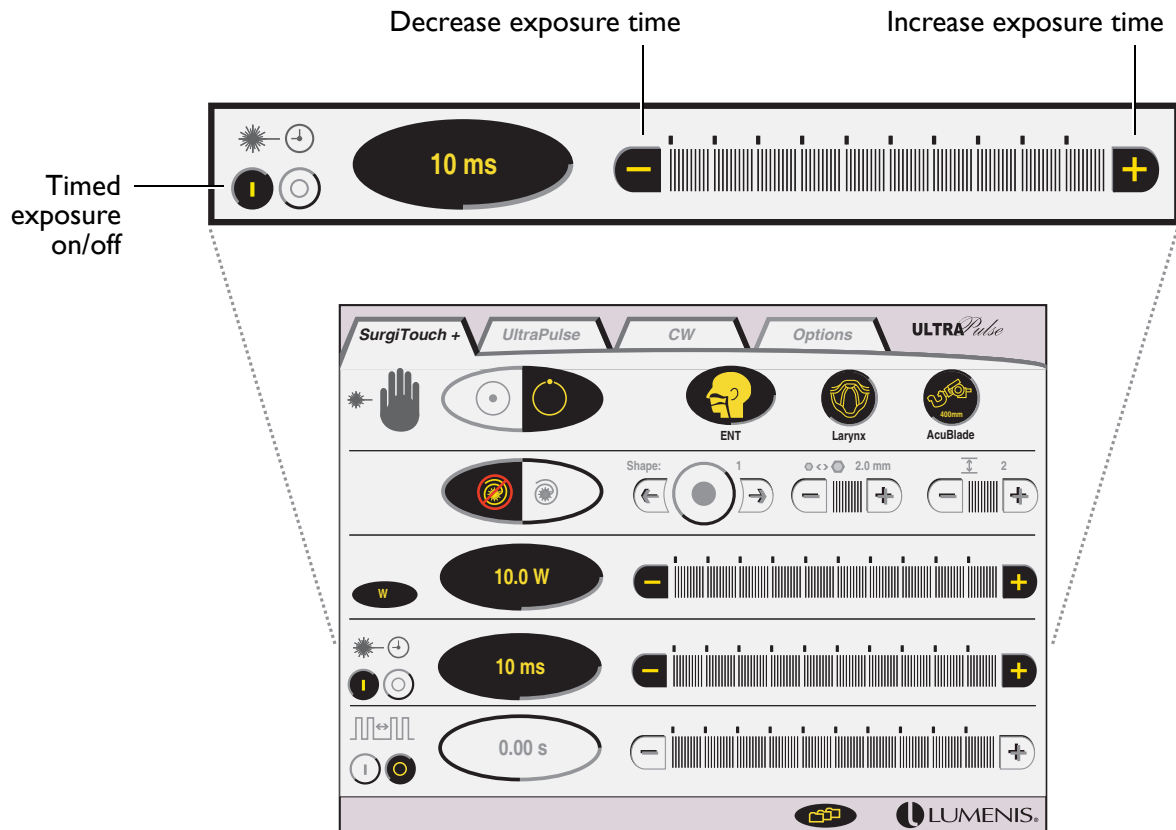
Repeat delay is available only when timed exposure is turned on. Combined, the repeat delay and timed exposure functions allow you to control the pace at which you operate.

When Repeat delay is set to 0 in Scan mode, the duration of the treatment is controlled entirely by the footswitch.

Setting Timed Exposure

(Non-scan mode only)

- 1 Press the  (on) button on the  (timed exposure) bar. The button highlights to indicate that timed exposure is active. The exposure time, in milliseconds, displays on the control screen.
- 2 Set the exposure time by pressing the  and  buttons on the timed exposure bar.
- 3 To turn off timed exposure, press the timed exposure  (off) button.



SurgiTouch+; Setting Timed Exposure (Non-Scan Mode Only)

Setting Repeat Delay

(Non-scan or Scan mode)

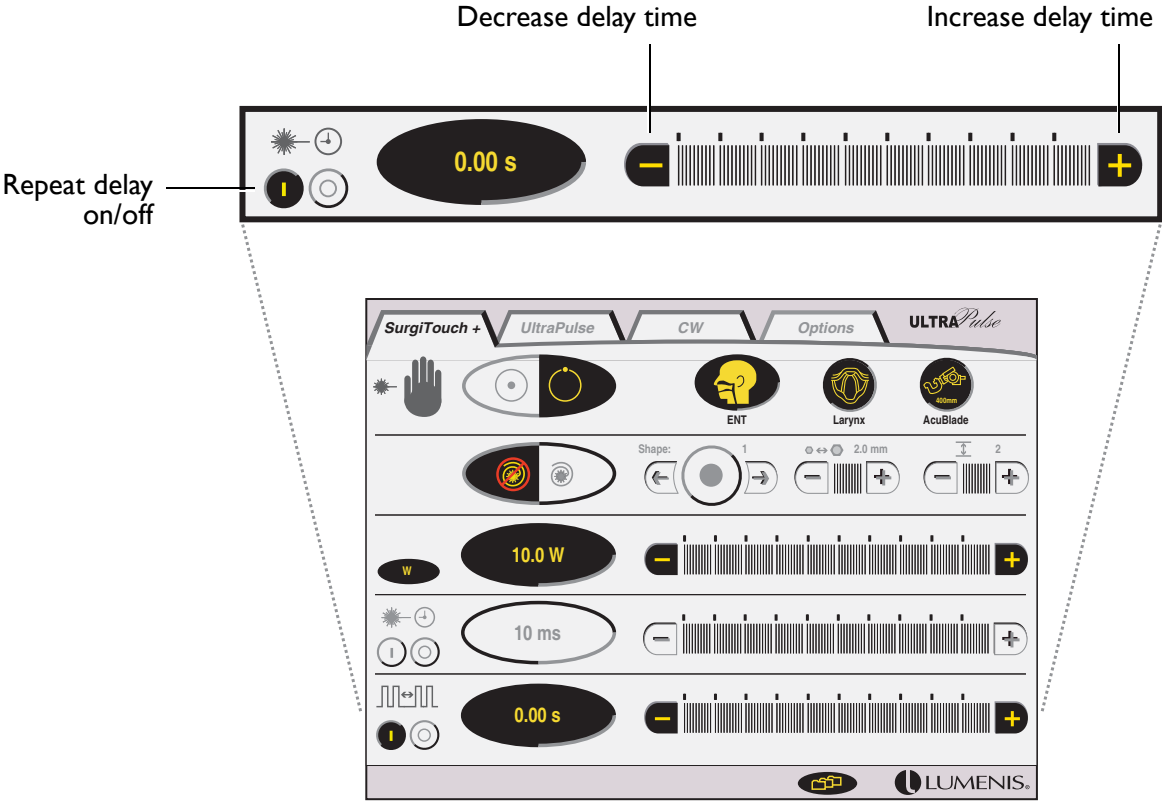
- 1 If the laser is in Non-scan mode, turn on and set timed exposure, as instructed in the previous section.

▶ In Scan mode, timed exposure is always on but is not adjustable.

- 2 Press the (I) (on) button on the [] (repeat delay) bar. The button highlights to indicate that repeat delay is active.

The delay time, in seconds, displays on the control screen. Available intervals are 0–5.0 seconds.

- 3 Set the repeat delay interval by pressing the – and + buttons on the repeat delay bar.
- 4 To change from repeat delay to single timed exposure, press the repeat delay (O) (off) button. To turn off all timed exposures, press the timed exposure (O) (off) button.



SurgiTouch+; Setting Repeat Delay (Non-Scan or Scan Mode)

UltraPulse

Overview

- Setting the Energy or Fluence 79
- Setting the Repetition Rate or Average Power 82
- Timed Exposure and Repeat Delay in UltraPulse Mode 84
- Setting Timed Exposure 85
- Setting Repeat Delay 86

Setting Treatment Values

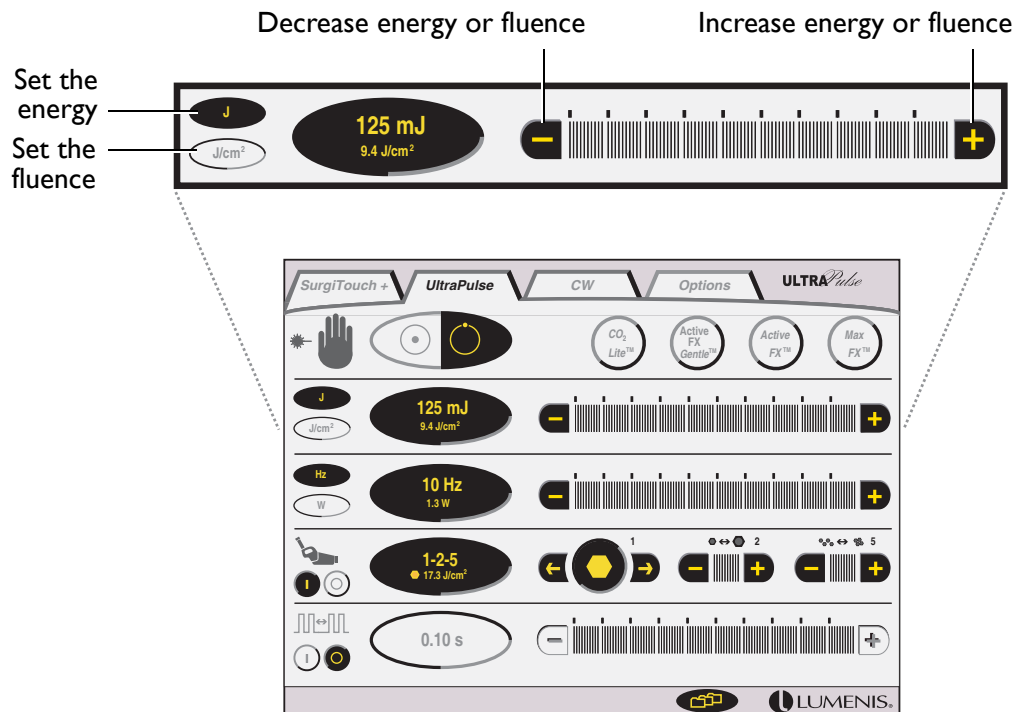
In UltraPulse mode, the available treatment settings are energy, rate (or power), timed exposure, and repeat delay. Fluence is adjustable in UltraPulse CPG mode only. To select UltraPulse mode, press the **UltraPulse** tab at the top of the control screen, or access UltraPulse mode through **SurgiTouch+**, **Aesthetic** and one of the mode buttons: **ActiveFX/MaxFX** or **PigmentFX**.

Setting the Energy or Fluence

- 1 Press the **J** (energy) button or the **J/cm²** (fluence) button. The selected button highlights to indicate whether energy or fluence is active.
- 2 Select the desired energy or fluence by pressing the **-** and **+** buttons on the energy/fluence bar. The default energy setting is 100 millijoules.

⚠ CAUTION - The energy shown on the energy display indicates the energy delivered to the end of the articulated arm, 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 energy.

▷ Some energy settings may not be available at higher repetition rate settings. If you attempt to select an energy that is unavailable at the existing repetition rate setting, the system will emit a low tone, indicating that the value is not available. Reducing the repetition rate may increase the amount of available energy.



UltraPulse—Setting the Energy or Fluence (CPG Controls Active)

Energy Level and Fluence

In UltraPulse mode, fluence, or energy density, determines the nature of the laser-tissue interaction. Fluence is defined as energy per unit area and is measured in joules per square centimeter (J/cm^2).

Ablation of tissue with minimal thermal artifact requires pulse fluence above the ablation threshold of approximately $5 \text{ J}/\text{cm}^2$.¹ In the following table, which shows fluence values at various spot sizes and energy settings, the shaded area highlights this critical range. Note, however, that for some applications, the required fluence may be considerably higher.



WARNING - The table values are approximations and will vary with slight changes in spot size. The table should not be used to set treatment parameters, but simply as a guide to fluence and its relationship with laser energy and spot size. Serious tissue damage can occur as a result of incorrect energy settings; use the lowest acceptable energy settings until you understand the biological interaction between the laser energy and tissue.



CAUTION - As indicated in the following table, fluence is inversely related to spot size; for any constant energy setting, fluence will decrease as spot size is increased. For this reason, any increase in spot size must be accompanied by a corresponding increase in energy if an equivalent fluence is desired.

-
1. Fitzpatrick, R.E., J. Ruiz-Esparza, M.P. Goldman, "The Depth of Thermal Necrosis Using the CO_2 Laser: A Comparison of the Superpulsed mode and the Conventional Mode." *Journal of Dermatology and Surgical Oncology*, 1991, Vol 17, pages 340-344.

Energy (mJ)	Fluence (J/cm ²)										
	Spot Size (mm)										
	0.2	1.0	1.3	2.0	2.25	2.5	3.0	3.5	4.0	5.0	6.0
1	3.18	0.13	0.08	0.03	0.025	0.02	0.014	0.01	0.008	0.005	0.004
2	6.37	0.25	0.15	0.06	0.05	0.04	0.03	0.02	0.016	0.01	0.007
5	15.9	0.64	0.38	0.16	0.13	0.10	0.07	0.05	0.04	0.03	0.02
10	31.8	1.27	0.75	0.32	0.25	0.20	0.14	0.10	0.08	0.05	0.04
25	79.6	3.18	1.88	0.80	0.63	0.51	0.35	0.26	0.20	0.13	0.09
30	95.54	3.82	2.26	0.96	0.75	0.61	0.42	0.31	0.24	0.15	0.11
40	127.39	5.10	3.02	1.27	1.01	0.82	0.57	0.42	0.32	0.20	0.14
50	159.2	6.37	3.77	1.59	1.26	1.02	0.71	0.52	0.40	0.25	0.18
60	191.08	7.64	4.52	1.91	1.51	1.22	0.85	0.62	0.48	0.31	0.21
70	222.9	8.9	5.28	2.23	1.76	1.42	0.99	0.73	0.56	0.36	0.25
80	254.8	10.2	6.03	2.55	2.01	1.63	1.13	0.83	0.64	0.41	0.28
90	286.6	11.5	6.78	2.87	2.27	1.83	1.27	0.94	0.72	0.46	0.32
100	318.5	12.7	7.54	3.18	2.52	2.04	1.42	1.04	0.80	0.51	0.35
125	398.1	15.9	9.42	3.98	3.15	2.55	1.77	1.30	1.00	0.64	0.44
150	477.7	19.1	11.3	4.78	3.77	3.06	2.12	1.56	1.19	0.76	0.53
200	636.9	25.5	15.1	6.37	5.03	4.08	2.83	2.08	1.59	1.02	0.71
225	716.6	28.7	17.0	7.17	5.66	4.59	3.18	2.34	1.79	1.15	0.80


Pulse Fluence at Various Energy Settings and Spot Sizes




As explained fully in the “Energy level and fluence” section of this manual, the shaded area of the above table shows the critical range where the combined spot sizes and energy settings produce a pulse fluence of greater than or equal to 5 J/cm².


Setting the Repetition Rate or Average Power

The repetition rate and power controls allow you to specify the speed at which you work. Repetition rate refers to the number of energy pulses delivered per second. Power refers to the average output power of the laser, in watts.

 There is a direct correlation between repetition rate and average power. The UltraPulse laser allows you to select either the repetition rate or the average power. When you adjust the repetition rate, the resultant change in power also displays on the control screen. Similarly, when you adjust the power, the resultant change in repetition rate also displays.

 Not all rates/powers are available at all energy levels. If you attempt to select a pulse rate or power that is unavailable at the selected energy level, the system will emit a low tone, indicating that the value is not available. To achieve the higher rate or power, you will need to lower the energy setting. Note, as discussed in “Energy level and fluence” in this chapter, that lowering the energy also lowers the fluence.

To set the repetition rate:

- 1 Press the  (rate) button.

The button highlights to indicate that rate is active. The repetition rate, in hertz, displays on the control screen.


- 2 Set the repetition rate by pressing the **-** and **+** buttons on the repetition rate bar.

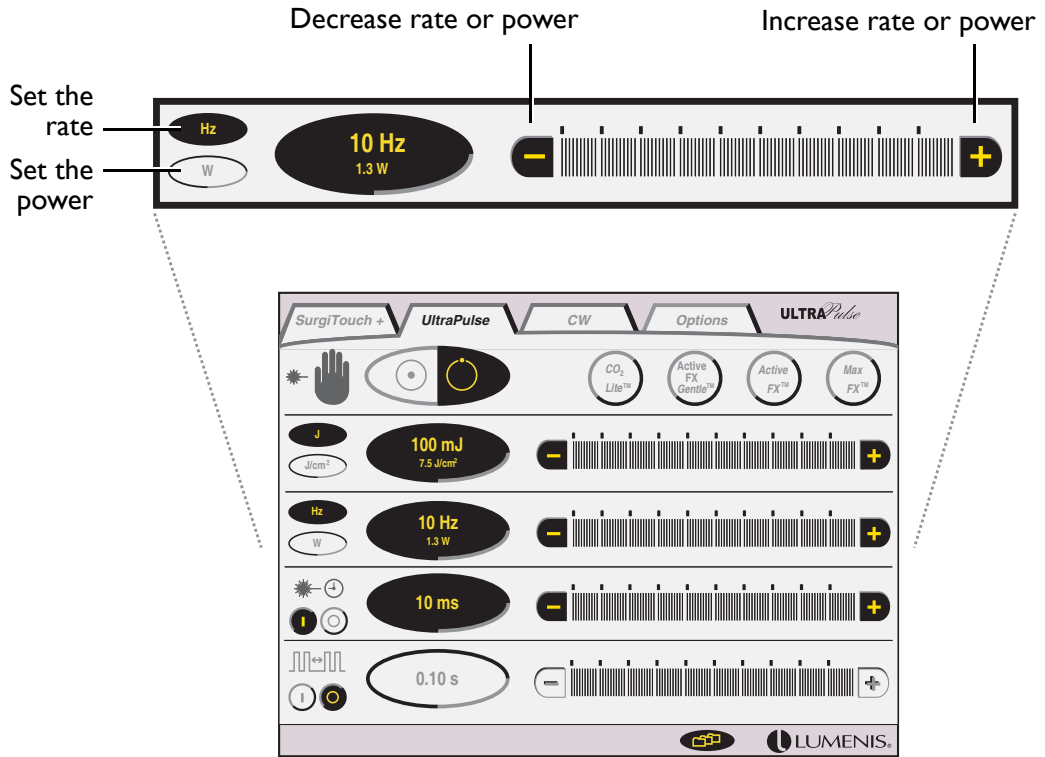
To set the average power:

- 1 Press the  (power) button.

The button highlights to indicate that power is active. The average power, in watts, displays on the control screen.

- 2 Set the power by pressing the **-** and **+** buttons on the power bar.

 **CAUTION** - The power shown on the power display indicates the power delivered to the end of the articulated arm, 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.



UltraPulse—Setting the Repetition Rate or Average Power

Timed Exposure and Repeat Delay in UltraPulse Mode

In UltraPulse mode, timed exposure is adjustable only when the UltraScan Encore CPG is not connected to the laser. When the CPG is attached and turned on, timed exposure is on but is not adjustable; in this case, exposure time is determined by the CPG settings.

Procedures requiring extremely brief treatment durations are difficult to control with a footswitch. Timed exposure allows a level of precision that is unavailable with the footswitch alone.

With timed exposure off, treatment duration is controlled entirely by depressing and releasing the footswitch; treatment duration is continuous until the footswitch is released.

With timed exposure on, treatment energy is delivered only for a specified duration, after which treatment stops. Treatment also stops if the footswitch is released before the specified duration is complete. To deliver additional exposures, the footswitch must be released and depressed again.



Repeat delay allows you to repeatedly deliver timed exposures to the target tissue, with a set interval between each exposure. For example, if repeat delay is set to 1.5, the laser delivers treatment, delays 1.5 seconds, delivers treatment again, delays again, and so on, until the footswitch is released.


Repeat delay is available only when timed exposure is turned on. Combined, the repeat delay and timed exposure functions allow you to control the pace at which you operate.


Setting Timed Exposure

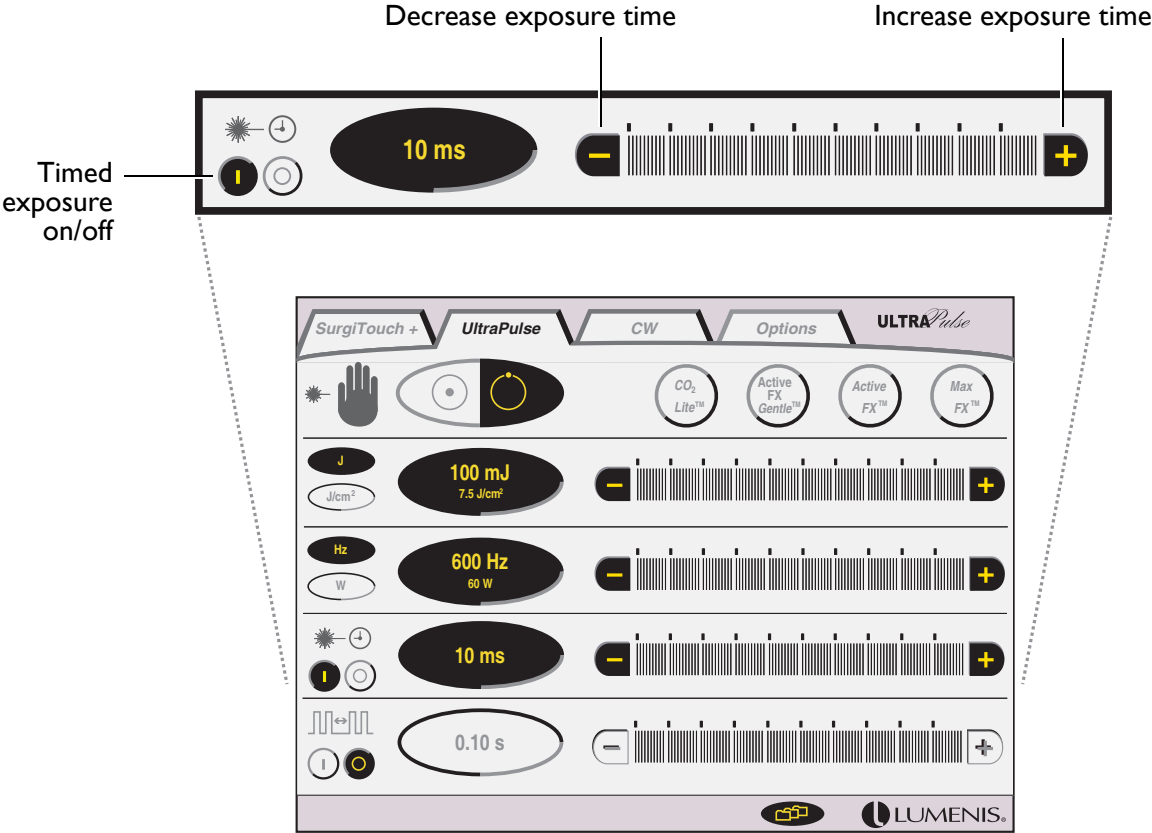
1 Press the  (on) button on the  (timed exposure) bar. The button highlights to indicate that timed exposure is active.

The exposure time, in milliseconds, and the number of pulses to be delivered display on the control screen.

2 Set the exposure time by pressing the  and  buttons on the timed exposure bar.



 In UltraPulse mode, exposure time increments are dependent upon the rate setting; the higher the rate, the smaller the increments, and hence, the more control you have over exposure time.

3 To turn off timed exposure, press the timed exposure  (off) button.





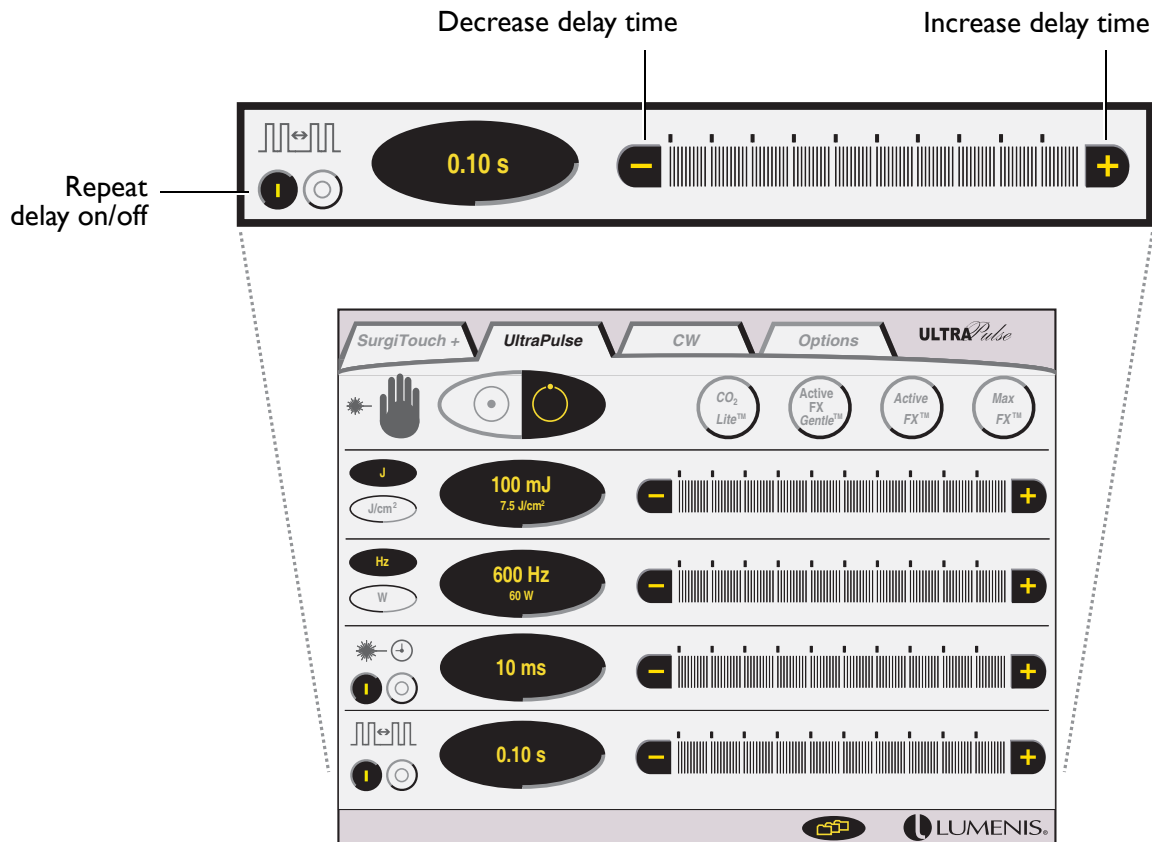
UltraPulse—Setting Timed Exposure

Setting Repeat Delay

- 1 Turn on and set timed exposure, as instructed in the previous section.
- 2 Press the  (on) button on the  (repeat delay) bar. The button highlights to indicate that repeat delay is active.

The delay time, in seconds, displays on the control screen. Available repeat delay intervals are 0.1–5.0 seconds.

- 3 Set the delay time by pressing the **–** and **+** buttons on the repeat delay bar.
- 4 To change from repeat delay to single timed exposure, press the repeat delay  (off) button. To turn off all timed exposures, press the timed exposure  (off) button.



UltraPulse—Setting Repeat Delay

CW

Overview

- Setting the Power 89
- Timed Exposure and Repeat Delay in CW Mode 91
- Setting Timed Exposure 92
- Setting Repeat Delay 93

Setting Treatment Values

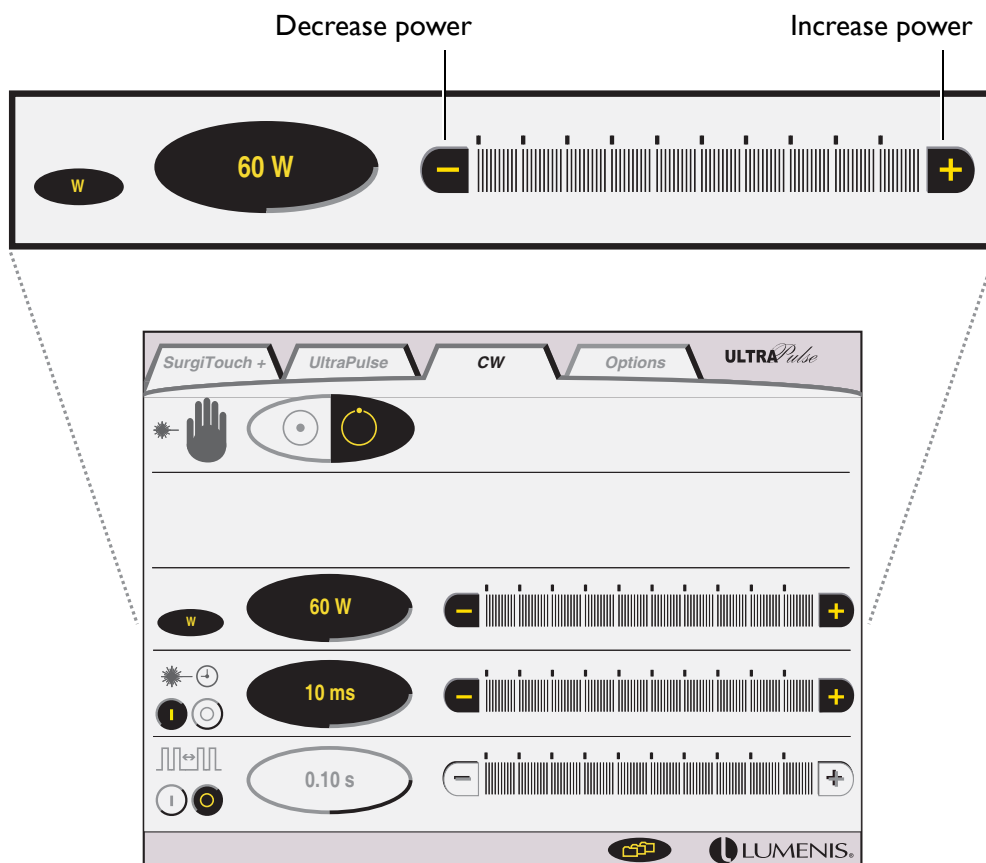
In CW (continuous wave) mode, the available treatment settings are power, timed exposure, and repeat delay. To select CW mode, press the CW tab at the top of the control screen.

Setting the Power

Press the **-** and **+** buttons on the power bar.



CAUTION - The power shown on the power display indicates the power delivered to the end of the articulated arm, 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.



CW—Setting the Power

Power and Power Density

In CW mode, power density determines the nature of the laser-tissue interaction. Power density is defined as power per unit area and is measured in watts per square centimeter (W/cm^2). The following table shows power density values at various delivery system spot sizes and power settings.

⚠ WARNING - The table values are approximations and will vary with slight changes in spot size. The table should not be used to set treatment parameters, but should be used simply as a guide to power density and its relationship with laser power and spot size. Serious tissue damage can occur as a result of incorrect power settings; use the lowest acceptable settings until you understand the biological interaction between the laser power and tissue.

⚠ CAUTION - As indicated in the table, 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.

Power (W)	Power Density (W/cm^2)										
	Spot Size (mm)										
	0.2	1.0	1.3	2.0	2.25	2.5	3.0	3.5	4.0	5.0	6.0
10	31850	1270	750	320	250	200	100	140	80	50	40
20	63690	2550	1510	640	500	410	280	210	160	100	70
30	95540	3820	2260	960	760	610	430	310	240	150	110
40	127390	5100	3120	1270	1010	820	570	420	320	200	140
50	159240	6370	3770	1590	1260	1020	710	520	400	260	280
60	191080	7640	4520	1920	1510	1220	850	620	480	310	210

Power Density at Various Power Settings and Spot Sizes

Timed Exposure and Repeat Delay in CW Mode

In CW mode, timed exposure is always adjustable. Procedures requiring extremely brief treatment durations are difficult to control with a footswitch. Timed exposure allows a level of precision that is unavailable with the footswitch alone.

With timed exposure off, treatment duration is controlled entirely by depressing and releasing the footswitch; treatment duration is continuous until the footswitch is released.

With timed exposure on, treatment power is delivered only for a specified duration, after which treatment stops. Treatment also stops if the footswitch is released before the specified duration is complete. To deliver additional exposures, the footswitch must be released and depressed again.



Repeat delay allows you to repeatedly deliver timed exposures to the target tissue, with a set interval between each exposure. For example, if repeat delay is set to 1.5 s, the laser delivers treatment, delays 1.5 seconds, delivers treatment again, delays again, and so on, until the footswitch is released.

Repeat delay is available only when timed exposure is turned on. Combined, the repeat delay and timed exposure functions allow you to control the pace at which you operate.


Setting Timed Exposure

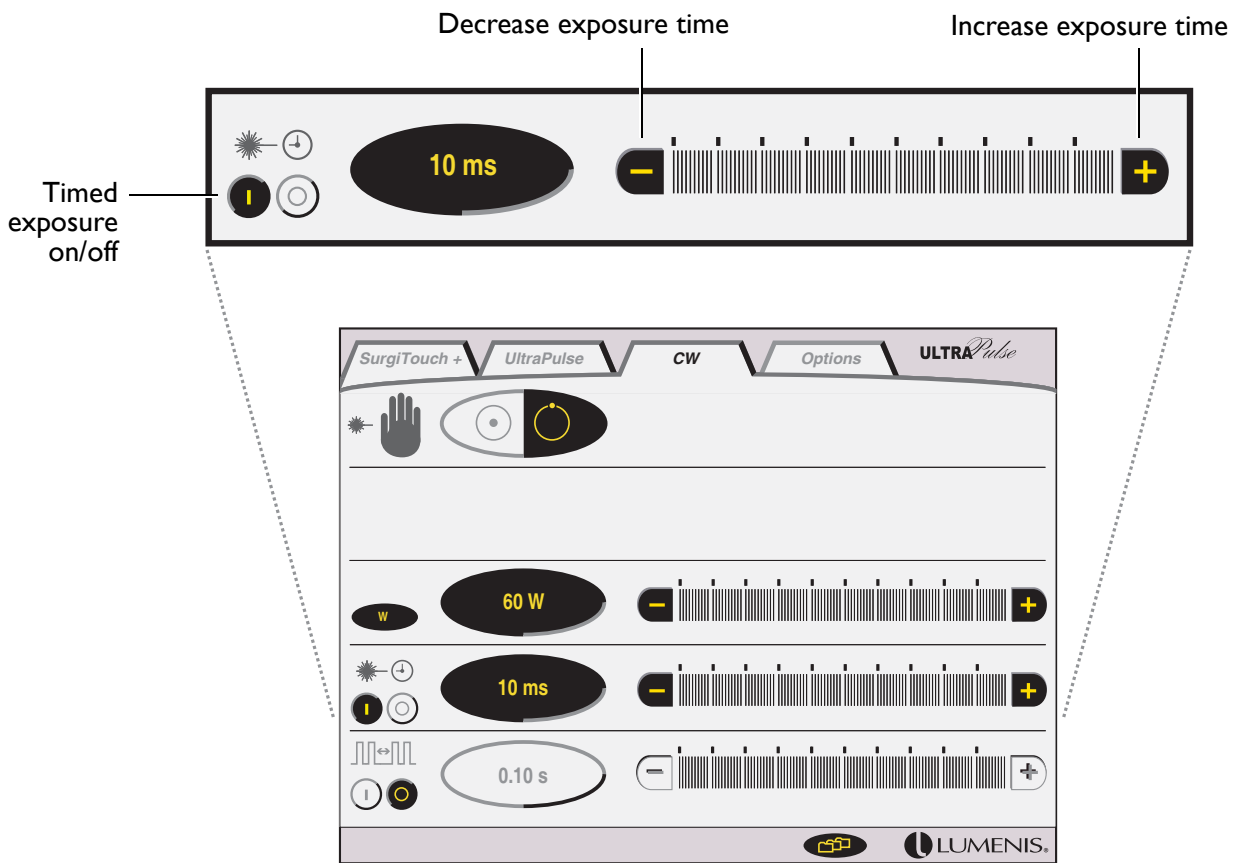
- 1 Press the  (on) button on the  (timed exposure) bar. The  button highlights to indicate that timed exposure is active.

The exposure time, in milliseconds, displays on the control screen.

- 2 Set the exposure time by pressing the  and  buttons on the timed exposure bar.



In CW mode, exposure time is available in 1-millisecond increments.

- 3 To turn off timed exposures, press the timed exposure  (off) button.





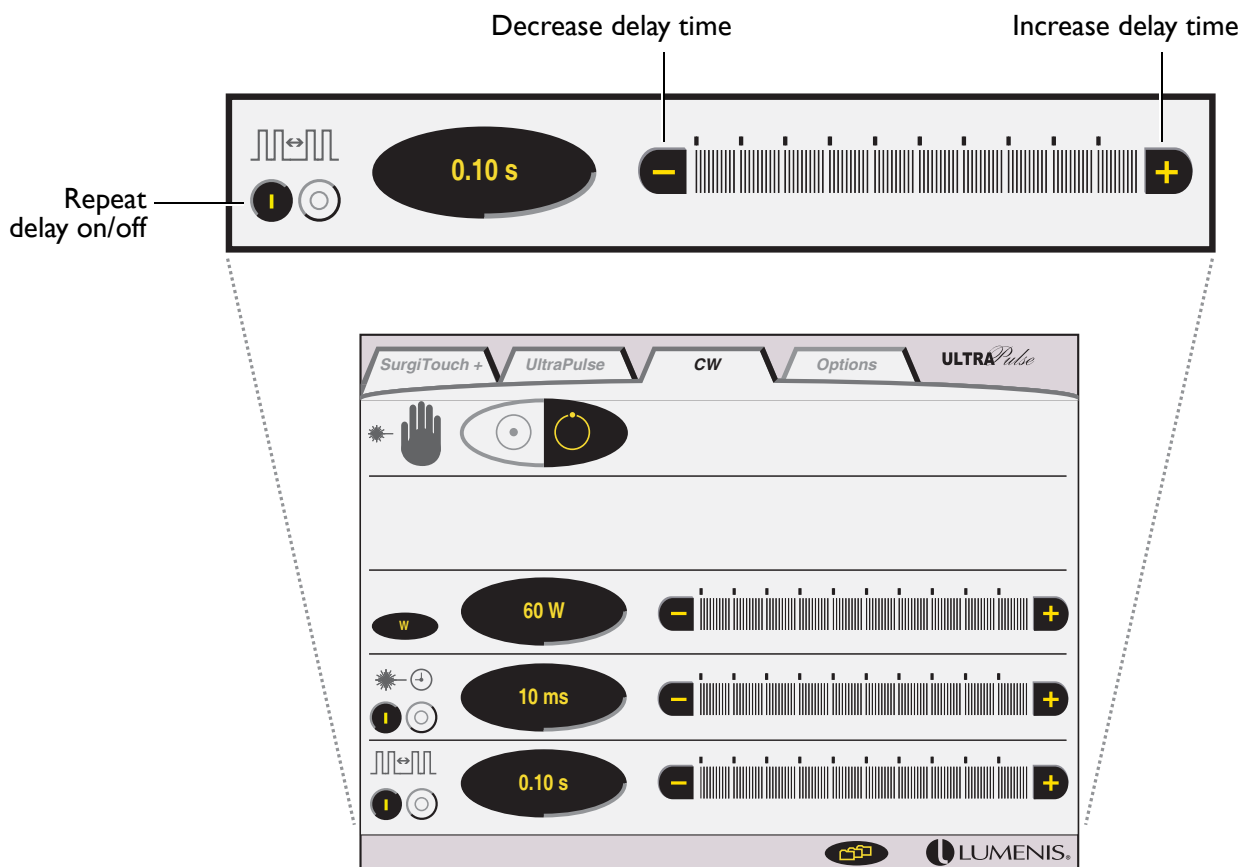
CW—Setting Timed Exposure

Setting Repeat Delay

- 1 Turn on and set timed exposure, as instructed in the previous section.
- 2 Press the  (on) button on the  (repeat delay) bar. The button highlights to indicate that repeat delay is active.

The delay time, in seconds, displays on the control screen. Available repeat delay intervals are 0.1–5.0 seconds.

- 3 Set the delay time by pressing the **–** and **+** buttons on the repeat delay bar.
- 4 To change from repeat delay to single timed exposure, press the repeat delay  (off) button. To turn off all timed exposures, press the timed exposure  (off) button.



CW—Setting Repeat Delay

Maintenance

Overview

- Troubleshooting Guide 97
- User Maintenance 104
- Electrical Utilities 105
- Specifications 107
- External Door Interlock Pin Assignments 110
- Calibration Procedure 111
- Warranty Information 113
- Decontamination of Returned Equipment 113

Troubleshooting Guide

If the instrument fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction. First, please check for the following items:

Electrical Power Source

Verify that the electrical disconnect switch, the circuit breaker, is turned on.

Laser Console Electrical

Verify that the laser is on and properly connected to an electrical service outlet.

Delivery System Connection

Verify that the delivery system is properly connected.

External Door Interlock


If the external door interlock is used in conjunction with a remote switch, verify that the external door interlock plug is inserted in the external door interlock receptacle. Close the interlocked door.







Articulated Arm







Verify that the articulated arm is properly positioned.





Problem	Probable Cause	Solution
System does not turn on. Control screen does not illuminate.	The laser is not plugged in.	⇒ Place the laser main power circuit breaker in the off (down) position, insert the laser electrical plug into the appropriate outlet, then place the laser main power circuit breaker in the on (up) position.
	The building power (main electrical service) is turned off.	⇒ Turn on the building power.
	The laser main power circuit breaker is in the off (down) position.	⇒ Place the laser main power circuit breaker in the on (up) position.
	The electrical outlet is defective.	⇒ Use another outlet or have the outlet professionally tested and, if appropriate, repaired.

Problem	Probable Cause	Solution
No treatment beam output although the aiming beam operates properly.	There is an internal laser system failure.	⇒ Contact your local Lumenis representative.
	The footswitch is defective.	⇒ With the laser in ready mode, verify that the laser emission icon appears in the laser status display when the footswitch is depressed. If the laser emission icon does not appear when the footswitch is depressed, contact your local Lumenis representative.
No treatment beam output and no aiming beam. Control screen displays and indicators are normal.	The articulated arm is improperly positioned.	⇒ Reposition the articulated arm. See “Releasing and orienting the articulated arm” in the General Operation section of this manual.
	There is an internal laser system failure.	⇒ Contact your local Lumenis representative.
Treatment beam and aiming beam are out of alignment.	The articulated arm is improperly positioned.	⇒ Reposition the articulated arm. See “Releasing and orienting the articulated arm” in the General Operation section of this manual.
	The articulated arm or laser system is internally misaligned.	⇒ Contact your local Lumenis representative.
Inadequate or no aiming beam (does not apply when waveguide delivery devices are in use).	The aiming beam is off or at a low setting.	⇒ Adjust the aiming beam intensity on the Options screen. If you are unable to fix the problem, contact your local Lumenis representative.
	The lumen or optics of the delivery device are dirty.	⇒ Verify that the lumen and optics of the delivery device are clean, as instructed in your delivery device operator manual.
	The articulated arm is improperly positioned.	⇒ Reposition the articulated arm. See “Releasing and orienting the articulated arm” in the General Operation section of this manual.
“CPG mirror position error” advisory message appears.	The CPG or SurgiTouch communication cable was attached to the laser system while the system is turned on.	⇒ Turn the system off, connect the cable and wait 15 minutes before turning the system back on. Resume normal operation.

Problem	Probable Cause	Solution
Inadequate treatment beam or tissue effect.	The treatment or aiming beam is not properly aligned.	⇒ See “Treatment beam and aiming beam are out of alignment” above.
	The lumen or optics of the delivery device are dirty.	⇒ Verify that the lumen and optics of the delivery device are clean, as instructed in your delivery device operator manual.
	The delivery device is not properly connected.	⇒ Verify that the delivery device is properly connected, as instructed in your delivery device operator manual.
	Insufflation or purge is not properly connected (for procedures requiring insufflation or purge, where applicable)	⇒ Verify that the insufflation or purge is properly connected, as instructed in your delivery device operator manual.
Articulated arm does not move freely.	The communication cable is too tight around the articulated arm joints.	⇒ Reroute the cable to provide adequate operational length at the joints.
	The arm mechanism is jammed or bent.	⇒ Contact your local Lumenis representative.
“Attach footswitch” advisory message appears.	The footswitch cable is not properly connected to the laser console, or the footswitch cable is defective.	⇒ Ensure that the footswitch is properly connected to the laser console and that the footswitch cable is not damaged. If the condition continues, restart the laser system. If the condition persists, contact your local Lumenis representative.
“Release footswitch before ready” advisory message appears.	The footswitch has been depressed while trying to enter ready mode.	⇒ Release the footswitch. Press the  button to acknowledge the message. Press the ready button to continue, ensuring that the footswitch is not depressed.
“SurgiTouch+ user interface not accessible” advisory message appears.	Your UltraPulse laser is an Encore model; the SurgiTouch+ interface is not activated.	⇒ The UltraPulse Encore model is fully upgradeable to SurgiTouch. Contact your local Lumenis representative for upgrade information.
“CPG is not compatible” advisory message appears.	The UltraScan Encore CPG handpiece model that is attached is not compatible with the laser system.	⇒ Disconnect the CPG and attach the correct one, if available. Verify that your CPG has a blue label before attempting to use it with UltraPulse laser. If the condition persists, contact your local Lumenis representative.

Problem	Probable Cause	Solution
“CPG attached—entering CPG mode” advisory message appears.	The CPG has just been attached, or the communication cable has been re-connected.	⇒ Press the  button to acknowledge the message.
“CPG detached—exiting CPG mode” advisory message appears.	The CPG has been intentionally disconnected.	⇒ Press the  button to acknowledge the message.
	The communication cable is not properly attached to the laser console or CPG handpiece, or the communication cable is defective.	⇒ Verify that the communication cable is securely plugged into the cable receptacles on the laser console and CPG and that the cable is not damaged. If the condition persists, contact your local Lumenis representative.
“Attach the UltraScan Encore CPG” advisory message appears.	You have selected the Resurfacing CPG application without attaching the CPG handpiece.	⇒ Attach the CPG handpiece, then press the Resurfacing CPG button again. ⇒ To operate without the CPG, press the  button to acknowledge the message, then select a non-CPG application.
“UltraScan Encore CPG is attached” advisory message appears.	You have inadvertently selected a non-CPG application or mode.	⇒ To continue operating in CPG mode, press the  button to acknowledge the message.
	You have tried to select a non-CPG application or mode with the UltraScan Encore CPG still attached.	⇒ Disconnect the CPG, then make your non-CPG selection again.
	You have attached the UltraScan Encore CPG with a non-CPG application selected.	⇒ Select the Resurfacing CPG application.
“SurgiTouch Scanner detached” advisory message appears.	The UltraPulse SurgiTouch Scanner has been intentionally disconnected.	⇒ Press the  button to acknowledge the message.
	The communication cable is not properly attached to the laser console or UltraPulse SurgiTouch Scanner, or the communication cable is defective.	⇒ Verify that the communication cable is securely plugged into the cable receptacles on the laser console and UltraPulse SurgiTouch Scanner and that the cable is not damaged. To continue in Scan mode, press the  (Scan) button. If the condition persists, contact your local Lumenis representative.

Problem	Probable Cause	Solution
<p>“Attach the UltraPulse SurgiTouch Scanner” advisory message appears.</p>	<p>You have inadvertently selected a scanning application or delivery device.</p>	<p>⇒ Select a non-scanning application or delivery device.</p>
	<p>You have selected a scanning application or delivery device without attaching the UltraPulse SurgiTouch Scanner.</p>	<p>⇒ To operate with the selected scanning application and delivery device, attach the UltraPulse SurgiTouch Scanner, then press the  (Scan) button.</p> <p>⇒ To operate in Non-scan mode, without the UltraPulse SurgiTouch Scanner, press the  button.</p>
	<p>The communication cable is not properly attached to the laser console or UltraPulse SurgiTouch Scanner, or the communication cable is defective.</p>	<p>⇒ Verify that the communication cable is securely plugged into the cable receptacles on the laser console and UltraPulse SurgiTouch Scanner and that the cable is not damaged. To operate in Scan mode, press the  (Scan) button. If the condition persists, contact your local Lumenis representative.</p>
<p>“SurgiTouch Scanner is attached” advisory message appears.</p>	<p>You have inadvertently selected a non-scanning application or delivery device.</p>	<p>⇒ To operate with the UltraPulse SurgiTouch Scanner, select a scanning application and delivery device.</p>
	<p>You have attached the UltraPulse SurgiTouch Scanner while in CW or UltraPulse mode.</p>	<p>⇒ To operate with the UltraPulse SurgiTouch Scanner, press the SurgiTouch+ tab, then select a compatible application and delivery device.</p>
<p>“Scan mode is not available” advisory message appears.</p>	<p>Scan mode is not available with the attached delivery device. Some delivery devices can only be used in Non-scan mode.</p>	<p>⇒ Attach a compatible scanning delivery device or, if appropriate, operate in Non-scan mode with the selected delivery device. Press the  button to acknowledge the message. Contact your local Lumenis representative for additional product information.</p>
<p>“Verify that purge is connected” advisory message appears.</p>	<p>You have selected an application or delivery device that commonly requires air or gas purge.</p>	<p>⇒ Verify that the purge device is properly connected, as instructed in your delivery system operator manual. Press the  button to acknowledge the message.</p>
<p>“Verify that insufflation is attached” advisory message appears.</p>	<p>You have selected an application or delivery device that commonly requires an insufflation system.</p>	<p>⇒ Verify that the laparoscopic insufflation device is properly connected, as instructed in your delivery system operator manual. Press the  button to acknowledge the message.</p>

Problem	Probable Cause	Solution
“Energy High” advisory message appears.	The laser detected a higher level of energy than the level selected by the user.	⇒ Press the  button to acknowledge the message. If the condition continues, turn off the system for five seconds, then restart. If the condition persists, contact your local Lumenis representative.
“Energy Low” advisory message appears.	The laser detected a lower level of energy than the level selected by the user.	⇒ Press the  button to acknowledge the message. If the condition continues, turn off the system for five seconds, then restart. If the condition persists, contact your local Lumenis representative.
“Remote interlock” advisory message appears.	The remote interlock has been activated by the opening of an interlocked door or an improperly connected interlock plug.	⇒ Close the interlocked door or connect the interlock plug. Press the  button to acknowledge the message.
“Coolant Too Hot” advisory message appears.	The coolant in the laser is overheating.	⇒ Verify that nothing is blocking the front or rear vents on the laser. Verify that there is adequate space between the laser system and walls or other treatment room equipment. Allow the system to run without depressing the footswitch for 5 minutes or until the “Coolant Too Hot” advisory message clears.
“Coolant Warm” advisory message appears.	The coolant in the laser is beginning to overheat.	⇒ Verify that nothing is blocking the front or rear vents on the laser. Verify that there is adequate space between the laser system and walls or other treatment room equipment. Allow the system to run without depressing the footswitch for 5 minutes or until the “Coolant Warm” advisory message clears.
A numeric advisory code appears.	The laser is malfunctioning.	⇒ Press the  button to acknowledge the message. If the condition continues, turn off the system for five seconds, then restart. If the advisory code reappears, record the code and contact your local Lumenis representative.

Problem	Probable Cause	Solution
“Error # 181” advisory code appears.	User command insertion error; if the user presses a succession of tabs too quickly, error # 181 will appear.	<ul style="list-style-type: none"> ⇒ Slow down your transiting from screen to screen; allow each screen to finish loading completely before advancing to the next screen. ⇒ If error # 181 appeared: <ul style="list-style-type: none"> - Go to the Options screen - Pause scanner operation (see page 49) - Resume scanner operation - Press the desired tab again. ⇒ Alternately, restart the system. ⇒ If all of the above fails, refer to Lumenis' service department.
Microscanner is Overheating	The CPG's body feels warmer than normal to your touch	<ul style="list-style-type: none"> ⇒ Shut down the laser system, disconnect the microscanner and refer to Lumenis' service department.
Microscanner is Emitting Smoke	The body of the microscanner emits smoke not normally associated with the DeepFX treatment.	<ul style="list-style-type: none"> ⇒ Shut down the laser system, disconnect the microscanner and refer to Lumenis' service department.
Microscanner Fell To the Floor	The scanners may have become mis-aligned.	<ul style="list-style-type: none"> ⇒ Perform the Laser Beam Alignment Check, as described in the accessory's manual. ⇒ If the check result is satisfactory, proceed with normal operation. ⇒ If the check result is not satisfactory, refer to Lumenis' service department.

User Maintenance

Annual Laser Maintenance

Preventative maintenance, safety, power, and calibration checks should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance.

Laser Repair

All laser repairs should be performed by a Lumenis-certified service engineer. For training and information, contact your local Lumenis service representative.

Clean the External Surfaces of the Laser Console

Use a cloth dampened with a noncaustic cleaning solution, such as soap and water, isopropyl alcohol, or a “hospital-grade” disinfectant, to wipe the external surfaces of the laser console. Dry with a clean cloth, or allow to air dry.

Clean the Laser Control Screen

Use a soft cloth to apply antistatic glass or plastic cleaner to the laser control screen.



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

Water Utilities

No water utilities are required for this laser. It has a self-contained cooling system.

Electrical Utilities

UltraPulse lasers are available in several electrical configurations. Electrical power should be set up according to the model ordered. The two line wires in the conduit shall be connected to the building power (both have live voltages), and the green/yellow wire must be connected to the building ground.

Systems Designed for Use Outside of Europe

The 100/117 VAC configuration must be supplied from a dedicated $117 \pm 10\%$ VAC, single-phase, 50/60 Hertz source. The wiring should be rated for 20 amps (as per local codes) “Hospital Grade” (NEMA 5-20R). The system can be installed with a removable or lockable wall plug or hardwired. The 100/117 VAC configuration may be changed to a 200/208 VAC configuration. This internal change must be made by a Lumenis-certified service representative. Call your local Lumenis representative for information.

The 200/208 VAC configuration must be supplied from a dedicated 200, 208, or $230 \pm 10\%$ VAC, single-phase, 50/60 Hertz source. The wiring should be rated for 16 amps (as per local codes) “Hospital Grade” (NEMA L6-30R). The system can be installed with a lockable wall plug or hardwired. Such a connection will ensure compliance with allowable leakage current levels per UL2601 for this device. Leakage current does not exceed 5 mA.

Systems Designed for Use in the European Community Under MDD

In order to comply with the European Community Medical Devices Directive 93/42/EEC and harmonized standard EN 60601-2-22, the 200/230 VAC configured UltraPulse laser must either be permanently connected to a 16A, 230 VAC, 50 Hz supply mains in accordance with national wiring regulations, or connected by means of a dedicated single phase, 16A, 250V wall socket and lockable plug combination designed to ensure the connection is “mechanically secured against accidental loosening”. Such a connection will ensure compliance with allowable leakage current levels per IEC 601 for this device. Leakage current for these systems does not exceed 5mA.

Hard-Wired Configurations

If the system is to be hardwired to the electrical service, prior to installation, the customer's engineer or electrical contractor will be responsible for ensuring that the proper electrical requirements are available at the site. After the Lumenis Service representative arrives, the customer's engineer or electrical contractor will be responsible for connecting the power cable supplied with the system to the service box, in accordance with local codes.

Removable or Lockable Wall Socket and Plug Configurations

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

Systems Designed for Use Outside of Europe

In most instances, customers must purchase a suitable electrical connection kit locally. However, for 208 VAC systems installed in the United States only, customers may order an installation kit from Lumenis (Lumenis part number 0616-369-01).

Systems Designed for Use in European communities Under MDD

To comply with the European Community Medical Devices Directive 93/42/EEC, the 16A, 250V wall socket and lockable plug combination must comply with EN 60309 (=IEC 309).

An installation kit can be ordered via your local Lumenis representative or, alternately, may be sourced locally. The wall socket and plug combination must meet the following specifications:

Plug: MK LN 9024, 16A 220-250V, IP67, IEC 309

Wall Socket: MK LN 9324, 16A 220-250V, IP67, IEC 309

Specifications

Specifications are subject to change without notice.

UltraPulse Laser	
Treatment beam	
Type	Sealed carbon dioxide, radio frequency (RF) excited
Active medium	Low-pressure mixture of carbon dioxide, nitrogen, helium, and xenon gases
Repetition rate	1 to 1,000 Hz
Pulse width	Up to 2 ms
Principal output (invisible, infrared)	10.6 μm
Beam mode (dominant)	TEM ₀₀
Laser beam spot size	Controlled by delivery system
CDRH classification	Class IV
European MDD Laser Classification	Class 4
UltraPulse mode	
Energy-per-pulse	
1 mJ increments	2–10 mJ
5 mJ increments	10–30 mJ
10 mJ increments	30–100 mJ
25 mJ increments	100–225 mJ
Repetition rate	1–1,000 pulses-per-second (Hz), adjustable
Power	1–60 watts, adjustable
Timed exposure	1 ms–1.0 second, adjustable in 1 ms increments
Repeat delay	Off time: 0.1–5.0 seconds
CW (continuous wave) mode	
Power	
0.05 watt increments	0.05–0.5 watts
0.1 watt increments	0.5–1.0 watts
0.5 watt increments	1.0–5.0 watts
1.0 watt increments	5.0–10 watts
5.0 watt increments	10–60 watts
Timed exposure	0.01–1 second, adjustable in 1 ms increments
Repeat delay	Off time: 0.1–5.0 seconds

UltraPulse Laser	
Aiming beam	
Type	Diode
Power	5.0 mW maximum
CDRH classification	Class IIIa
European MDD laser classification	3A
Principal output	635 nm
Cooling	Internal, closed-cycle, liquid-to-air heat exchanger
Electrical requirements	
100–120 VAC input power Voltage Frequency Wall outlet	100, 110, 115, or 120 VAC \pm 10% 50/60 Hz, Single phase 20 A, Dedicated service
200–240 VAC input power Voltage Frequency Wall outlet	200, 208, 220, 230, or 240 VAC \pm 10% 50/60 Hz, Single phase 16 A
100 VAC input power Voltage Frequency Wall outlet	100 VAC \pm 20% 50/60 Hz, Single phase 15 A
Environmental requirements	
Maximum altitude	3048 meters (10,000 feet)
Operating temperature	10°C to 25°C (50°F to 77°F)
Maximum humidity	90% Relative
Physical characteristics	
Office version Height Width Depth Weight	100 cm (40 inches) to top of console; 144 cm (57 inches) to top of vertical folded stored arm 34 cm (13.6 inches) front; 27 cm (10.8 inches) rear 51 cm (20 inches) 123 kg (270 lbs)
Operating room version Height Width Depth Weight	100 cm (40 inches) to top of console; 195 cm (77 inches) to top of vertical folded stored arm 34 cm (13.6 inches) front; 27 cm (10.8 inches) rear 51 cm (20 inches) 128 kg (280 lbs)
Power cable length	6.7 meters (22 feet)
Footswitch cable length	2.9 meters (9.5 feet)
Scanner communication cable length	2 meters (6.5 feet)

This product is latex free.

Laser safety eyewear

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

Compatible delivery systems

The laser is intended for use only with Lumenis-qualified delivery systems. Refer to the UltraPulse Delivery Device Connection Diagram in the General Operation section of this manual for a list of compatible delivery systems.

Operation specifications by model

Voltage (VAC)	UltraPulse power	Energy-per-pulse	Principal output
100	1–40 W*	2–225 mJ	10.6 μ m
200/208/220/230/240	1–60 W	2–225 mJ	10.6 μ m
100/110/115/120	1–60 W*	2–225 mJ	10.6 μ m

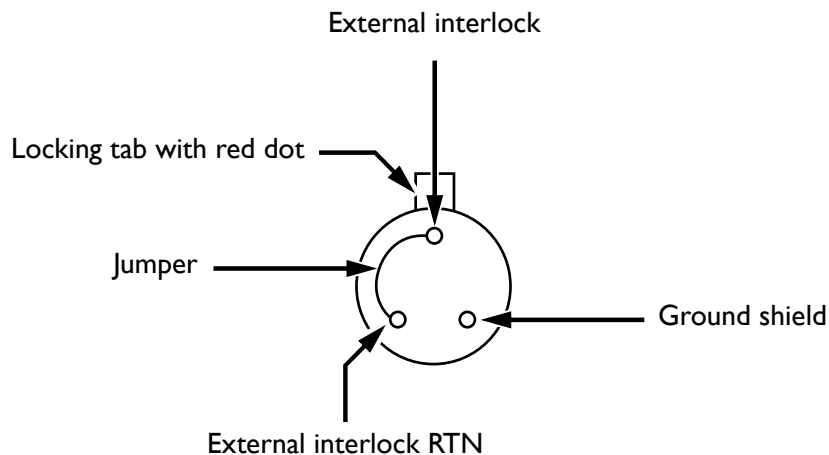
*Power limited to 20W at energies above 175mJ

External Door Interlock Pin Assignments

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

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

Pin assignments are as follows:



***External Door Interlock Pin Assignments
(solder side of plug shown)***

Calibration Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV, and European EN 60825 Class 3 and 4 medical lasers supply their customers with power calibration instructions.

Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Questions regarding this procedure should be referred to your local Lumenis representative.

Disclaimer Warning

Calibration is a service procedure to be done only by Lumenis-certified Service Engineers or customers who have taken and passed a Lumenis Service Certification Training course. Adjustment by anyone other than a trained Lumenis Service Engineer or a certified customer voids any existing manufacturer's warranty on the instrument. Contact your local Lumenis representative for information on service training courses or to purchase a service manual for the laser. It is company policy not to distribute service tools outside of the Lumenis Service Organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

Calibration Instructions

Verify Maximum Power

- 1 Ensure that all personnel are wearing the appropriate laser safety eyewear.
- 2 Position a power meter 15 cm (6 inches) from the output end of the laser articulated arm.
- 3 Turn on the laser as instructed in the Operation section of this manual.
- 4 Place the laser in UltraPulse mode.
- 5 Set the laser energy-per-pulse and power to the maximum settings.
- 6 Target the aiming beam at the power detector.
- 7 Place the laser in ready mode.
- 8 Depress the footswitch to deliver the laser energy into the power meter head. Maintain delivery of the laser energy for 20 seconds.
- 9 Record the power meter reading and release the footswitch. If the power meter reading falls above or below $\pm 20\%$ of maximum power for your laser, discontinue this procedure and contact your local Lumenis service representative.

Calibrate Laser Power

- 1 Place the system in UltraPulse mode. Set energy to 100 millijoules, and rate to 300 hertz.
- 2 Observing the power meter reading, adjust the E1 GAIN potentiometer (R40) on the main PCB until the laser power coming out of the end of the arm reaches 30 watts.
- 3 Connect oscilloscope probe channel a to TP35 (ENER1) and channel b to TP40 (ENER2).
- 4 Adjust the E2 GAIN potentiometer (R49) to match the peak integrated gain value as observed at TP35 and TP40.
- 5 Check the power readings across the operating range of the laser, and verify the consistency of the power readings with the power displayed on the control screen.

Warranty Information

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

Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment shipped to Lumenis US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a “Hospital Disinfectant.” To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided at the back of this manual) must be enclosed in the package, or Lumenis will assume that the product is contaminated and will assess the customer with cleaning costs.

Any decontamination inquiries should be directed to the Lumenis US service offices.

Safety and Regulatory

Overview

- Introduction 117
- Laser Safety Eyewear 118
- Additional Ocular Protection 121
- Additional Safety Considerations 122
- Regulatory Compliance 129

Introduction

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

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

Laser Safety Eyewear

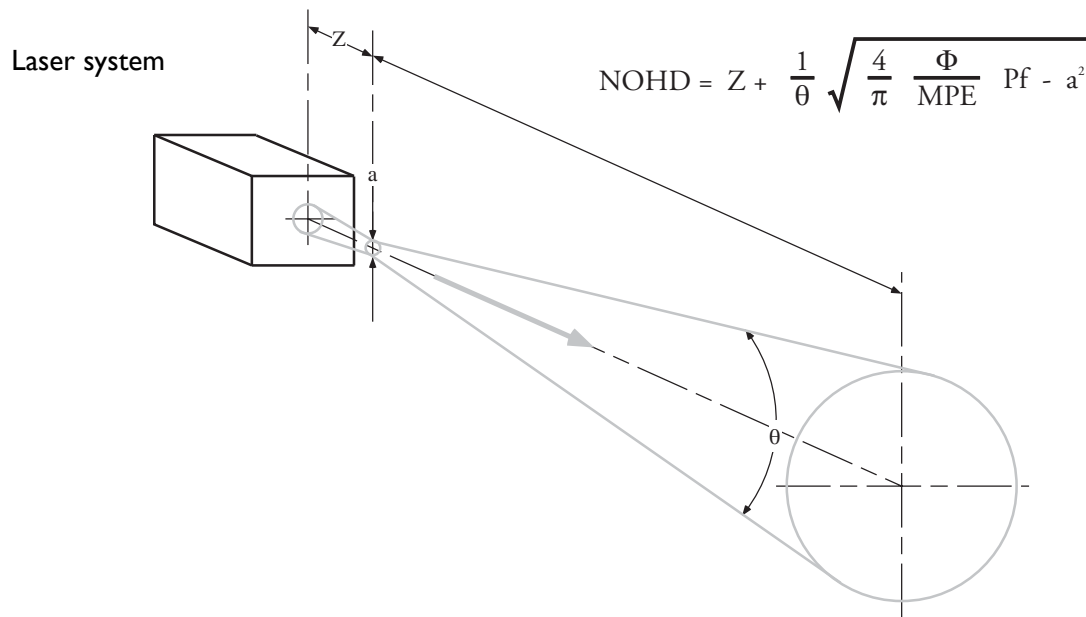
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1-2000, ANSI Z136.3-2005, or European Standard EN 60825.

The following formula was used to calculate the worst case NOHD for Lumenis UltraPulse lasers and compatible delivery systems:

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

where,

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



Using this approach we derive the following values:

Laser System	θ	Φ	MPE	Pf	a	Z
UltraPulse Encore and SurgiTouch models	0.00224	60W	0.1 W/cm ²	2	0.6 cm	1.0 cm

which results in a *worst case* NOHD of:

Laser System	NOHD
UltraPulse Encore and SurgiTouch models	175 meters

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a *minimum* optical density (OD) of:

Laser System	OD
UltraPulse Encore and SurgiTouch models	4.88


Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1-2000, section 4.6.2 and Appendix C. For users who must comply with EN 207, the safety eyewear must have a protection class of:

Laser System	EN 207 Class
UltraPulse Encore and SurgiTouch models	L4





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

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








- 1 To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
- 2 Close the treatment room door during operation of the laser.
- 3 External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

 A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

Additional Ocular Protection

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


Additional Safety Considerations


-
-  **WARNING** - Spot size and laser energy are independently controlled. If the user changes to a delivery system with a smaller spot size during a procedure, the user must remember that the energy or power density will increase.
 -  **CAUTION** - US federal law restricts this device to sale by or on the order of a physician.
 -  **CAUTION** - 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.
 -  **CAUTION** - Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam, possibly resulting in chemical burns or noxious gases. Therefore, use only stainless steel surgical instruments designed specifically for laser use.
 -  **CAUTION** - Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened.
 -  **CAUTION** - Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
 -  **CAUTION** - When using carbon dioxide as a purge gas, the treatment room must be adequately ventilated. Uncontrolled carbon dioxide gas flow can cause suffocation in a confined area.
-


Fire Hazards


Operating room personnel should be aware of the following safety considerations and potential fire hazards when using a surgical CO₂ laser:


- A CO₂ laser beam can ignite most nonmetallic materials.
- Use fire-retardant drapes and gowns.
- A UL-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 or fire could occur.

 **WARNING** - 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.

 **WARNING** - 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** - 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.

 **WARNING** - 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.

Airway Precautions

Use of the laser in the presence of oxygen increases potential fire hazard. When performing a laser procedure, the surgeon and anesthesiologist should carefully consider airway management. Oxygen concentrations should be as low as clinically permissible during airway laser procedures. Anesthetic gases should be least-supportive of combustion.

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.

The endotracheal tube cuff can be inflated with saline to protect it from inadvertent penetration. The saline can be dyed with methylene blue so that evidence of cuff-penetration by the laser will readily appear on surrounding gauze sponges. The endotracheal tube can be further protected by strategic placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry, as this increases potential fire hazard.

Smoke Evacuation—Laser Plume Pollution Hazards



CAUTION - Laser plume may contain viable tissue particulates.





CAUTION - The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.


Users 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. The vacuum tubing or probe used to evacuate the laser plume should not be used to suction blood or fluids unless it is specifically designed and set up to perform both functions simultaneously.
- Instruments with built-in features to enhance evacuation of the laser plume (such as speculums and laryngoscopes) should be used whenever possible.
- Special in-line vacuum systems designed for evacuation of the laser plume may be installed. Flow capabilities should be adequate to effectively remove the laser plume.
- Repeated suction of the laser plume into standard hospital wall suction systems without the use of an in-line filter system may eventually clog that system, requiring extensive repair. For minor procedures, wall suction may be used; however, first install an in-line disposable filter.


Protecting Nontarget Tissues


 **WARNING** - 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 familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.


 **WARNING** - Except during actual treatment, the system must always be in the standby mode. Maintaining the system in the standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.


 **WARNING** - Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution depressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch depressed is the correct one to avoid unintended laser exposure.


 **WARNING** - Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; contact your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.


 **WARNING** - Never place hands or other objects in the path of the laser beam. Severe burns could occur.


 **WARNING** - Dirty optics degrade laser energy transmission. Cleaning the device optics or adjusting the laser articulated arm may eliminate this problem; however, this may also effectively increase the laser energy delivered to the treatment site, causing an unintended tissue effect and possible serious tissue damage. Therefore, it is important that after cleaning the device optics or adjusting the laser articulated arm, and prior to surgical use, the surgeon test the system and device to verify the lowest effective settings for the specific procedure. The lowest effective treatment settings should be used until the biological interaction and surgical effect are verified. Settings can then be increased in appropriate increments until the optimum treatment settings are obtained.

 **WARNING** - Backstops exposed to continuous CO₂ laser energy may become excessively hot. Do not allow a hot backstop to touch tissue or any flammable materials. Doing so may cause possible injury or fire.

 **CAUTION** - Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.

 **CAUTION** - 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.

 **CAUTION** - To prevent unintended laser discharge, always turn off the laser before connecting a delivery system.

 **CAUTION** - Use caution when performing the laser beam alignment check, as instructed in the delivery device operator manual. Care should be taken to ensure that the alignment procedure is not performed in line with the patient, operating room personnel, or flammable materials.





CAUTION - Metal instruments used behind the area of treatment, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid reflection.

Nontarget tissues may be protected in the following ways:

- Saline soaked gauze sponges, moistened cotton-tipped applicators, or titanium rods may be used as backstops for the laser beam.
- Saline may be used in the abdomen to absorb stray laser energy.
- Specialized instrumentation such as laparoscopes with laser beam backstops and retractors designed to protect nontarget tissues may be used.
- 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 nontarget tissue.

Electrical Safety

 **WARNING** - Never open the laser console protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.

 **WARNING** - To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

Residual Current Circuit Breaker

Lumenis strongly recommends the installation of a residual current circuit breaker (RCCB), also referred to as a ground fault circuit interrupter (GFCI).

This is an electrical wiring device that disconnects a circuit whenever it detects that the electric current is not balanced between the phase ("hot" or "live") conductor and the neutral conductor. Such an imbalance is sometimes caused by current leakage through the body of a person who is grounded and accidentally touching the energized part of the circuit. A lethal shock can result from these conditions; RCCBs are designed to disconnect quickly enough to mitigate the harm caused by such shocks.

The RCCB should be obtained locally and be installed by a qualified electrician, and the maximum rated leakage current must be 130 mA.

Regulatory Compliance

Lumenis lasers and delivery systems comply with 21 CFR Chapter 1, Subchapter J, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

CE-labeled devices comply with all appropriate performance standards as specified in Annex II of the Medical Device Directive MDD 93/42/EEC as amended by 2007/47/EC.

Emergency Off Push Button

The laser has an emergency off push-button that immediately turns off the laser.

Key Lock Switch

To prevent unauthorized use, the laser can only be turned on with the master key, the key can only be removed when the laser is turned off, and the laser only operates when the key is inserted into the keyswitch. When the keyswitch is turned to the start position, the laser power-up sequence is initiated.

Location of Controls

Operation and adjustment controls are located so that the user need not be exposed to laser radiation during laser operation or adjustment.

Protective Housing

The laser has a protective housing that prevents unintended human access to laser radiation above Class I limits. The housing must only be opened by a Lumenis-certified technician.

External Door Interlock

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

Safety Interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the laser does not have, and is not required to have, any safety interlocks within the meaning of US FDA 21 CFR, Section 1040 or European EN 60825-1. However, the protective housing cannot be easily opened without special tools.

Manual Reset

If laser emission is externally interrupted during treatment by remote interlock activation, the laser will automatically go into standby and the safety shutter will revert to a closed position. To resume treatment, manually reset the laser by placing the laser in ready mode.

If laser emission is interrupted during treatment by main electrical power loss, the laser system will automatically turn off. To resume treatment after an electrical power loss, the system must be manually restarted by rotating the keyswitch to the start position.

Electronic Fault Detection Circuitry

If the electronic system detects a fault condition, laser exposure cannot occur. The high voltage power supply is turned off, the high voltage capacitor is discharged, the safety shutter is closed, and the footswitch is disabled.

Some fault conditions may be cleared by the operator. Refer to the Troubleshooting Guide in this manual for additional information.

Safety Shutter

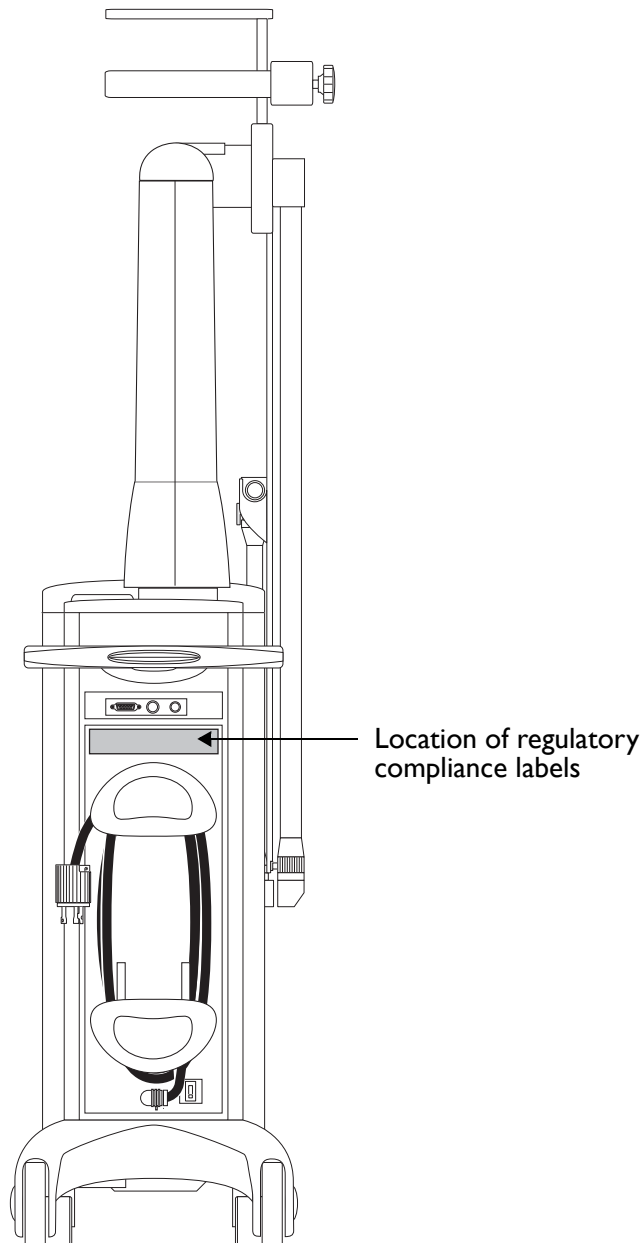
The laser includes an electronic safety shutter that prevents unintentional laser emission. The safety shutter opens only when the user places the system in ready mode and depresses the footswitch. The safety shutter remains closed when the system is turned off, during self-test at system turn on, when the system is placed in standby mode, or when the safety monitor detects a fault.

Laser Emission Indicators

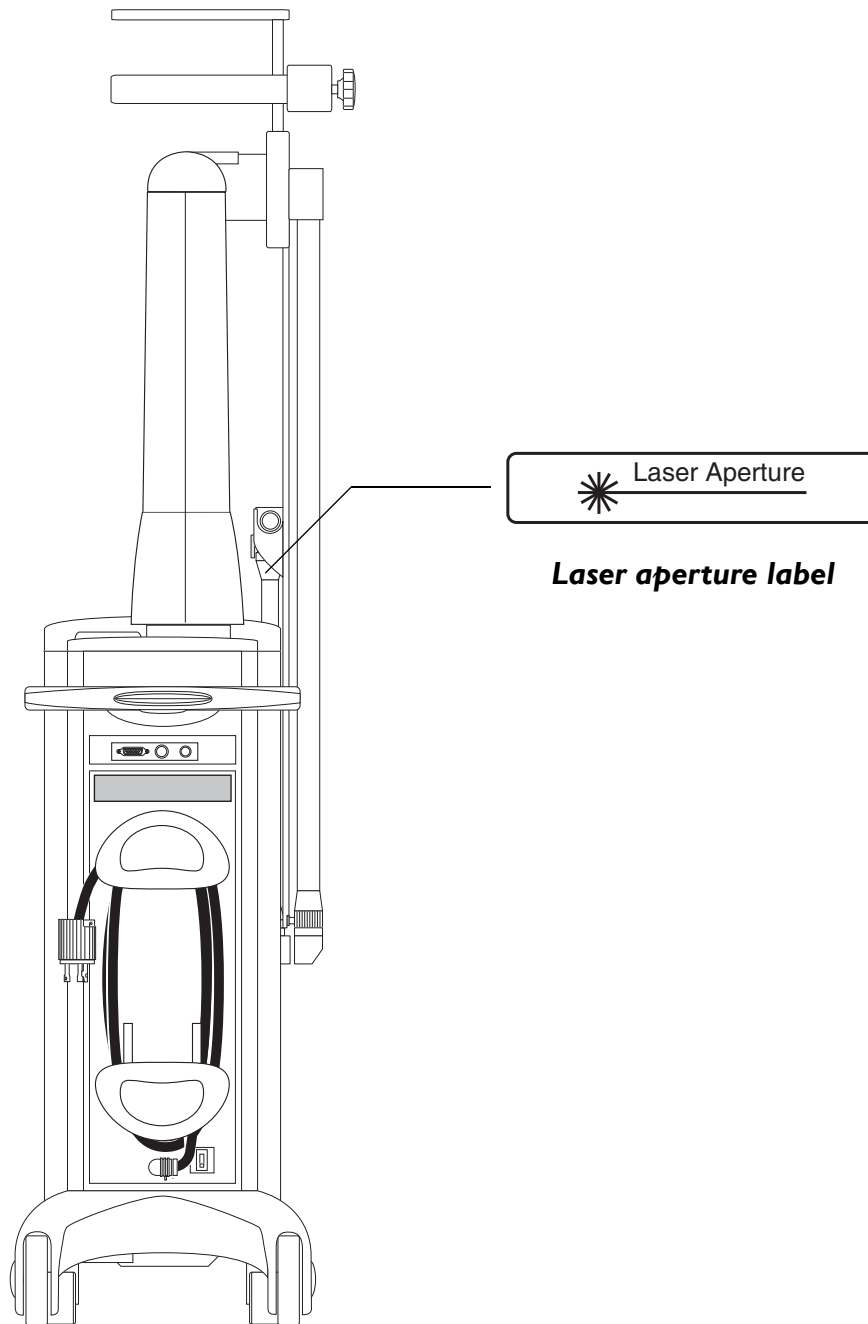
The ✱ (laser startup emission indicator) appears on the control screen during system startup and on the Options screen at all times to alert the user that the system is able to emit laser radiation. Before treatment beam delivery, the system emits a low-pitched tone to indicate the beginning of a two-second delay until laser radiation is accessible. After two seconds, the system emits a high-pitched tone to indicate that laser radiation is accessible. During treatment beam delivery, ⚠ (laser emission indicator) appears in the laser status display on the treatment screen to indicate that laser emission is occurring.

Location of Regulatory and System Labels

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



Location of Regulatory Compliance Labels



Location of Regulatory Compliance Labels



Lumenis contact information



Danger label



ETL compliance label

IP 20

Ingress protection



CE mark (for MDD-compliant products)

Regulatory Compliance Labels



(Read and comprehend the operator manual before use.)

Attention, read manual

CAUTION:
U.S. FEDERAL LAW RESTRICTS
THIS DEVICE TO SALE BY OR ON
THE ORDER OF A PHYSICIAN


**US FDA Prescription use
device statement**

THIS PRODUCT COMPLIES
WITH 21 CFR, CHAPTER I,
SUBCHAPTER J

**DHHS Certification
(for FDA-compliant systems)**

MADE IN ISRAEL
U.S. AND INTERNATIONAL
PATENTS PENDING

Patents pending

REF
SN


**Part number, serial number,
and manufacturing date**

100 D 120V~ 50/60 Hz 20A, 1 ϕ	or	200 D 240V~ 50/60 Hz 16A, 1 ϕ
---	----	---

Electrical specification

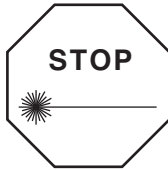
Regulatory Compliance Labels



Type BF electric shock protection



Electrical shock hazard warning



Emergency stop



(Danger. Possible explosion hazard if used in the presence of flammable anesthetics, oxygen, or nitrous oxide.)

Flammable anesthetics and gases warning



Class I equipment



Mains switch



Footswitch receptacle



Communication cable receptacle



Remote interlock receptacle

Regulatory Compliance and System Labels

Indications for Use

Overview

- General Indications 139
- Aesthetic (Dermatology/Plastic Surgery) Indications 142
- Podiatry Indications 152
- Otolaryngology (ENT) Indications 153
- Gynecology and GYN Laparoscopy Indications 159
- Neurosurgery Indications 161
- Orthopedics Indications 162
- General and Thoracic Surgery Indications 163
- Dental and Oral Surgery Indications 164
- Genitourinary Indications 166
- Clinical Studies Referenced 167

General Indications

The UltraPulse CO₂ laser is intended for use in surgical and aesthetic procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue in medical specialties including:

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

The carbon dioxide wavelength is indicated for use in specific surgical and aesthetic applications, as detailed in this chapter. Read and comprehend all of the following general contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for appropriate specialties.

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



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.



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

General Laser Contraindications

- Do not use the UltraPulse CO₂ laser on hard tissues, such as bone or teeth.
- Do not use the CO₂ laser for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the CO₂ laser on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective
- Do not use the UltraPulse CO₂ laser where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.

General Laser Warnings and Precautions



WARNING - There is a risk of infection and scarring associated with any surgical procedure. Therefore, appropriate pre-and post-surgical care should always be practiced.



WARNING - Purge gases used with CO₂ delivery devices and waveguides may increase the risk of gas embolism where large, open cranial veins are present. Monitor all patients undergoing cranial procedures for gas embolism, which may occur even without the use of the laser.



CAUTION - Laser test patching should be considered prior to treatment to avoid unexpected results.

General Laser Recommendations

- The surgeon must employ appropriate patient selection and pre- and post-operative management.
- Select the appropriate delivery device for the intended application after consulting with surgical experts, reviewing the published literature, and attending procedure-specific training programs. See the UltraPulse Delivery Device Connection Diagram in the General Operation section of this manual for a list of compatible delivery devices.
- 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 CO₂ laser will entirely eliminate any disease entity. Repeat treatment or alternative therapies subsequently may be required.

Aesthetic (Dermatology/Plastic Surgery) Indications

The UltraPulse 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)



Clinical study¹ demonstrated that skin resurfacing of wrinkles, rhytids, and furrows with the UltraPulse CO₂ laser increases the amount of sub-epidermal collagen.

- 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

1. Study I in "Clinical studies referenced" at the end of this chapter

- 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, periungual, 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

▷ Clinical studies¹ demonstrate that CO₂ laser blepharoplasty provides cosmetic results that are equivalent to cold steel blepharoplasty, is up to 33% faster than cold steel blepharoplasty, provides good hemostasis and visualization of the surgical field, and results in less ecchymosis, edema, and bruising when compared to cold steel.

▷ Clinical studies² demonstrate that using the UltraPulse CO₂ laser for the creation of recipient sites for hair transplantation, when compared to cold steel, results in faster operative times, reduced bleeding, no compression of laser created sites, and greater hair density due to vaporization of scalp tissue from laser created sites.

1. Studies 2–7 in “Clinical studies referenced” at the end of this chapter
 2. Studies 8–11

Safety Considerations for Dermatology and Plastic Surgery

Read “Safety considerations for laser skin resurfacing” in this section for information that is specific to resurfacing procedures.

Contraindications

In some treatments (for example, tattoo removal), scar tissue formation has been reported which may fade or become permanent. Therefore, use of the CO₂ laser for cosmetic removal of dermal skin lesions may be contraindicated in patients unwilling to accept the potential risk of scar formation.

Complications and Expected Sequelae

General dermatology and plastic surgery complications include:

- scarring
- ulceration
- persistent edema
- infection
- persistent erythema

General 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

Safety Considerations for Laser Skin Resurfacing

Read “Safety considerations for dermatology and plastic surgery” in this section for additional considerations.

Contraindications

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

- have taken Acutane® (isotretinoin) 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

Precautions and Recommendations



CAUTION - Lower energy densities may cause excessive thermal injury to underlying tissue through conducted heat. High energy densities may result in excessive tissue vaporization.



CAUTION - Overlap of treatment spots when using the TrueSpot 2.0mm Collimated handpiece will cause increased energy density and thermal effect to the treatment area.



CAUTION - The energy density and thermal effect obtained with the UltraScan Encore CPG can be increased by two variables: 1) pattern overlap; and 2) selection of the pattern density variable of the CPG control.

- For superficial ablation of tissue, UltraPulse mode of operation with the UltraScan Encore CPG or TrueSpot 2.0mm handpiece is recommended to limit depth of thermal injury or char.

Complications and Expected Sequelae

Laser skin resurfacing 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
- preauricular flap necrosis
- postauricular skin slough/loss

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)
- reactivation of herpes simplex

▶ The incidence and duration of postoperative hyperpigmentation may be higher in subjects with mildly sun-damaged skin (Class I) than in subjects with moderate to severe sun-damaged skin (Class II/III).

▶ The incidence of immediate postoperative pain may be higher in subjects with mildly sun-damaged skin (Class I) when treated more aggressively (with more than one laser pass).

▶ Less aggressive laser treatment may be associated with increased postoperative burning sensation, while more aggressive laser treatment may be associated with decreased postoperative burning sensation.

Patient Care and Treatment Recommendations for Laser Skin Resurfacing

-
- ▶ 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.
 - ▶ Throughout the preoperative, operative, and postoperative time-period, antibiotic and/or antiviral medications should be prescribed prophylactically and/or as needed, at the discretion of the physician.
-

Preoperative Preparation Of the Skin

- Prior to laser skin resurfacing, sunscreen (Coppertone® Shade® Sunblock, or equivalent UVA/UVB protection; Schering-Plough HealthCare Products, Inc., Memphis, TN, USA) and Retin-A® (Ortho Pharmaceutical Corporation, Dermatological Division, Raritan, NJ, USA) should be applied topically once daily in the morning for a minimum of 2 weeks.
- Subjects with an increased risk for hyperpigmentation, typically identified as having skin types III, IV, V and VI (classified as individuals who tan and/or have skin pigmented from light brown to black), should apply topical hydroquinones¹, such as Melanex® (Neutrogena Dermatologics, Los Angeles, CA, USA), or an equivalent depigmenting agent, twice daily, in the morning and evening, for a minimum of 2 weeks, preferably 4 to 6 weeks, prior to laser skin resurfacing.
- Preoperative topical application of retinoids, such as Retin-A or Renova® (Ortho Pharmaceutical Corporation), may be used for its collagen regeneration benefits.²
- Laser test patching should be considered prior to treatment, especially for subjects identified as having skin types III, IV, V and VI.

1. Study 12 in “Clinical studies referenced” at the end of this chapter
2. Study 12

Preoperative Medications

- Particularly in subjects with a history of herpes simplex virus (HSV), antiviral therapy, such as oral acyclovir or a similar antiviral, is recommended. Additionally, a subject with a history of recurrent HSV should be covered with a similar or higher dose, administered from 1 to 2 days preoperative.
- Particularly for those patients with a history of frequent outbreaks of facial HSV, clinicians recommend antiviral agents such as Valtrex[®] (Galxo Wellcome, Inc., Research Triangle Park, NC, USA) or Famvir[®] (SmithKline Beecham Pharmaceuticals, Philadelphia, PA, USA).¹
- For women prone to vaginal candidiasis, prophylactic oral antiyeast medications may be used.²
- Clinicians often recommend administering an oral antibacterial agent with coverage for Pseudomonas aeruginos, such as Cipro[®] (Bayer Corporation, West Haven, CT, USA); though its potential overgrowth of other noncovered bacteria or candida should be considered.³

1. Studies 12 and 13 in “Clinical studies referenced” at the end of this chapter
2. Study 12
3. Studies 12 and 13

Suggested Delivery Devices

Laser skin resurfacing with the UltraPulse laser is usually performed with either the TrueSpot 2.0mm collimated handpiece or the UltraScan Encore CPG handpiece. The TrueSpot 2.0mm handpiece is used for freehand manual resurfacing. The UltraScan Encore CPG is used for automated scanning.

CoolScan and CO₂ Lite modes are only available with the UltraScan Encore CPG. CoolScan is a non-linear scanning mode. CO₂ Lite is used to perform light skin resurfacing.



CO₂ Lite mode can be used to limit depth of tissue injury. A single pass is recommended when operating in CO₂ Lite mode, and fluence is limited to 2.25–3.75 J/cm². The resulting tissue effect is thermal coagulation confined to the epidermis (depth of coagulation is approximately 60–100µm), with aesthetic outcomes and post-operative healing times similar to that achieved with the Erbium:YAG laser.¹

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.

Postoperative Care

- Subjects should maintain a barrier coating of Vaseline[®] (Chesebrough-Pond's USA Co., Greenwich, CT, USA), or an equivalent occlusive ointment or dressing, to prevent direct contact between the treated tissue and the air during the healing process.



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 7 and 14 days postoperatively.

- Subjects should apply cool water and white vinegar soaks to the treated area at least 4 times daily, making sure to reapply the occlusive ointment or dressing between soaks.
- Subjects should avoid unprotected exposure to sunlight.

2 weeks postoperative:

Subjects should discontinue use of occlusive ointment or dressing and begin the use of a facial moisturizer.

4 weeks postoperative:

Subjects should resume daily use of sunscreen and Retin-A[®]. At the discretion of the physician, subjects with Types III-VI skin may also resume use of topical hydroquinones¹, such as Melanex[®], or an equivalent depigmenting agent (twice daily).

1. Study 12 in "Clinical studies referenced" at the end of this chapter

Podiatry Indications

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

- Laser ablation, vaporization and/or excision of soft tissue for the reduction, removal, and/or treatment of:
 - verrucae vulgares/plantar (warts), including paronychia, periungual, 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

Safety Considerations for Podiatry

Complications

General podiatry complications include:

- infection
- ulceration of tissue

Laser matrixectomy complications also include:

- sterile inflammatory condition

Otolaryngology (ENT) Indications

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


- 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 esophagodiverticulostomy (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


Safety Considerations for ENT


Read “Safety considerations for LAUP” and “Safety considerations for myringotomy/tympanostomy” in this section for information regarding specific ENT procedures.


Warnings and Precautions


 **WARNING** - To prevent airway fires and severe injury to the patient, protect endotracheal tubes from exposure to the CO₂ wavelength, or use CO₂ laser-resistant endotracheal tubes.

 **WARNING** - To prevent airway fires and severe injury to the patient, do not direct the CO₂ laser at any tracheal tube in any oxygen-enriched environment, or any other environment that supports combustion.

 **WARNING** - To prevent airway fires and severe injury to the patient, consideration of the type of anesthesia and ventilation are important.

 **WARNING** - To prevent severe injury to the patient, middle ear surgery should be performed with appropriate parameters, considering acoustic and thermal effects.

 **CAUTION** - Nasal and laryngeal probes (waveguides) produce a divergent beam with a minimum spot size close to the tip of the instrument.

 **CAUTION** - Avoid placing the tip of the nasal or laryngeal probe (waveguide) in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.

Complications and Expected Sequelae

General ENT complications include:

- unintended thermal injury from combustion of anesthesia or other volatile surgical preparation solutions
- excessive bleeding
- infection
- edema
- hearing loss

Zenker’s Diverticulum

- transient soft tissue emphysema
- mediastinitis

Tonsil Ablation/Tonsillectomy

- transient dysphagia
- mucosa lesions

Cordotomy

- formation of granuloma

Turbinate Reduction/Ablation

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

Safety Considerations for LAUP

Read “Safety considerations for ENT” in this section for additional considerations.

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, or patients with disproportionately short necks.

Precautions



CAUTION - The physician should take appropriate precautions when evaluating and selecting patients presenting with chronic palatal snoring and other significant symptoms of sleep apnea.

Complications


LAUP complications include:


- excessive bleeding
- infection
- edema
- rhinophonia
- nasopharyngeal stenosis
- velopharyngeal incompetence

Safety Considerations for Myringotomy/Tympanostomy (Tympanic Membrane Fenestration)

Read “Safety considerations for ENT” in this section for additional considerations.

Precautions and Recommendations

 **CAUTION** - Clinical studies¹ have shown that patency time is directly related to the diameter of the laser fenestration. The average diameter used is 2.0mm; therefore, clinical judgement and caution should be used when exceeding this diameter.

 **CAUTION** - Uncooperative pediatric patients should be appropriately restrained during office OtoLAM myringotomy/tympanostomy procedures.

- It is recommended that a local or topical anesthesia be administered prior to the OtoLAM myringotomy/tympanostomy procedure.
- Following laser-assisted myringotomy/tympanostomy, a pressure-equalizing tube may be used in situations when long-term ventilation has been determined to be necessary.
- Refer to the current published literature on myringotomy/tympanostomy for clinical parameters and techniques.

Complications

Myringotomy/tympanostomy complications include:

- scarring
- transient otorrea
- infection
- recurrence of otitis media

1. Studies 20–22 in “Clinical studies referenced” at the end of this chapter

Gynecology and GYN Laparoscopy Indications

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

- 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

Safety Considerations for Gynecology and GYN Laparoscopy

Contraindications

- Use of the CO₂ laser is contraindicated for patients who are not candidates for general surgery, where local or spinal epidural anesthesia is inappropriate.
- Use of the CO₂ laser is contraindicated for laparoscopic applications where laparoscopy is contraindicated.

Complications

Gynecology and laparoscopic surgery complications include:

- excessive bleeding
- infection
- excessive thermal injury or vaporization of tissue
- gas embolism
- subcutaneous emphysema

Precautions for Laparoscopic Surgery



CAUTION - When using a laser laparoscope or waveguide accessory, maintain an adequate flow of CO₂ purge gas through the delivery device. 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.



CAUTION - Ensure that the laser laparoscope is properly aligned and a clear, round aim beam is visible at all times.



CAUTION - Laparoscopic waveguides produce a divergent beam with a minimum spot size close to the tip of the instrument.



CAUTION - Avoid placing the tip of the waveguide in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.

Neurosurgery Indications

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

- 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)

Safety Considerations for Neurosurgery

Contraindications

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

Warnings



WARNING - Using the laser to open the dura causes shrinkage that may make closure difficult or impossible.

Complications

There are no known complications specific to the use of the CO₂ laser in neurosurgery. However, the physician is advised to consult current literature for any new information on potential neurosurgery complications relating to CO₂ laser treatment.


Orthopedics Indications


The UltraPulse laser is indicated for incision, excision, and vaporization of soft tissue in orthopedic surgery, including the following applications:

- 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

Safety Considerations for Orthopedics

Warnings and Precautions

 **WARNING** - When performing arthroscopic surgery with waveguides where purge gas is required, control the purge gas with a tourniquet to prevent pressurization of an enclosed space (for example, shoulder), which can result in gas embolism or systemic subcutaneous emphysema.

 **CAUTION** - 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.

Complications

Orthopedics complications include:

- subcutaneous emphysema
- synovitis

General and Thoracic Surgery Indications

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

- 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, pilar cysts, and mucous cysts of the lips
- pilonidal cyst removal and repair
- abscesses
- other soft tissue applications

Safety Considerations for General and Thoracic Surgery

Refer to Gynecology Indications in this chapter for safety considerations that are specific to laparoscopic procedures.

Contraindications

Use of the CO₂ laser is contraindicated for laparoscopic procedures where laparoscopy is contraindicated.

Complications

General and thoracic surgery complications include:

- excessive bleeding
- infection
- excessive thermal injury or vaporization of tissue

Dental and Oral Surgery Indications

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

- 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

Safety Considerations for Dental and Oral Surgery

Contraindications

Use of the CO₂ laser is contraindicated for hard tissue applications.

Precautions



CAUTION - 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.

Complications

Dental and oral surgery complications include:

- laser damage to teeth through inappropriate use
- infection

Genitourinary Indications

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

- benign and malignant lesions of external genitalia
- condyloma
- phimosis
- erythroplasia

Safety Considerations for Genitourinary Procedures

Complications

There are no known complications specific to the use of the CO₂ laser in genitourinary procedures. However, the physician is advised to consult current literature for any new information on potential genitourinary complications relating to CO₂ laser treatment.

Clinical Studies Referenced

1. Randomized, prospective clinical study sponsored by Coherent Medical Group (now Lumenis, Inc.).
2. Morrow D; Morrow L. "CO₂ Blepharoplasty: A Comparison with Cold-Steel Surgery." *J Dermatol Surg Oncol* 1992; 18:307–313.
3. David L. "The Laser Approach to Blepharoplasty." *J Dermatol Surg Oncol* 1988; 14:7:741–746.
4. David L; Sanders G. "CO₂ Laser Blepharoplasty: A Comparison to Cold Steel and Electrocautery." *J Dermatol Surg Oncol* 1987; 13:2:110–114.
5. Baker S; Muenzler W; Small R; Leonard J. "Carbon Dioxide Laser Blepharoplasty." *Ophthalmology* 1984; 91:238–244.
6. David L; Abergel R. "CO₂ Laser Blepharoplasty." *Cosmetic Surgery of the Skin: Principles and Techniques*, B.C. Decker, Philadelphia, PA, 1991, Chapter 15:295–300.
7. Glassberg E; Babapour R; Lask G. "Current Trends in Laser Blepharoplasty." *Dermatol Surg* 1995; 21:1060–1063.
8. Unger W. "Laser Hair Transplantation II." *Dermatol Surg* 1995; 21:759–765.
9. Fitzpatrick R. "Laser Hair Transplantation—Tissue Effects of Laser Parameters." *Dermatol Surg* 1995; 21:1042–1046.
10. Ho C; Nguyen Q; Lask G; Lowe N. "Mini-Slit Graft Hair Transplantation Using the Ultrapulse Carbon Dioxide Laser Handpiece." *Dermatol Surg* 1995; 21:1056–1059.
11. Unger W; David L. "Laser Hair Transplantation." *J Dermatol Surg Oncol* 1994; 20:515–521.
12. Kilmer S; Linsmeier M D. "Preoperative Preparation of the Laser Resurfacing Patient." *Operative Techniques in Otolaryngology—Head and Neck Surgery* 1997; 8(1):31–34.
13. Goldman M. "Postoperative Care of the Laser Resurfacing Patient." *Operative Techniques in Otolaryngology—Head and Neck Surgery* 1997; 8(1):35–36.
14. Rosenberg G J. "Full Face and Neck Laser Skin Resurfacing." *Plastic and Reconstructive Surgery* 1997; 100(7):1846–54.
15. Adrian R. "A Clinical and Histological Comparison of Low Fluence Pulsed Carbon Dioxide and Erbium Lasers in the Treatment of Photoaged Skin." *Laser Surg Med Suppl*. 1999; 11(suppl):28.

16. Adrian R. “Comparative Studies of Superficial and Deep Resurfacing Using the UltraPulse CO₂ Laser and Erbium:YAG Laser in Photodamaged Skin.” Unpublished clinical data on file at Lumenis, Inc. 1999.
17. Chernoff W G. “Histological Perspective of Laser Resurfacing.” *Operative Techniques in Otolaryngology—Head and Neck Surgery* 1997; 8(1):2–8.
18. Ross V E; Naseef G S; McKinlay J R; Barnette D J; Skrobal M; Grevelink J; Annserson R R. “Comparison of Carbon Dioxide Laser, Erbium:YAG Laser, Dermabrasion and Dermatome.” *Journal of the American Academy of Dermatology* 2000; 42(1):92–105.
19. Fitzpatrick R E; Tope W D; Goldman M P; et al. “Pulsed Carbon Dioxide Laser, Trichloroacetic Acid, Baker-Gordon Phenol, and Dermabrasion: A Comparative Clinical and Histological Study of Cutaneous Resurfacing in a Porcine Model.” *Arch Dermatol* 1996; 132:469–471.
20. Sedlmaier B; Jivanjee A; Gutzler R; Huscher D; Jovanovic S. “Duration of Middle Ear Ventilation After Laser Myringotomy with the CO₂ Laser Otoscope OtoScan.” *HNO* 2000; 49(6):447–53.
21. Silverstein H; Jackson L E; Rosenberg S I; Conlon W S. “Pediatric Laser-Assisted Tympanostomy.” *Laryngoscope* 2001; 111(5):905–6.
22. Silverstein H; Kuhn J; Choo D; Krespi Y P; Rosenbergi S I; Rowan P T; “Laser Assisted Tympanostomy.” *Laryngoscope* 1996; 106:9:1:1067–74.

Decontamination Certificate

Under the provisions of Postal Law, Title 18, United States Code, Section 1716, and Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, “etiologic agents, diagnostic specimens and biological products...are nonmailable...”

The undersigned therefore certifies that the Lumenis equipment being returned herein by

Individual/Institution

City, State, Country

has undergone decontamination with a commercially available germicide cleared for use as a “Hospital Disinfectant” and is clean and free from biohazards, including—but not limited to—human or animal blood, tissue or tissue fluids or components thereof.

The undersigned also agrees to reimburse Lumenis for any costs incurred in cleaning the enclosed equipment, in the event said item(s) is/are received by Lumenis in a contaminated condition.

Model

Model

Serial Number (if applicable)

Serial Number (if applicable)

Lumenis RMR Number

Lumenis RMR Number

Typed/Printed Name

Position/Title

Signature

Date

