LightSheer® Duet™

Diode Laser System

Operator Manual

LUMENIS®

Enhancing Life. Advancing Technology.

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Manufactured by Lumenis, Ltd.
P.O.B. 240
Yokneam 20692, Israel
Tel: +972.4.959.9000

Authorized Representative:
Lumenis GmbH Germany
Heinrich-Hertz-Strasse 3
D-63303 Dreieichenhain
Germany

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 wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual treatment and recovery at an approved recycling facility.

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

Lumenis provides web-based collection, recycling and reporting arrangements to the business end-user for equipment marked with the crossed-out wheelie bin. Please visit www.lumenis.com/recycling to understand what arrangements Lumenis has made in each EU Member State.

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Safety and Regulatory

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Regulatory Compliance

The LightSheer Duet system complies with 21 CFR, Chapter I, Subchapter J, as administered by the Center for Devices and Radiological Health (CDRH) of the 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 ammended by 2007/47/EC. The LightSheer system is classified as a Class IV laser by the CDRH and as a Class 4 laser by the European Standard EN 60825-1.

⚠ **WARNING - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.**

The following precautions are extensive but may not be complete. Laser users are advised to supplement these precautions with information regarding technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. For more information refer to ANSI Z136.3, ANSI Z136.1, and EN 207 for recommendations on the safe use of lasers in health care facilities. Please follow the recommendations of the latest edition of these standards. In particular, the use of safety eyewear with an adequate optical density rating for the LightSheer wavelength must be used for all persons with the potential for laser exposure.

All persons operating the LightSheer Duet laser system or in the vicinity of the laser must be aware of the potential hazards. Be certain all personnel carefully review the following safety information. Only authorized individuals with appropriate laser training and knowledge should operate, assist in the operation of, or provide maintenance to the LightSheer system. For information on training, contact Lumenis Customer Support.

In Canada this device must be installed and operated according to CAN/CSA-Z386-92: Laser Safety in Health Care Facilities.

There are no user-serviceable parts in the LightSheer system, and all service and repair must be performed only by the factory or authorized field service technicians. See the Maintenance and Troubleshooting section of this manual for troubleshooting and routine maintenance instructions.

Ocular hazards

WARNING - The light emitted by the LightSheer laser is capable of causing serious eye damage or blindness.

The LightSheer system is to be operated only in an enclosed room with protective eyewear for all persons. Direct eye exposure is not safe at any distance within the room. All windows in the laser room must be covered with opaque material, and measures should be taken to prevent unauthorized access to the room. A remote interlock is provided, which can be connected to the treatment room doors disabling laser output if the door is opened during a procedure. In addition, compliance with ANSI Z136.3 and EN 60825-1 requires that laser safety signs be posted at all entrances whenever the laser is in use. An approved sign is provided with each system along with protective eyewear. Additional eyewear or safety signs may be obtained from Customer Support.

WARNING - All persons in the treatment room, including the patient, must wear appropriate eye protection whenever the main power and keyswitch are on. The protective eyewear must have an optical density (OD) of 5 or greater at the wavelength of 790 – 830 nanometers. For users outside the U.S., the appropriate standard may be EN 207, in which case the safety eyewear must have a protection class of L5.

WARNING - While operating the LightSheer system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.

WARNING - Avoid directing the laser beam anywhere other than within the holster or at the intended treatment area. Stray laser light and reflection is always a potential hazard and may cause serious injury.

WARNING - Do not treat eyebrows, eyelashes, or other areas within the bony area surrounding the orbit. The light emitted by the LightSheer laser is capable of causing serious eye damage or blindness. For maximum safety, metal eye goggles must be worn by the patient for all facial treatments.

Ocular safety considerations:

- Identify the laser room clearly by posting approved laser safety signs in prominent locations.
- Cover all windows to prevent laser light from escaping the laser room.
- Restrict entry to the laser room when the laser is in use. Allow access only to those personnel both essential to the procedure and well trained in laser safety.

- Never direct the laser beam at anything other than within the holster or at the intended treatment site.
- Never look directly into the laser aperture at the distal end of the handpiece.
- All persons in the treatment room must wear approved laser safety eyewear with an optical density of 5 or greater at the LightSheer wavelength of 790 - 830 nanometers. For users outside the U.S., the appropriate standard may be EN 207, in which case the safety eyewear must have a protection class of L5. This includes the operator, patient, nurses, and any other persons in the room.
- Do not attempt to remove the protective covers on the handpiece, which could allow exposure to high-intensity laser light.

Electrical hazards

The LightSheer Duet laser system uses high-voltage internal components, which have the potential to cause serious injury or fatal electrical shock. It is possible for the high voltage components to retain a charge for some period of time even after the laser has been turned off.

No part of the exterior housing, except the holsters, should be removed except by trained and authorized LightSheer laser technicians. Do not soak or spray the laser console, handpieces or touchscreen in fluids because this can result in damage to the equipment and electrical shock. Do not operate the system if the power cord is frayed or otherwise damaged. Clean the touchscreen only when the LightSheer system is turned off.

⚠ **WARNING - Opening the exterior housings may cause exposure to hazardous optical radiation and electrical voltage even after the laser has been turned off. No portion of the exterior housing, except the holsters, should be removed by anyone other than a trained and authorized technicians. Do not operate the system if the power cord is frayed or otherwise damaged.**

⚠ **WARNING - Do not operate the laser system if any coolant leakage or spillage is observed, as this may lead to electric shock or death. Turn off the laser and contact your Lumenis representative.**

Laser plume precautions

CAUTION - The user should be aware that laser plumes do present a potential hazard. Plumes may be potentially hazardous, both in terms of particulate matter and infectivity. Special care must be taken to limit the exposure of both patient and user to any laser plume smoke or vapor.

CAUTION - Laser plume may contain viable tissue particulates.

CAUTION - The user should wear surgical masks that remove particles as small as 0.3 µm. Surgical gloves should also be worn.

Fire hazards

The potential for fire hazards exists because the absorption of laser energy may raise the temperature of any material. While this principle is the basis of many useful medical and surgical applications, it requires that precautions be taken against igniting combustible materials. For the LightSheer Duet laser system, the following precautions should be taken:

- Allow any flammable liquids used for cleaning the skin or handpiece insert, such as alcohol, to fully evaporate before treatment.
- Anesthetics administered topically or by inhalation must be approved as nonflammable.
- Exercise particular care in the use of oxygen, which can accelerate the combustion of any flammable material.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When required, these materials may be made more fire resistant by keeping them moist with water. Clothing should be kept well away from the area of treatment.
- Do not operate the laser with any cover or drape over the laser.

WARNING - Do not operate the LightSheer system in the presence of flammable liquids (such as alcohol or acetone) or flammable gases (such as ether).

Health hazard during treatment

High power laser light targets the melanin in the hair and the hair shaft. The heat absorbed by the melanin is transferred to the cells in the follicle, resulting in effective hair removal and permanent reduction. The heated hairs will sometimes vaporize, leading to the "burning hair smell" which often accompanies laser hair removal. While generally safe, this laser plume can condense on the cold ChillTip of the LightSheer. Condensed on the ChillTip, the hair material may harden and will absorb subsequent pulses of laser light. While most of the ChillTip will remain very cold, the burned hair material will become very hot and can lead to burns as the insert is moved across the epidermis. Lumenis has received reports of injuries to patients including superficial burns, 1st degree burns, 2nd degree burns and hyperpigmentation that are directly attributed to the failure of the user to keep the ChillTip clean during hair removal procedures.

Chemical hazard

⚠ **WARNING - Always wear gloves during treatment and it is recommended to wear long sleeves. This prevents skin contamination with the cooling solution if there is a break in the cooling lines.**

The LightSheer laser is cooled by a closed loop cooling system. The system is used to maintain the operating temperature of the lasers in the handpiece and the ChillTip for the ET handpiece.

Prevention

Always inspect the system and handpiece before powering up. Do not move the system around with the handpiece or umbilical, this will stress the umbilical and also cause the system to fall over if the wheels are locked on the system or cart.

Clean-up procedure

Turn off the system and unplug from the AC outlet. Use paper towels to wipe up all of the spill. Use any household cleaning agent to wipe down the area affected to prevent skin contact and to remove the slipping hazard if it spills on the floor.

If in contact with skin, immediately wash with soap and water and remove affected clothing. If there are skin irritations, seek medical attention.

If in contact with eyes, flush for 15 minutes and seek medical attention.

The cooling solution to be used is an Ethylene Glycol mixture. It has a light green color and feels silky to the touch. It is diluted to 80% water and 20% Ethylene Glycol.

LightSheer Safety Features

The LightSheer laser system is designed to be safe and convenient for both the operator and patient. The most important safety-related features for all systems are described below. See the Operation section of this manual for descriptions and operating instructions for these and all other system features.

Safety features unique to the laser system or handpiece are in the following sections. New devices and applications will be added as an appendix in the manual.

Safety interlocks

The LightSheer system contains a comprehensive monitoring system that allows operation only when numerous safety conditions have been met. A fault must be corrected and the system reset before laser operation is re-enabled. The monitoring system includes the following:

- Remote interlock: An external door interlock receptacle and plug are provided to disable the laser if the treatment room doors are opened.
- System time out which disables the laser if it has not been used for 15 minutes. This feature is designed to help prevent unintended exposure and reduce mechanical wear.
- Energy monitoring to verify that the laser output is within specific energy tolerances for every laser pulse. If abnormally low or high laser current (indicative of optical energy) is detected, a system fault is triggered and the user is notified.
- Temperature monitoring which disables system operation if the diode temperature or ChillTip (on the ET handpiece only) is outside the operating range.

Audible emission indicator

For operator feedback and safety, each laser pulse is accompanied by an audible beep. No attempt should be made to disable or impair this emission indicator, and in the unlikely event that emission occurs without an audible beep, use of the system should be discontinued until proper performance is established.

Electronic shutter

As a safety feature and in compliance with U.S. and international regulations, the LightSheer Duet system contains an electronic shutter to help prevent inadvertent laser emission. Located in the console, the shutter is an electronic switch that is independent of, and in addition to, the normal energy circuit for the laser pulse. The shutter is directly controlled by the handpiece enable and system mode; laser emission is prohibited by the shutter if the system handpiece enable is active and the laser is not in ready mode. This is unlike conventional lasers, which rely upon shutters to block the beam during warm-up, alignment, and other times.

Handpiece enable

To help prevent unintended emission, laser output occurs only if the handpiece enable is active, the laser is in ready mode, and the handpiece trigger is pressed.

ET handpiece

With the laser in ready mode, the operator must first press the handpiece enable button, which opens the safety shutter, and then press the handpiece trigger to delivery the treatment pulses to the patient. The enable button is unlit when disabled and lit when enabled. The enable button becomes disabled after being idle for more than 30 seconds.

HS handpiece

With the laser in ready mode, the operator must first press the handpiece enable button, which opens the shutter, and then press the handpiece trigger to initiate the vacuum function. Once the target vacuum is reached, the treatment pulses are delivered to the patient. The enable button is unlit when disabled and lit when enabled. The enable button becomes disabled after being idle for more than 30 seconds.

Handpiece trigger

ET handpiece

With the handpiece enable active and the system in ready mode, the laser can be fired repetitively by (1) either pressing and releasing the trigger for each pulse, or (2) keeping the trigger continuously pressed, in which case the laser will fire repetitively for as long as the handpiece trigger is pressed.

HS handpiece

With the handpiece enable active and the system in ready mode, the laser can be fired by pressing and releasing the handpiece trigger for each treatment of 1-3 pulses. The trigger must be pressed each time to perform multiple treatments.

Handpiece design

Several aspects of the ET and HS handpiece design also contribute to the safety of the LightSheer Duet system. Since the laser emission originates in the handpiece itself and not in the console as in conventional lasers, there is no need for an articulated arm or other beam delivery system with inherent beam quality and alignment concerns. The laser emission is confined to the handpiece, so there is no hazardous optical radiation in the console or umbilical.

ET Handpiece

The sapphire tip is placed against the patient's skin during system use, reducing stray light while increasing the therapeutic effectiveness.

The ET handpiece console connector is keyed to connect to the left side of the system (when facing the system).

HS handpiece

The handpiece is placed against the patient's skin during use; a vacuum pump creates suction and draws the skin into the treatment handpiece, thus reducing stray light while increasing the therapeutic effectiveness.

The HS handpiece console connector is keyed to connect to the right side of the system (when facing the unit).

LightSheer Duet safety features

Keyswitch

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 ⏻ (on) position, the laser power-up sequence is initiated.

Emergency stop switch

Releasing the handpiece trigger will stop all laser emission. In the event of an emergency, the laser can be shut down immediately by pushing the emergency stop button located near the keyswitch on the console. To restore operation, rotate the button in the clockwise direction until it pops out again. Then follow the standard startup sequence. Since the emergency stop switch is not intended for routine use, follow the procedure in the Operation section of this manual for normal shutdown.

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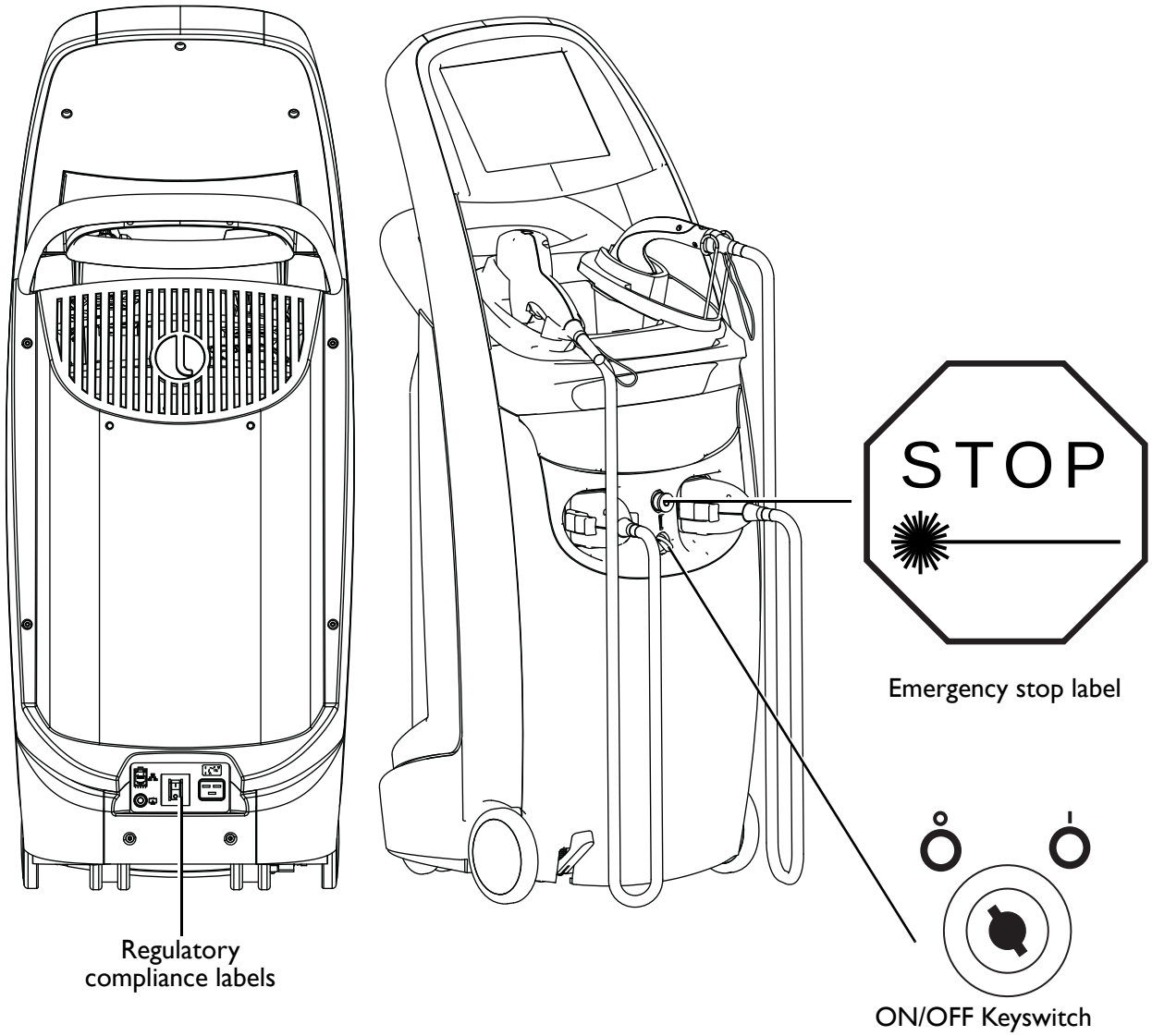
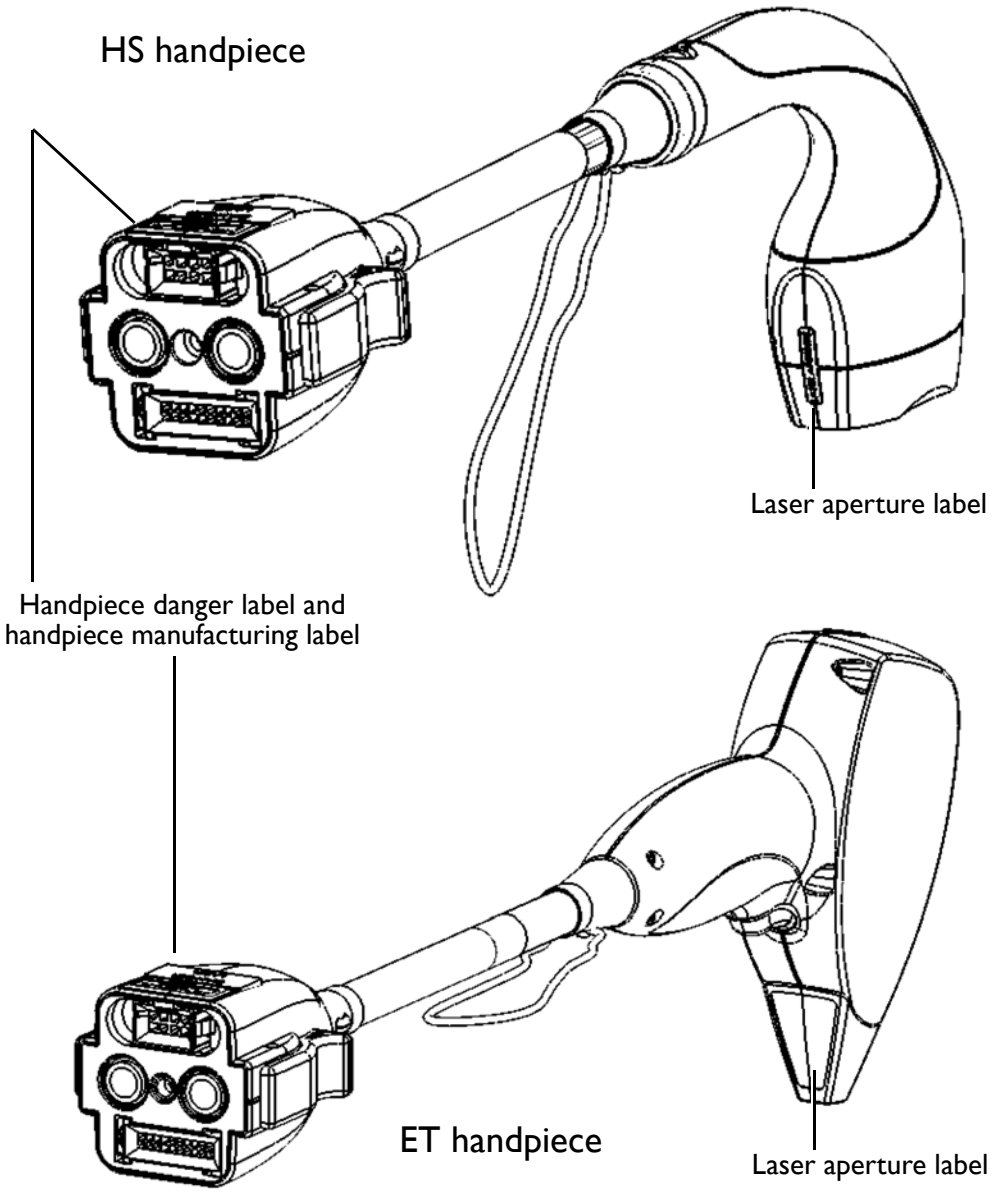
Location of Regulatory and System Labels

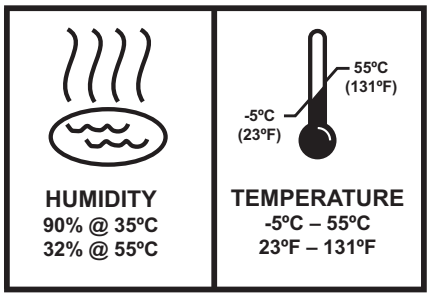
As required by national and international regulatory agencies, appropriate warning labels have been mounted in specified locations.



Location of regulatory compliance labels



Location of regulatory compliance labels on handpieces



Nonoperating environmental specifications (on shipping box)

Manufactured by
LUMENIS®
P.O.B. 240
Yokneam 20692, Israel
+972.4.959.9000

Lumenis contact information

C SA® US

CSA compliance

MONTH/YEAR
P/N, REV
S/N

Model name, serial number, and manufacturing date

U.S. AND INTERNATIONAL
PATENTS PENDING

Patents pending

Caution: U.S. federal law restricts this device to sale by or on the order of a physician

FDA sales restriction

This equipment conforms to provision U.S. 21.CFR 1040.10 and 1040.11 as applicable

(for FDA-compliant systems)

DHHS certification

EC REP
Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
D-63303 Dreieich-Dreieichenhain
Germany
Phone: +49 (0)6103-8335-0

Authorized Representative

CE 0473

CE Mark

100 - 240 V~
50/60 Hz
15 A, 1ϕ

Electrical specification

Regulatory compliance labels

(Read and comprehend the operator manual before use.)

Attention, read manual

Mains connection

Type B electric shock protection HS handpiece

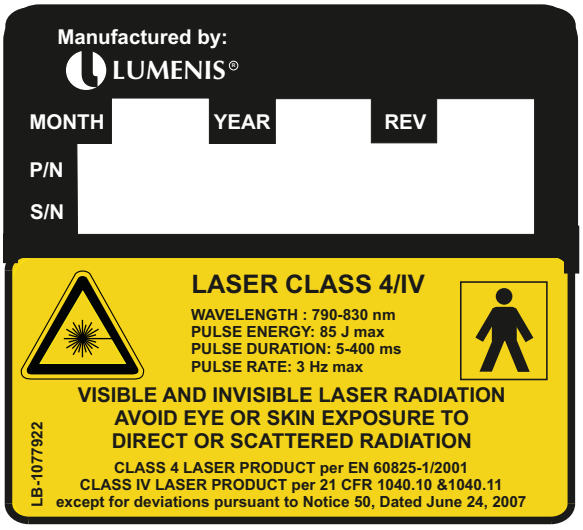
Type BF electric shock protection ET handpiece

External interlock receptacle

Keyswitch ON

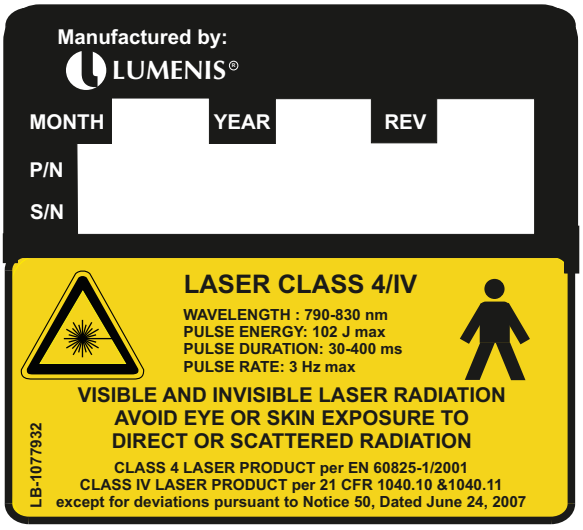
Keyswitch OFF

Handpiece manufacture date, part number, and serial number



ET handpiece danger label

Handpiece manufacture date, part number, and serial number



HS handpiece danger label

Regulatory compliance labels

Operation

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Introduction

> ⚠ **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 operator manual, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.**

The LightSheer laser system delivers pulsed infrared light intended for hair removal, permanent hair reduction, the treatment of leg veins, and benign pigmented lesions.

Based on state-of-the-art diode laser technology, the LightSheer system offers many advantages, including the combination of a favorable wavelength, excellent pulse characteristics, and unique integrated cooling in a lightweight and compact instrument. The console provides touchscreen computer control and a user-friendly interface, ensuring that treatments are performed with confidence and convenience.

The LightSheer Duet laser system consists of a console with touchscreen, a power cable, a large aperture, high-speed (HS) handpiece, and a standard (ET) handpiece.

HS handpiece

The HS handpiece features an open tip to which vacuum is applied. The vacuum draws the patient's skin into the tip before laser treatment, and releases the skin upon delivery of the pulses. The combination of larger aperture and vacuum affords the customer a faster treatment rate by covering a larger skin area with each laser pulse.

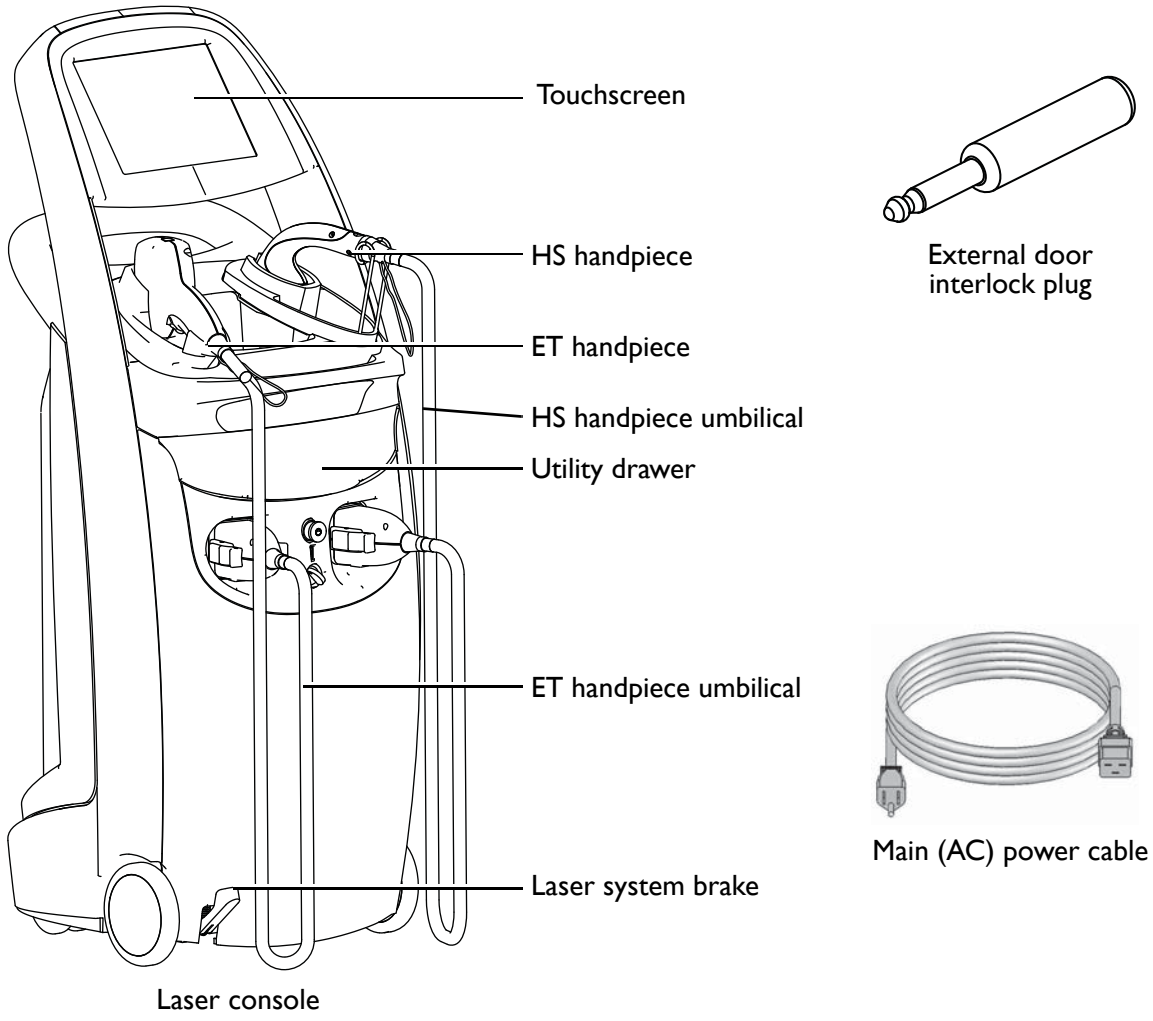
ET handpiece

The ET handpiece features a chilled sapphire tip that is pressed against the patient's skin during treatment. By conductively cooling the skin, the chilled handpiece tip increases the tolerated fluence, provides partial anesthesia, and reduces temperature-rise in the melanin-rich epidermis.

LightSheer Duet Components

The LightSheer Duet laser system is comprised of:

- a laser console with touchscreen and integrated holsters for handpiece calibration and storage
- a large aperture, high-speed (HS) handpiece
- a standard (ET) handpiece
- an external door interlock plug
- all electrical cables necessary for proper connection



LightSheer Duet components

Inspecting the components

When unpacking your LightSheer System, and before each use, inspect the components for dirt, debris, or damage.

Inspect each handpiece for cracks or other visible damage. A damaged handpiece may cause electrical shock, unintended laser exposure, injury to treatment room personnel or the patient, and/or fire in the treatment room.

Inspect each handpiece and handpiece umbilical for punctures or coolant leaks. Leaks or spills may result in electrical shock and/or death. Furthermore, loss of coolant may cause the laser system to overheat due to inadequate cooling.

Ensure that the power cord is not punctured or worn.

If any component requires cleaning, follow the directions provided in the Maintenance section of this manual.

If any component appears damaged, contact your local Lumenis service representative.

Laser console

The laser console houses the touchscreen, main power keyswitch, emergency stop button, control electronics, and power supply. The laser console also includes integrated holsters, which are used for both calibration and storage of the LightSheer Duet handpieces.

Touchscreen

The touchscreen provides an interface for operating and calibrating the system. Press the touchscreen lightly with a finger to select the on-screen functions.

⚠ **WARNING - Clean the touchscreen regularly as instructed in the Maintenance chapter of this manual to ensure proper performance. Excessive treatment oil, gel, lotion, or other contaminants on the touchscreen may cause erratic operation of the user interface buttons.**

External door interlock plug

The external door interlock plug must be inserted into the  (external interlock) receptacle on the rear of the laser console for the laser to operate. The plug may be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

Handpieces

Each handpiece contains laser diode arrays that generate the laser treatment light. Power and control signals are exchanged with the main console via the handpiece umbilical. Each handpiece is equipped with a wrist strap to prevent damage to the handpiece if inadvertently dropped.

The handpiece contains delicate optical components which may be damaged if dropped. The handpiece should be placed in the holster when not being used for treatment. The wrist strap should be worn whenever the system is in use. When the system is not in use, the handpiece should be secured to the console by looping the wrist strap around the wrist strap hook.

Do not allow sunblock or sunscreen products to contact the handpiece. The ingredients found in sunblock and sunscreen products may cause deterioration or damage to the handpiece material. If sunblock or sunscreen does contact the handpiece, clean the handpiece immediately to prevent possible damage.

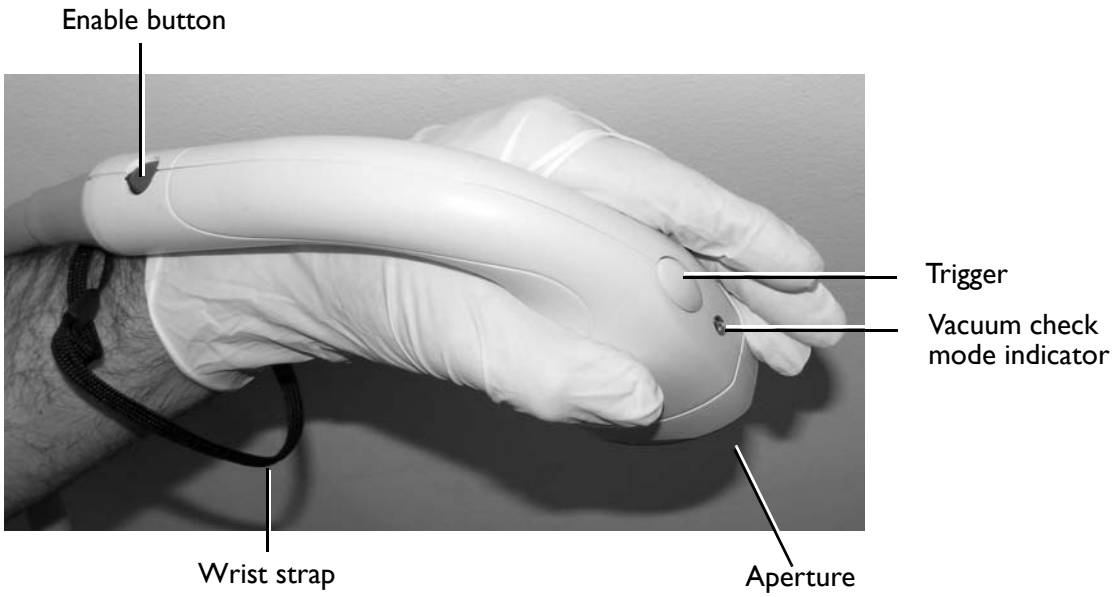
HS handpiece

The HS handpiece operates by drawing the patient's skin into the handpiece and against the aperture with a vacuum pump. The combination of larger aperture and vacuum affords a faster treatment rate by covering a larger skin area with each laser pulse.

HS handpiece disposable insert

The HS handpiece uses a removable, disposable insert that attaches to the handpiece aperture, and which must be replaced between patients, or during patient treatment if the tip becomes dirty or if the internal filters become clogged.

Replace the disposable insrt as needed, according to the instructions provided in the Maintenance section of this manual.



HS handpiece

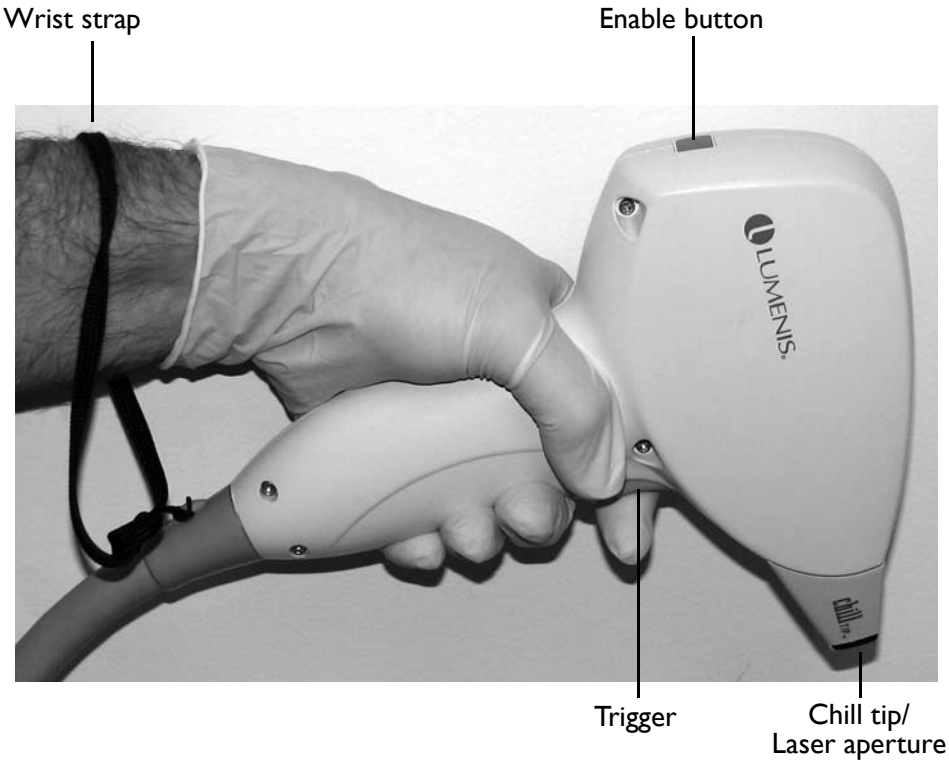
HS handpiece disposable insert

ET handpiece

The ET handpiece features a sapphire tip that provides contact cooling to the patient's skin during treatment. Cooling fluid is exchanged with the main console via the handpiece umbilical.

In standard operation, the handpiece tip is placed against the patient's skin and a laser pulse is delivered when the enable button is on and the handpiece trigger is pressed.

> For hair removal and treatment of benign pigmented lesions, direct pressure with the handpiece tip allows light to penetrate more deeply, decreases the amount of blood in the dermis, and conductively cools the epidermis if the tip is chilled. For treatment of leg veins, contact between the handpiece tip and skin is maintained for epidermal cooling, but no pressure is applied.



ET Handpiece

HS and ET handpiece holsters

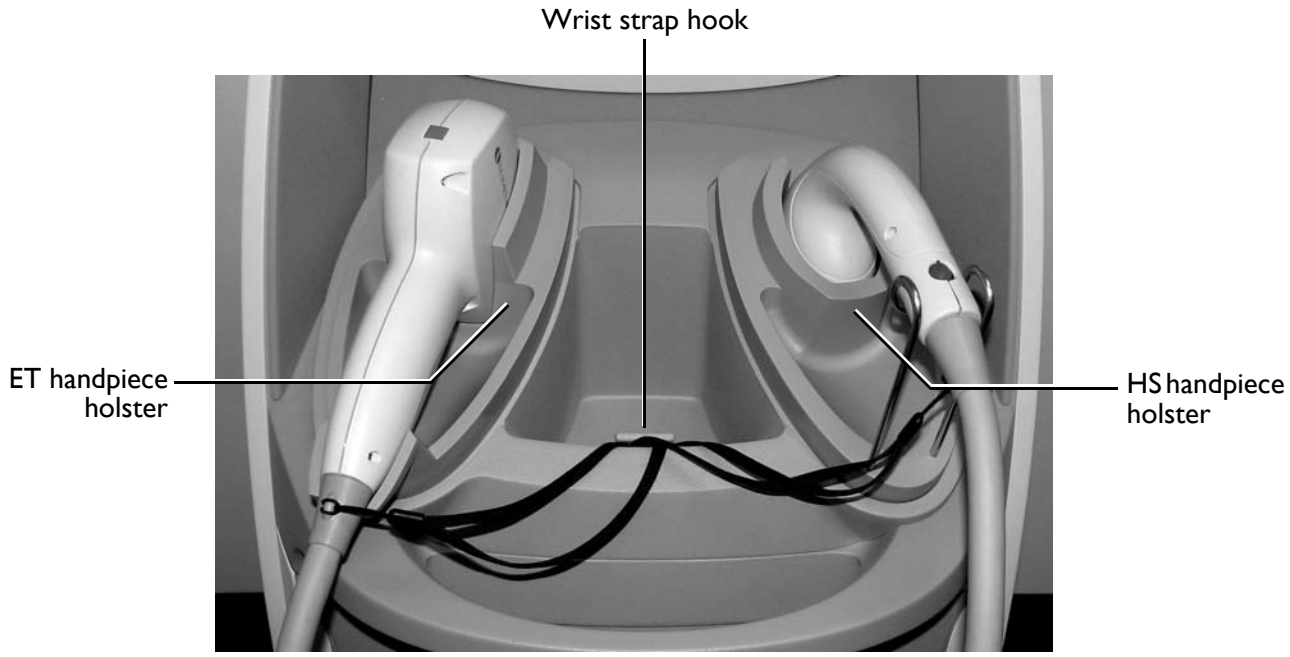
The HS and ET handpiece holsters are used to position and hold the handpieces during system calibration. Calibration is required after powering the system on, and may be initiated at other times by inserting a handpiece into its respective holster and firing the laser.

The holsters also provide convenient locations for resting the handpieces when moving the laser or when adjusting treatment parameters during patient treatment. Store handpieces in the holsters when the system is not in use.

If the protective glass window below a holster becomes dirty or covered with spilled liquid, remove the holster and clean the window according to the instructions provided in the Maintenance chapter of this operator manual.

Wrist strap hook

The wrist strap hook is used to secure the handpiece when the system is not in use. Loop the wrist strap around the wrist strap hook whenever the system is being moved to prevent the handpiece from falling out and being damaged.



Handpiece holsters and wrist strap hook

Installation Instructions

Laser Preparation

The laser is shipped directly from the factory to your site. Before using the laser, you must unpack the laser console, install the handpiece holsters, and attach the handpieces.

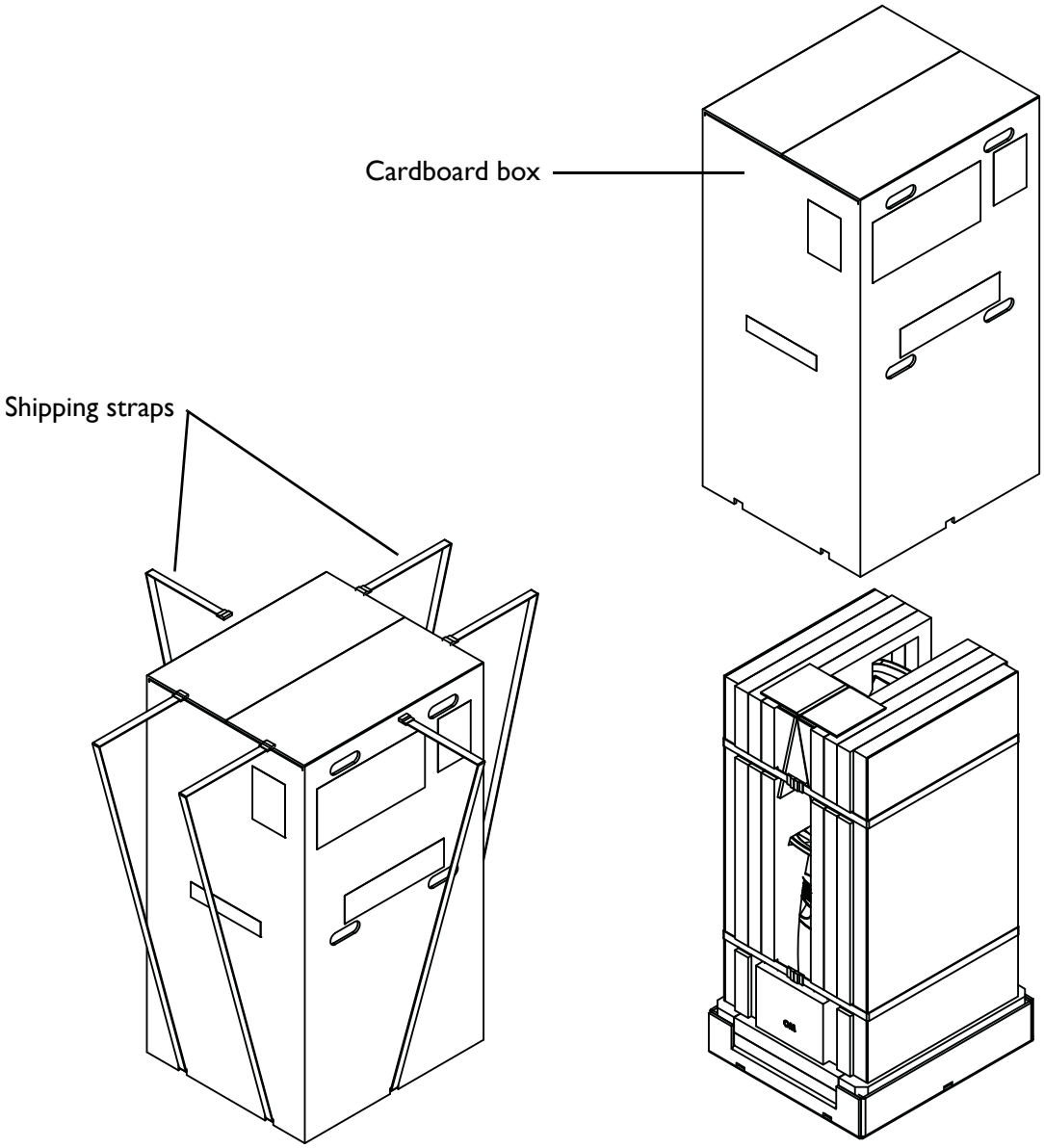
Guidelines to observe when moving the laser between locations are described under “Moving the laser console” later in this chapter.

Inquire from your local Lumenis representative for in-service training to ensure that you and your staff are experienced with the performance and safety considerations of the laser.

Unpacking the LightSheer Duet

1 Disconnect the three straps that secure the cardboard cap to the top of the shipping box.

2 Lift the cardboard box up and over the console.



3 Unbuckle the straps that secure the protective foam.

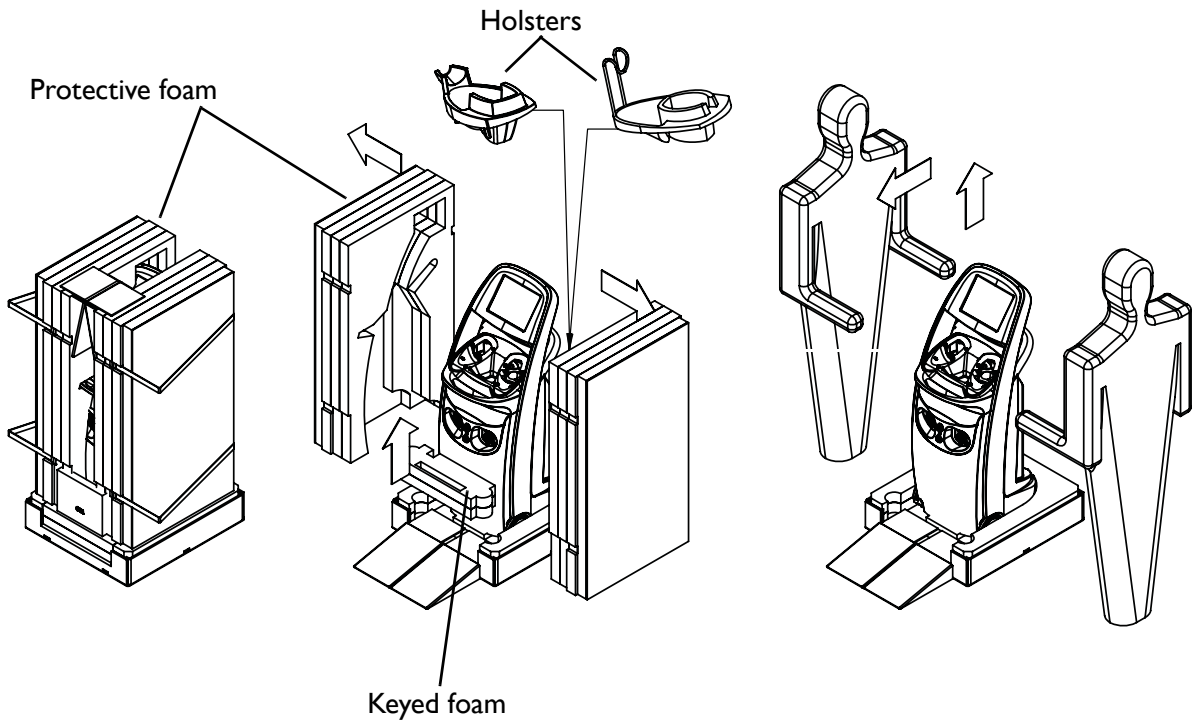
4 Remove the protective foam surrounding the console.

5 Remove and unpack the handpiece holsters.

6 Remove the keyed section of foam from the bottom and place the ramp in front of the system.

7 Remove the plastic covering from the laser console.

8 Remove the laser system from the bottom of the cardboard box.



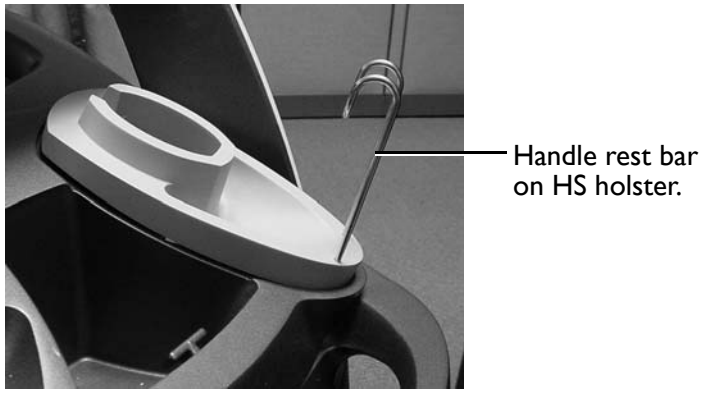
Installing the holsters

1 Unpack the holsters from their shipping container and locate the handpiece cradles on the laser console. The ET handpiece cradle is on the left side of the console; the HS handpiece cradle is on the right side of the console.

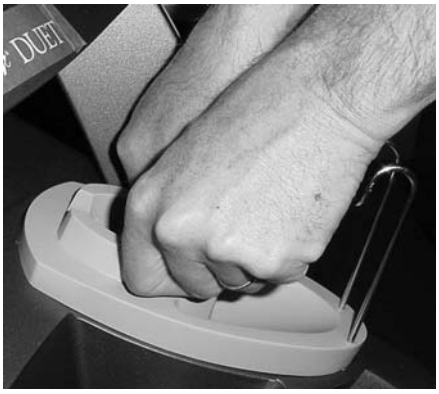
Location of holsters on the laser console

Install the HS handpiece holster

2 Place the HS handpiece holster into the cradle on the laser console, as shown. Identify the HS handpiece holster by the handle rest bar. The ET handpiece holster does not have a handle rest bar.



3 Press the upper-front of the holster until you feel or hear it snap securely into place. Press the sides and bottom of the holster until you feel or hear it snap securely into place.

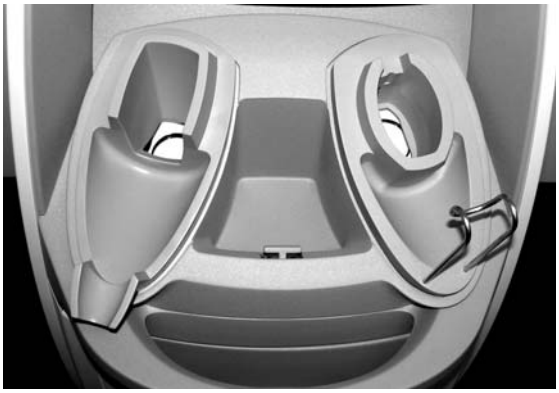


Install the ET handpiece holster

4 Place the ET handpiece holster into the cradle, as shown.

5 Squeeze the sides of the holster and push it into position, then release.

6 Ensure that both holsters are properly seated, with no gaps between the holster and console.



Holsters properly seated, with no gaps between holster and console

Attaching the handpieces to the LightSheer Duet

Attach the HS and ET handpieces to the laser console as follows:

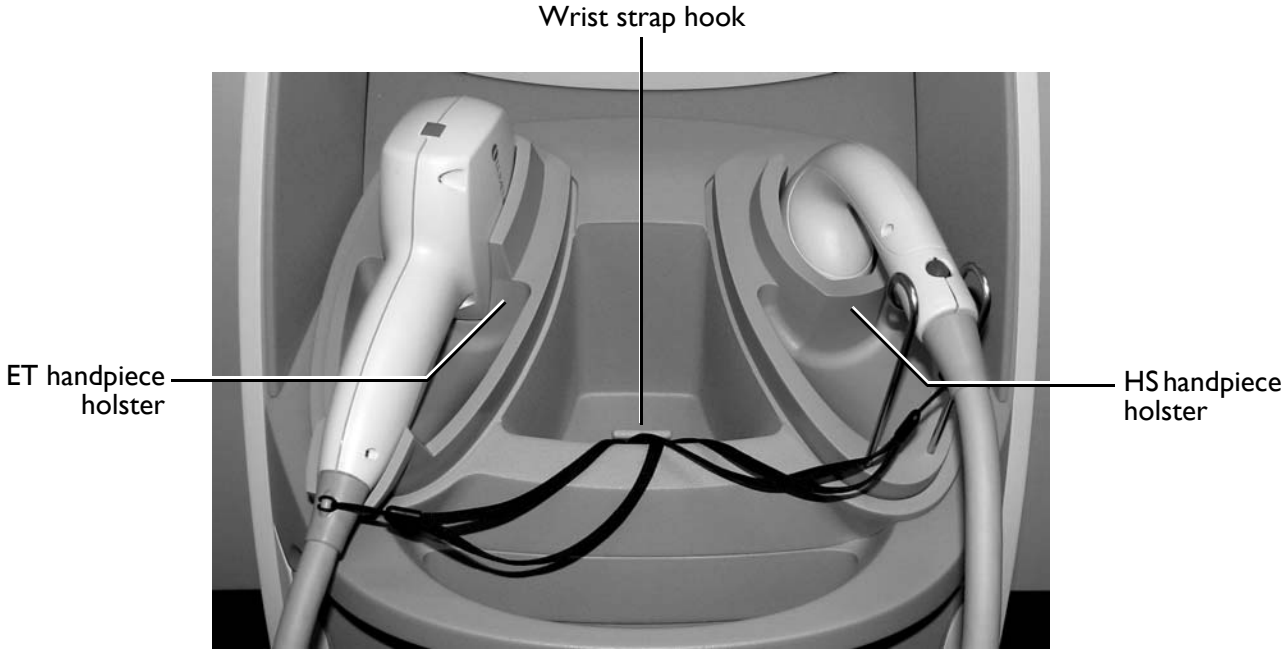
1 Unpack the HS and ET handpieces from their respective boxes.

> ⚠ **WARNING - The ET handpiece umbilical connector connects to the umbilical port on the left side of the laser console and the HS handpiece connector connects to the umbilical port on the right side of the laser console. They are not interchangable. Attempting to force an umbilical connector into an incorrect umbilical port may damage either the port or the connector.**

2 Securely seat each handpiece inside its matching holster and loop its handpiece strap around the center hook to prevent accidental damage while attaching the handpiece umbilical to the laser console.

> The handpiece umbilical cables may be very stiff when new. This is a normal result of the manufacturing process, which tightly integrates a large number of smaller cables into a convenient single cable. Your umbilical cables will become increasingly flexible and easier to position with regular use of the laser system.

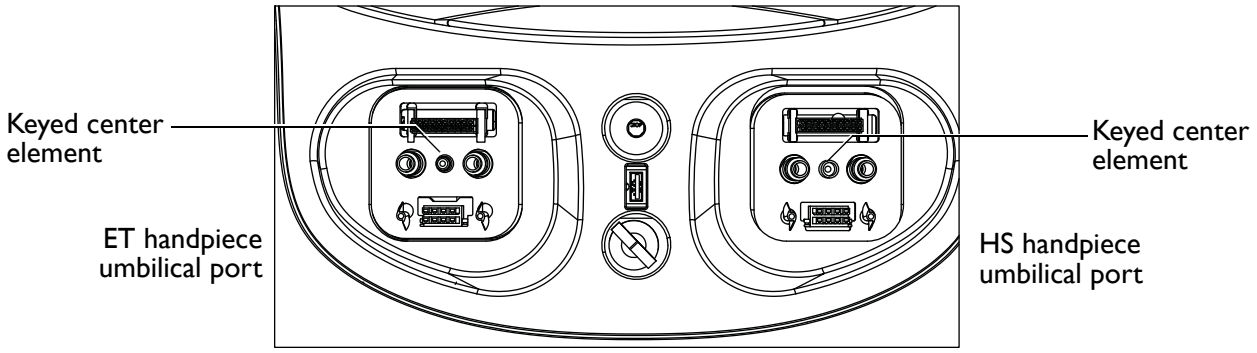
> Once the handpiece umbilical cables are connected to the laser console, it is usually not necessary to disconnect them. They should only be disconnected when necessary due to repair, replacement, shipping, or recycling of the system.



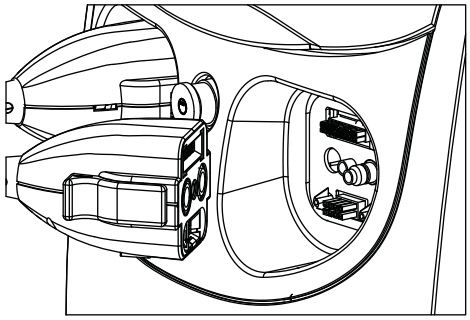
Handpiece holsters and wrist strap hooks

3 Align the umbilical connector with its corresponding umbilical port on the laser console.

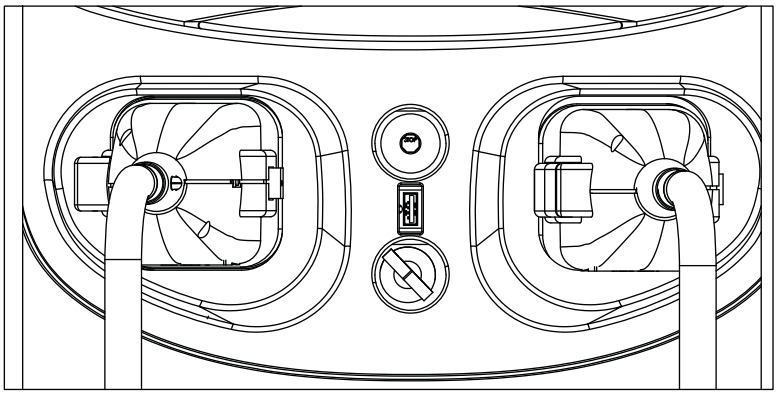
> The ports and connectors are "keyed" to prevent accidental connection to the wrong port. If the connector is not going into position smoothly, check that the electrical connections are aligned and that the center element of both the connector and umbilical port are the same color.



Align the elements on the connector with the corresponding elements on the umbilical ports, then plug the connector into the port. HS handpiece connector, with white center element, is shown.



4 Plug the connector into the port and push briskly until you feel both of the two locking mechanisms “click” into place. After feeling the first “click”, push harder on the opposite side of the plug until you hear the second “click”.



Installing an external door interlock

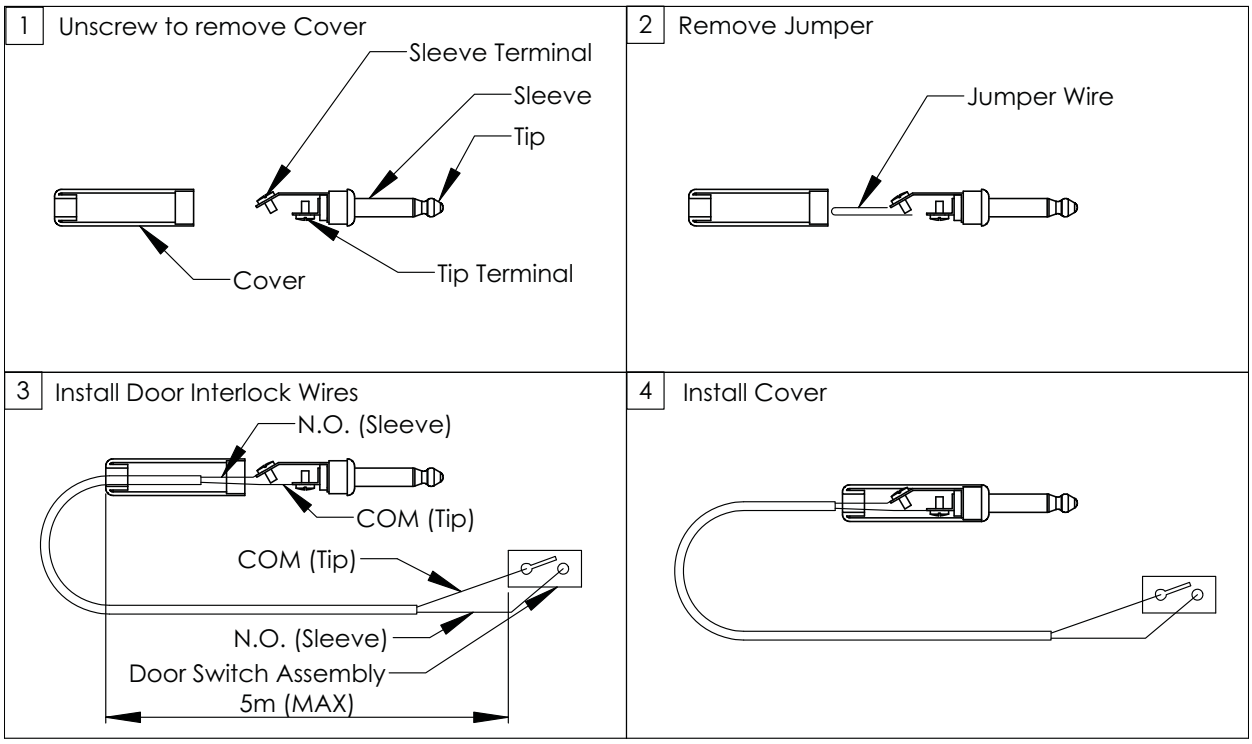
You may elect to install a remote switch (door interlock device) to monitor the treatment room door where the laser system is used. If the interlocked door is opened, the system will not emit laser light. The remote interlock plug (a ¼ inch mono audio plug) must be connected to a customer supplied door switch, where the switch is closed when the door is closed. The door switch contact must be rated for at least 12VDC/2A service, and the total length of cable from the door switch to the interlock plug should not exceed 5 m (16 ft.

If the laser system will be used in more that one room or at different sites, it will be necessary to wire each laser room door with a remote switch. Extra ¼ inch mono audio plugs are available for purchase.

The interlock plug must be wired as follows:

Tip: Connect the plug tip to the N.O. (Normally Open) contact of the switch. When the door is closed, the N.O. switch contact should be connected to switch COM (Ground Common).

Shaft: Connect the plug shaft to switch COM.



Connection Instructions

Plugging in the main power cable

1 Ensure that the keyswitch is in the ○ (off) position.

2 Ensure that the main power circuit breaker is in the **O** (off) position.

3 Unwrap the main power cable from the cable wrap on the rear of the laser console.

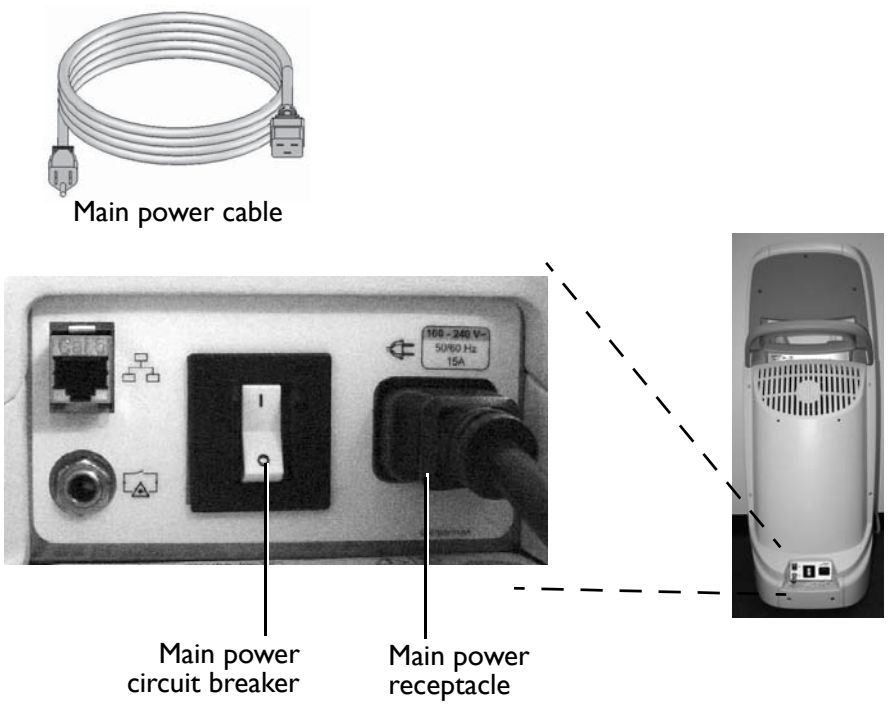
4 Insert the matching end of the main power cable into the main power receptacle on the rear of the laser console.

5 Insert the main power plug into the wall socket.

6 Verify that the key is inserted into the keyswitch and turned to the On position.

7 Verify that the Emergency stop switch is not engaged (turn the switch clockwise to verify).

8 When ready to use the laser, remember to switch the main power circuit breaker to the **I** (on) position.



Power cable connection

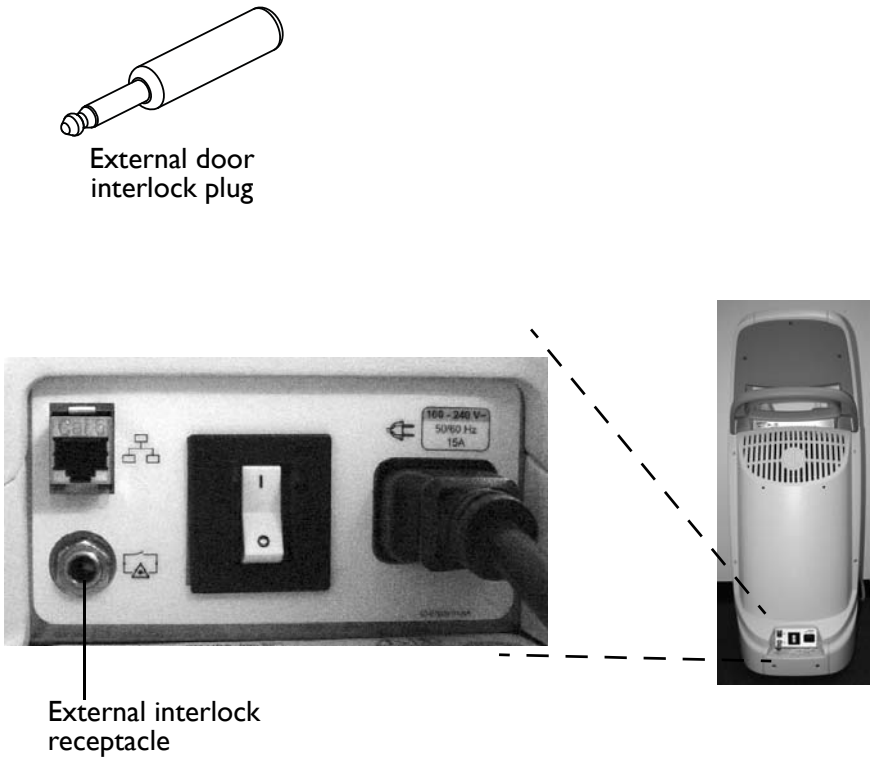
External door interlock

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.

Use of an external door interlock is optional; however, you must insert the interlock plug into the [⚠] (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 using an external door interlock, the laser automatically disables and returns to standby mode if the treatment door is opened or the interlock plug is removed. To resume treatment, close the treatment room door or reinsert the interlock plug, and press **Ready** on the touchscreen.

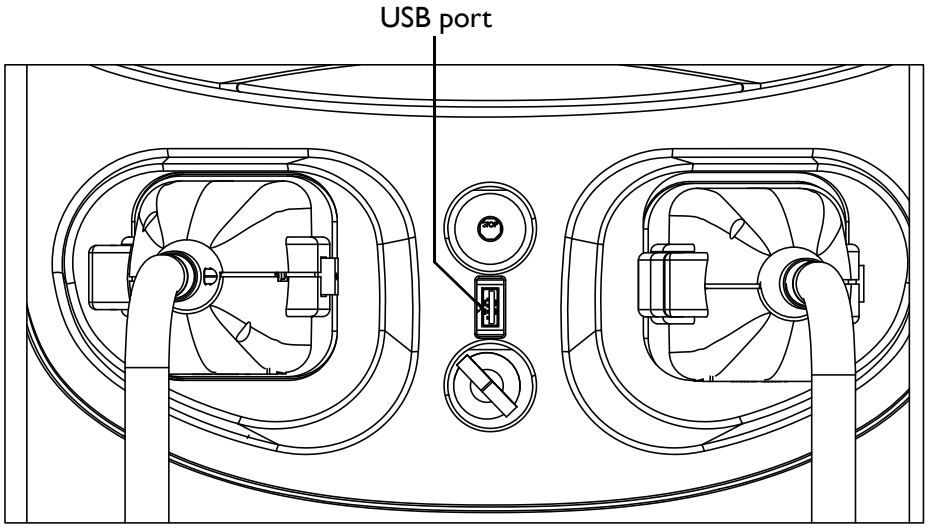
> The LightSheer Duet system is shipped with an external door interlock plug already connected. To set up a remote interlock switch, see "Installing an external door interlock" in this chapter, or contact your local Lumenis service representative.



External door interlock

USB port

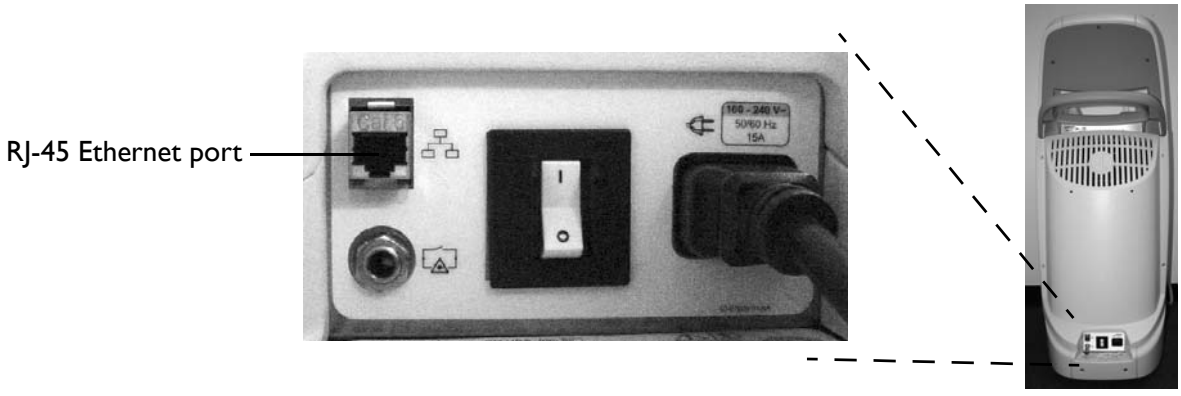
For Lumenis service use only.



USB port

RJ-45 Ethernet Port

For Lumenis service use only.



Ethernet port

Disconnecting and storing the laser components

1. Place the laser in standby mode.
2. Turn the keyswitch to the ○ (off) position and remove the key to prevent unauthorized use of the laser.
3. Turn off the main circuit breaker located on the back of the system.
4. Unplug the main power plug from the wall socket.
5. Wrap the power cable around the laser console handle.
6. Inspect and clean the handpieces, as instructed in the Maintenance chapter of this operator manual.
7. Store the handpieces in the corresponding holsters on the laser console.
8. If desired, disconnect the external door interlock, if used.
9. Clean the exterior surfaces of the laser, as instructed in the Maintenance chapter of this operator manual.

Laser Console Basics

Operator training

CAUTION - In the United States, federal law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

CAUTION - The LightSheer Duet system is only to be used by those adequately trained in the safe handling and operation of this system.

It is strongly recommended that, in addition to laser safety training of all clinic or operating room personnel, the user and institution adopt a training and safety program. For additional information, refer to the latest revision of ANSI Z136.3 or the latest revision of IEC 60825-1.

Users should attend:

- a training course,
- a hands-on training course under the preceptorship of a qualified user, and
- specialty-specific courses presented during academy or college meetings.

In addition to training, the practitioner should keep current with the relevant medical literature and thoroughly read and understand this manual.

Moving the laser console

Ensure that the laser is properly disconnected, as instructed in the previous section.

If engaged, disengage the system brake by cycling the brake foot lever to the raised (up) position.

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

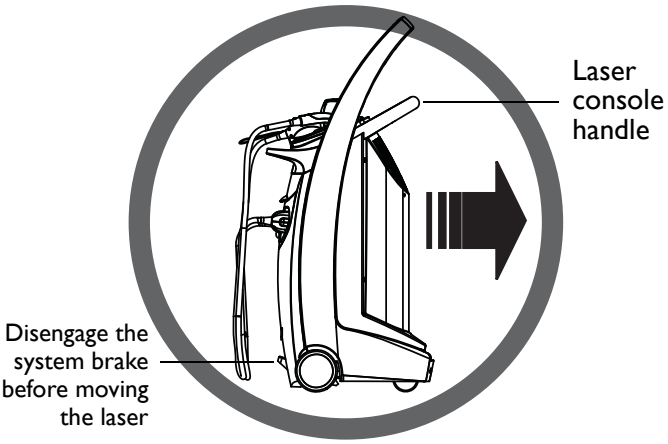
To avoid tipping the laser console when moving it, always observe the following precautions:
- Disengage the system brake
- Grasp the laser console handle while moving the laser
- Always pull the laser console to the desired location
- Never push the laser console

As with any heavy equipment, use caution when tilting the laser console or moving it up or down an incline. For optimum safety, use a second person when moving up or down a steep incline.

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

To prevent damage to the instrument, do not move the console by pulling on the handpiece or the umbilical. Pull the console by using the console handle to reposition the system.

Do not push the laser system



Grasping the laser console handle, pull the laser to the desired location

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

Adequate space around the laser console ensures proper air circulation for system cooling.

If desired, engage the system brake by cycling the brake foot lever to the pressed (down) position.

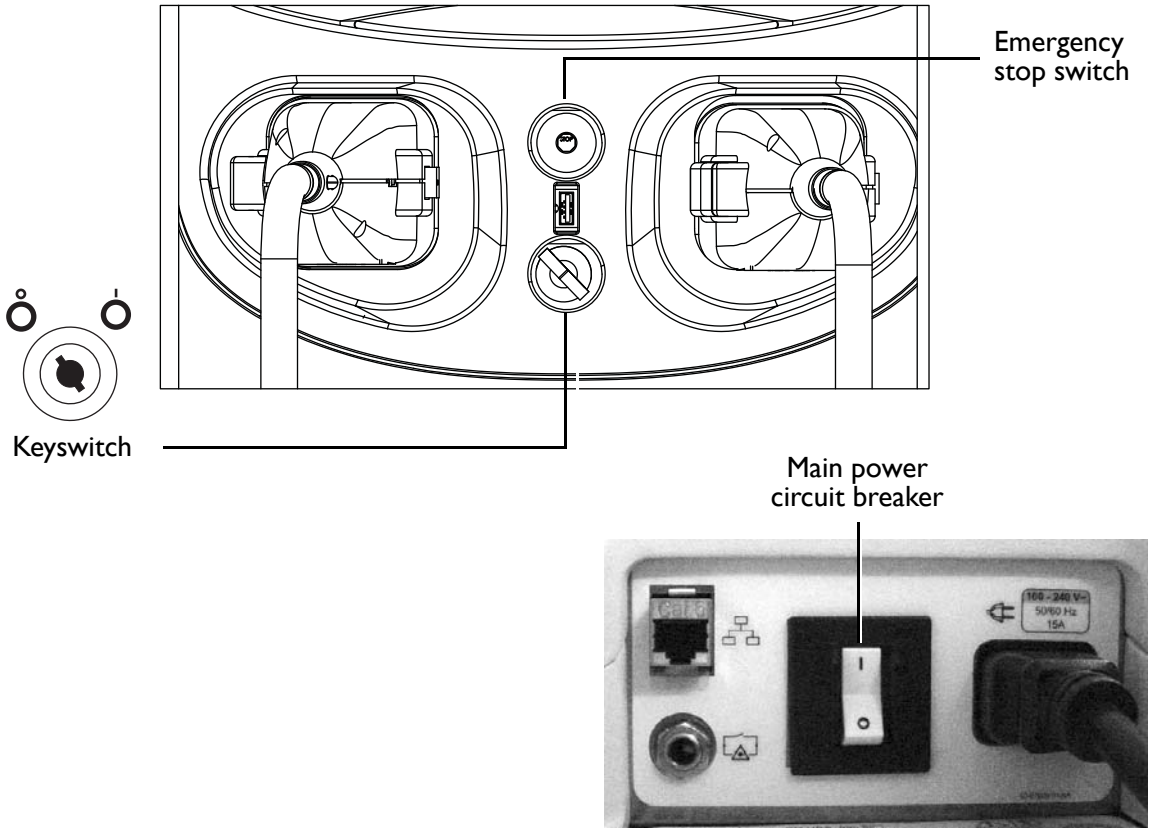
Turning on the laser

1. Verify the Emergency Stop switch is not engaged by turning the switch clockwise.
2. Insert the key into the keyswitch.
3. Turn the key to the ⏻ (on) position.
4. Verify that the main power cable is connected.
5. Verify that the main power circuit breaker is in the **I** (on) position.

   A laser self-test and warm-up begin.

   The self-test and warm-up take approximately one minute. When the self-test is successfully completed, the handpiece selection screen displays on the touchscreen.

> If any fault conditions are encountered during the laser self-test and warm-up, refer to the "Troubleshooting Guide" in the Maintenance chapter.



Main power circuit breaker and keyswitch

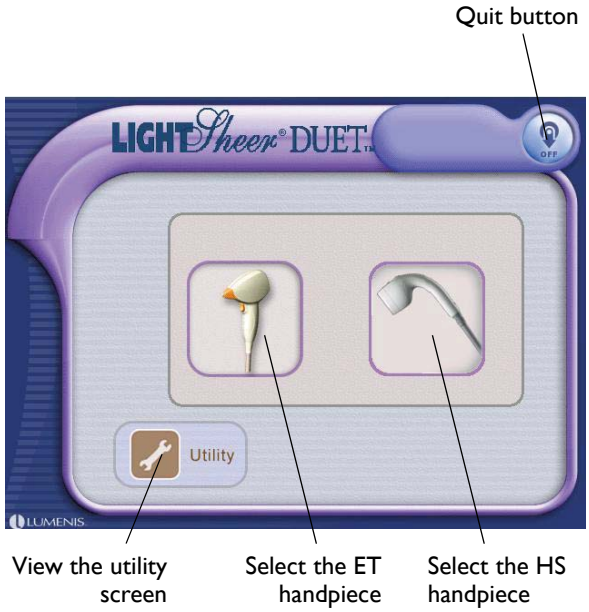
LightSheer Duet System Operation

When the self-test is successfully completed, the vacuum warning message displays on the touchscreen.

Self-test screen

Select the desired handpiece, either by selecting the corresponding icon on the touchscreen, or by removing the handpiece from its holster.

Upon selecting the desired handpiece, the calibration screen appears. Follow the calibration procedure, as described in the following section.



Handpiece selection screen

Calibrating the handpieces

Handpiece calibration is required upon system startup. Calibration is also recommended prior to each treatment. After calibration, the treatment screen for the selected handpiece displays on the touchscreen and the startup procedure is complete.

Energy calibration determines the optical output and verifies that the pulse energy is within specific tolerances. During calibration, an energy meter located beneath the handpiece holster measures the output energy of the handpiece. The system automatically sets the laser parameters over the operating range, determines the electrical parameters, and compares the measured and expected pulse energies.

If the system is already turned on, the operator may initiate a recalibration from the treatment screen at any time by positioning the handpiece in the holster, placing the system in Ready mode and waiting for the status indicator to display “READY”, enabling the handpiece, and pressing the handpiece trigger. Calibration is recommended prior to the start of each treatment.

⚠ **WARNING - The handpiece tip and energy meter window must be clean to ensure accurate calibration. An unclean tip or window will result in higher than indicated fluence, which may cause epidermal damage.**

Handpiece calibration procedure

1 On the LightSheer Duet startup screen, select the handpiece that you intend to calibrate. A screen will appear, reminding you to wear safety eyewear and clean the handpiece tip.

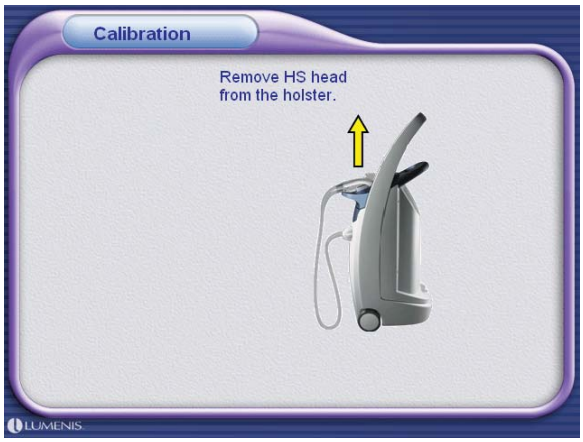
Pre-calibration warning: wear safety eyewear and clean handpiece tip

For accurate energy calibration, the handpiece tip and energy meter window must be clean and free of condensation. If condensation is present, dry the handpiece tip with a clean, dry gauze pad. If the handpiece tip or energy meter window is not clean, clean according to the instructions in the Maintenance chapter of this manual.

2 Press OK to proceed to the next step.

3 Remove the handpiece from the holster.

ET handpiece calibration screen — remove the handpiece



HS handpiece calibration screen — remove the handpiece

4 If calibrating an HS handpiece, ensure that the disposable insert is attached to the handpiece. Press OK to continue.

> ⚠ **CAUTION - Do not attempt to calibrate the HS handpiece without first attaching a disposable insert.**

HS handpiece calibration screen — ensure disposable insert is attached

5 Carefully reinsert the handpiece into the holster.

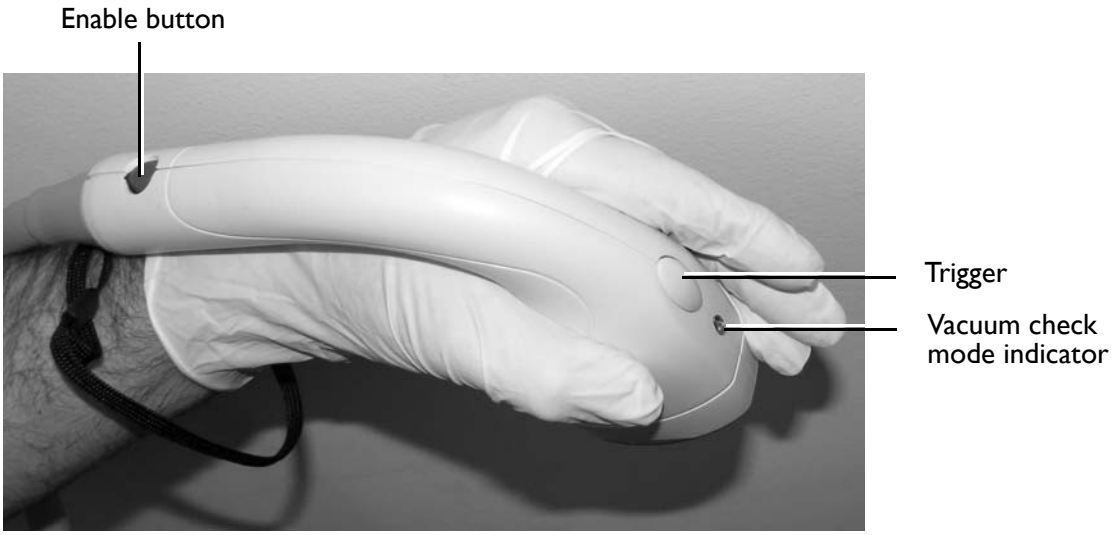
Verify that the handpiece aperture is pointing downward at the energy meter and that the handpiece is fully seated in the holster. A proximity switch will allow laser emission during calibration only if the tip of the handpiece is located within the holster.

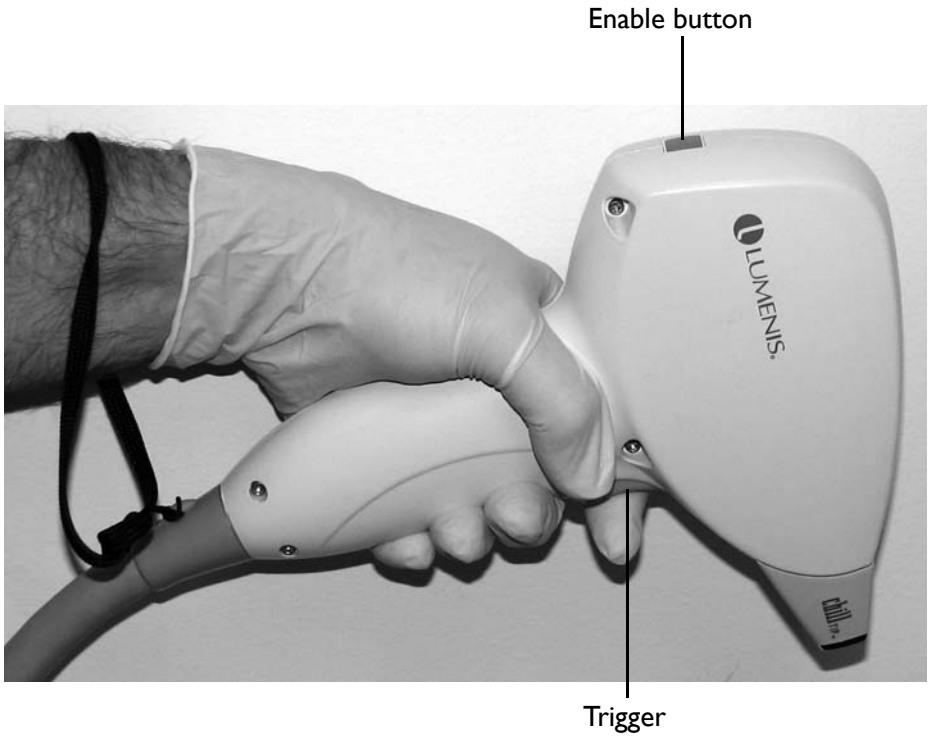
The touchscreen displays the calibration sequence and prompts the user to complete each step.

ET handpiece calibration screen — reinsert the handpiece

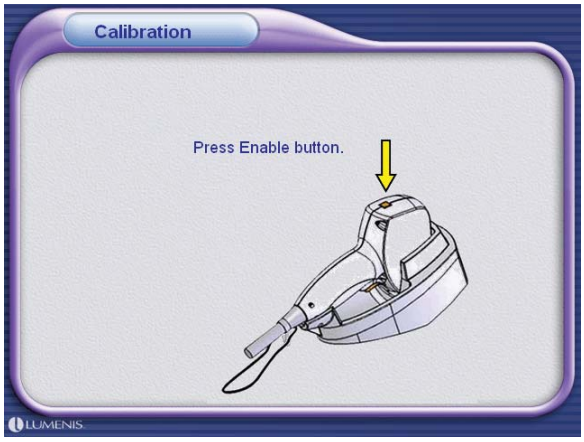
HS handpiece calibration sequence — reinsert the handpiece

6 When the enable icon appears (flashing arrow pointing at the enable button), press the handpiece enable button to enable the laser.

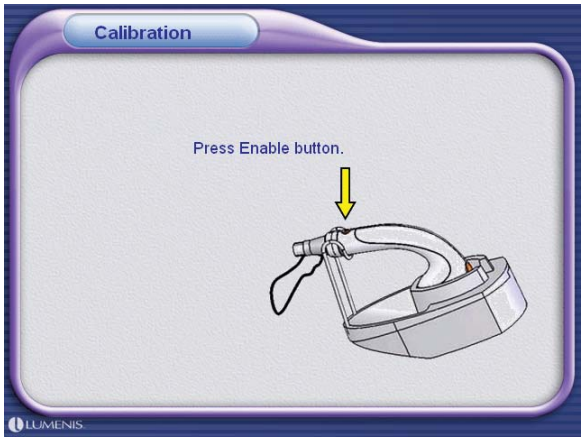




Location of handpiece enable and trigger buttons



ET handpiece calibration screen — press the enable button

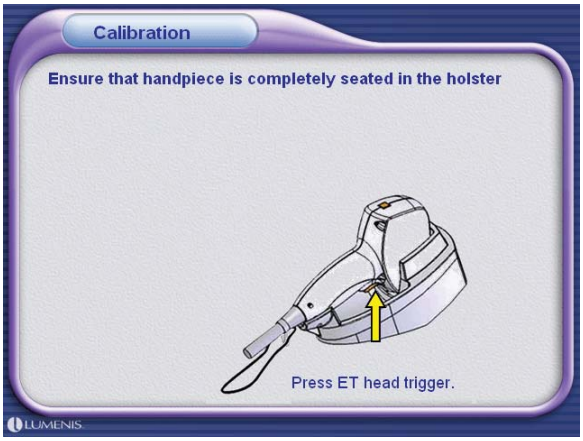


HS handpiece calibration screen — press the enable button

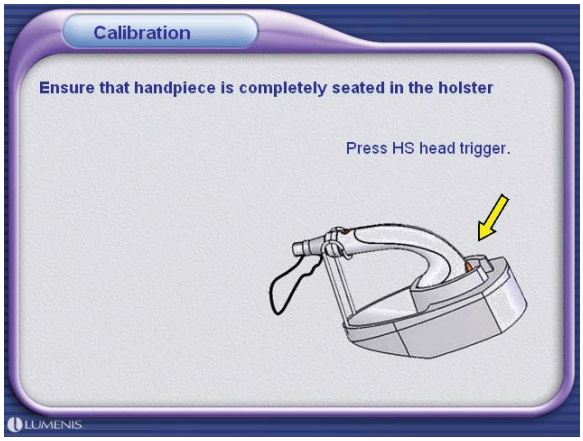
7 Press and hold the handpiece trigger.

> ⚠ **WARNING - While operating the LightSheer Duet system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.**

When the trigger icon appears (flashing arrow pointing at the trigger), press the handpiece trigger to fire the laser. **Keep the handpiece trigger pressed until all calibration shots are fired as indicated by the progress bar.**



ET handpiece calibration screen — press and hold the trigger

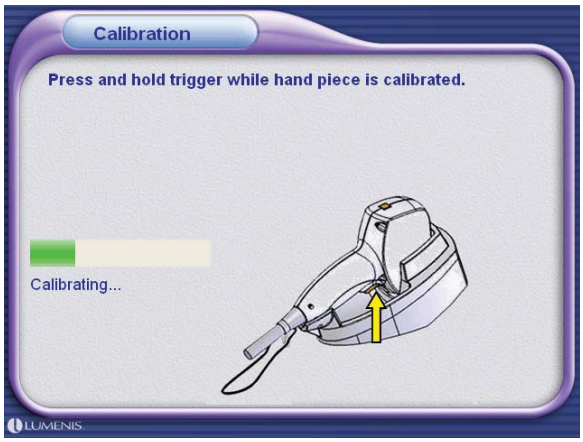


HS handpiece calibration screen — press and hold the trigger

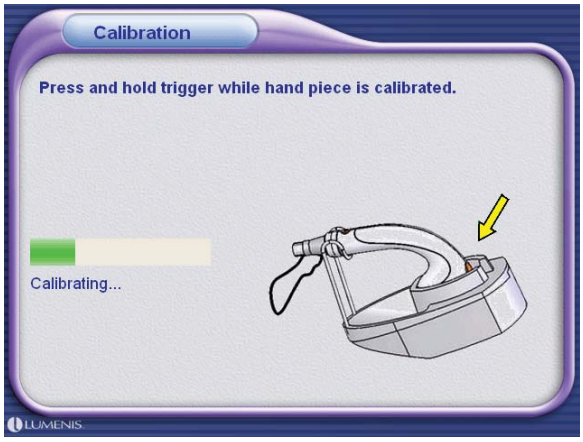
8 Wait until the system finishes performing the calibration.

Progress is displayed on the touchscreen, and a beeping sound will be audible when the laser fires.

> If the handpiece is removed from the holster or the handpiece trigger is released before the calibration is complete, the procedure is immediately stopped and must be repeated.



ET handpiece calibration screen — "calibrating"

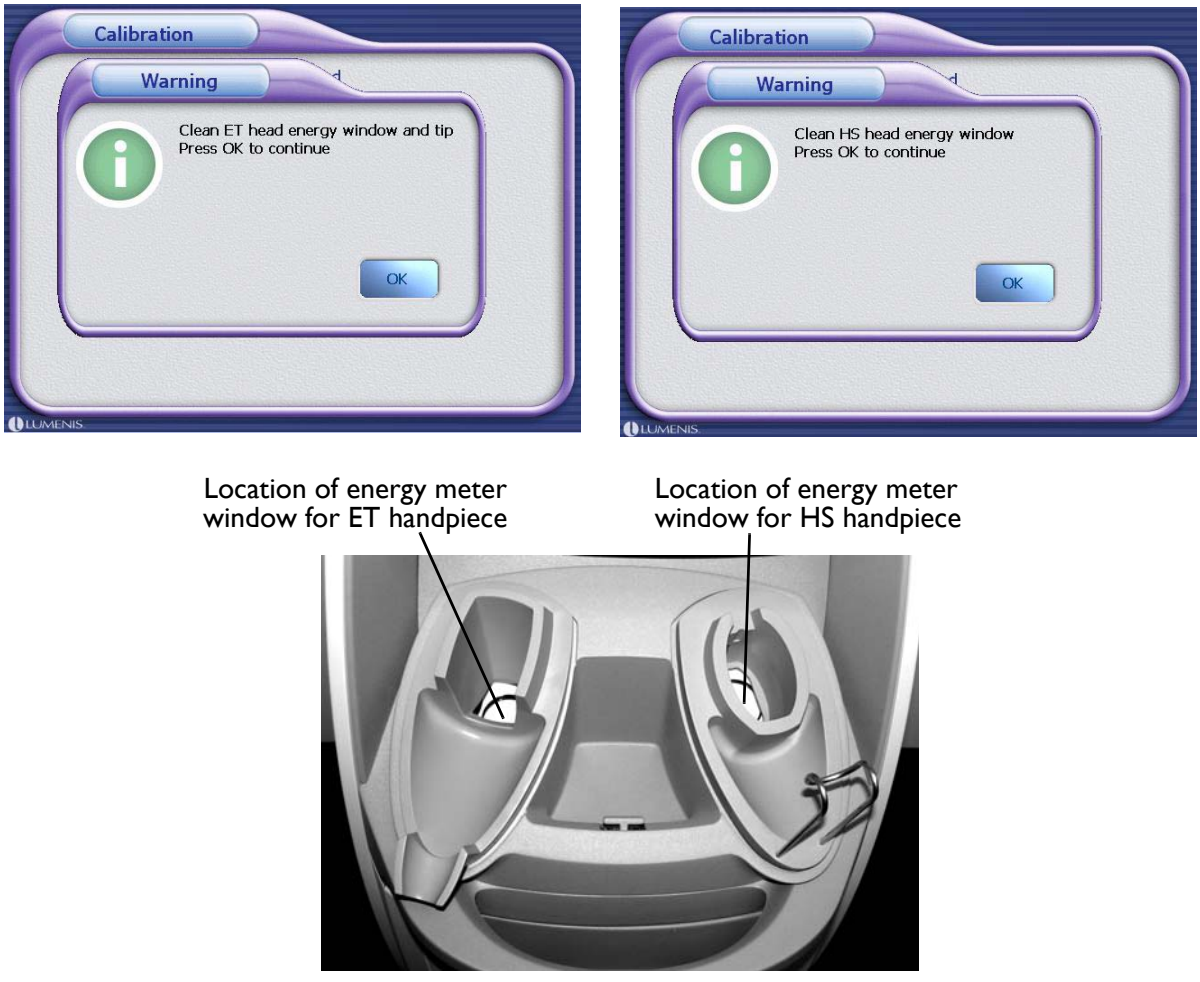


HS handpiece calibration screen — "calibrating"

9 Release the handpiece trigger.

10 If necessary, clean the handpiece tip and the energy meter window and then repeat the calibration sequence.

If an abnormal energy is measured, a screen will prompt you to clean the handpiece tip and the energy meter window (below the holster) because contamination or condensation can affect the reading. Carefully perform the cleaning per the Maintenance chapter of this manual and repeat the calibration sequence.



Handpiece calibration screens — clean energy meter window

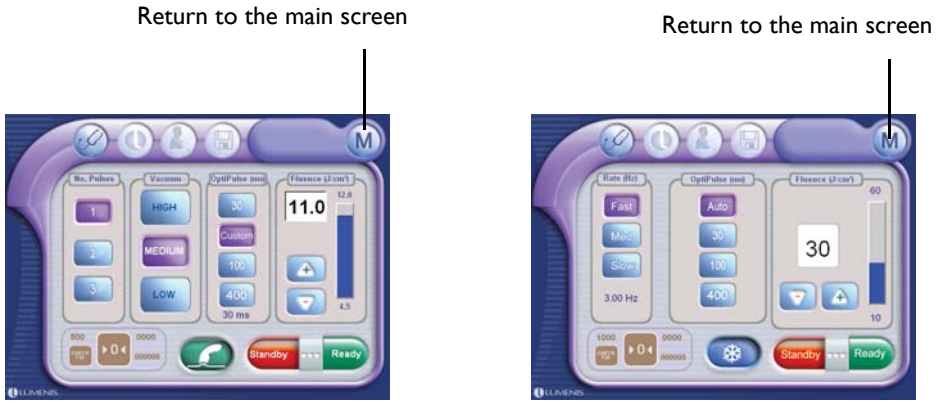
11 Repeat the calibration for the other handpiece, as needed.

After calibration is completed, the treatment screen is displayed and normal operation can proceed.

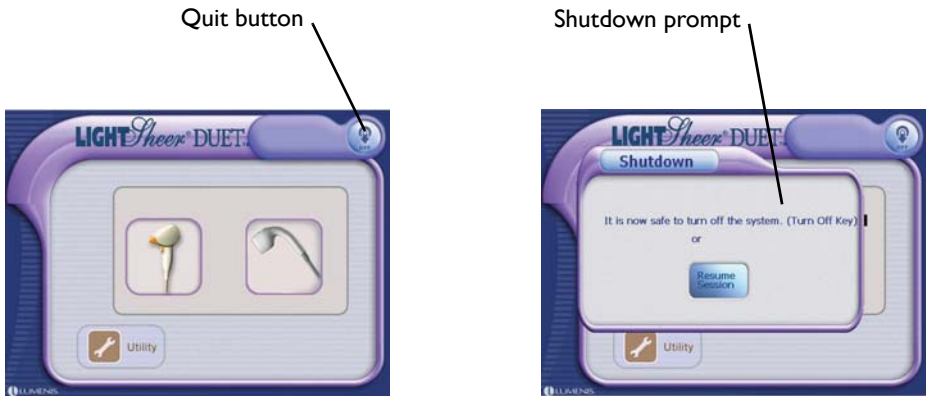
In compliance with national and international regulations, additional details of the calibration procedure are provided in the Maintenance chapter of this manual, although this information is intended for authorized service personnel only.

Turning off the laser

1 From the HS or ET treatment screen, press **M** (return to main) to return to the startup screen.



2 Press the Quit button on the startup screen and follow any prompts presented by the system.



3 Turn the keyswitch to the ○ (off) position. Remove the key to prevent unauthorized use of the laser.

Restarting the laser

1 Turn the keyswitch to the ○ (off) position; wait 5 seconds.

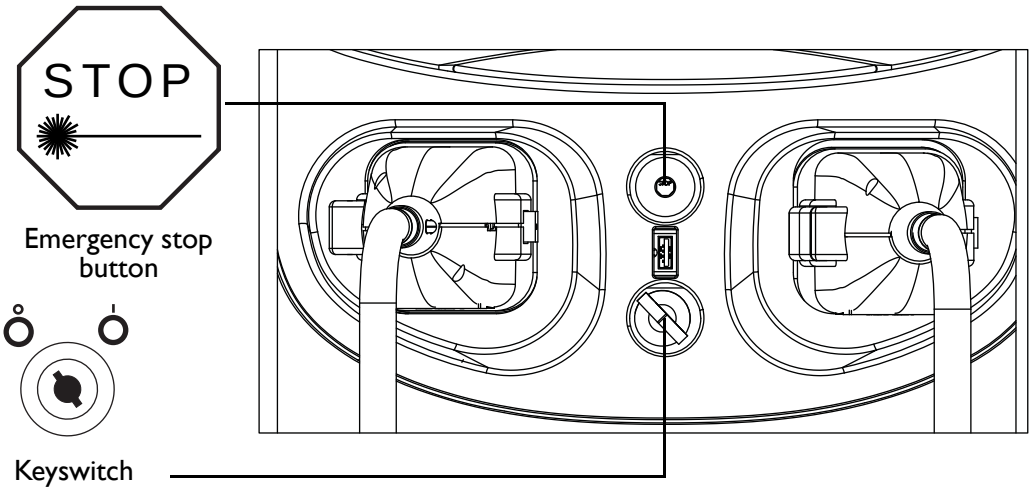
2 Turn the keyswitch to the ○ (on) position.

Emergency stop

In an emergency, press the emergency stop button on the front of the laser console to immediately turn off the laser.

To restore operation, rotate the button clockwise until it pops out and restart the instrument with the keyswitch. Use the keyswitch, rather than the emergency stop button for routine shutdown.

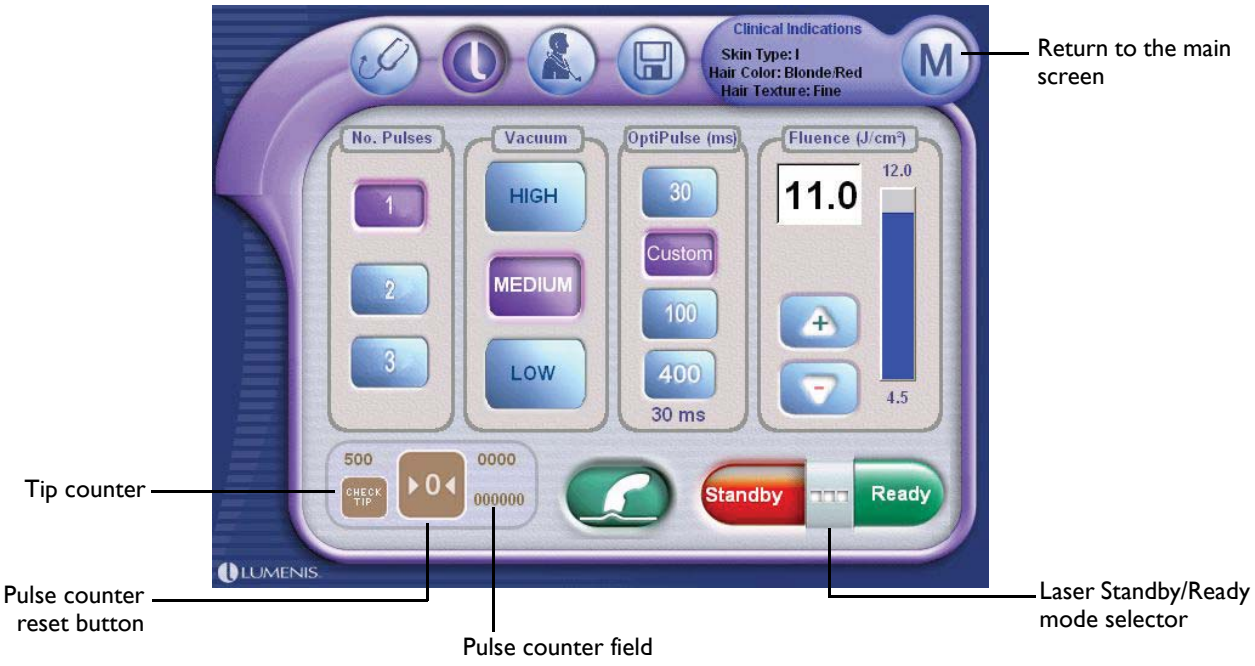
When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, unplug the main power plug from the wall socket, or turn off the main power circuit breaker.



Treatment Screen Basics

The LightSheer Duet laser system displays a unique treatment screen according to the handpiece you have selected. Touchscreen controls common to both the HS and ET handpiece screens are described in the following paragraphs.

> ⚠ **WARNING - Clean the touchscreen regularly as instructed in the Maintenance chapter of this manual to ensure proper performance. Excessive treatment oil, gel, lotion, or other contaminants on the touchscreen may cause erratic operation of the user interface.**

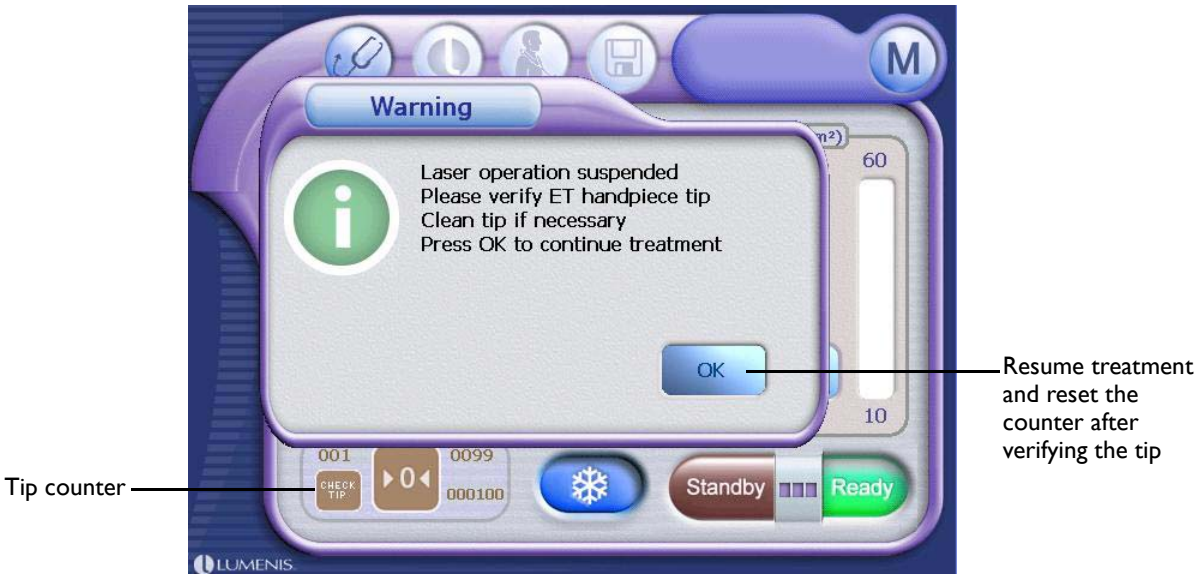


Controls and indicators common to both HS and ET handpieces (HS handpiece screen is shown)

Tip counter

The tip counter registers the number of shots remaining before the LightSheer Duet system suspends treatment and prompts the operator to inspect the handpiece tip. If necessary, clean the ET handpiece sapphire tip or replace the HS handpiece disposable insert, as described in the Maintenance section of this manual.

After verifying the tip, press OK to clear the warning, reset the counter, and continue treatment.



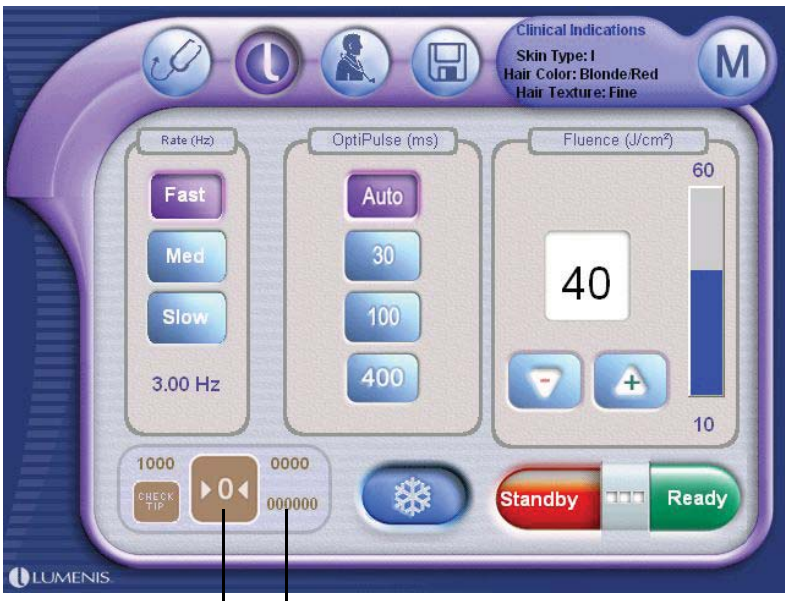
Verify the ET handpiece tip before resuming treatment

Verify the HS handpiece tip before resuming treatment

Pulse counter field

The pulse counter field displays (upper number) a reset-able counter useful for recording the number of pulses in a single session or for other short term uses, and (lower number) a cumulative counter that records the total number of shots on the LightSheer Duet system.

Press the >**0**< button to reset the session counter to zero.



Reset to zero

Pulse counter field
Upper number: number of pulses delivered by the currently selected handpiece during the current session
Lower number: displays the total number of pulses delivered by the currently selected handpiece.

Pulse counter and counter reset button (ET handpiece screen is shown)

Selecting the Laser Mode: Ready or Standby

WARNING - Except during actual treatment, the laser must always be in standby mode. Maintaining the laser in standby mode prevents accidental laser exposure if the handpiece trigger is inadvertently pulled.

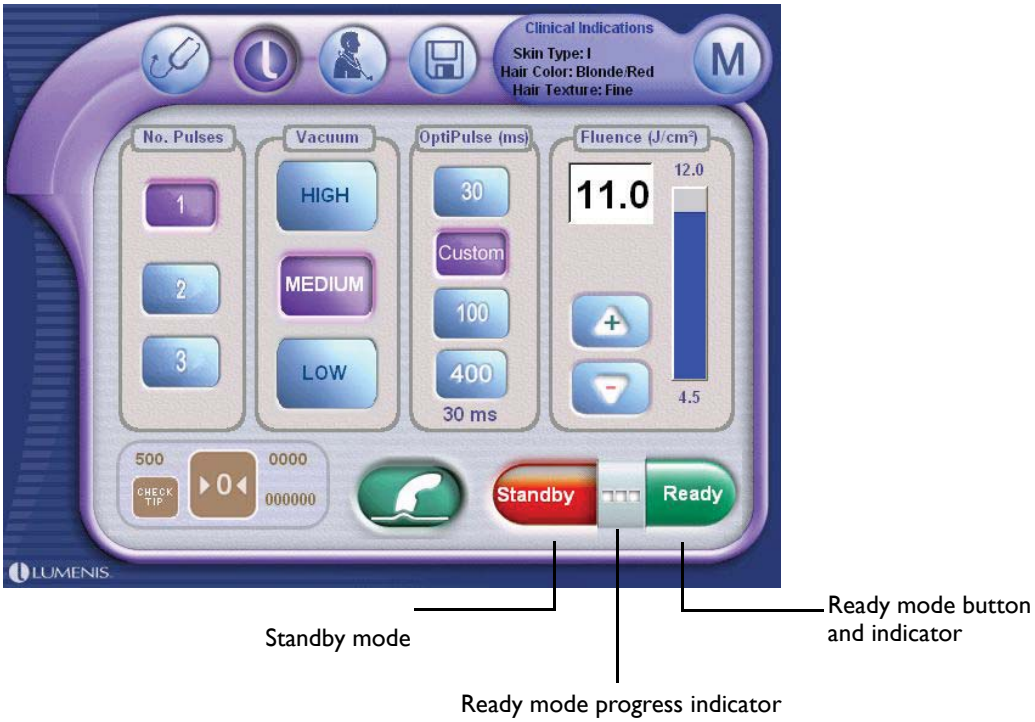
WARNING - Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in ready mode.

In ready mode, the trigger is enabled and the treatment beam is available. In standby mode, the trigger is disabled; no treatment beam is available.

- To select Ready mode, press **Ready;** the three indicators display the progress of transition from Standby to Ready mode. The green **Ready** button illuminates when Ready mode is active.
- To select Standby mode, press **Standby**. The red **Standby** button illuminates to indicate that the laser is in Standby mode.

The laser automatically switches from ready mode to standby mode if it remains idle for more than 5 minutes.

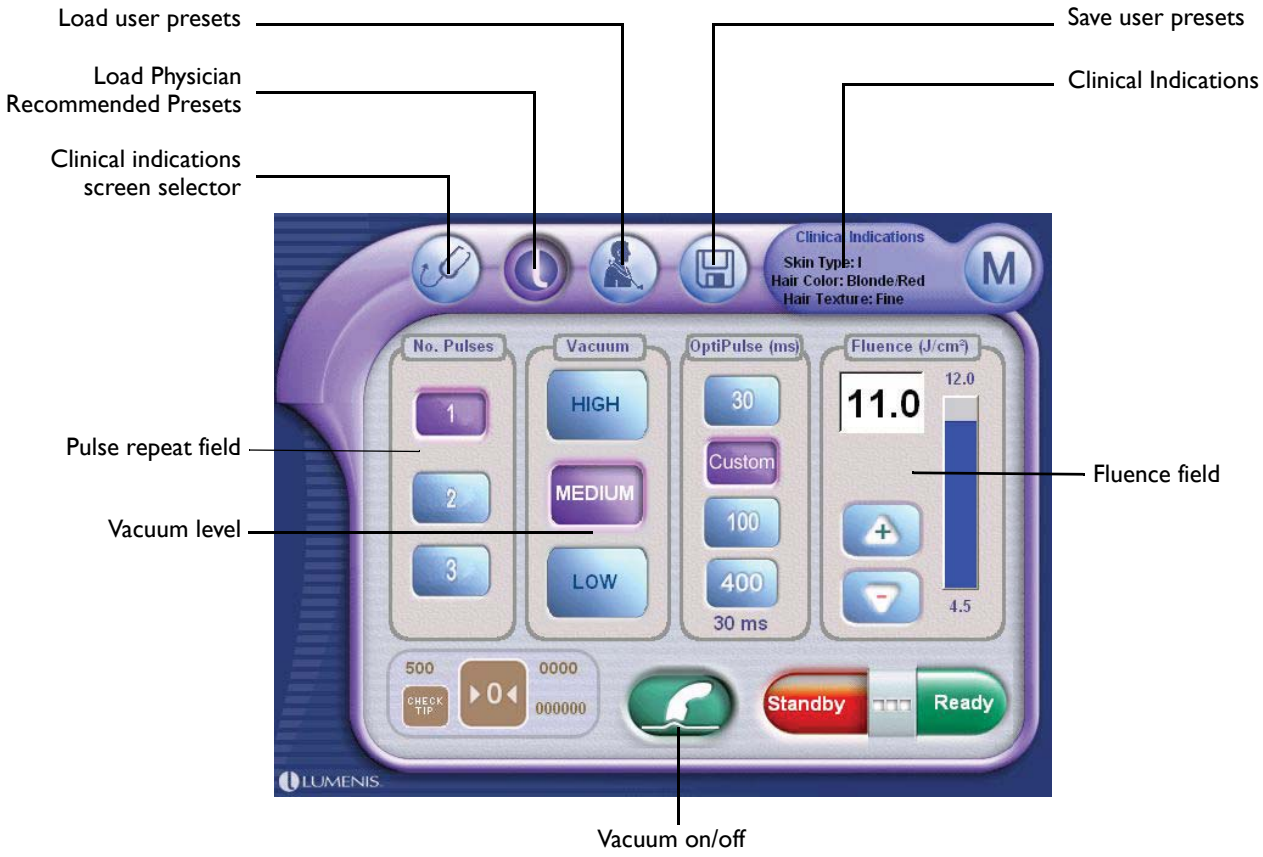
Even after selecting ready mode, you must press the handpiece enable button on your handpiece before pulling the handpiece trigger will fire the laser.



Ready and Standby controls (HS handpiece screen is shown)

HS handpiece Treatment Screen

After you have selected the HS handpiece on the startup screen and calibration is completed, the HS handpiece treatment screen is displayed.

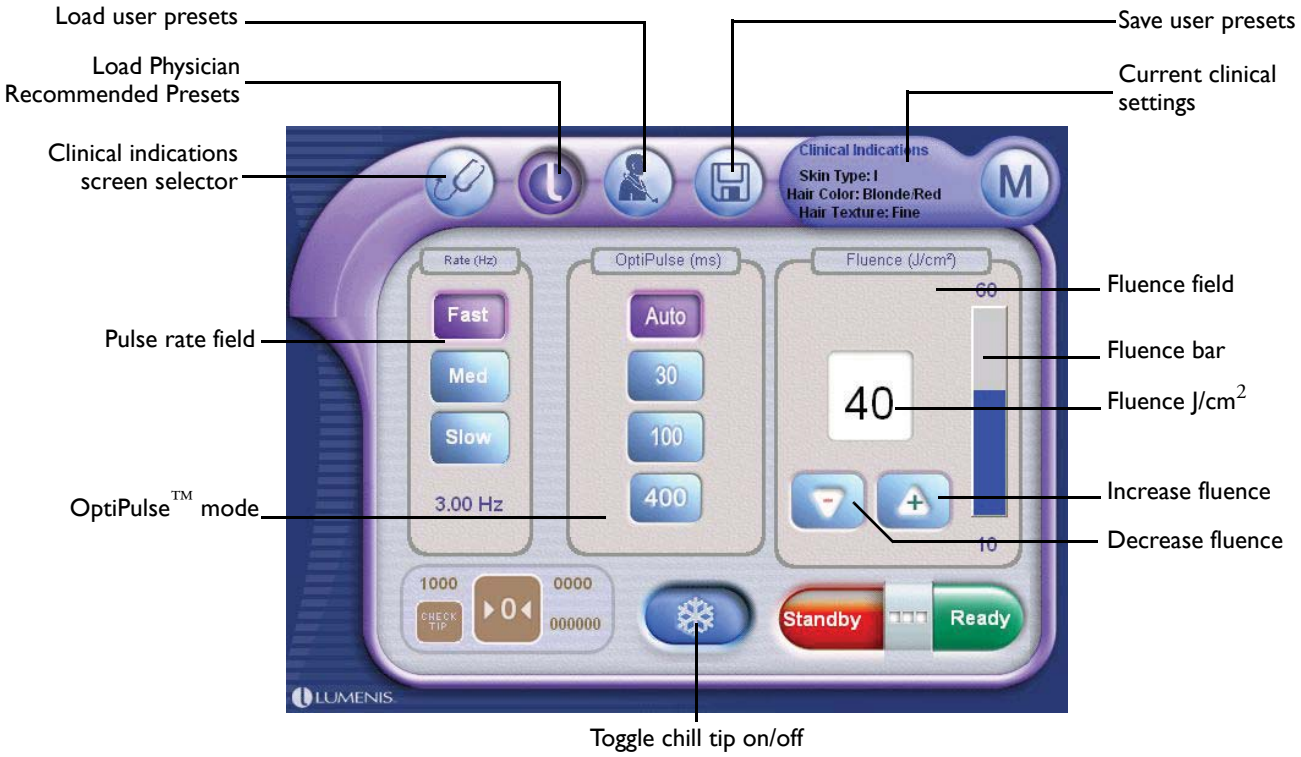


HS handpiece treatment screen

Field	Description
Pulse repeat	Select **1**, **2** or **3** to deliver up to three laser shots for each press of the trigger, at a rate of up to 2 shots per second.
Fluence	Select from 4.5 to 12 J/cm^2 in increments of 0.1 J/cm^2. For the **30 ms** mode the maximal fluence will be 6 J/cm^2.
Vacuum level	Selects the vacuum level: highest (18 inHg), medium (12 inHg), or lowest (8 inHg) available level.
Vacuum on/off	Toggles the vacuum pump on or off; only available when the laser is in Standby mode. Will automatically activate when the laser is placed in ready mode.
OptiPulse	OptiPulse has four user-selectable modes: **30 ms**", "**Custom**", "**100 ms**" and "**400 ms**". With "**Custom**" mode selected, the system will select the optimal pulse width based on the fluence and number of pulses selected.
Pulse interval	Displays actual pulse interval between pulses from 333 ms to 2000 ms. It is displayed at the bottom of the "No. Pulses" field.

ET Handpiece Treatment Screen

After you have selected the ET handpiece on the startup screen and calibration is completed, the ET handpiece treatment screen is displayed.



ET handpiece treatment screen

Control/Indicator	Description
Rate (Hz)	Select the "**Fast**" (1-3 Hz), "**Med**" (0.5-1.0 Hz) or "**Slow**" (0.5 Hz); the actual rate will be displayed at the bottom of the pulse rate field.
OptiPulse (Pulse width)	OptiPulse has four user-selectable modes: "AUTO", "30 ms", "100 ms", and "400 ms". In "30 ms", "100 ms", and "400 ms" modes, the pulse width is fixed at 30 ms, 100 ms, and 400 ms respectively, independent of the fluence setting. In "AUTO" mode, the system selects the pulse width allowable at a given fluence.
Fluence field	Displays the selected fluence, numerically, and as a bar indicating the fluence level in relation to the maximum available fluence for your current Rate and OptiPulse settings. Press the increase or decrease fluence selectors to adjust the desired fluence.
Toggle chill tip on/off	When first turned on, the ChillTip requires approximately 30 seconds to cool to its operating temperature, during which time the "COOLING" message is displayed on the screen. The laser cannot be fired if the ChillTip is on, but not adequately cold. For safety, the ChillTip is turned on by default and a confirmation screen appears when the ChillTip is switched off. In addition, if the ChillTip is turned off, the "OFF" indicator flashes red as a warning to the user. The status indicator on the treatment screen also indicates if the ChillTip is turned off. Using the LightSheer Duet system when the ChillTip is off can result in epidermal damage. Use extreme care when operating the system with the ChillTip off. Except in rare circumstances, the system should always be operated with the ChillTip turned on.

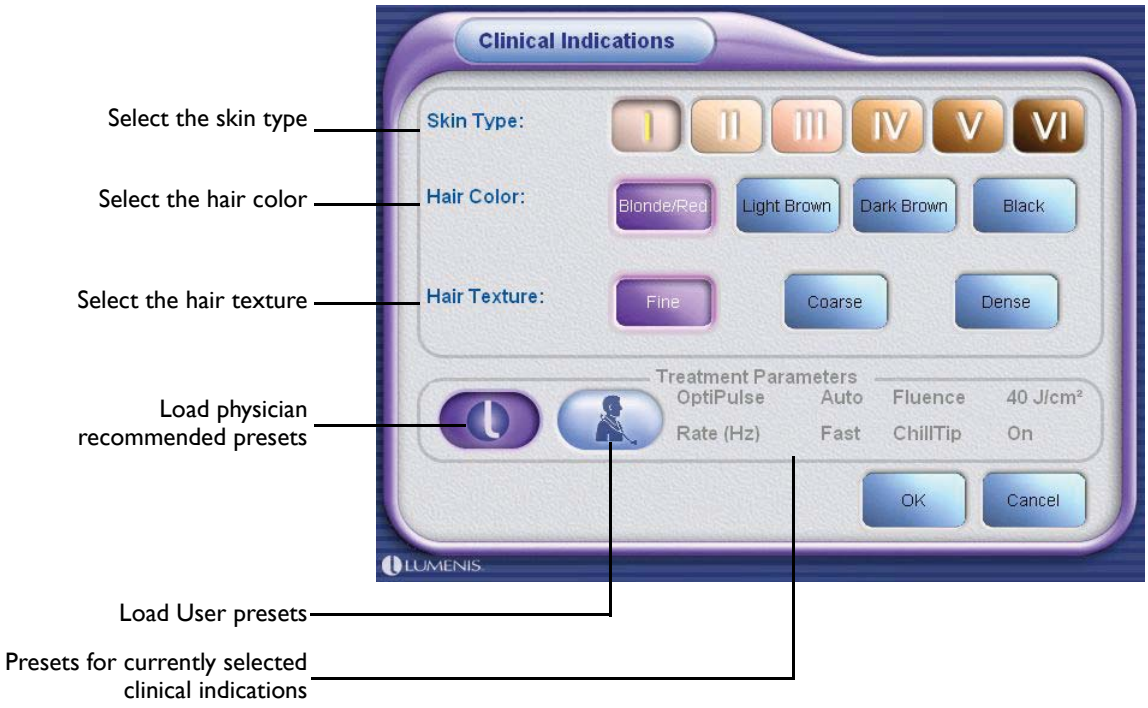
Control/Indicator	Description
Clinical indications screen selector 	Displays the clinical indications screen, described in the following section. 
Load physician recommended presets 	• Loads the physician recommended presets for the currently selected clinical indications into the treatment screen. Presets are Rate, OptiPulse selection, and Fluence. • This button is disabled if there are no clinical indications currently selected, or if there are no Lumenis presets for the currently selected clinical indications.
Load user presets 	• Loads previously-saved user presets for the currently selected clinical indications into the treatment screen. Presets are Rate, OptiPulse selection, and Fluence. • This button is disabled if there are no clinical indications currently selected, or if there are no previously-saved user presets for the currently selected clinical indications.
Save user presets 	Opens the Clinical Indications screen, which lets you save your currently selected treatment parameters for future retrieval with the **Load user presets** button.
Current clinical settings	Displays the currently selected patient clinical settings, if selected: • skin type (I through VI) • hair color (Blonde/Red, Light brown, dark brown, or black) • hair texture (Fine, Coarse, or Dense)

Hair with less melanin (pigment) is a known treatment challenge, and may result in less than optimal results.

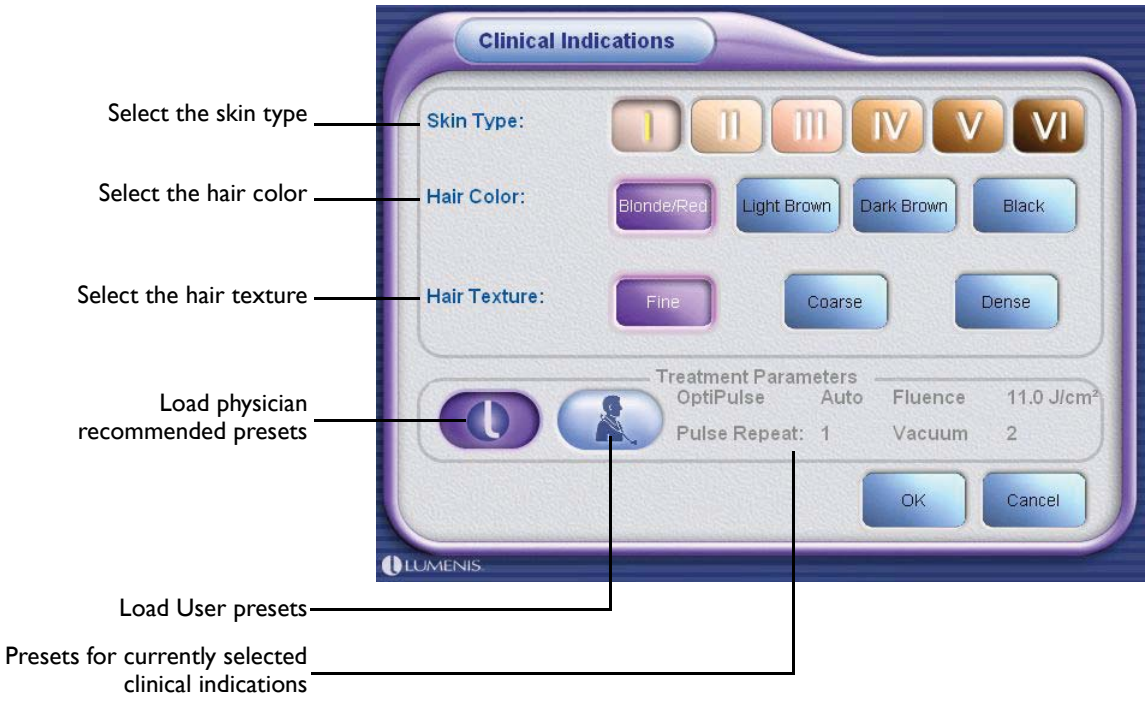
Hair color must be darker than skin color to be safely and effectively treated.

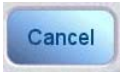
In cases where hair color is lighter than skin color, no presets are available.

Clinical Indications Screen for ET Handpiece



Clinical Indications Screen for HS Handpiece



Control/Indicator	Description
Skin Type	Selects the skin type
Hair Color	Selects the hair color
Hair Texture	Selects the hair texture
Treatment Parameters display	• Displays the Lumenis or User presets for the currently selected skin type, hair color, and hair texture. Presets are Rate, OptiPulse selection, and Fluence. • This field is displayed only after the Lumenis Preset or User Preset button has been pressed.
Load physician recommended presets 	• Loads the physician recommended treatment presets for the currently selected clinical indications into the treatment parameters display. Presets are Rate, OptiPulse selection, and Fluence. • This button is disabled if there are no clinical indications currently selected, or if there are no Lumenis presets for the currently selected clinical indications.
Load user presets 	• Loads previously-saved user treatment presets for the currently selected clinical indications into the treatment parameters display. Presets are Rate, OptiPulse selection, and Fluence. • This button is disabled if there are no clinical indications currently selected, or if there are no previously-saved user presets for the currently selected clinical indications.
OK 	Accepts the user selections and closes the screen. This button is inactive until the user has selected the skin type, hair color, and hair texture.
Cancel 	Closes the Clinical Indications screen without making a selection.

Physician recommended preset values for the ET handpiece

Skin Type	Hair Color	Hair Texture	Fluence (J/cm^2)	Pulse Duration [ms]
I	Blond/Red	Fine	40	Auto
		Coarse	35	Auto
		Dense	35	30
	Light Brown	Fine	40	Auto
		Coarse	35	Auto
		Dense	35	30
	Dark Brown	Fine	40	Auto
		Coarse	35	Auto
		Dense	35	30
	Black	Fine	40	Auto
		Coarse	35	Auto
		Dense	35	30
II	Blond/Red	Fine	35	Auto
		Coarse	30	Auto
		Dense	30	30
	Light Brown	Fine	35	Auto
		Coarse	30	Auto
		Dense	30	30
	Dark Brown	Fine	35	Auto
		Coarse	30	Auto
		Dense	30	30
	Black	Fine	35	Auto
		Coarse	30	Auto
		Dense	30	30
III	Blond/Red	Fine	30	Auto
		Coarse	25	30
		Dense	20	30
	Light Brown	Fine	30	Auto
		Coarse	25	30
		Dense	20	30
	Dark Brown	Fine	30	Auto
		Coarse	25	30
		Dense	20	30
	Black	Fine	30	Auto
		Coarse	25	30
		Dense	20	30

Skin Type	Hair Color	Hair Texture	Fluence [J/cm^2]	Pulse Duration [ms]
IV	Blond/Red	Fine	No Preset	No Preset
		Coarse	No Preset	No Preset
		Dense	No Preset	No Preset
	Light Brown	Fine	20	30
		Coarse	26	100
		Dense	24	100
	Dark Brown	Fine	20	30
		Coarse	26	100
		Dense	24	100
	Black	Fine	20	30
		Coarse	26	100
		Dense	24	100
V	Blond/Red	Fine	No Preset	No Preset
		Coarse	No Preset	No Preset
		Dense	No Preset	No Preset
	Light Brown	Fine	No Preset	No Preset
		Coarse	No Preset	No Preset
		Dense	No Preset	No Preset
	Dark Brown	Fine	22	100
		Coarse	18	100
		Dense	16	100
	Black	Fine	22	100
		Coarse	18	100
		Dense	16	100
VI	Blond/Red	Fine	No Preset	No Preset
		Coarse	No Preset	No Preset
		Dense	No Preset	No Preset
	Light Brown	Fine	No Preset	No Preset
		Coarse	No Preset	No Preset
		Dense	No Preset	No Preset
	Dark Brown	Fine	25	400
		Coarse	20	400
		Dense	20	400
	Black	Fine	25	400
		Coarse	20	400
		Dense	20	400

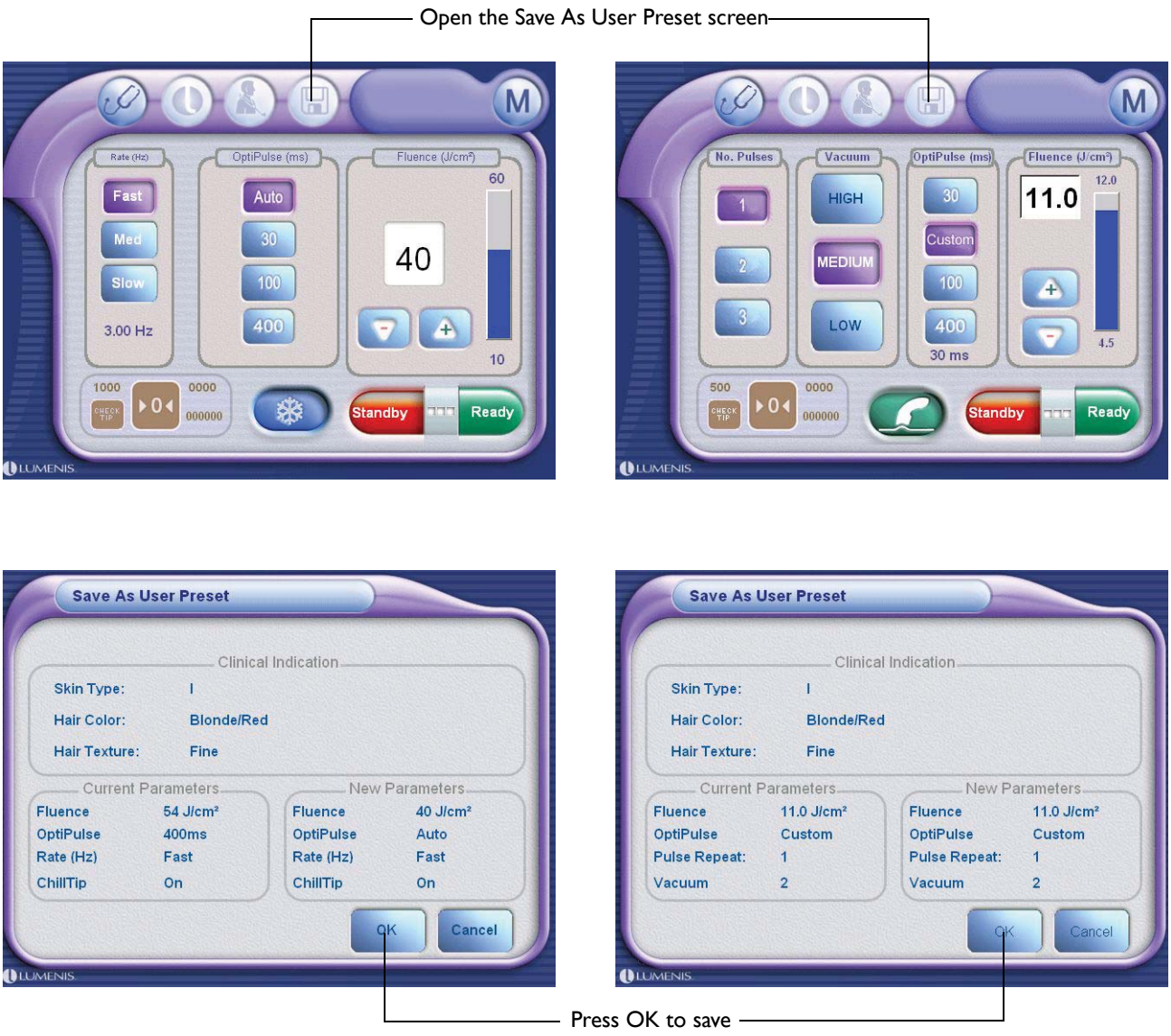
Physician recommended preset values for the HS handpiece

Skin Type	Hair Color	Hair Texture	Fluence (J/cm^2)	Pulse Duration [ms]	Level of Vacuum	Number of Pulses
I	Blond/Red	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Light Brown	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Dark Brown	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Black	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
II	Blond/Red	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Light Brown	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Dark Brown	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
	Black	Fine	11	Custom	Medium	1
		Coarse	10	Custom	Medium	1
		Dense	9	Custom	Medium	1
III	Blond/Red	Fine	10	Custom	Medium	1
		Coarse	9	Custom	Medium	1
		Dense	8	Custom	Medium	1
	Light Brown	Fine	10	Custom	Medium	1
		Coarse	9	Custom	Medium	1
		Dense	8	Custom	Medium	1
	Dark Brown	Fine	9	Custom	Medium	1
		Coarse	8	Custom	Medium	1
		Dense	8	Custom	Medium	1
	Black	Fine	9	Custom	Medium	1
		Coarse	8	Custom	Medium	1
		Dense	8	Custom	Medium	1

Skin Type	Hair Color	Hair Texture	Fluence (J/cm^2)	Pulse Duration [ms]	Level of Vacuum	Number of Pulses
IV	Blond/Red	Fine	8	Custom	Medium	1
		Coarse	7	Custom	Medium	1
		Dense	6	Custom	Medium	1
	Light Brown	Fine	8	Custom	Medium	1
		Coarse	7	Custom	Medium	1
		Dense	6	Custom	Medium	1
	Dark Brown	Fine	6	Custom	Medium	1
		Coarse	6	Custom	Medium	1
		Dense	6	Custom	Medium	1
	Black	Fine	6	Custom	Medium	1
		Coarse	6	Custom	Medium	1
		Dense	6	Custom	Medium	1
V	Blond/Red	Fine	No Preset	No Preset	No Preset	No Preset
		Coarse	No Preset	No Preset	No Preset	No Preset
		Dense	No Preset	No Preset	No Preset	No Preset
	Light Brown	Fine	6	100	Medium	1
		Coarse	5	400	Medium	1
		Dense	4.5	400	Medium	1
	Dark Brown	Fine	5.5	400	Medium	1
		Coarse	5	400	Medium	1
		Dense	4.5	400	Medium	1
	Black	Fine	5.5	400	Medium	1
		Coarse	5	400	Medium	1
		Dense	4.5	400	Medium	1
VI	Blond/Red	Fine	No Preset	No Preset	Medium	1
		Coarse	No Preset	No Preset	No Preset	1
		Dense	No Preset	No Preset	No Preset	1
	Light Brown	Fine	No Preset	No Preset	No Preset	1
		Coarse	No Preset	No Preset	No Preset	1
		Dense	No Preset	No Preset	No Preset	1
	Dark Brown	Fine	5.5	400	Medium	1
		Coarse	5	400	Medium	1
		Dense	4.5	400	Medium	1
	Black	Fine	5.5	400	Medium	1
		Coarse	5	400	Medium	1
		Dense	4.5	400	Medium	1

Save As User Preset screen

1 Click on the Save Button:



2 Select OK after verifying settings. Preset is now saved.

Create a user preset

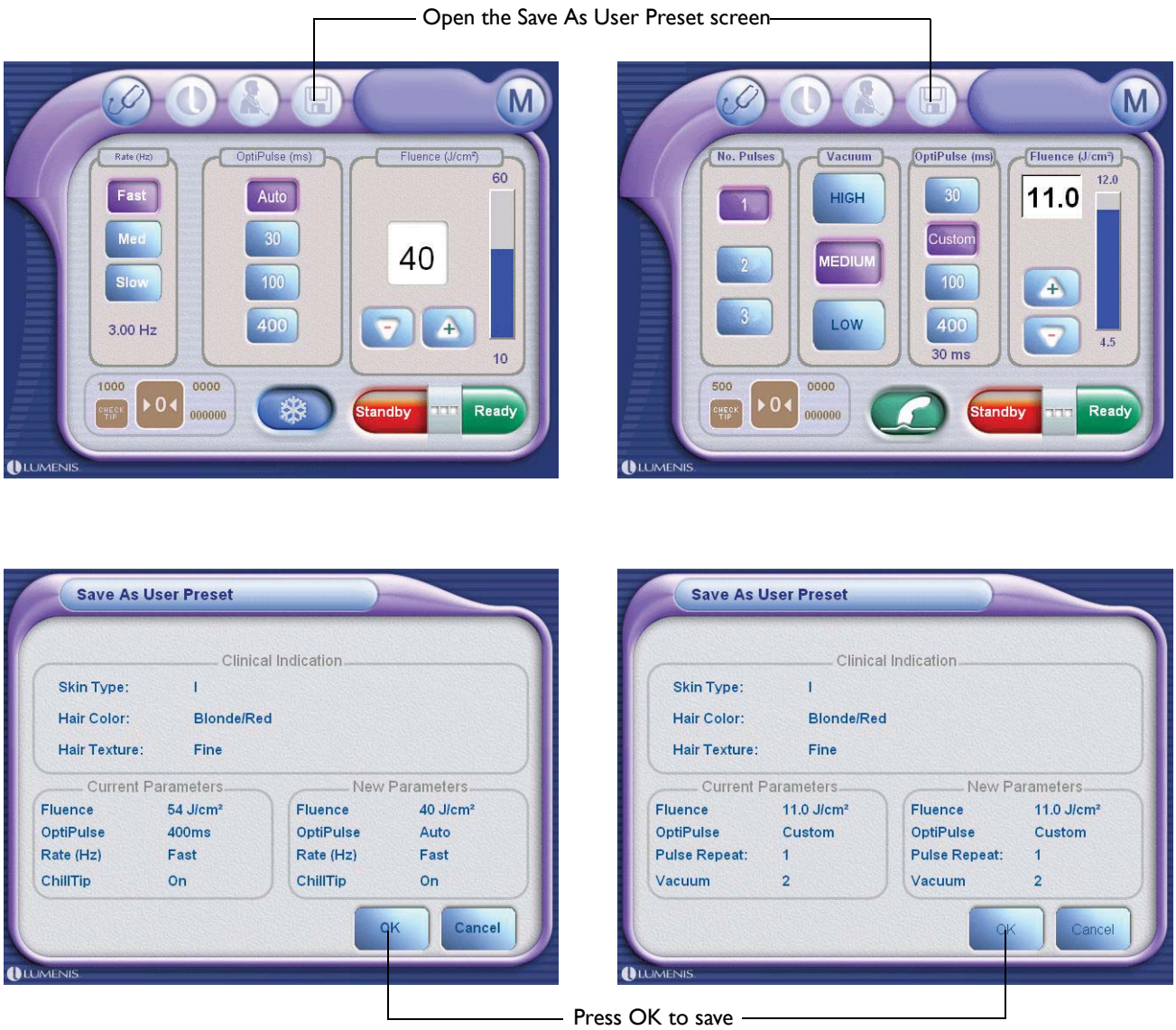
1 Click on the Clinical Indications screen selector button.

2 Select skin and hair options. If Lumenis or user preset buttons are highlighted, the parameter already exists.

3 If neither is on, select the OK button to return to the treatment screen window.

4 Click on the Save button.

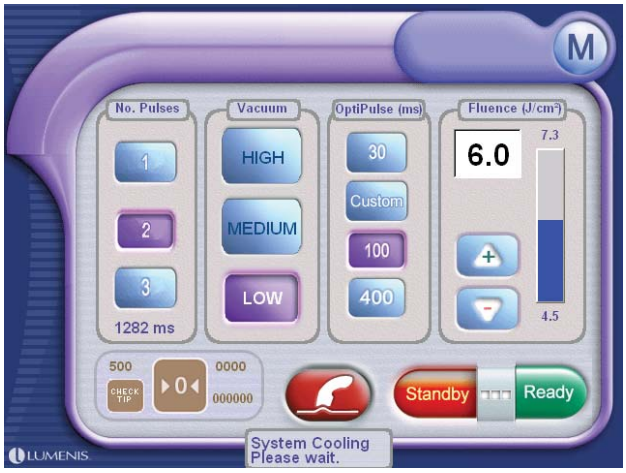
5 Select the OK button after verifying settings. Preset is now saved.



System Messages

"System Cooling"

When necessary, the system will pause operation to activate cooling of the selected handpiece. During system cooling the LightSheer Duet system automatically returns to standby mode, the **Ready** button on the touchscreen is disabled, and the enable buttons on the handpieces deactivate. You may still set parameters; however, the system cannot be returned to ready mode until after the required operating temperature is reached and the "System Cooling" message clears.



HS handpiece "System Cooling" message

ET handpiece "System Cooling" message

Recoverable error

Clear recoverable errors by pressing the **Clear** button on the error message. Continue the procedure; if the error continues to appear, contact your Lumenis representative.

Example of a recoverable error

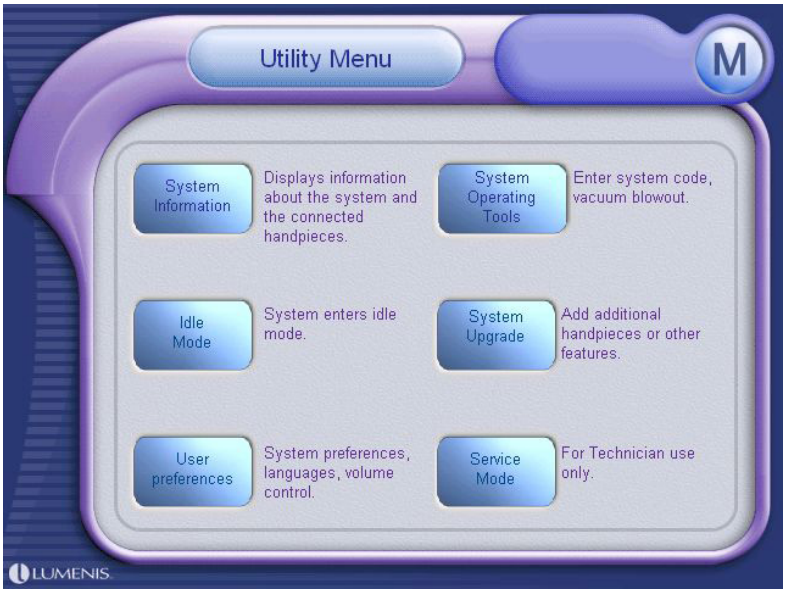
Non-recoverable error

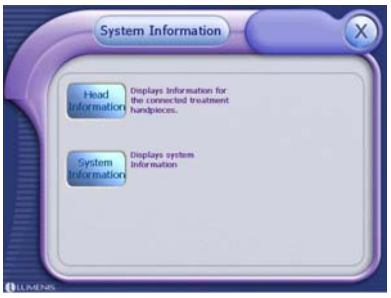
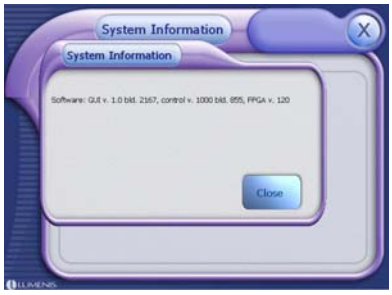
Non-recoverable errors require a system restart. To restart the system after a non-recoverable error, turn the keyswitch to the ○ (off) position, wait 30 seconds, and then turn the keyswitch to the ○ (on) position. If the error persists, contact your Lumenis representative.

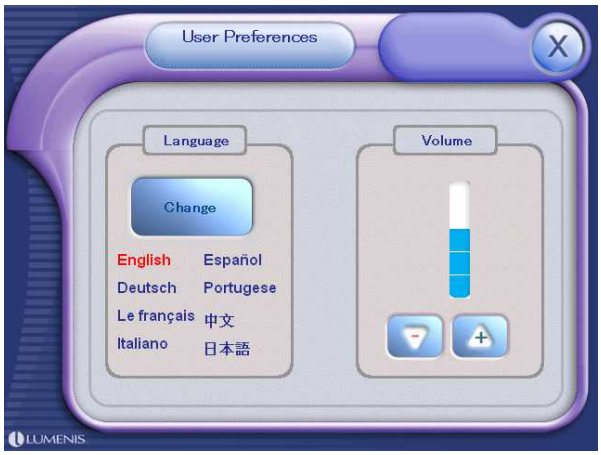
Example of a non-recoverable error

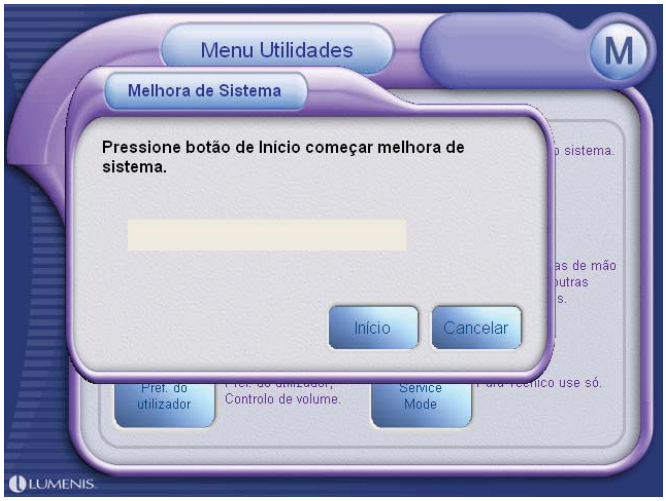
Setting System Options

Select the Utility Menu screen



Utility menu	Description
System Information	Displays information about the system software and the connected handpieces. Press **System Information** again to display the current system software revision.   Display the handpiece hardware information  Display the current system software revision
Idle Mode	Press to place system into idle mode. System will also enter into idle mode automatically after a period of inactivity. 

User Preferences	• Adjust the system volume by pressing the - or + buttons on the touchscreen until the system beeps at the desired volume. • Press the **Change** button or press on the desired language button to select the desired language. 
System Operating Tools	• Pressing the **Vacuum Purge** button will cause the system to reverse the vacuum direction and eliminate any blockage within the HS handpiece vacuum lines. This is only for laser systems which use the HS handpiece. It is recommended to purge once at the beginning of the day or as needed for better vacuum. • The **Enter Code** button is intended for use by authorized Lumenis service personnel to access the service screen and special operating modes.   Purge the HS handpiece vacuum  Enter code

System Upgrade	• Press the **Upgrade** button on the Utility screen. • Connect the USB drive into the front panel's USB portand press **Start**. • Wait for the upgrade processto complete. • For handpieces complete the upgrade first, shutdown the system, install the handpiece, and restart. 

Laser Operation

Preoperative instructions

1 Verify that the laser and its components are properly connected, as instructed in “Connection Instructions” in this chapter.

2 Post the “Laser in Use” warning sign outside the treatment room door.

3 If necessary, turn on the main electrical service (wall circuit breaker).

4 Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See “Ocular hazards” in the Safety and Regulatory chapter for laser safety eyewear information.

5 If using the HS handpiece, install a new disposable insert prior to treating the patient.

6 If using the ET handpiece, clean the sapphire tip, as described in the Maintenance section of this operator manual.

7 If the laser is not already on, turn on the laser, as instructed in “Laser Console Basics” in this chapter.

8 Select the HS or ET handpiece and perform the startup calibration. After calibration, the treatment screen is displayed and the startup procedure is complete. If the system is already on, new calibration is unnecessary.

Intraoperative instructions for the HS handpiece

1 Prepare the patient, as described in "Patient Treatment" in this chapter.

WARNING - Do not apply treatment gel to the patient's skin when using the HS handpiece. Unlike the ET handpiece, treatment gel is not needed and should not be used with the HS handpiece.

WARNING - Clean the touchscreen regularly as instructed in the Maintenance section of this manual to ensure proper performance. Excessive treatment oil, gel, lotion, or other contaminants on the touchscreen may cause erratic operation of the user interface.

2 Select the desired pulse repeat, fluence, and vacuum settings.

Always check the fluence reading prior to triggering the laser to verify that the desired value is displayed on the screen.

3 Reset the pulse counter, if desired.

If the number of laser pulses for this session will be tracked, press the reset button to the left of the shot counter to zero the counter.

4 Position the handpiece for treatment. Refer to "Patient Treatment" in this chapter for recommendations on correctly positioning the handpiece.

5 Select ready mode on the laser touchscreen.

6 Press the handpiece enable button to enable the handpiece.

7 Press the handpiece trigger to fire the laser.

For safety, laser output occurs only if the handpiece is enabled, vacuum suction has been applied, and the handpiece trigger is pressed.

If the HS handpiece cannot achieve sufficient vacuum suction, the system will display a notification message; release and then re-press the trigger to clear the message.

For operator feedback and safety, an audible beep accompanies each laser pulse as an emission indicator.

WARNING - Immediately cease use of the laser if the touchscreen becomes unresponsive, or if the trigger fails in the pressed state. Deactivate the laser either by pressing the emergency stop button or turning the laser keyswitch to the OFF position. After waiting one minute, turn the keyswitch to the ON position. If the laser remains unresponsive, do not use the laser; contact your local Lumenis service representative.

Intraoperative instructions for the ET handpiece

1 Prepare the patient, as described in “Patient Treatment” in this chapter.

> ⚠ **WARNING - Clean the touchscreen regularly as instructed in the Maintenance section of this manual to ensure proper performance. Excessive treatment oil, gel, lotion, or other contaminants on the touchscreen may cause erratic operation of the user interface.**

2 Select the desired rate, OptiPulse pulse width, and fluence.

Set the fluence by pressing the fluence adjustment up and down arrows to increase or decrease the setting.

Always check the fluence reading prior to triggering the laser to verify that the desired value is displayed on the screen.

3 Reset the pulse counter, if desired.

If the number of laser pulses for this session will be tracked, press the reset button to the left of the shot counter to zero the counter.

4 Press the ChillTip button to toggle the cooling to the sapphire tip on and off. For safety, the ChillTip is turned on by default and a confirmation screen appears when the ChillTip is switched off.

> ⚠ **WARNING - Using the LightSheer Duet system when the ChillTip is off can result in epidermal damage. Use extreme care when operating the system with the ChillTip off. Except in rare circumstances, the system should always be operated with the ChillTip turned on.**

5 When the ChillTip is turned on (also the default), verify the ET handpiece is properly chilling by physically touching the ChillTip.

6 Apply a thin layer of gel to the area to be treated to facilitate ChillTip movement across skin and improve contact cooling.

7 Position the handpiece for treatment. Refer to “Patient Treatment” in this chapter for recommendations on correctly positioning the handpiece.

8 Select ready mode on the laser touchscreen.

9 Press the handpiece enable button to enable the handpiece.

10 Press the handpiece trigger to fire the laser.

For safety, laser pulses will occur only if both the handpiece is enabled and the handpiece trigger is pressed. Pressing and releasing the handpiece trigger will result in a single pulse being fired from the laser. Fire additional pulses by pressing and releasing the handpiece trigger for each additional pulse.

The maximum pulse repetition frequency allowed by the system is two pulses per second, so very rapid triggering will not result in more rapid firing.

The laser may be operated in a repetitively pulsed mode by continuously holding down the handpiece trigger. In this case, the laser will automatically fire at the default pulse repetition rate until the handpiece trigger is released.

⚠ **WARNING - Repeatedly treating the same spot on the epidermis may cause burns; therefore, the handpiece should be moved around while in repetitively pulsed mode.**

⚠ **WARNING - Ensure that the chilled sapphire tip is in contact with the skin prior to laser emission. Repetitively pulsed mode should be utilized only by experienced users, since proper handpiece technique is essential to ensure tip contact with skin prior to emission. Refer to "Patient Treatment" later in this chapter.**

For operator feedback and safety, an audible beep accompanies each laser pulse as an emission indicator.

⚠ **WARNING - Immediately cease use of the laser if the touchscreen becomes unresponsive, or if the trigger fails in the pressed state. Deactivate the laser either by pressing the emergency stop button or turning the laser keyswitch to the OFF position. After waiting one minute, turn the keyswitch to the ON position. If the laser remains unresponsive, do not use the laser; contact your local Lumenis service representative.**

Pulse width and fluence combinations in OptiPulse "AUTO" mode

With OptiPulse set to "AUTO" mode, the pulse width for a given fluence is set to a predetermined value; the pulse width (in ms) will be equal to half the fluence value displayed on the touchscreen. The following table shows examples of the fluence and "AUTO" pulse width combinations across the operating range:

Fluence (J/cm^2)	Pulse width (ms)
10	5
15	7.5
20	10
25	12.5
30	15
35	17.5
40	20
60	30

Pulse Width and Fluence Combinations in OptiPulse "Auto" Mode

Note that the pulse width (in ms) is the fluence (in J/cm^2) divided by two. The OptiPulse "AUTO" mode is not available with a fluence setting above 60 J/cm^2.

In "30 ms", "100 ms", and "400 ms" modes, the pulse width is fixed at 30 ms, 100 ms, and 400 ms respectively, independent of the fluence setting.

Pulse width and fluence combinations in OptiPulse "CUSTOM" mode (HS handpiece)

With OptiPulse set to "CUSTOM" mode, the pulse width for a given fluence is set to a calculated value. The pulsewidth is based on current available and calculated to the fastest pulsewidth available. The OptiPulse "CUSTOM" mode is only available from 30ms to 70ms.

In "30 ms", "100 ms" and "400 ms" modes, the pulse width is fixed at 30 ms, 100 ms, and 400 ms respectively, independent of the fluence setting.

Postoperative instructions

When patient treatment is complete:

1. Place the laser in standby mode.
2. Turn off the laser, as instructed in “Laser Console Basics” in this chapter.
3. If the HS handpiece was used, discard the HS disposable insert.
4. Clean and store the handpiece.

   After patient treatment, clean the handpiece according to the instructions provided in the Maintenance section of this manual. After cleaning, place the handpiece in its holster.

⚠ **WARNING - While operating the LightSheer Duet system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.**

Patient Treatment

Patient treatment is the responsibility of licensed practitioners; therefore, the following information is provided only as a general guideline. Users should consult experienced practitioners and medical journals for more detailed and current information.

See the Indications for Use chapter in this operator manual for information on indications for use, contraindications, warnings, precautions, complications and side effects.

⚠ **WARNING - The maximum tolerated fluence is generally inversely proportional to skin pigmentation for a given pulse width. As the skin pigmentation increases, the fluence is usually decreased to reduce laser absorption and heating in the epidermis. When treating darker skin, delivering the fluence over a longer pulse duration can also reduce epidermal heating. As noted below, skin cooling reduces temperature rise in the epidermis and is necessary to avoid potential epidermal damage, especially in tanned or darker skinned patients.**

⚠ **WARNING - Do not treat eyebrows, eyelashes, or other areas within the bony area surrounding the orbit. The light emitted by the LightSheer Duet laser is capable of causing serious eye damage or blindness. For maximum safety, metal eye goggles must be worn by the patient for all facial treatments.**

Patient consultation

The physician should conduct a patient consultation prior to treatment and provide detailed information on the nature of their problem, the treatment options, risks, benefits, complications, and anticipated outcome prior to treatment. As part of the consultation, the patient should be informed that multiple treatments may be necessary. Those patients having leg vein or benign pigmented lesion treatments should be informed that hair removal may occur at the treatment site as a result of the treatment. The patient consultation should also include a medical history and exam with particular attention paid to contraindications. Patients should be treated with test spots and assessed for side effects before a full treatment is performed.

Pre-treatment procedure

WARNING - Carefully shave the skin surface immediately prior to treatment. Visible hairs can get very hot when the laser fires and cause localized thermal injury to the epidermis. After shaving, thoroughly clean the patient's skin surface to remove any hair debris.

WARNING - The prior use of depilatories or other hair removal treatments, such as waxing, plucking, or electrolysis, within 6 weeks prior to treatment is a relative contraindication.

Hair removal and permanent hair reduction

In the hair removal clinical studies of the LightSheer diode laser system, the treatment area was typically shaved and cleaned immediately prior to laser treatment. Shaving reduces pain by eliminating the absorption of laser energy by surface hair. Carefully shave and clean the skin surface since visible hairs can get very hot when the laser fires and cause localized thermal injury to the epidermis.

Treatment of leg veins and benign pigmented lesions

For treatment of leg veins or benign pigmented lesions, the treatment area should be carefully shaved and cleaned immediately prior to laser treatment. These steps minimize the risk of epidermal injury, pain, odor, and debris. Carefully shave and clean the skin surface since visible hairs can get very hot when the laser fires and cause localized thermal injury to the epidermis.

Dosimetry

The two dosimetry parameters for the LightSheer diode laser system are pulse width and fluence. General dosimetry considerations are described below. Physicians are strongly advised to consult experienced practitioners and medical journals for more detailed and current information.

General principles

In selective photothermolysis, pulsed laser energy is absorbed by a chromophore or pigmented target (melanin or oxyhemoglobin, in this case) which has greater optical absorption at the laser wavelength than surrounding tissue. During the pulse, absorption converts radiant energy into heat within the target, raising its temperature. The heat is initially confined to the target but will begin to conduct to the cooler surrounding tissue. However, the conduction time is relatively slow, and for a suitably brief pulse, the temperature of the target may have resulted in thermal denaturation while the surrounding tissue remains below this threshold. Thus, higher fluence generally results in greater heating since more optical energy is delivered to the absorbing chromophore.

Skin color

The maximum tolerated fluence is generally inversely proportional to skin pigmentation for a given pulse width. As the skin pigmentation increases, the fluence is usually decreased to reduce laser absorption and heating in the epidermis. When treating darker skin, delivering the fluence over a longer pulse duration can also reduce epidermal heating. As noted below, skin cooling reduces temperature rise in the epidermis and is necessary to avoid potential epidermal damage, especially in tanned or darker skinned patients.

When treating dark-skinned patients (phototypes V & VI) with the ET handpiece and OptiPulse 400 ms mode, test spots should be administered prior to treatment to determine the maximum tolerated dose (MTD). Begin treatment with a conservative fluence setting, below the MTD, to minimize side effects.

Furthermore, exercise caution when treating phototypes V & VI with the HS handpiece as well: begin with low fluence and single pulses to minimize side effects.

- Always perform a test patch on the intended treatment area during the first treatment session.
- For skin types I-IV, wait at least 2-30 minutes after performing the test spot to observe skin tissue reaction; and adjust parameters as needed.
- For skin styles V & VI, wait at least 48 to 72 hours after performing the test spot to observe skin tissue reaction; and adjust parameters as needed.

See the Indications for Use section of this manual for more information.

Hair color

The minimum fluence for effective hair removal is generally correlated with hair color. For the same efficacy, higher fluence is usually necessary for lighter-haired patients since their hair contains relatively little melanin. Pulse duration is generally correlated with hair diameter. Shorter pulse durations are effective for finer hair, while longer pulse durations are effective for coarser hair.

HS handpiece placement and technique

Typically, the handpiece is positioned using a "pick and place" technique:

1 Press the enable button prior to applying the tip onto the tissue.

2 Position the handpiece tip on the target tissue, making a complete seal prior to pressing the trigger.

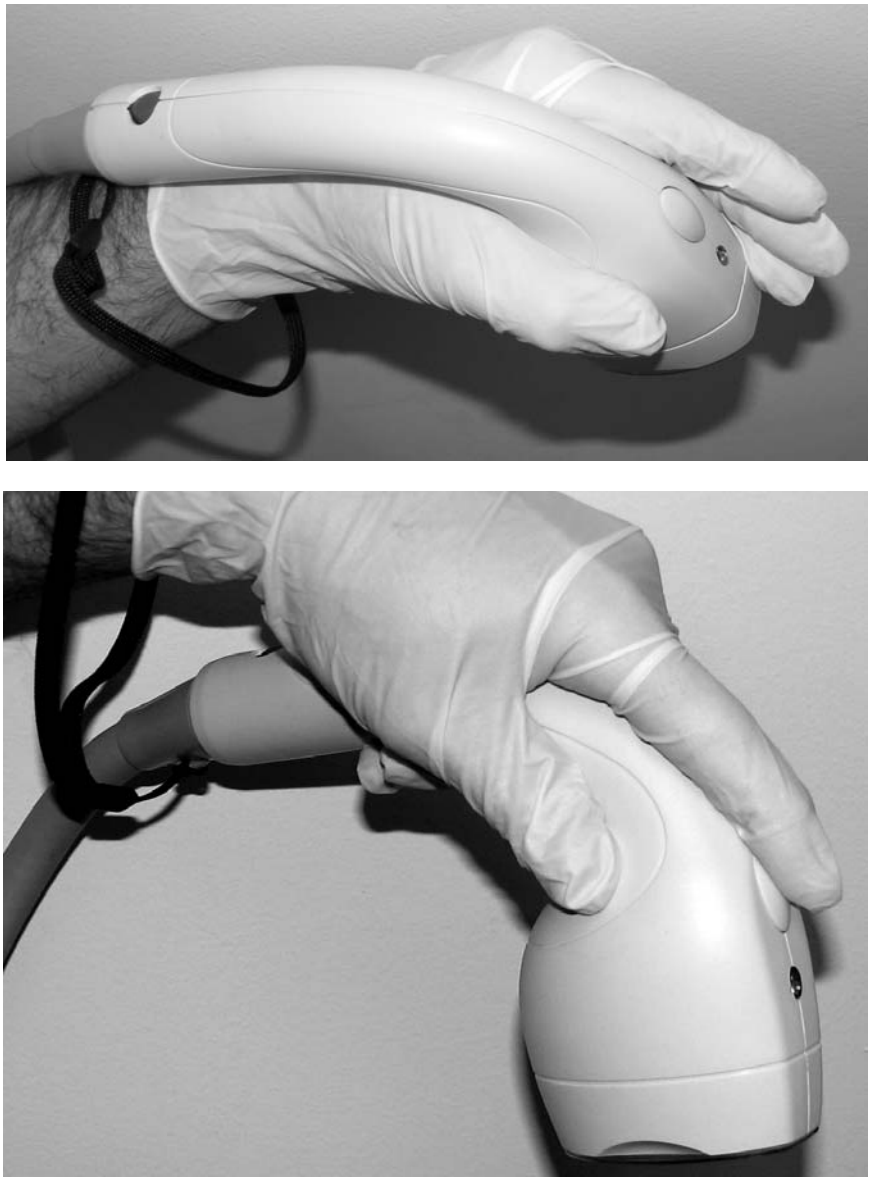
3 Press the trigger button to initiate treatment. The system will activate the vacuum. Once the specified amount of vacuum (High, Medium, or Low) has been applied, the laser energy is delivered.

4 The trigger button needs to be held during the entire cycle. When the programmed cycle of 1-3 pulses is completed, the trigger button can be released.

5 After the vacuum is released, the handpiece can be repositioned to the next treatment area.

If at any point during treatment the operator decides to discontinue the cycle, the button can be released and the treatment will be terminated.

Two ways of holding the HS handpiece during treatment are shown below.

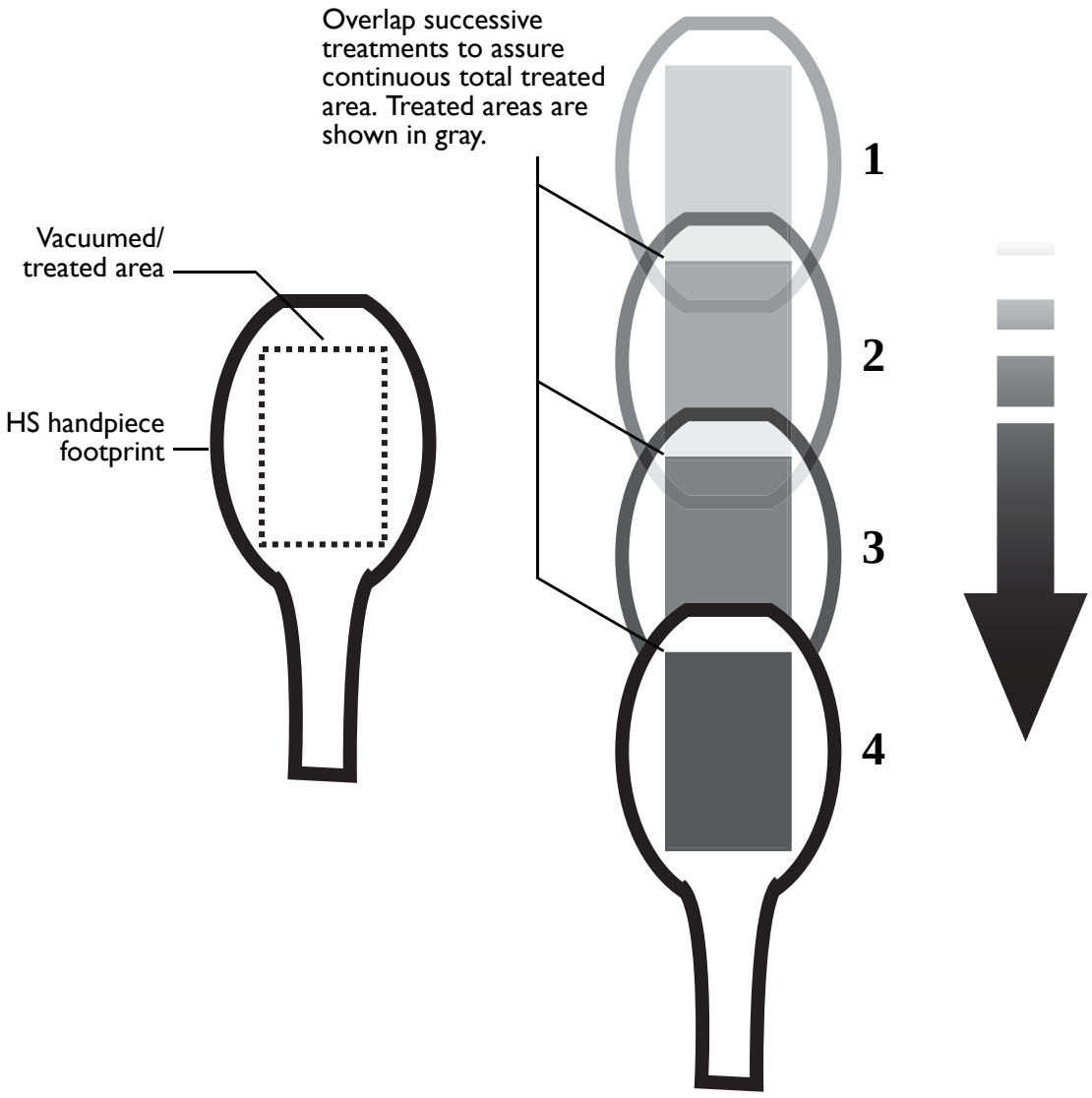


Two ways of holding the HS handpiece during treatment

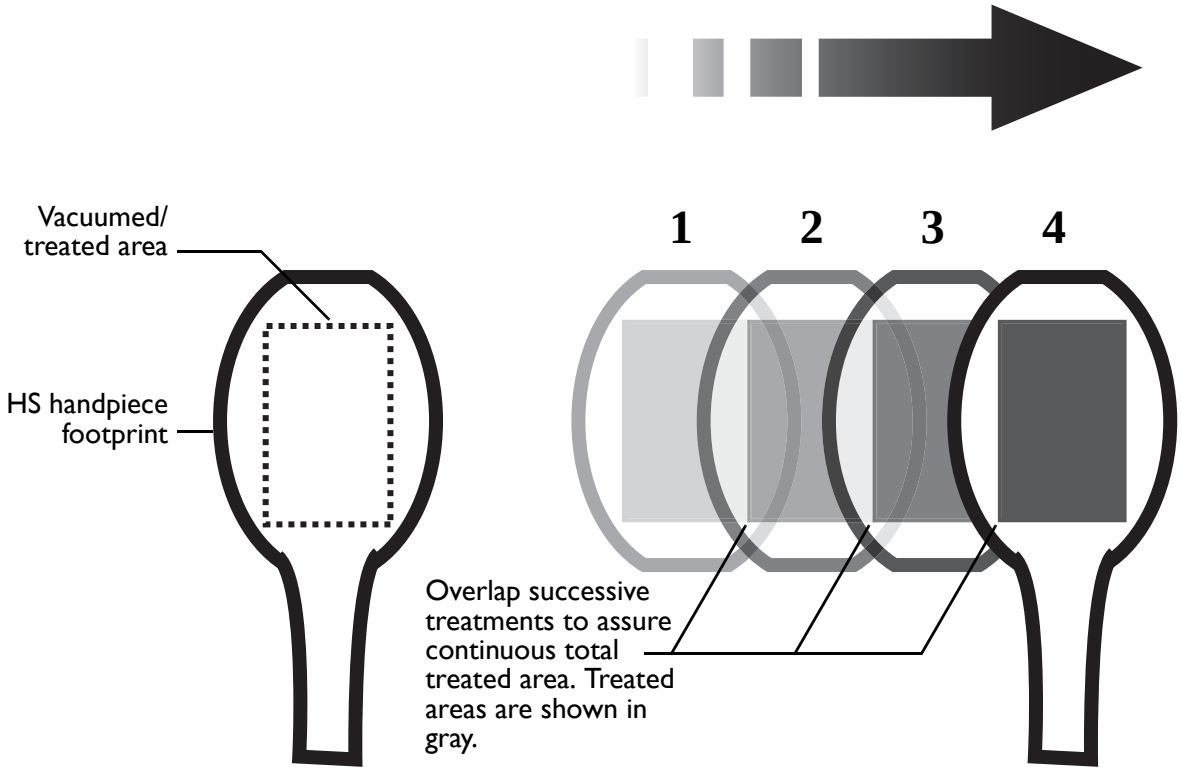
Coverage technique using the HS handpiece

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

The treatment area of the HS handpiece is 22 x 35 millimeters, which is a smaller area than the footprint of the HS handpiece tip; therefore, to assure continuous and complete coverage, it is necessary to overlap vacuumed/ treated areas by approximately 30% side-to-side and by 40% from end to tip.



Assuring continuous end-to-tip coverage using the HS handpiece



Assuring continuous side-to-side coverage using the HS handpiece

ET handpiece placement and technique

Typically, the handpiece is positioned using a “pick and place” or “bouncing” technique. For hair removal and treatment of benign pigmented lesions, the tip is pressed against the skin with moderate pressure to make good contact and then the laser is fired. For treatment of leg veins, contact is made with the skin, but no pressure is applied.

For proper epidermal cooling, the chilled sapphire tip should contact the skin approximately 1/10 – 1/4 second before the pulse. In the “pick and place” method, the tip is picked up from the skin immediately after the pulse, moved to the next treatment location, and then lowered against the skin. In the “bouncing” technique, the tip is kept continuously in contact with the skin and moved (in a bouncing manner) to the next treatment location immediately after the laser pulse, making sure that the insert is pressed to the skin when the laser light is applied.

WARNING - Ensure that the chilled sapphire tip is in contact with the skin prior to laser emission.

WARNING - Repetitively pulsed mode should be utilized only by experienced users, since proper handpiece technique is essential to ensure tip contact with skin prior to emission.

Skin cooling with the ET handpiece

By conductively cooling the skin, the chilled handpiece tip can increase the tolerated fluence by reducing the temperature-rise in the epidermis and providing partial anesthesia. Skin cooling with the ChillTip is highly recommended for all patients being treated with the ET handpiece, especially in tanned or darker-skinned patients who will have greater absorption of laser energy in the epidermis than will fair-skinned patients. Due to the stretching and lower fluences used with the HS handpiece, contact skin cooling is not necessary.

Tip cleaning

WARNING - The sapphire tip of the ET handpiece must be kept clean during patient treatment. Foreign matter on the tip will get hot due to absorption of laser light and can cause epidermal injury and substantially increased pain.

Carefully follow the cleaning instructions in the Maintenance section of this operator manual.

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Maintenance

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Introduction

The only user-performed maintenance required for the LightSheer Duet system is frequent cleaning of the handpiece, handpiece tip, touchscreen, and energy meter window.

To ensure proper performance, it is recommended that a check of the internal energy meter be performed annually by an authorized field service technician or by returning the system to the factory.

In the event that the LightSheer Duet system fails to operate properly, please consult the Troubleshooting Guide later in this chapter. If the problem persists, contact Customer Support at (877) LUMENIS.

There are no user-serviceable parts, and all service and repair should be performed only by the factory or authorized field service technicians.

⚠ **WARNING - Opening any protective exterior housing, except the holsters, may cause exposure to hazardous optical radiation and electrical voltage even after the laser has been turned off, may result in damage to the instrument, and may void the warranty. Only trained and authorized LightSheer Duet technicians should perform service and repairs.**

Cleaning and Disinfecting

WARNING - Do not spray, soak, or pour any type of fluid or cleaning agent directly on the handpiece, console, or touchscreen as it could lead to operator injury or result in damage to the equipment.

CAUTION - Do not allow sunblock or sunscreen products to contact the handpiece. The ingredients found in sunblock and sunscreen products may cause deterioration or damage to the handpiece material. If sunblock or sunscreen does contact the handpiece, clean the handpiece immediately to prevent possible damage.

WARNING - While operating the LightSheer Duet system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.

Cleaning during treatment

HS handpiece

WARNING - The disposable insert must be kept clean during patient treatment. Foreign matter on the disposable insert will get hot due to absorption of laser light and can cause epidermal injury.

Prepare the patient's skin by shaving any existing hair and cleaning the skin prior to conducting treatment.

Keep the HS handpiece's window and disposable insert clean at all time during treatment. Whenever you see any contamination on the window's surface, use a lint-free gauze pad wetted with alcohol to clean the window and then clean with a dry gauze pad. Frequently observe the disposable insert for damage and replace it if necessary.

The window of the HS handpiece is fabricated of fused silica and thus is extremely hard. Vigorous wiping with a gauze pad will not harm the window.

ET handpiece

WARNING - The sapphire tip of the ET handpiece must be kept clean during patient treatment. Foreign matter on the tip will get hot due to absorption of laser light and can cause epidermal injury and substantially increased pain.

The sapphire ChillTip on the ET handpiece must be cleaned often, depending on the treatment area and hair density. Wipe more frequently in areas of high hair density. The wiping should be performed with gauze pads wetted with distilled water. Follow by wiping with a clean, dry gauze pad to ensure that any residue or haze is completely removed. This cleaning typically requires only a few moments during treatment.

The clear region of the ET handpiece tip is fabricated of sapphire and thus is extremely hard. Vigorous wiping with a gauze pad will not harm the sapphire tip.

Cleaning and disinfecting the handpiece between patients

HS handpiece

The HS handpiece tip is not reusable; replace the HS tip with a new disposable insert between each new patient.

ET handpiece

The ET handpiece and handpiece tip must be thoroughly cleaned between patients to avoid potential cross contamination. Use an antibacterial/ antiviral cleaning solution that is compatible with the handpiece materials, such as Cavicide® or Virex™; follow the manufacturer's recommendations on the product label.

Never use an abrasive cleanser or cleaning pad that could scratch the handpiece or handpiece tip.

Never use any fibrous wipe or towel that could leave lint on the tip, as the fibers could carbonize on the tip and result in patient burns.

Cleaning the energy meter windows

Each handpiece has a corresponding holster on the laser console. Beneath the holster is a glass-covered energy meter. If this protective glass window on either holster becomes dirty or covered with spilled liquid, remove the holsters and clean the window.

To remove, place fingers in the holster and gently pull the insert out of the console top.

Before cleaning, wear gloves to avoid getting fingerprints or smudges on the window. Clean the window in the same manner as the handpiece tip or by using common glass cleaners. Remove any residue or haze remaining on the energy meter window by wiping with a clean, dry towel.

To reinstall the holsters, see "Installing the holsters" in the Operation section of this operator manual.

Cleaning the touchscreen

WARNING - Do not spray, soak, or pour any type of fluid or cleaning agent directly on the handpiece, console, or touchscreen as it could lead to operator injury or result in damage to the equipment.

WARNING - The LightSheer Duet system should be turned off prior to cleaning the touchscreen.

WARNING - Do not clean the touchscreen with an abrasive cleaner or material as it can result in damage to the touchscreen.

To clean the touchscreen, apply a small amount of a non-abrasive glass cleaner to a clean, soft cloth. Using the cloth, gently wipe the surface of the touchscreen to remove any dirt. Completely wipe away any residue remaining from the glass cleaner. When cleaning, do not force debris or fluid into the gasket surrounding the touchscreen as excessive debris can cause the touchscreen to malfunction. Allow the touchscreen and the surrounding gasket to dry before resuming operation.

WARNING - Clean the touchscreen regularly to ensure proper performance. Excessive treatment oil, gel, lotion, or other contaminants on the touchscreen may cause erratic operation of the user interface buttons.

Cleaning the console

Clean the external surfaces of the laser console and handpiece periodically with a cloth wetted with a cleaner, such as alcohol, distilled water, Cavicide®, or Virex™. Dry with a clean cloth.

⚠ **WARNING - Do not spray, soak, or pour any type of fluid or cleaning agent directly on the handpiece, console, or touchscreen as it could lead to operator injury or result in damage to the equipment.**

HS handpiece Maintenance

The HS handpiece uses a removable, disposable insert that attaches to the handpiece aperture, and which must be replaced between patients, or during patient treatment if the tip becomes dirty or if the filters become clogged.

Replacing the HS handpiece disposable insert

Replace the disposable insert as follows.

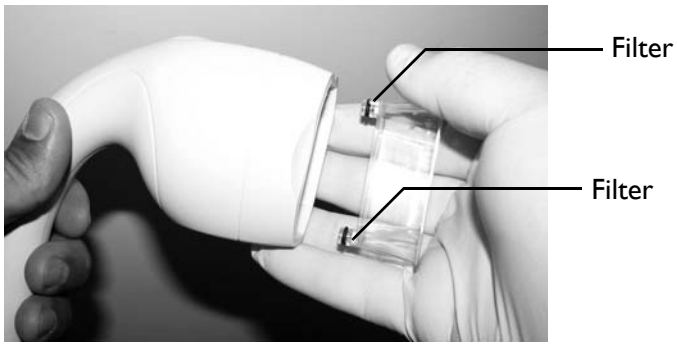
1 Pull the disposable insert from the handpiece, as shown.

2 Push the new insert into the handpiece until seated.

Understanding the HS handpiece filters

Each disposable insert contains two filters: one filter is active and the other is reserve. If the vacuum performance of the HS handpiece appears to decline during use, visually inspect the filters of the insert. If the active filter seems to be clogged, remove the tip, rotate it 180 degrees and reinsert it into the handpiece to use the reserve filter. Run a vacuum check and resume regular treatment. If both filters are clogged, replace the disposable insert, as described in this chapter.

It is normal for some burned hair to become attached to the interior surfaces of the disposable insert during treatment. These small bits of debris do not substantially affect the performance of the HS handpiece.



Remove insert and rotate to use the other filter

Troubleshooting Guide

Laser will not turn on

Verify that the following items have been completed:

- The AC power cord is firmly and fully inserted into the power socket on the back panel and into a live electrical wall socket.
- The main power circuit breaker is in the **I** (on) position.
- The keyswitch is turned to the on position.
- The emergency stop button has been disengaged by rotating the button clockwise until it pops out.

If the problem persists, call Customer Support.

Laser fails to operate properly

Maximum fluence is less than 100 J/cm^2 for the ET handpiece

The LightSheer Duet only allows a fluence setting above 60 J/cm^2 in OptiPulse 400 ms mode. Verify that 400 ms mode has been selected from the treatment screen. If fluence is still insufficient for treatment, carefully clean the handpiece tip and energy meter window and recalibrate the system. If fluence is still insufficient for treatment, contact Customer Support.

OptiPulse "AUTO" mode is disabled (ET handpiece)

OptiPulse "AUTO" mode is not available with a fluence setting above 60 J/cm^2. Verify that the fluence setting displayed on the treatment screen is less than or equal to 60 J/cm^2. If "AUTO" mode is still not available, carefully clean the handpiece tip and energy meter window and recalibrate the system. If "AUTO" pulse width mode is still disabled and is required for treatment, contact Customer Support. Note that operation in "30 ms", "100 ms", or "400 ms" mode will usually still be enabled.

Calibration does not progress

For calibration to proceed, the following steps must be performed in order: (1) lift the handpiece out of the holster, (2) reinsert the handpiece in the holster, (3) press the enable button on the handpiece, (4) depress the handpiece trigger, and (5) continue to depress the handpiece trigger until all calibration shots are fired. Note that the order of the above sequence is enforced and the touchscreen will prompt the user to complete each step in order. A common user error is to release the handpiece trigger before all calibration shots have been fired.

If the system does not sense the handpiece in the holster, ensure that the handpiece is correctly positioned in the holster. Also verify that nothing is blocking the proximity sensor located beneath the holster.

If the problem persists, contact Customer Support.

Laser will not fire

The laser will fire only when the status displays “READY”.

If using the ET handpiece and the status displays “COOLING”, wait for the ChillTip to reach its operating temperature, at which point the status will change to “STANDBY”. If the status displays “READY”, and depressing the handpiece trigger while the HP is enabled does not result in emission, contact Customer Support.

If using the HS handpiece, you must wait until the proper vacuum level is reached at the tip before you can fire the laser. To ensure that the proper vacuum level is reached, verify that the tip is fully sealed against the tissue and that the disposable insert is not clogged.

Laser remains in “COOLING” status

The “COOLING” message is displayed only when the ChillTip is actively cooling, which normally requires about 30 seconds. If the status does not eventually change from “COOLING” to “STANDBY”, it indicates a cooling problem and it is necessary to contact Customer Support.

Low Fluence – Full fluence range is not available with OptiPulse set to 400 ms mode

The laser is incapable of delivering the requested fluence in 400 ms mode. Shut down the system. Carefully clean the handpiece tip and protective window above the energy meter. Restart and recalibrate the system. Enter the treatment screen and attempt to set the desired fluence. If the available fluence is still insufficient for the desired treatment, contact Customer Support. Note: if this error occurs, the user should still be able to set a different set of treatment parameters.

Low Fluence – Full fluence range is not available in all OptiPulse modes of operation

The laser is incapable of delivering the requested fluence in the requested OptiPulse mode. Shut down the system. Carefully clean the handpiece tip and protective window above the energy meter. Restart and recalibrate the system. Enter the treatment screen and attempt to set the desired fluence. If the available fluence is still insufficient for the desired treatment, contact Customer Support. Note: if this error occurs, the user should still be able to operate the system with a different set of treatment parameters.

Paused: Please wait while the laser system cools to proper operating temperature

This message will appear temporarily upon returning from “sleep” mode. Occasionally, if the laser has been stored in a hot location, this message will

appear temporarily. This behavior is normal and the message will clear automatically when the laser cools. However, if the message appears for longer than five minutes, it indicates a possible malfunction of the cooling system and the LightSheer Duet system should be turned off to prevent damage from overheating. Contact Customer Support.

Paused: Remote interlock is open

This message appears whenever the remote interlock switch is open. If the switch has not been wired to the clinic room door or other remote switch, ensure that the interlock switch jumper plug on the rear of the upper console is fully seated in its receptacle. If the remote interlock connector has been externally wired, check the external circuit.

Stopped: A system fault has been detected

The system reports a fault when it detects an abnormal hardware or software error.

If the fault is related to calibration, shut down the system as described in "Turning off the laser" in the Operation chapter of this manual, and carefully clean the handpiece tip and the energy meter window located beneath the holster (see "Cleaning and Disinfecting" in this manual). Restart the system and perform another calibration. If the fault occurs again, note the error code and contact Customer Support.

If the system fault is unrelated to calibration (for example, the fault occurs while firing in the treatment screen), restart the system and attempt to perform another calibration and enter the treatment screen. If the fault occurs again, note the error code and contact Customer Support.

Information Messages

These messages are used to inform the user of actions that are ongoing and delay the treatment or limit the treatment available. These are not error messages and do not require a service call, but messages to let operator know of any changes.

Message	Description
This handpiece has a limited functionality	This shows that the life of the laser package in the handpiece is beginning to shorten. This is not an alarm to immediately return the handpiece. If you do not use the full treatment range available, it is still okay to use.
System Cooling	This message will appear the first time after initial calibration and the system goes into the selected treatment screen. Between treatments, the system may need to cool. The message will clear when cooling is complete.

Error Messages

The LightSheer Duet laser system displays two types of errors: errors requiring a system restart, and errors advising the user of hardware problems and/or requiring user attention. If a problem persists, even after performing the recommended action, contact your Lumenis service representative.

Errors requiring a system restart

Error #	Error Message	Recommended User Action
E32	Watchdog timer error	Turn system off. Wait 30 seconds and then turn system on. If problem persists after system restart – call Lumenis service.
E104	5V power supply out of range	
E105	3.3V power supply out of range	
E142	TEC temperature sensor failure	
E147	Coolant temperature sensor failure	
E171	FPGA error	
E400	Unable to connect to control processor	
E54	HS handpiece disconnected	Turn system off. Reconnect handpiece or connect new handpiece. Wait 30 seconds, and then turn system on.
E70	ET handpiece disconnected	

Errors limiting system functionality

Error #	Error Message	Recommended User Action
E123	EPI pump fuse broken	Can still use the HS handpiece. Turn system off. Wait 30 seconds and then turn system on. If problem persists after system restart – call Lumenis service.
E141	EPI temperature out of range	
E143	EPI temperature sensor failure	
E145	ET backplane temperature sensor failure	
E124	Vacuum pump fuse broken	Can still use the ET handpiece. Turn system off. Wait 30 seconds and then turn system on. If problem persists after system restart – call Lumenis service.
E146	HS backplane temperature sensor failure	

Errors requiring user attention and may require a system restart

Error #	Error Message	Recommended User Action
E81, E83	Laser diode over current	Clear error. If error persists, turn the system off, wait 30 seconds, and then turn the system on. If problem persists after system restart – call Lumenis service.
E82, E84	Diode current too low	
E86	Power supply fault	
E88	Power supply voltage error on PCB	
E90	Pulse width out of range	
E94	Laser-off over current (A)	
E95	Laser-off over current (B)	
E98	Software internal error	
E101	24V power supply out of range	
E102	12V power supply out of range	
E103	-12V power supply out of range	
E106	Drive 24V power supply out of range	
E107	Drive 16.5V power supply out of range	
E108	Drive 12V power supply out of range	
E109	Drive dirty 12V p.supply out of range	
E110	Drive -12V power supply out of range	
E111	Drive 5V power supply out of range	
E112	Main TEC over current	
E113	EPI TEC over current	
E114	Electronic Shutter Failure	
E115	Electronic Shutter Failure	
E122	Coolant pump fuse burned. Call service.	
E320	ET calibration out of range	
E321	ET calibration inconsistent	
E322	ET calibration not self consistent	
E340	HS calibration out of range	
E341	HS calibration inconsistent	
E342	HS calibration not self consistent	
E401	Serial protocol retry limit exceeded	
E402	Serial protocol output buffer underflow	
E403	HASP not connected	
E427	Persistent files corrupted. Call service.	
E600	Demo mode current too high	

Errors identifying hardware problems and/or requiring user attention

Error #	Error Message	Recommended User Action
E21	Remote Interlock Open	Check door is closed, check door interlock is seated. Clear error.
E43, E44	HS handpiece trigger error	Press and release trigger button. Clear error.
E63, E64	ET handpiece trigger error	
E45, E46	HS Handpiece tip error	Verify that the removable tip is correctly inserted by removing and then reinserting the tip. Clear error.
E47	Release HS handpiece enable button	Release the handpiece enable button.
E65	Release ET handpiece enable button	Release the handpiece enable button.
E48	HS Handpiece enable failed to time-out.	Clear error. Place laser in Ready mode. Press Enable button.
E66	ET Handpiece enable failed to time-out	
E49	HS Handpiece tip not installed	Install the disposable insert.
E50	ET Handpiece must be in the cradle	Put handpiece into cradle.
E67	HS Handpiece must be in the cradle	
E51	HS H.P. SPI flash memory error	Clear the error message.
E68	ET H.P. SPI flash memory error	
E52	Remove handpiece from the cradle	Remove handpiece from the cradle.
E53	HS trigger pressed	Release the handpiece trigger.
E69	ET trigger pressed	
E132	Heat sink over temperature	Wait for system to cool down.
E133	EPI over temperature	
E136	Coolant over temperature	
E137	ET diode temperature out of range	
E138	HS diode temperature out of range	
E144	Please wait for system warm up	

Troubleshooting Form

The following form is provided to assist the user in recording error messages and codes that are displayed on the screen. Please provide this information when contacting Customer Support. This information will assist Customer Support in more quickly determining the cause of the problem.

Date	*Code Number*	*Error Message*	*Treatment Parameters/System Settings When Error Occurred*

Calibration Details and Output Monitoring

Details of the energy calibration procedure and output monitoring are provided in this section for compliance with governmental regulations only. See “Calibrating the handpieces” in the Operation chapter of this manual for operator calibration instructions.

⚠ **WARNING - Do not attempt to manually calibrate or otherwise adjust the output of the laser. Such action may cause exposure to hazardous optical radiation and electrical voltage, result in damage to the instrument, and void the warranty. Only trained and authorized LightSheer Duet technicians should perform maintenance and service.**

Automated calibration procedure

Automated calibration procedure is a required procedure that executes on every system startup upon handpiece selection or after 25000 pulses fired in one treatment/power up session. The user must follow the instructions displayed on the screen. The system will make all calculations and adjustments automatically.

General approach

The purpose of the automated calibration is to determine a transfer function between optical energy and drive current for every laser pulse width mode for every handpiece. During normal operation, the LightSheer Duet’s software uses the transfer function to set the drive current to accurately produce the desired fluence.

The general approach is as follows:

1. The laser output is measured as a function of input parameters.
2. A generalized transfer function is calculated, correlating input and output parameters.
3. The newly calculated transfer function is checked against the previous transfer function for abnormality.

Detailed approach - ET handpiece

Within the Treatment mode, the user may request 30ms, 100ms, 400ms, and Auto (5-30ms) pulse width modes. Calibration begins by compartmentalizing the calibration data into pulse width mode categories. Specifically, each pulse width mode has its own unique calibration data, exclusive of the other modes except for **Auto** mode, which uses the 30ms calibration data.

Each pulse width mode is calibrated by firing a number of fixed pulse width shots (30ms for 30ms mode and Auto mode, 100ms for 100ms mode, and thirteen 5ms pulses in a 389ms envelope for 400ms mode) at two current levels. Once all calibration shots have been successfully fired, transfer functions are calculated.

For 100 msec mode and 400 msec mode, the least square fit functions will be used to describe transfer functions. For Auto mode, the 30ms values for Slope Efficiency and Threshold Intercept are used.

The next step is calculating the maximum fluence value for each mode of operation.

The final phase of the calibration calculation series is determining the headroom, the additional capacity above 'normal operation', for each mode.

ET handpiece calibration data acquired in 6 shots:

Pulse #	*Pulse width*	*Current*	*Used for mode:*
1	30	12 A	30 ms; AUTO
2	30	45 A	30 ms; AUTO
3	100	9.5 A	100ms
4	100	26 A	100ms
5	400	12 A	400 ms Burst
6	400	38 A	400 ms Burst

Detailed approach - HS handpiece

Within the Treatment mode, the user may request 30ms, 100ms, 400ms, and Custom (30-70ms) pulse width modes. Calibration begins by compartmentalizing the calibration data into pulse width mode categories. Specifically, each pulse width mode has its own unique calibration data, exclusive of the other modes except **Custom** mode, which uses the 30ms calibration data and 70 ms calibration data.

Each pulse width mode is calibrated by firing a number of fixed pulse width shots (30ms and 70ms for 30ms mode and Custom mode, 100ms for 100ms mode, and thirteen 5ms pulses in a 389ms envelope for 400ms mode) at two current levels. Once all calibration shots have been successfully fired, transfer functions are calculated.

For 100 msec mode and 400 msec mode the least square fit functions will be used to describe transfer functions. For Custom mode, the 30ms and 70ms values for Slope Efficiency and Threshold Intercept are used.

The next step is calculating the maximum fluence value for each mode of operation.

The final phase of the calibration calculation series is determining the headroom, the additional capacity above 'normal operation', for each mode.

HS handpiece calibration data acquired in 8 shots:

Pulse #	*Pulse width*	*Current*	*Used for mode:*
1	30	18 A	30 ms; Custom
2	30	38 A	30 ms; Custom
3	70	18 A	Custom
4	70	38 A	Custom
5	100	12 A	100ms
6	100	26 A	100ms
7	400	15 A	400 ms Burst
8	400	38 A	400 ms Burst

Electrical Utilities

The LightSheer Duet laser system is designed to meet UL60601-1, IEC 60601-1, IEC 60601-2-22, IEC 60825-1, and CSA 22.2. The laser is available in one electrical configuration with a universal input ranging from 100–240 V~, 15 Amps maximum current.

The supplied Hospital Grade cord set should be used with a standard 20 A wall outlet. The supplied cord set will vary according to the electrical conventions for the country in which the laser will operate.

⚠ **CAUTION - To verify that the system is disconnected from the power mains, observe that the main power cord is disconnected from the system's main power receptacle and from the wall socket.**

Electromagnetic Compatibility

Like other electrical medical equipment, the LightSheer Duet requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the LightSheer Duet must be installed and operated according to the EMC information provided in this manual. See Appendix 1, EMC Guidance and Manufacturer's Declarations.

The LightSheer Duet has been designed and tested to comply with IEC60601-1-2:2001+A1:2004 (Edition 2.1) requirements for EMC with other devices.

⚠ **WARNING - This system is intended for the use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.**

⚠ **CAUTION - Portable and mobile RF communications equipment may affect the normal function of the LightSheer Duet.**

⚠ **WARNING - Do not use cables or accessories other than those provided with the LightSheer Duet, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.**

⚠ **WARNING - If the LightSheer Duet is used adjacent to or stacked with other equipment, observe and verify normal operation of the laser system in the configuration in which it will be used prior to using it in a surgical procedure.**

Technical Specifications

Laser Handpiece	ET Handpiece	HS Handpiece
Type	AlGaAs laser diode array	
Nominal wavelength	790 – 830 nm	
Maximum peak power (average during pulse)	1600 W	
Pulse width	5 – 400 ms	30 – 400 ms
Pulse repetition rate	≤ 3 Hz	≤ 3 Hz
Pulse fluence	10 – 100 J/cm^2	4.5 – 12 J/cm^2
Pulse energy	85 J max	102 J max
Spot size (W × D) mm (in.)	9 × 9 mm (0.35 × 0.35 in.)	22 × 35 mm (0.87 × 1.4 in.)
Beam divergence	20° × 20° nominal	33° × 33° nominal
Classifications		
FDA classification	Class II medical device	
CDRH classification	Class IV laser	
MDD classification	IIB	
IEC 60825-1 classification	Class 4 laser	
IEC 60601-1 classification	Class I, Type BF	
Operation classification	Intermittent/Continuous	
Nominal ocular hazard distance	50 m (164 feet)	
Protective eyewear		
Optical density at 790 – 830 nm	≥ 5	
Input power recommended service		
Voltage	100 – 240 V	
Frequency	50/60 Hz	
Current	15 A	
Utility connection	Single-phase grounded outlet	
Physical parameters		
Size (W × D × H) cm (in.)	44 × 50 × 112 cm (17.4 × 19.7 × 44 in.)	
Weight	48 kg (105 lbs.)	
Operating radius of umbilical	1.8 m (71 in.)	
Environmental requirements (operating conditions)		
Temperature	15 – 40°C, 60 – 104°F	
Humidity	10 – 70%	

Pressure	90 – 110 kPa (13 – 16 psi)
Environmental requirements (nonoperating conditions)	
Maximum altitude	Standard commercial shipping altitude
Temperature	-5 – 55°C (23 – 131°F)
Humidity	90% at 35°C (95°F) non-condensing 32% at 55°C (137°F) non-condensing
Vibration	Meets MIL 810E-514.4 transportation and vibration requirements; capable of surviving transport by standard air, sea, and land carriers.
Shock	Meets the requirements of ASTM D6179

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.

Returning the Laser to Lumenis

To package the laser for return shipment to Lumenis, you must disconnect the handpieces from the laser console, remove the holster, and then separately pack the laser console, handpieces, and any other components that require shipment.

1. Shut down the laser, as described in the Operation section of this manual.
2. Disconnect the handpieces.
3. Pack the handpieces.
4. Remove the holster.
5. Pack the laser console by reversing the instructions described in "Unpacking the laser console" in the Operation chapter of this manual.

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Indications for Use

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Introduction

WARNING - The Indications for Use and Safety and Regulatory sections of this operator manual should be carefully read and comprehended in their entirety before attempting to use the laser system. Particular attention should be given to all cautions and warnings pertaining to the safe use of the laser.

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

The LightSheer Duet laser system is intended to effect temporary hair removal and/or permanent hair reduction. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime. The number of regrowing hairs must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4 – 12 months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in a treated area.

The LightSheer Duet system is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. HS handpiece treatments should only be performed on tanned skin after the recommended test spot protocol has been employed, to verify the appropriate parameter settings prior to any treatment. Use added caution due to sun exposure.

HS handpiece

In addition to temporary hair removal and permanent hair reduction, the LightSheer HS handpiece is intended for the treatment of benign vascular and pigmented lesions.

ET handpiece

In addition to temporary hair removal, permanent hair reduction, leg veins, and benign vascular lesions, the LightSheer ET handpiece is intended for the treatment of vascular lesions including angiomas, hemangiomas, telangiectasias; as well as the treatment of pseudofollilculitis barbae and benign pigmented lesions.

Theory of operation

The therapeutic basis of the LightSheer Duet laser system is selective photothermolysis. To effect hair removal, the 800 nanometer laser light penetrates deeply into the dermis where the optical energy is preferentially absorbed by the melanin in hair, causing a rapid heating of the hair shaft and follicle that disables the follicle. For leg vein treatment, the optical energy is absorbed by oxyhemoglobin, causing photocoagulation of blood vessels in the dermis. For benign pigmented lesions, the optical energy is absorbed by melanin-containing cells in the pigmented lesion, causing rapid heating and thermal damage to the lesion. The duration of the laser pulses is long enough to disable the hair follicle, coagulate the vein, or be absorbed by the target chromophore, while short enough to limit heat transfer to the surrounding tissue.

As with any laser, appropriate care must be taken to ensure safe and proper use. The entire user manual should be thoroughly reviewed and understood before operating the instrument. Furthermore, as discussed below, the operator should attend a laser training course before using the LightSheer system.

Contraindications

Patients who have had prior problems with laser therapy, should be carefully screened before treatment. Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser treatment.

Laser hair removal, treatment of leg veins, or treatment of benign pigmented lesions should not be attempted in patients with:

- active infections in the treatment site;
- active infection or a history of herpes simplex in the treatment area;
- use of oral Isotretinoin (such as Accutane) within the preceding 6 months;
- history of keloid formation;
- history of livedo reticularis, an autoimmune vascular disease;
- hypersensitivity at the treatment site to any agents, solution, or gel used in the treatment, if no alternative exists;
- use of anticoagulants before the washout period, per the package insert, and at the physician's discretion;
- presence of refluxing varicose veins feeding the telangiectases;
- personal history of melanoma;
- dysplastic nevi in the area to be treated;
- history of bleeding disorders;
- history of collagen, vascular or immunosuppression disorders;
- tattoos at the treatment sites;
- significant concurrent skin conditions affecting areas to be treated or any inflammatory skin conditions;
- active cold sores, open lacerations or abrasions on the area to be treated;
- history of immune deficiency (including HIV infection or AIDS).

Relative contraindications

- history of erythema ab igne, which is an acquired persistent reticulated erythematous and pigmented rash of the skin produced by prolonged or repeated exposure to moderately intense heat or infrared radiation;
- use of depilatories or other hair removal treatments, such as waxing, plucking, tweezing, or electrolysis, in the treatment area within the preceding 6 weeks;
- chronic or cutaneous viral, fungal or bacterial infections in the treatment area;

- photosensitivity disorder that can be exacerbated by infrared light;
- history of skin cancer or pre-cancerous lesions at the treatment sites;
- use of medications, herbal supplements, perfumes or cosmetics that may affect sensitivity to light.

Warnings

Darker skin types and individuals with a suntan are at a higher risk for pigmentary changes in the treatment area. These patients should be treated with lower fluences and/or longer pulse durations than similar skin types that are untanned.

Sun exposure to the treatment area immediately after treatment and for one month following treatment may also increase the risk of pigmentary changes in the treatment area. Patients should be instructed to use a broad spectrum sunscreen (SPF 15 or greater) on a daily basis.

Observe all safety precautions described in the Safety and Regulatory chapter and elsewhere in this manual.

⚠ **WARNING - The light emitted by the LightSheer laser is capable of causing serious eye damage or blindness. All persons in the treatment room, including the patient, the operator, and any observers, must wear appropriate eye protection whenever the main power and keyswitch are on.**

Precautions

The physician should only attempt laser treatment after adequate training and familiarity with laser safety and with the device.

⚠ **CAUTION - The laser can cause epidermal injury. The risk increases with greater laser fluence and skin pigmentation.**

In general, both treatment effectiveness and inflammatory response to skin injury are fluence related. Higher fluence levels result in greater effectiveness and also higher inflammatory response and increased likelihood of epidermal damage. Begin treatment with a conservative exposure dose and increase the fluence gradually until the desired effect is observed.

⚠ **CAUTION - Perform test spots on patients and assess side effects before performing a full treatment. Side effects may not develop until several days following exposure. The risk of side effects is greater on dark-skinned patients, however, light-skinned patients may also develop side effects.**

Complications and Side Effects

The most common side effects are erythema, edema (redness and swelling), and perifollicular edema, which may occur immediately after laser treatment and typically resolve within a few days.

Other side effects may include hyperpigmentation and hypopigmentation (darkening or lightening of the skin) of the treated areas. Side effects of treatment are fluence-dependent and skin type dependent. Transient skin pigmentation changes may resolve within a few months, but may last longer. In rare cases, skin pigmentation changes may be permanent.

The following complications and side effects may also be observed:

- irritation, itching, burning sensation, or pain during treatment or following treatment;
- superficial erosions of the treated area may be visible after laser treatment;
- burns;
- crusting and blistering of the treated area;
- erythema ab igne, which is the development of an acquired persistent reticulated erythematous and pigmented rash of the skin produced by prolonged or repeated exposure to moderately intense heat or infrared radiation;
- transient exacerbation of hair growth;

- purpura confined to the exposure area may be evident for several days following treatment;
- pruritis may occur in rare cases;
- contact dermatitis or irritant dermatitis may occur in some cases;
- infection at the treatment site;
- mild to moderate pain may occur during or after treatment;
- as with the use of any laser system, scarring is a possibility, but is rare;

In the event of a death or serious injury/illness, immediately contact Regulatory Affairs at Lumenis, 5302 Betsy Ross Dr., Santa Clara, CA, 95054, USA, telephone number (877) LUMENIS, (877) 586-3647 (toll free). For those outside of the United States, refer to the Customer Support, Sales, and Service listing for the representative in your area to contact. A serious injury/serious illness is an injury or illness that is: a) life threatening, even if temporary in nature; b) results in permanent impairment of a body function or permanent damage to a body structure; or c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent damage or impairment is defined as irreversible damage or impairment that is not trivial.

Clinical Studies

Hair removal and permanent hair reduction

The results of clinical studies have shown that the length of time necessary to determine whether a treated area exhibits a stable, long-term or permanent hair reduction varies according to the specific body site treated. If a treated area exhibits a reduction in hair for a period longer than the total growth cycle for that area, then the hair reduction may be expected to be stable, long-term or permanent. The following table shows the duration of hair growth cycles for the body sites treated in the clinical studies cited in this report.

Location	*Telogen (months)*	*Anagen (months)*	*Total (months)*
Back	3-6	3-6	6-12
Thigh	3-6	3-6	6-12
Arm	3-5	1-2	4-7
Calf	3-4	4-5	7-9

Duration of Growth Cycles

Clinical studies have been conducted at the Massachusetts General Hospital and the Laser and Skin Surgery Center of New York to assess the safety and effectiveness of the LightSheer system for permanent hair reduction. A combined total of 92 patients were treated and were followed up at 1, 3, 6, and 9 months after 1 or 2 treatments with the LightSheer system. Thirty-five (35) patients also had follow up after 12 months. Hair loss was defined as the percentage of terminal hairs absent after treatment compared with the number before treatment. The percentage of hair loss was evaluated at each follow up visit after 1 and 2 treatments.

Seven test sites and 1 control site were mapped on each patient's thigh, back, arm, or calf. The test sites were treated with fluences ranging from 15 – 40 J/cm^2. After one month, two of the test sites received a second treatment with fluences of 40 J/cm^2. Clinical assessment and digital imaging were performed within one hour of laser treatment.

The results of this study show that there are two separate effects: hair growth delay and permanent hair reduction. A growth delay, or temporary loss of hair, is seen in all patients (100%) at all laser fluences tested. Temporary hair loss is generally sustained for 1 – 3 months.

At 6 months and thereafter, hair regrowth stabilized and there was no significant difference between regrowth at the 6, 9, and 12 month follow ups. A subsequent published extension to this study reported continued stabilization at an average of 20 months following treatment[1]. This indicates a stable number of hairs and is consistent with the definition of permanent

reduction of hair and with the growth cycle of hair follicles, which is 6 – 12 months for the back and thighs, and shorter for other body sites.

On average, a significant, permanent reduction in hair was seen at the 12 month follow up at all test sites and fluences as compared to untreated sites. The amount of hair loss increases with higher fluence levels and with multiple treatments. Approximately 89% of patients demonstrated permanent hair loss at 12 months. The average percentage of permanent hair loss for each test site is presented in the following table.

Fluence	*Number of Treatments*	*Average Permanent Hair Reduction After 12 Months*
5 ms, 15 J/cm^2	1	26.6%
10 ms, 20 J/cm^2	1	25.9%
15 ms, 30 J/cm^2	1	29.4%
20 ms, 40 J/cm^2	1	32.5%
20 ms, 40 J/cm^2	2	46.6%
20 ms, 40 J/cm^2 3x	2	46.2%
20 ms, 40 J/cm^2 3x	1	38.5%
Control	0	5.5%

Average Percentage of Permanent Hair Reduction

Eleven percent of patients showed less than 10% hair loss when treated with the LightSheer system, so cannot be considered to have any permanent hair loss.

1. Goldberg D. Topical solution-assisted laser hair removal. *Lasers Surg Med* 1995;suppl 7(44).

Pseudofolliculitis barbae treatment using the ET handpiece

General treatment modalities used for pseudofolliculitis barbae (topical tretinoin cream, corticosteroids, topical and oral antibiotics, surgical depilation, electrolysis, and tedious shaving regimens) have had disappointing results. The LightSheer system provides sufficient tissue penetration needed for follicular damage, causing temporary or permanent hair reduction in hair density in the areas treated, and improving the acute and chronic changes of pseudofolliculitis barbae.

In one clinical study[1], patients with lighter skin types (predominantly I–III) were treated using a pulse width of 20 ms and treatment fluences which ranged from 30–38 J/cm^2. The results of these studies have shown complete hair-growth delays of 3 to 6 weeks' duration (depending on the treatment site) and a decrease in hair density of greater than 50%. In this clinical trial, all patients reported greater than 75% improvements in pseudofolliculitis papules and pustule formation after three treatments. These patients were uniformly satisfied with their treatment and noted improvement after just one treatment session.

In another clinical study[2], patients with darker skin types (IV–VI) were safely treated using pulse widths of 30 and 100 ms and fluences ranging from 20–45 J/cm^2. Test spots were routinely performed and results were observed at one week. In most instances, treatment fluences were chosen to be 5 J/cm^2 less than the maximum tolerated to provide a safety margin. Most patients noted a significant reduction in pseudofolliculitis barbae activity after a single treatment.

1. Kauvar ANB. Treatment of pseudofolliculitis with a pulsed infrared laser. Arch Dermatol 2000;136:1343-6.

2. Adrian RM, Shay KP. 800 nanometer diode laser hair removal in African American patients: a clinical and histologic study. J Cutan Laser Ther 2000;2(4):183-90.

Bibliography

A partial bibliography of medical and scientific articles pertinent to laser-based hair removal, leg vein treatment, and benign pigmented lesion treatment is listed below. As the field is rapidly evolving, operators are strongly urged to stay current with the relevant literature.

Hair removal with LightSheer

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2. Rao J, Goldman MP. Prospective, comparative evaluation of three laser systems used individually and in combination for axillary hair removal. Dermatol Surg, Dec 2005; 31(12): 1671-6; discussion 1677.

3. Benedetto AV, Lewis AT. Pilonidal sinus disease treated by depilation using an 800 nm diode laser and review of the literature. Dermatol Surg, May 2005; 31(5): 587-91.

4. Bouzari N, Tabatabai H, Abbasi Z, Firooz A, Dowlati Y. Laser hair removal: comparison of long-pulsed Nd:YAG, long-pulsed alexandrite, and long-pulsed diode lasers. Dermatol Surg, Apr 2004; 30(4 Pt 1): 498-502. (PBP000280)

5. Manuskiatti WM, Tantikun N. Treatment of Trichostasis Spinulosa in Skin Phototypes III, IV, and V with an 800 nm Pulsed Diode Laser. Dermatologic Surgery, 2003; Vol. 29: 85-88.

6. Klavuhn KG, Green D. Importance of Cutaneous Cooling During Photothermal Epilation: Theoretical and Practical Considerations. Lasers in Surgery and Medicine, 2002; Vol. 31: 97-105.

7. Eremia S, Li C, Newman N. Laser Hair removal with Alexandrite Versus Diode Laser Using Four Treatment Sessions: 1-Year Results. Dermatologic Surgery, 2001; Vol. 27: 925-930.

8. Hamilton MM, Dayan SH, Caniol PJ. Laser Hair Removal Update. Facial Plastic Surgery, 2001; Vol. 17(3): 219-222.

9. Handrick C, Alster TS. Comparison of Long-Pulsed Diode and Long-Pulsed Alexandrite Lasers for Hair Removal: A Long-Term Clinical and Histologic Study.Dermatologic Surgery, 2001; Vol. 27: 622-626.

10. Lou WW, Quintana AT, Geronemus RG, Grossman, MC. Prospective Study of Hair Reduction by Diode Laser (800 nm) with Long-Term Follow-Up. Dermatologic Surgery, 2000; Vol. 26: 428-432. (PB0000213)

11. Lin TY, Dierickx CC, Campos VB, Farinelli WA, Rosenthal RR. Reduction of Regrowing Hair Shaft Size and Pigmentation After Ruby and Diode Laser Treatment. Archive of Dermatology, 2000; Vol. 292: 60-67.

12. Campos VB, Dierickx CC, Farinelli WA, Lin TY, Manuskiatti W, Anderson RR. Hair Removal with an 800-nm Pulsed Diode Laser. Journal of American Academy of Dermatology, 2000; Vol. 43: 442-447.

13. Dierickx CC. Hair Removal by Lasers and Intense Pulsed Light Sources. Seminars in Medicine and Surgery, 2000; Vol. 19: 267-275.

14. Adrian RM, Shay KS. 800 Nanometer Diode Laser Hair Removal in African American Patients: A Clinical and Histologic Study. Journal of Cutaneous Laser Therapy, 2000; Vol. 2: 183-190.

15. Dierickx CC, Alora MB, Dover JS. A Clinical Overview of Hair Removal Using Lasers and Light Sources. Dermatologic Clinics, 1999; Vol. 17: 357-366.

16. Williams RM, Gladstone HB, Moy RL. Hair Removal Using an 810 nm Gallium Aluminum Arsedide Semiconductor Diode Laser. Dermatologic Surgery, 1999; Vol. 25: 935-937.

17. Yamauchi PS, Kelly AP, Lask GP. Treatment of Pseudofolliculitis Barbae with the Diode Laser. Journal of Cutaneous Laser Therapy, 1999; Vol. 1: 109-111.

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18. Narurkar V. Evaluation of a New 400 ms Extended Pulse LightSheer System for Safe and Effective Hair Removal. Lumenis, 2003. (PBP000270)

19. Campos VB. Safe and Effective Long-term Hair Reduction in Tanned Patients Using an 800 nm Diode Laser. Lumenis, 2002. (PB0000234) Japan Society of Aesthetic Surgery, November 14, 1999. Lumenis, 2000.

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30. Klavuhn KG. Coverage Rate: The Influence of Laser Parameters on Treatment Time. Coherent, 2000. (PBP000131)

Other applications with LightSheer

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2. Soden CE, Smith K, Skelton H. Histologic Features Seen in Changing Nevi After Therapy with an 810 nm Pulsed Diode Laser for Hair Removal in Patients with Dysplastic Nevi. International Journal of Dermatology, 2001; Vol. 40: 500-504.

3. Boyd AS, Binhalm JQ. Use of an 800-nm pulsed-diode laser in the treatment of recalcitrant dissecting cellulites of the scalp. Archives of Dermatology, 2002; Vol. 138: 1291-1293.

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4. Kilmer SB, Chotzen VA, McClaren M. Use of LightSheer Diode Laser for the Treatment of Benign Pigmented Lesions. Lumenis, 2000. (PB0000215)

5. Campos MD, Anderson RR, Diereckx CC. Use of an 800 nm High-Power Diode Laser for the Treatment of Leg Vein Telangiectasia. Lumenis, 2002. (PB0000216)

Customer Support, Sales, and Service

In addition to the following Lumenis offices, which provide customer support, sales, and service, Lumenis has distributors worldwide. Contact your local office for the distributor in your vicinity.

Lumenis
5302 Betsy Ross Dr.
Santa Clara, CA, 95054, USA
General Sales and Service:
Tel:408.764.3000 / 877.LUMENIS
Fax:408.764.3999 / 800.505.1133
Service Center:
Tel: 877.LUMENIS or 877.586.3647
Fax: 408.763.3327

Lumenis (Germany) GmbH*
Heinrich-Hertz-Strasse 3
63303 Dreieich-Dreieichenhain, Germany
Tel:+ 49.6103.8335.0
Fax:+ 49.6103.8335.300
(*Authorized Representative per Medical Device Directive 93/42/EEC as ammended by 2007/47/EC)

Lumenis (France) SARL
Orsay, France
Tel:+ 33.1.69.33.14.20
Fax:+ 33.1.60.19.57.23

Lumenis (Italy) SRL
Rome, Italy
Tel:+ 39.06.90.75.230
Fax:+ 39.06.90.75.269

Lumenis (UK) Ltd.
London, United Kingdom
Tel:+ 44.20.8324.4200
Fax:+ 44.20.8324.4222

Lumenis Ltd.
Yokneam, Israel
Tel:+ 972.4.959.9000
Fax:+ 972.4.959.9050

Lumenis Japan Co. Ltd.
Tokyo, Japan
Tel:+ 81.3.5789.8300
Fax:+ 81.3.5789.8301

Lumenis (HK) Ltd.
Hong Kong
Tel:+ 852.2174.2800
Fax:+ 852.2722.5151

Lumenis (China) Ltd.
Beijing, China
Tel:+ 86.10.6510.2620
Fax:+ 86.10.6510.2621

Internet: www.Lumenis.com
Email: information@lumenis.com

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Appendix 1

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EMC Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
LightSheer Duet is intended for use in the electromagnetic environment specified below. The customer or the user of LightSheer Duet should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	LightSheer Duet uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	LightSheer Duet is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning statement is heeded: **Warning:** This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

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

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

LightSheer Duet is intended for use in the electromagnetic environment specified below. The customer or the user of LightSheer Duet should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the LightSheer Duet system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17P
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	d = 1.17P 80 MHz to 800 MHz d = 2.33P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LightSheer Duet system is used exceeds the applicable RF compliance level above, the LightSheer Duet system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LightSheer Duet unit.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the LightSheer Duet System

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

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

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

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

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

Appendix 2

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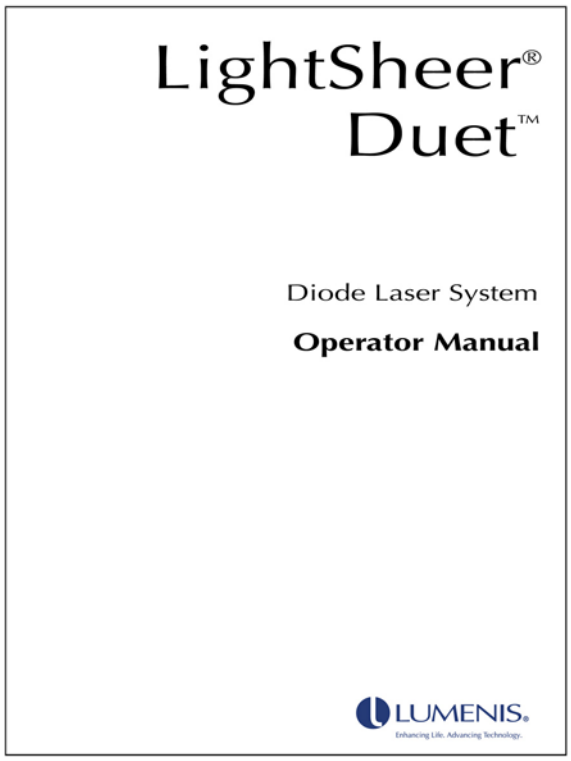
Accessory Kit Components

	
Power Cord, 15A, 125VAC	Power Cord, 20A, 250VAC

	
Operator Manual	Multi-Language Operator Manual CD

LIGHTSheer Diode Laser System — LUMENIS

SUGGESTED FLUENCES FOR TREATING LEG VEINS WITH THE LIGHTSHEER DIODE LASER SYSTEM USING 100 MS PULSE DURATION[a]

Fitzpatrick Skin Type	Description	Initial Treatment Parameters[a,c] for Blue/Purple Vessels up to 2.0 mm in Diameter (Fluence & Pulse Duration)[c,e]	Initial Treatment Parameters[a,c] for Red Vessels up to 2.0 mm in Diameter (Fluence & Pulse Duration)[c,e]	Follow-Up Treatment Parameters[c,d] – All Vessels up to 2.0 mm in Diameter (Fluence & Pulse Duration)[c,e]
I	light white skin always burns, never tans	30-60 J/cm² 30–100 ms	40-60 J/cm² auto–30 ms	40-60 J/cm² auto–30 ms
II	light white skin always burns sometimes tans	30-50 J/cm² 30–100 ms	40-50 J/cm² auto–30 ms	40-50 J/cm² auto–30 ms
III	medium white skin sometimes burns always tans	30-40 J/cm² 30–100 ms	30-40 J/cm² auto–30 ms	30-40 J/cm² auto–30 ms
IV	dark/olive white and Asian skin rarely burns always tans	30-40 J/cm² 30–100 ms	30-40 J/cm² 30 ms	30-40 J/cm² 30 ms
V	light brown skin	20–30 J/cm² 100 ms	20–30 J/cm² 100 ms	20–30 J/cm² 100 ms
VI	medium to dark brown, African and African-American skin	15–25 J/cm² 100 ms	15–25 J/cm² 100 ms	15–25 J/cm² 100 ms
All Skin Types	tanned skin[i]	See Footnote i	See Footnote i	See Footnote i

[a] Recommended by Christine C. Dierickx, M.D. & Valeria Campos, M.D. and performed with a 12x12 mm spot size.
[b] If hair is present in treatment area, patient should be shaved prior to treatment. ChillTip™ should be in contact with tissue without compressing the vessel.
[c] Target largest vessels only during initial treatment.
[d] Target smaller vessels or vessels with diminished diameters during follow-up treatments.
[e] Clinical endpoints: immediate vasoconstriction, thrombosis or immediate vessel disappearance, delayed swelling or erythema, persistent intra-vascular coagulation of larger veins.
[f] Typically, 2–3 treatments are required at 3–4 week intervals. One pass per treatment session only – otherwise, matting may be induced.
[g] Exact parameters for follow-up treatments will depend on how the patient responds to the initial treatment. For best results, patients should wear firm pantyhose support for three days after each treatment.
[h] With darker skin types, high fluence levels should be approached with caution, using increments of 2–3 J/cm².
[i] Because of the different degrees of tan, specific parameters for use on tanned skin cannot be recommended. Treatment provider should use their best judgment to determine whether to treat patient by performing a test spot at the safest parameters and then evaluating clinical response.

LightSheer treatment parameters are provided as a guide and are not a substitute for clinical observation of laser-tissue interaction and clinical endpoints. Training is available for the LightSheer. Contact your Lumenis sales representative.

Guideline: LightSheer Leg Veins Treatment

LIGHTSheer Diode Laser System — LUMENIS

TYPICAL FLUENCES FOR TREATMENT WITH THE LIGHTSHEER DIODE LASER SYSTEM USING THE 9x9 MM SPOT SIZE

Fitzpatrick Skin Type	Description	Starting Fluences[1] (Test Spots)	Tolerated Fluences[1]	Pulse Duration
I	light white skin always burns, never tans	40 J/cm² Wait at least 15–30 minutes. Observe epidermal response, increase or decrease by 2–5 J/cm².	15–60 J/cm²	Auto 30 ms – high hair density areas
II	light white skin always burns sometimes tans	35 J/cm² Wait at least 15–30 minutes. Observe epidermal response, increase or decrease by 2–5 J/cm².	15–60 J/cm²	Auto 30 ms – high hair density areas
III	medium white skin sometimes burns always tans	30 J/cm² Wait at least 15–30 minutes. Observe epidermal response, increase or decrease by 2–5 J/cm².	10–45 J/cm²	Auto – finer hair 30 ms – coarser hair or high hair density areas
IV	dark/olive white and Asian skin rarely burns always tans	20–25 J/cm² Wait at least 15–30 minutes Observe epidermal response, increase or decrease by 2–3 J/cm².	10–40 J/cm²	30 ms – finer hair 100 ms – coarser hair or high hair density areas
V	light brown skin	15–20 J/cm² Wait at least 48–72 hours. Observe epidermal response, increase or decrease by 2–3 J/cm².	10–35 J/cm²	100 ms
VI	medium to dark brown, African and African-American skin	10–15 J/cm² Wait at least 48–72 hours. Observe epidermal response, increase or decrease by 1–2 J/cm².	10–30 J/cm²	100 ms
All Skin Types	tanned skin	• Use low range of fluences recommended for one skin type darker than patient's skin type with no tan (e.g. treat tanned skin type III as skin type IV) • Perform test spots on areas with same degree of tan as area to be treated.		100 ms

[1] Recommended by Eliot Battle Jr. MD
[2] From: **Study of Very Long-Pulsed (100 ms) High-Powered Diode Laser for Hair Reduction on all All Skin Types.** 2000, Eliot Battle Jr. MD, R.Rox Anderson MD

LightSheer treatment parameters are provided as a guide and are not a substitute for clinical observation of laser-tissue interaction and clinical endpoints. Fluences may be higher with 400 ms pulse. Training is available for the LightSheer. Contact your Lumenis sales representative.

Guideline: LightSheer 9mm Treatment 400 ms

Disposable Inserts (x 30)

Safety Glasses

	
Opaque Eye Shields	Opaque Eye Shields Foam Replacements

	
Laser Danger Door Sign	System Keys

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