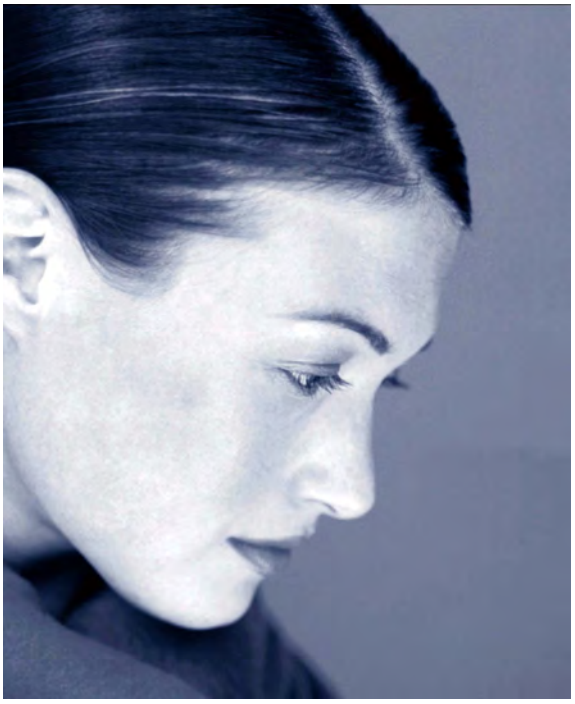

Operator Manual

Xeo Series

CUTERA™

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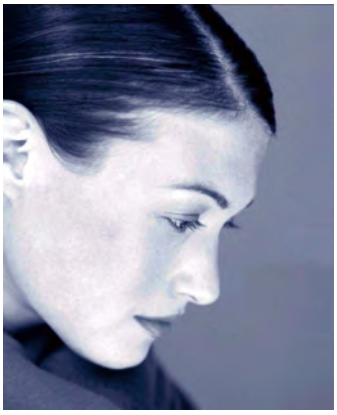


Operation

Introduction

The Xeo series of systems are the latest evolution in the Cutera gold-standard CoolGlide® Nd:YAG laser platform. Since its introduction, the CoolGlide with its patented tissue cooling handpiece has been the preferred modality for aesthetic laser-based procedures. In recent years, the non-ablative procedure, made possible through the most powerful CoolGlide laser has demonstrated the utility of 1064 nm wavelength and Nd:YAG-based technology for cosmetic dermatology. The Xeo series of systems expand upon this experience with features that make them more adaptable, and easier to use in various clinical settings. The new Xeo series of systems were designed to be easily learned and operated.

The new CoolGlide Xeo, Xeo *SA* and the Genesis *Plus* systems allow clinicians a broader selection of treatment handpieces, while enhancing the Cutera commitment to providing upgrade paths for new treatment technologies.

Our patented ClearView 1064 nm Nd:YAG handpiece, the OPS600 (Optimized Pulsed Spectrum) and the LP560 (Long Pulse) handpieces extend the capabilities of the Xeo series of systems to a full range of aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue.

The Cutera Xeo series of systems, along with the different handpieces are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have any questions regarding your system, or associated handpieces, contact your local Cutera representative.

WARNING

Any laser or pulsed light emitting device can generate highly concentrated light which may cause injury if improperly used. To protect patients and operating personnel, the entire system operator manual, including the *Safety and Regulatory* sections, should be carefully read and comprehended before operation.

Characteristics of the 1064 nm Nd:YAG Laser Beam

The Nd:YAG laser wavelength (1064 nm) falls in the near infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye; therefore, a low power, visible aiming beam that is coaxial with the invisible treatment beam is used to target tissue.

The 1064 nm Nd:YAG laser light is absorbed by melanin as well as the hemoglobin containing target tissues with appropriate parameters. This makes the Nd:YAG laser useful for treating multiple indications.

Characteristics of the OPS600

The OPS600 handpiece emits a 600 - 850 nm pulsed-light, which falls in the visible to the near infrared region of the electromagnetic spectrum. This wavelength is visible to the human eye, therefore an aiming beam is not necessary.

The 600 - 850 nm pulsed-light is intended for use in the treatment of benign pigmented lesions.

Characteristics of the LP560

The LP560 handpiece emits a 560 - 1200 nm pulsed-light, which falls in the visible to the near infrared region of the electromagnetic spectrum. This wavelength is visible to the human eye, therefore an aiming beam is not necessary.

The 560 - 1200 nm pulsed-light is also intended for use in the treatment of benign pigmented lesions.

System Preparation

The CoolGlide Xeo, Xeo *SA* and Genesis *Plus* systems are shipped directly from the factory to your site. Your local Cutera representative will initially uncrate, inspect, set up and install the system to ensure that it is working properly before use. In addition, Cutera provides in-service and training to ensure that your staff is experienced with appropriate performance and safety considerations. Thereafter, you or the staff at your facility will be performing the daily maintenance routines associated with the system and with the three handpieces used during the procedure (inspecting & cleaning of the OPS600 or LP560 pulsed-light handpieces and the ClearView 1064nm laser handpiece, connecting of the preferred pulsed-light handpiece) as well as performing basic system safety checks. These procedures are detailed later in this chapter and in the *Maintenance* section of this manual.

Most staff personnel prefer to inspect and perform a functional system check prior to scheduled cases. Doing so will ensure adequate time to troubleshoot problems or contact your service representative with the least amount of disruption to patients and schedules.

Xeo System Components

Your Xeo system will comprise of different components depending upon the model purchased.

The CoolGlide Xeo and the Genesis *Plus* systems consist of a laser console, a laser handpiece which is permanently connected, at least one user-detachable pulsed-light handpiece, a touch screen control panel, footswitch and a dual handpiece resting tree. Other components necessary for operation, such as an external door interlock plug and all electrical cables, are also included.

The Xeo-*SA* system console is similar to the CoolGlide Xeo and Genesis *Plus* console in appearance with the exception of the laser handpiece and the dual handpiece resting tree. This system will not have a laser handpiece and will use a single handpiece resting tree. The Xeo *SA* will include at least one user-detachable OPS600 or LP560 handpiece (depending upon the type purchased).

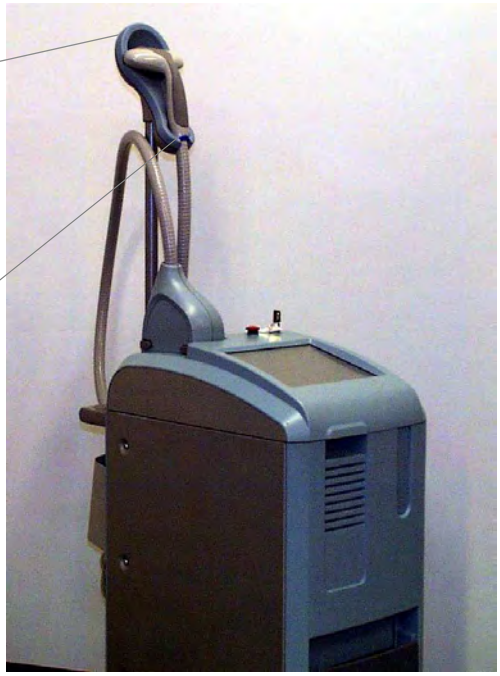
OPS600 or LP560 Handpieces

System Console

1064 nm Nd:YAG Handpiece

CoolGlide Xeo or Genesis Plus System

OPS600 or LP560 Handpieces

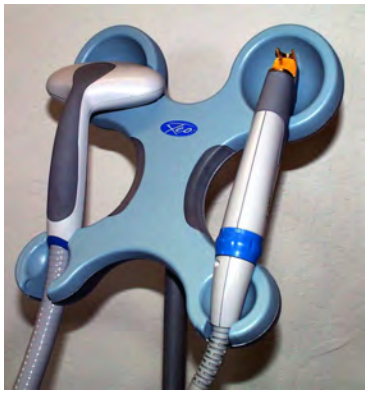


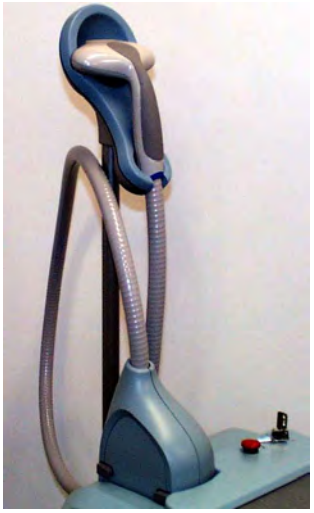
System Console

Xeo SA System

Touchscreen

CoolGlide Xeo or Genesis Plus Handpiece Resting Tree





Xeo SA Handpiece Resting Tree

Remote Interlock Plug

Footswitch

System Console

The system console houses the touchscreen control panel, the main power keyswitch, emergency off switch, control electronics, the 1064 nm laser umbilical with handpiece, the laser source with their associated optics, and power supply. The system console is the central unit to which all handpieces are attached. For the CoolGlide Xeo and Genesis *Plus* models the ClearView 1064 nm Nd:YAG handpiece is permanently attached to the laser console. All other handpieces are user-detachable. All handpieces are connected to the console through umbilicals, which enables the 1064 nm Nd:YAG laser, 600 - 850 nm or the 560 - 1200 nm pulsed-light to the be delivered to the treatment site at the appropriate spot size. The touchscreen control panel allows you to select treatment settings.

Footswitch

The footswitch activates the laser or pulsed-light treatment beams.

Remote Interlock Plug

The remote interlock plug is a safety feature that shuts off the system power. When the remote interlock plug is wired to an external door switch it becomes a remote external door interlock and if the treatment room door is opened or the remote interlock plug is removed the system will turn itself OFF.

Handpiece Delivery Systems

Several light delivery systems are available for use with the three Cutera models described here. They include the permanently attached ClearView 1064 nm Nd:YAG handpiece, and the user-detachable OPS600 & LP560 handpieces. Information on the handpieces are detailed later on in this manual.

Inspect the Xeo System Components

Before connecting the CoolGlide Xeo, Genesis *Plus* or the Xeo *SA* components, inspect the individual components, cables, and electrical connections for any dirt, debris, or damage. Check all electrical cables to ensure they are not frayed or split. Inspect both handpieces, as instructed in the *Maintenance* section of this operator manual.

WARNING

Always turn the system OFF before inspection of the handpieces. Never look directly into the handpiece(s) even when wearing protective eyewear. Never look directly into the laser beam or at scattered light from metallic or other reflective surfaces. Both the 1064 nm Nd:YAG laser beam and the pulsed-light delivered by handpieces can cause permanent eye damage.

NOTE

Do not touch the window on the ClearView 1064 nm Nd:YAG handpiece; finger oils may damage the coating.

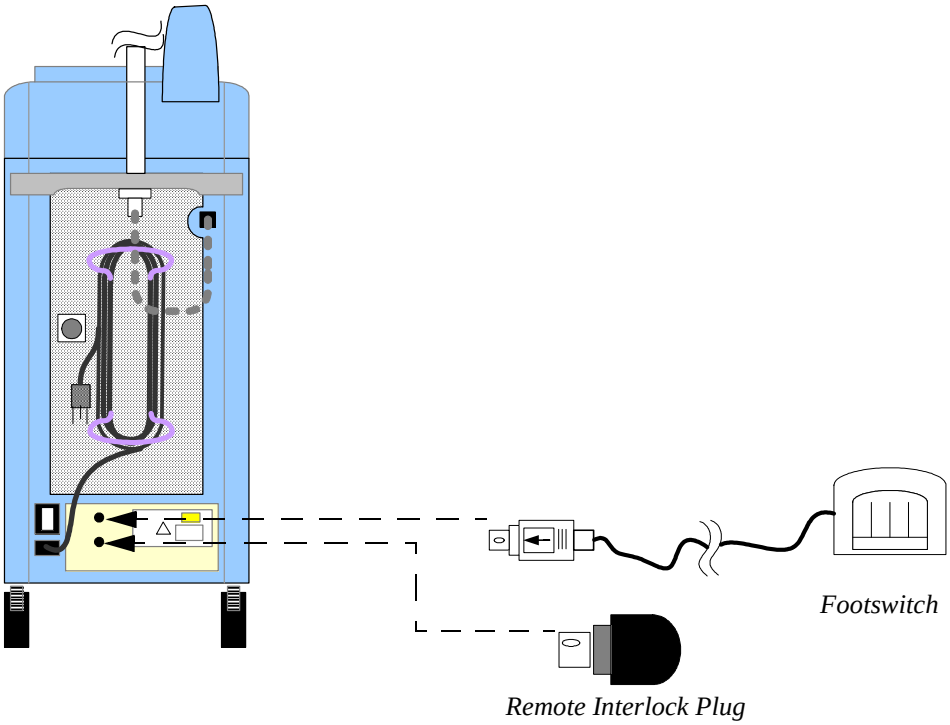
Connect the Footswitch and the Remote Interlock Plug

Plug the footswitch cable into the footswitch receptacle. If the footswitch is not properly connected when the system is turned ON, a pop-up screen with an animated illustration will be displayed on the touchscreen and the system cannot be placed into READY mode. *An illustration of the pop-up screen is displayed later in this chapter.*

The Remote Interlock plug is a safety feature that turns off the system power if the treatment room doors are opened or the Remote Interlock plug is removed while the system is ON.

Use of an external door switch wired to the Remote Interlock plug is optional; however, the Remote Interlock plug must be inserted into the interlock receptacle whether or not an external door switch is used. The system remains OFF until the plug is inserted into the receptacle and the system is restarted.

When using an external door switch, the system completely shuts down if the treatment room door is opened or the Remote Interlock plug is removed. To resume treatment, close the treatment room door or reinsert the Remote Interlock plug, and restart the system using the keyswitch.



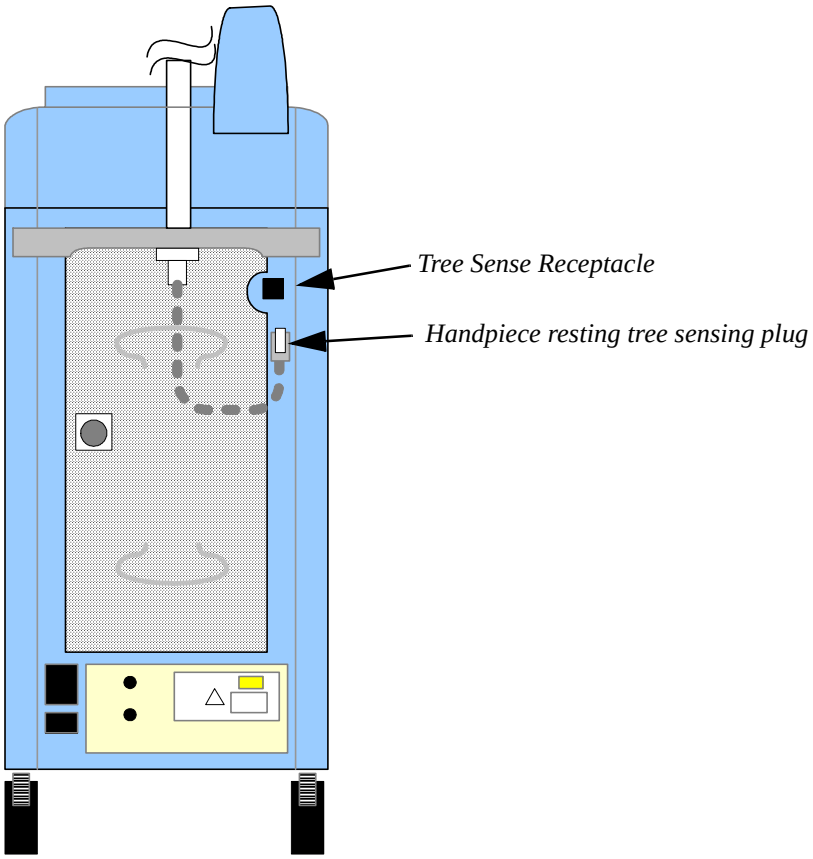
Connecting the Footswitch & Remote Interlock Plug

Connect the OPS600 or LP560 Handpiece

Before connecting the OPS600 or the LP560 handpiece to the system, be sure the handpiece Resting Tree assembly is installed into its mounting mechanism, which is part of the handle, and is locked into place. Then plug the handpiece Resting Tree sensing plug into the mating receptacle at the top right-hand corner of the rear panel cover.

NOTE

Be sure the sensing plug jack locks into place in the receptacle.



1. Place the OPS600 or the LP560 handpiece on the left side of the handpiece resting tree.

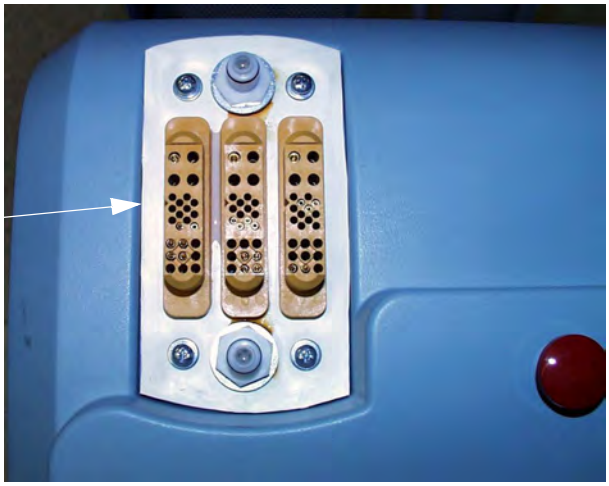
NOTE

This only applies to the CoolGlide Xeo or the Genesis *Plus* system. The Xeo *SA* will have only one position on the resting tree.

2. Once the OPS600 or the LP560 handpiece is properly resting in the Resting Tree, route the umbilical so not to interfere with the operator or patient.

3. Depress the two buttons on the handpiece plug until a click is heard and align the connector over the top cover.

Align the OPS600 or LP560 handpiece umbilical connector over this receptacle



4. Press gently to align the fittings and once aligned, press firmly.

NOTE

It is important to always listen for **two audible clicks** when installing the OPS600 or the LP560 handpiece. The handpiece engagement only occurs when both clicks are heard.

NOTE

When removing the OPS600 or the LP560 handpiece, it is important to turn the system OFF and let the system rest for approximately 30 seconds before removing the OPS600 or the LP560 handpiece, otherwise damage to the system will occur. When removing the handpiece be sure to press the two buttons before removing.

Placement of the ClearView 1064 nm Nd:YAG Handpiece

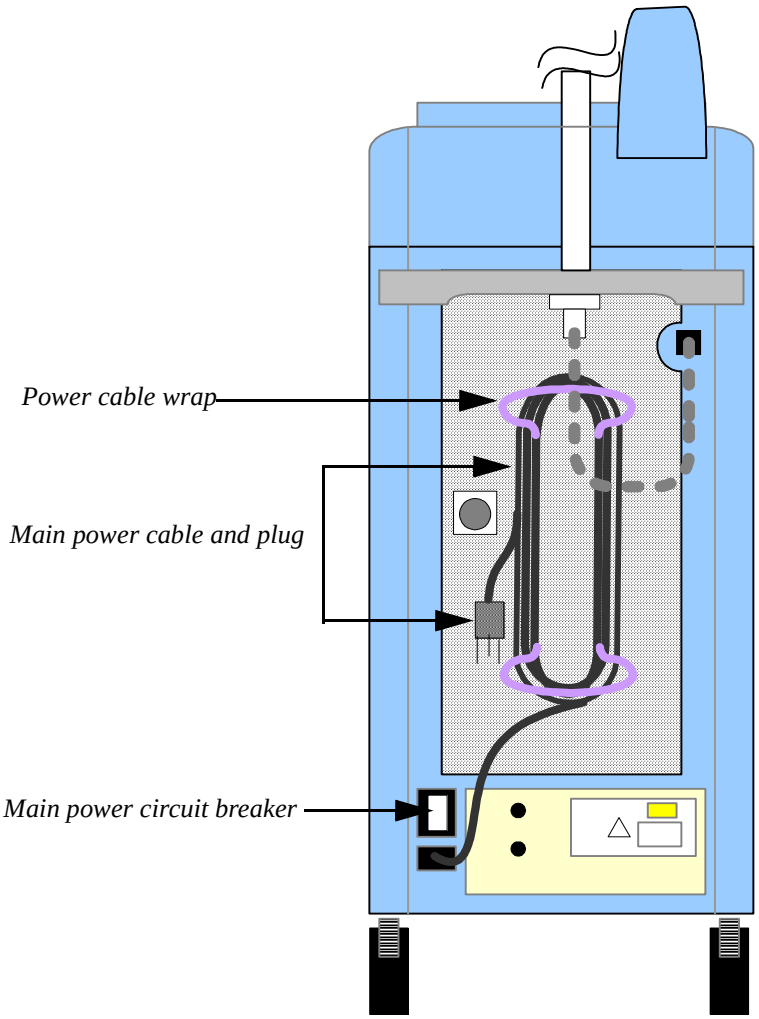
If your model is a CoolGlide Xeo or the Genesis *Plus* system, you will have the ClearView 1064 nm Nd:YAG handpiece available that is permanently attached to the system. Simply place the ClearView 1064 nm Nd:YAG handpiece on the right side of the resting tree.

Connect the Main Power Cable

1. Ensure that the system main power circuit breaker is OFF (down) and that the system keyswitch is in the **O** (OFF) position.

2. Insert the receptacle end of the power cable into the mating AC receptacle on the system and insert the AC plug into the AC wall socket.

3. Insert the mains power cord plug into the appropriate wall socket and turn the main electrical service ON. Ensure that the main power circuit breaker is in the up (ON) position.



Main power circuit breaker and main power plug

System Basics

Turn On the System

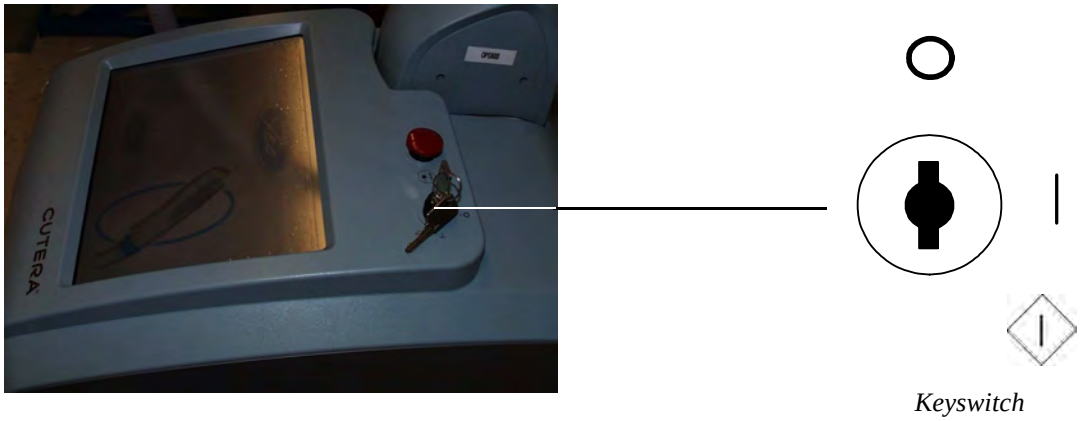
Insert the key in the keyswitch, turn to the  (START) position, hold for a full second, and release. Upon release, the key automatically springs back to the **I** (ON) position.

The start-up screen (Cutera name) appears and begins a self-test routine. After approximately 10-15 seconds, the system emits an audible tone, the self-test message disappears, and the touchscreen displays a Selection Screen. The Selection Screen will indicate what model type the console is and will display an image of the handpiece(s) that are connected to the system.
Additionally, the user can also access the Information & Adjustment screen by depressing the “i” icon at the top left corner of the screen.

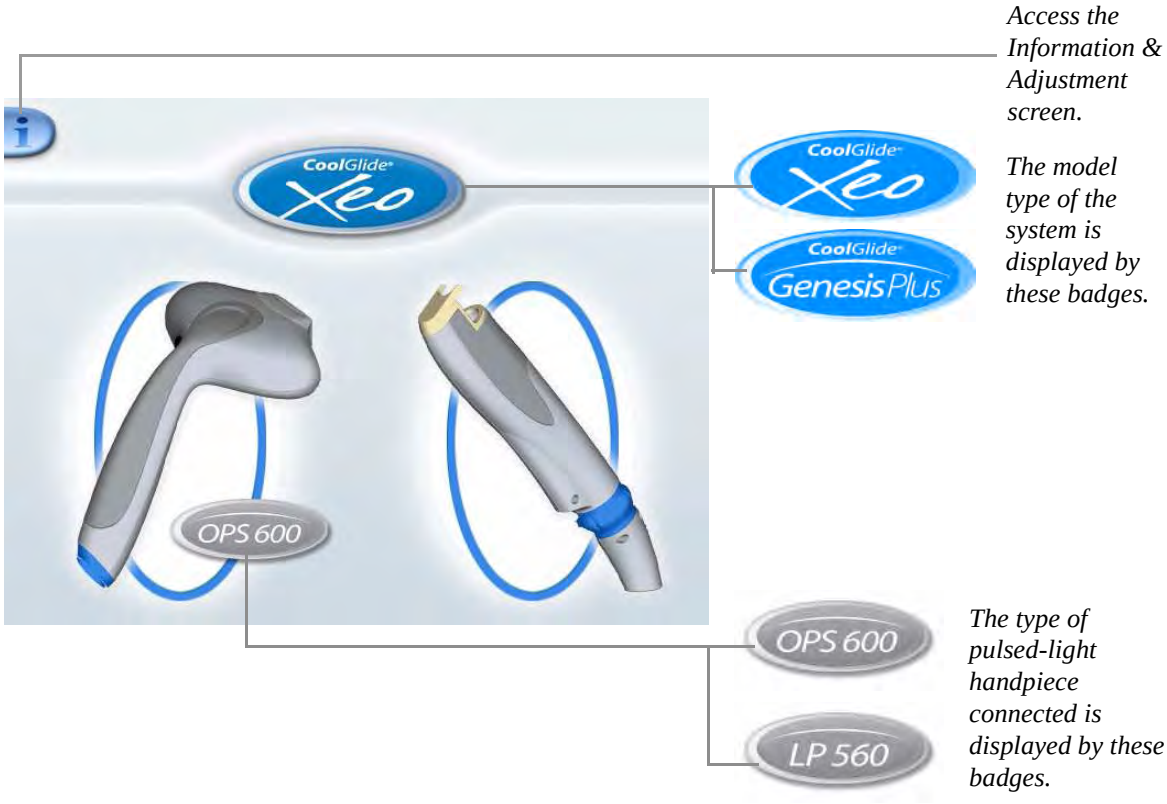
NOTE

The types of handpieces that may be connected to the console are preprogrammed into the system. If an incorrect handpiece is connected, an error is displayed.

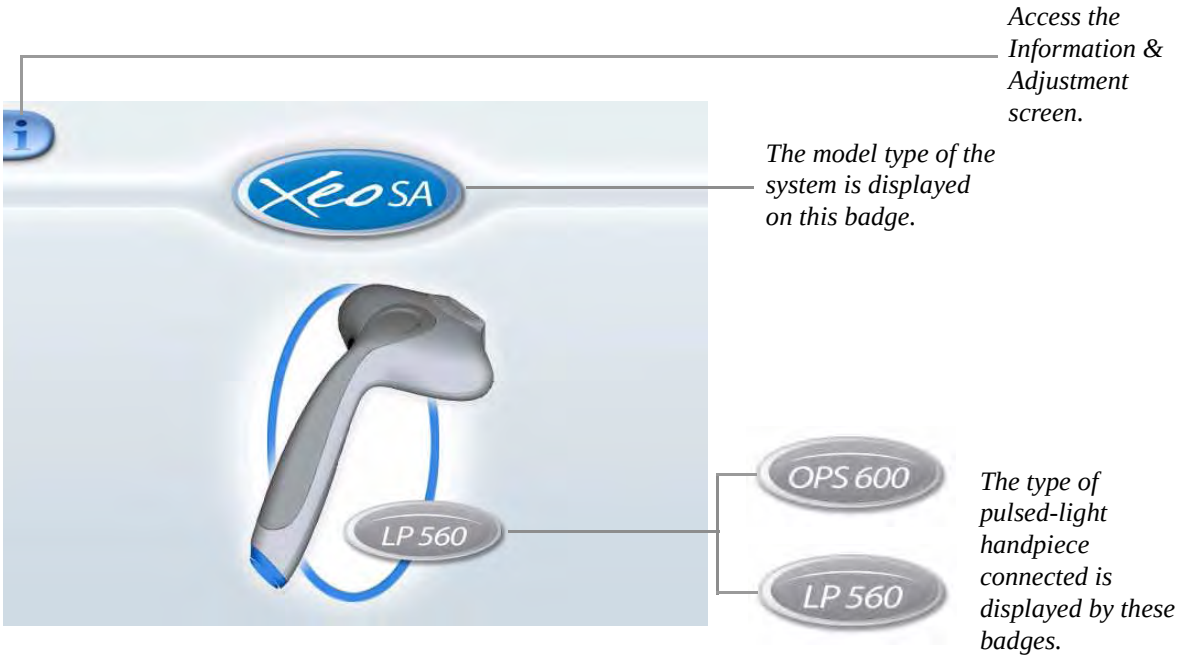
The user must select one of the handpieces displayed. Selecting a handpiece results in a display of the control screen appropriate to the handpiece selected and at this point the system is in STANDBY mode. Once the user selects one of the handpieces shown on the touchscreen display, an audible tone is heard, and this allows the user to select the READY mode.



Controls for turning on and restarting the CoolGlide Xeo, Xeo SA and Genesis Plus



The CoolGlide Xeo and Genesis Plus Selection Display



The Xeo SA Selection Display

The handpiece selection control screen will be shown as a “solid” icon. If one of the handpieces are removed from the resting tree, the second handpiece resting on the resting tree will show as unselectable by becoming a lighter shade icon. In order to select the second handpiece, the first handpiece must be placed back on the resting tree and the second handpiece selected on the handpiece control screen.

If the ClearView 1064nm Nd:YAG handpiece is selected, the system will go into laser STANDBY mode.

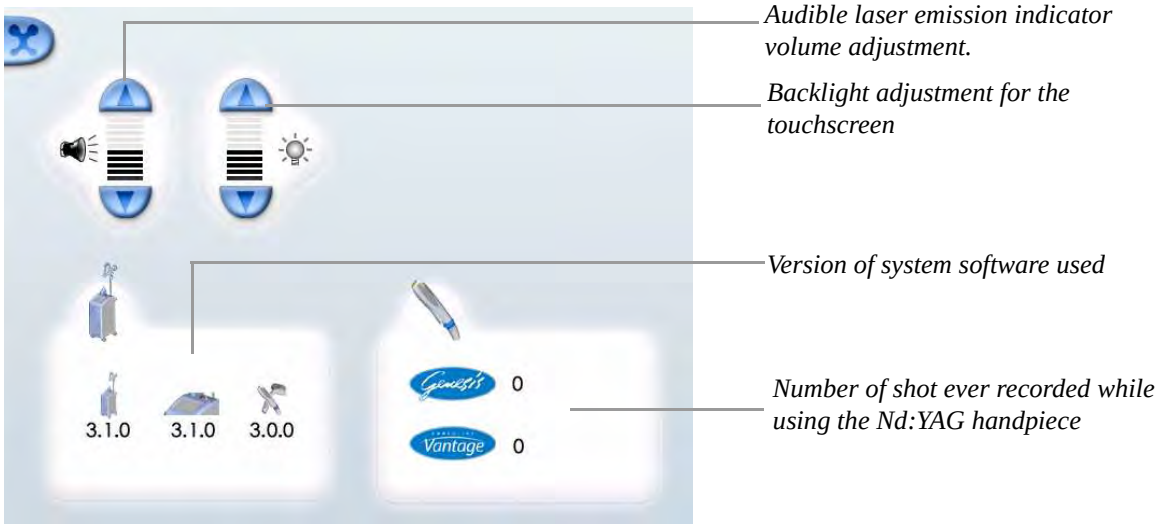
If the user-detachable handpiece is selected, the system will go into either the OPS600 or LP560 STANDBY mode, depending upon the handpiece connected.

If any fault conditions, advisory messages, or error codes appear in the pop-up display during self-test, refer to the *Troubleshooting* section of this operator manual.

Information & Adjustment screen

The Information & Adjustment screen allows the user to access the following:

- Adjust the laser emission indicator volume. *Refer to the Audible Tones subtopic.*
- Adjust the backlighting of the touchscreen.
- Allow the user to view the version of the system software.
- View the total number shots ever recorded while using the Nd:YAG handpiece.



Information & Adjustment Screen

Restart the System

To restart the system:

1. Turn the keyswitch to the **O** (OFF) position.

2. WAIT 5 SECONDS before turning the keyswitch to the  (START) position. Release the key. The system will go through its normal start-up sequence.

Turn Off the System

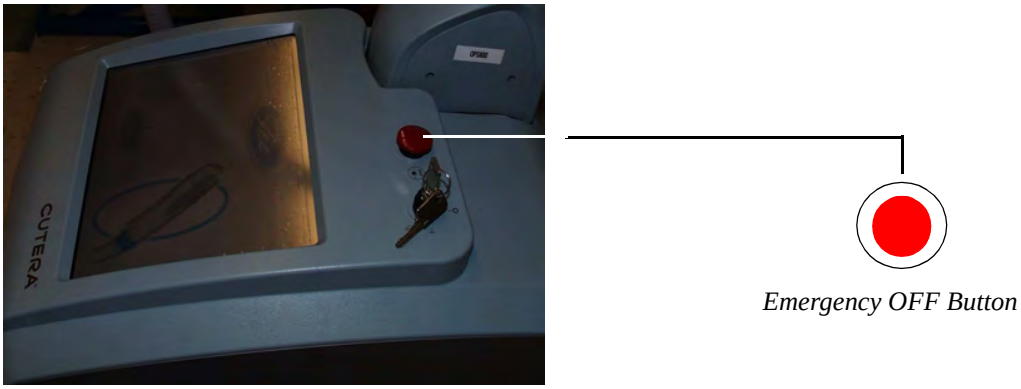
Under normal operating conditions, turn the keyswitch to the **O** (OFF) position.

NOTE

When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all the internal circuits, turn off the main power circuit breaker and disconnect the electrical service.

Emergency Off

In an emergency, press the red Emergency OFF button to immediately turn off the system.



Emergency OFF Button

Disconnect the System

1. Turn the keyswitch to the **O** (OFF) position.

2. Set the main circuit breaker to the OFF position.

3. Remove the power plug from the electrical outlet and wrap the power cable around the cable wrap.

4. Place the footswitch on the footswitch storage mount on the rear of the laser console. Coil the footswitch cable and store it inside the footswitch holder. Do not wrap the footswitch cable around the power cable wrap.

5. If your model includes a ClearView 1064 nm Nd:YAG handpiece, store it in the in the pouch located at the front of the console.

(Front of the Console)

CAUTION

When the storing the ClearView handpiece in the pouch, do not coil the umbilical too tightly, as damage to the internal optical fiber will occur.

6. Disconnect the OPS600 or LP560 handpiece by pressing both buttons on the connector and then lifting the connector.

Depress both buttons before removing the handpiece

WARNING

Never disconnect the OPS600 or LP560 handpiece while the system is ON, otherwise, severe damage to the power supply will occur. Always turn the system OFF and allow the system to rest for approximately 30 seconds before disconnecting the handpiece.

NOTE

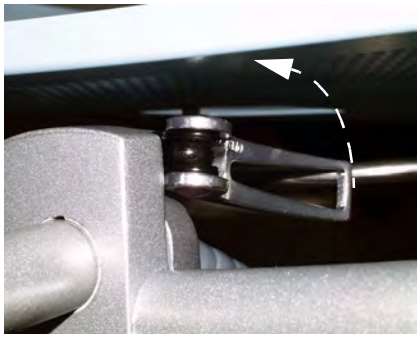
It is normal to see a few drops of water at the connector base.

7. Store the OPS600 or LP560 handpiece in its designated carrying case.

8. Lower the handpiece tree by releasing the clamp at the tree pole base.

NOTE

If transporting the system in a vehicle, remove the tree sensing line connector, release the tree clamp, and then remove the handpiece tree completely.



To release, pull-up

Move the System

1. Disconnect the system as described above.

CAUTION

Always disconnect the system as described above when moving the system any distance other than within one room. Handpieces may be dislodged from the Resting Tree when the system is moved over thresholds or uneven surfaces. Damage will occur to handpieces when dropped.

WARNING

Water must be drained from the system if the system is stored in temperatures below freezing. Freezing may result in damage to critical or delicate components.

2. Replace the vented filler cap with a sealed filler cap to prevent water from leaking.

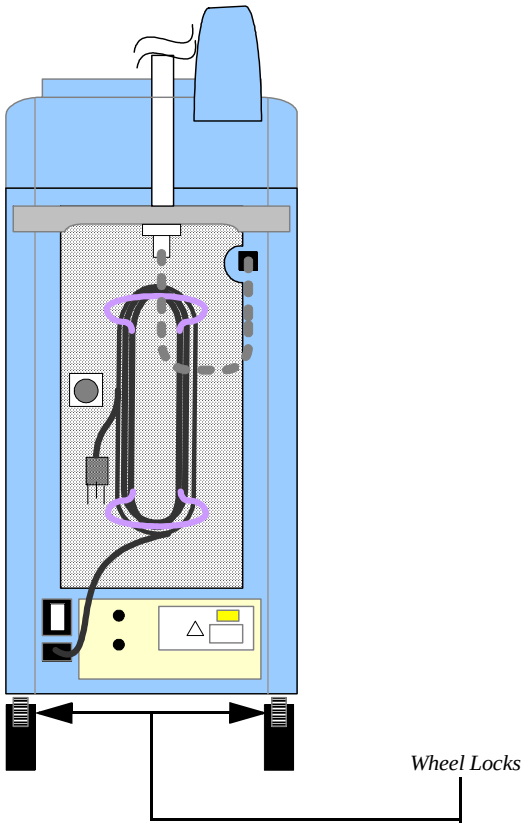
3. Unlock the console wheels by disengaging the wheel locks.

4. Move the system console to the desired site. Position the console no less than 20 centimeters (8 inches) from walls, furniture, or other equipment. Adequate space around the system console ensures proper air circulation.

CAUTION

Never use the handpieces or umbilical cords to move the system. Moving the system using the handpieces or umbilicals may irreparably damage the handpieces and/or the umbilicals.

5. Lock each of the system console wheels by engaging each wheel lock.



Moving the System

General System Functions

Xeo Applications and Capabilities

The CoolGlide Xeo platform encompasses a wide range of dermatologic treatments. Laser pulse fluence, spot size, pulse width and repetition rate parameter combinations can be used to treat small and larger vascular conditions and vessels, to perform non-ablative skin therapy, and to remove hair. In addition, the user-detachable handpieces available with the Xeo can be used to treat pigmented lesions.

Your CoolGlide Xeo system is configured either to treat all of these indications, or a subset of them. Depending on your particular configuration, some laser parameters, such as particular spot sizes or fluences, may not be available. The types of user-detachable handpieces that will function with your CoolGlide Xeo are also determined by your configuration. To determine your configuration, examine the external label located at the lower console rear panel. The label will have a system serial number, followed by a series of designators. Use this table to determine the applications your CoolGlide Xeo system can be used to perform:

-H	Laser hair removal
-FV	Laser treatment of facial vessels
-LV	Laser leg vein treatment
-GT	Laser non-ablative skin therapy
-OPS600	Pulsed light treatment of pigmented lesions
-LP560	Pulsed light treatment of pigmented lesions

Audible Tones

The CoolGlide Xeo, Xeo *SA* and the Genesis *Plus* systems will emit a single audible tone with every control screen selection or when an error condition has occurred. Additionally, audible laser emission tones are generated during treatment exposures.

Audible laser emission indicator volume can be increased from the minimum setting up to a volume where it can be clearly heard over the system sound level. To adjust the audible laser emission volume, depressing the “i” button at the top left hand corner of the handpiece selection screen.

The user can increase or decrease the audible laser emission indicator volume by pressing the UP or DN buttons.

NOTE

The audible laser emission indicator volume cannot be reduced to a point where there is no audible tone output.

CoolGlide Xeo/Xeo SA/Genesis Plus System Status: Ready and Standby Mode

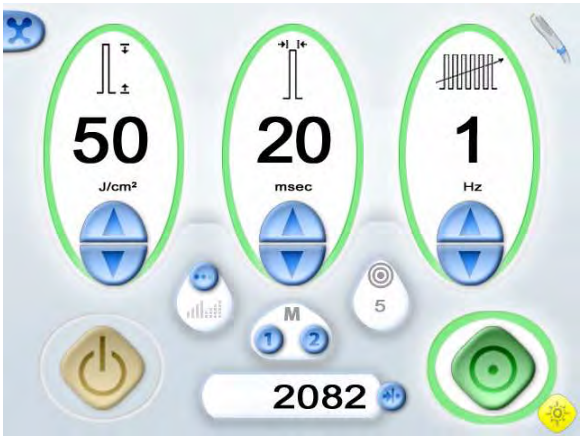
The READY and STANDBY buttons on the touchscreen control the laser or one of the user-detachable handpieces. The display screen shows the selected mode.

(In the 1064 nm Nd:YAG Mode)
In STANDBY mode, the footswitch is disabled and the internal safety shutter is closed; no treatment or aiming beams are available. At system start-up and after self-test, the system automatically goes into STANDBY mode by displaying the hand-piece selection screen. Once the 1064 nm Nd:YAG handpiece is selected, the display will show the 1064 nm Nd:YAG control screen in STANDBY mode. When READY mode is selected, the footswitch is enabled, the safety shutter is open, and the treat-ment and aiming beams become available. Depressing the footswitch discharges the treatment energy pulse from the ClearView 1064 nm Nd:YAG Handpiece. In READY mode, the READY button, the J/cm^2, milliseconds, and the Hertz displays are high-lighted in green on the touchscreen. The system will emit an audible tone to indicate emission, and a yellow indicator next to the READY button will also illuminate when there is laser emission. The aiming beam is visible in READY mode only when using the 1064 nm Nd:YAG handpiece.

NOTE

No aiming beam is seen when the system is in STANDBY mode.

1064 nm Nd:YAG STANDBY Mode

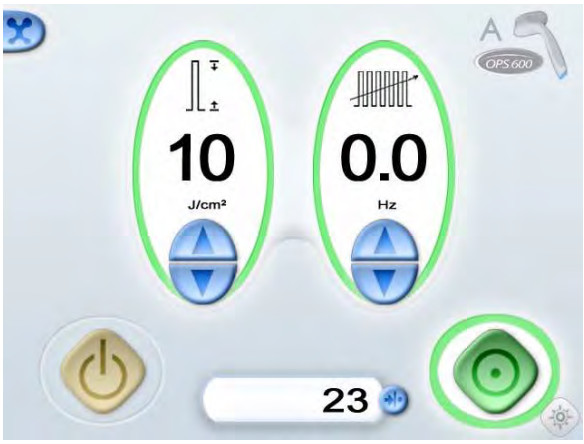


1064 nm Nd:YAG READY Mode

(In OPS600 Mode)

In STANDBY mode, the footswitch is disabled and no treatment beam is available. At system start-up and after the system self-test, the system automatically goes into STANDBY mode displaying the handpiece selection screen. In READY mode, the footswitch is enabled and depressing the footswitch produces 600 - 850 nm light from the OPS600 handpiece. In READY mode, the READY button, the J/cm^2, pulses, and the Hertz displays are highlighted in green on the touchscreen. The system will also emit an audible tone to indicate emission with each pulse.

OPS600 STANDBY Mode



OPS600 READY Mode

NOTE

There will not be an aiming beam when using the OPS600 handpiece.

If the system is not used for more than three minutes, the system will automatically enter into STANDBY mode.

WARNING

Except during actual treatment, the system must always be in the STANDBY mode. Maintaining the system in STANDBY mode prevents accidental treatment beam exposure if the footswitch is inadvertently depressed.

WARNING

Verify that all persons in the treatment room are wearing the appropriate treatment beam safety eyewear before placing the system in READY mode.

(In LP560 Mode)
In STANDBY mode, the footswitch is disabled and no treatment beam is available. At system start-up and after the system self-test, the system automatically goes into STANDBY mode displaying the handpiece selection screen. In READY mode, the footswitch is enabled and depressing the footswitch produces 560 - 1200 nm light from the LP560 handpiece. In READY mode, the READY button, the J/cm^2, pulses, and the Hertz displays are highlighted in green on the touchscreen. The system will also emit an audible tone to indicate emission with each pulse.

LP560 STANDBY Mode

LP560 READY Mode

NOTE

There will not be an aiming beam when using the LP560 handpiece.

If the system is not used for more than three minutes, the system will automatically enter into STANDBY mode.

WARNING

Except during actual treatment, the system must always be in the STANDBY mode. Maintaining the system in STANDBY mode prevents accidental treatment beam exposure if the footswitch is inadvertently depressed.

WARNING

Verify that all persons in the treatment room are wearing the appropriate treatment beam safety eyewear before placing the system in READY mode.

Pop-Up Screen

When the system detects an abnormality during self-test or while the system is READY mode, a pop-up screen will appear with a corresponding error code(s). If the error or abnormal condition is successfully cleared, the pop-up screen can be cleared by pressing the “X” in the upper right-hand corner. Refer to the *Maintenance* section of this manual.

Pop-Up Screen

Depending upon the fault detected, some faults will display an animated illustration (i.e. footswitch disconnected and water low).

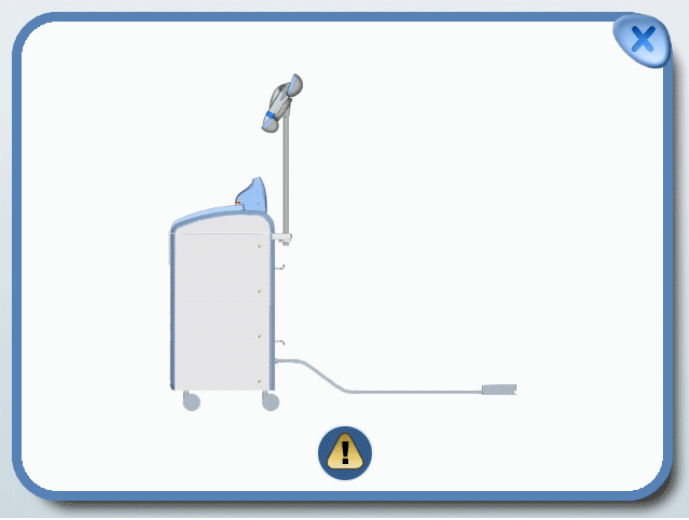


Illustration of the footswitch disconnected

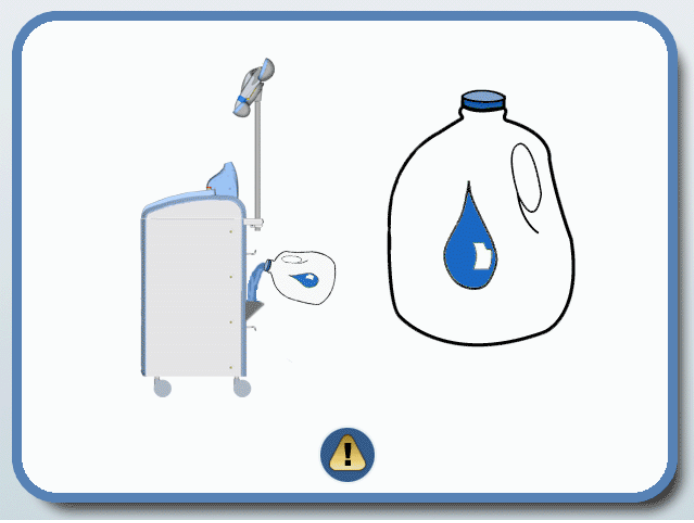


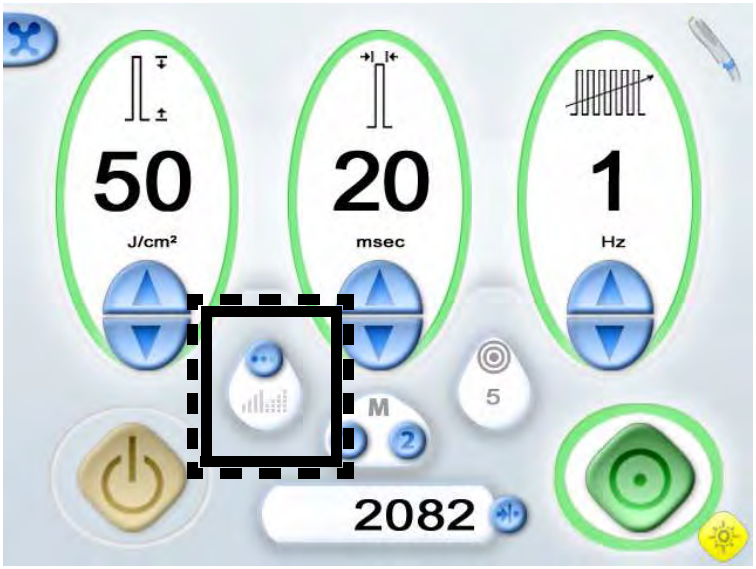
Illustration of water low

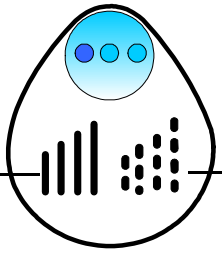
Aiming Beam

All aiming beam functions are controlled on the touchscreen display and can only be enabled while in the 1064nm Nd:YAG mode.

NOTE

The OPS600 or the LP560 handpiece must be set on the resting tree and the ClearView 1064 nm Nd:YAG hand-piece removed from the resting tree in order to adjust the aiming beam.





Four intensities in continuous aim mode

Four intensities in blink aim mode

Set the Aiming Beam Mode & Intensity

To adjust the aiming beam intensity, press the Aiming Button on the touch screen. The Aiming Beam Intensity Indicator will display the intensity status. Point the ClearView Handpiece at the targeted treatment site. Press the Aiming Beam button again to toggle through the modes and intensities. There are four intensities in continuous and blink modes as well as an OFF mode.

NOTE

The aiming beam intensity and mode can be set independently for each spot size.

Displays and Indicators

The CoolGlide Xeo, Xeo *SA* and Genesis *Plus* systems also include various indicators and controls to ensure safe and accurate operation.

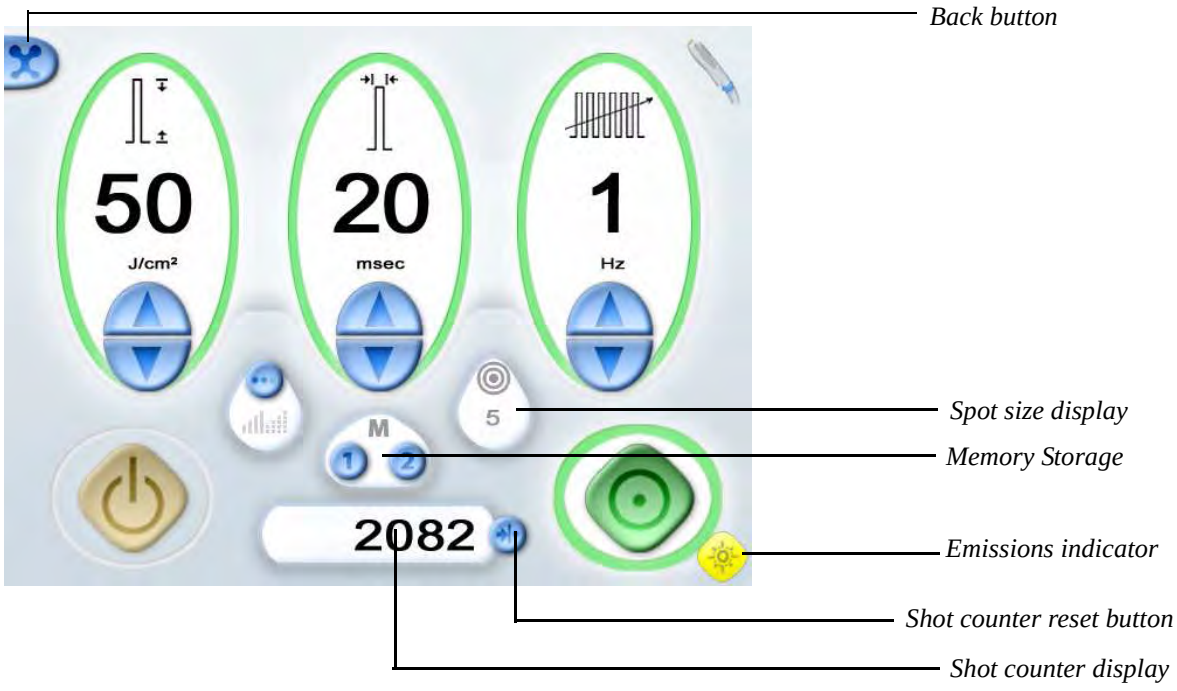
(In 1064 nm Nd:YAG Mode)

- A shot counter display including a shot counter reset button. The system will record the total number of laser shots that the system has fired since the counter was most recently reset.
- A spot size display, which displays the spot size setting of the ClearView Handpiece.
- A memory storage feature, which allows the user to store and recall frequently used operating parameters. There are two memory banks in the memory storage feature, which will allow the user to store two different operating parameters. Pressing and holding the memory button (1) or (2) for more than three seconds will save the fluence, rep rate and pulse-width settings shown on the display.
  Pressing the memory buttons for less than three seconds will recall the previously stored operating parameters.

NOTE

When storing or recalling the memory, you must press and hold the button on the display until an audible tone is heard. Two beeps will sound when storing data and one beep will sound when recalling data. Any existing operating parameters stored in memory will be overwritten with new operating parameters.

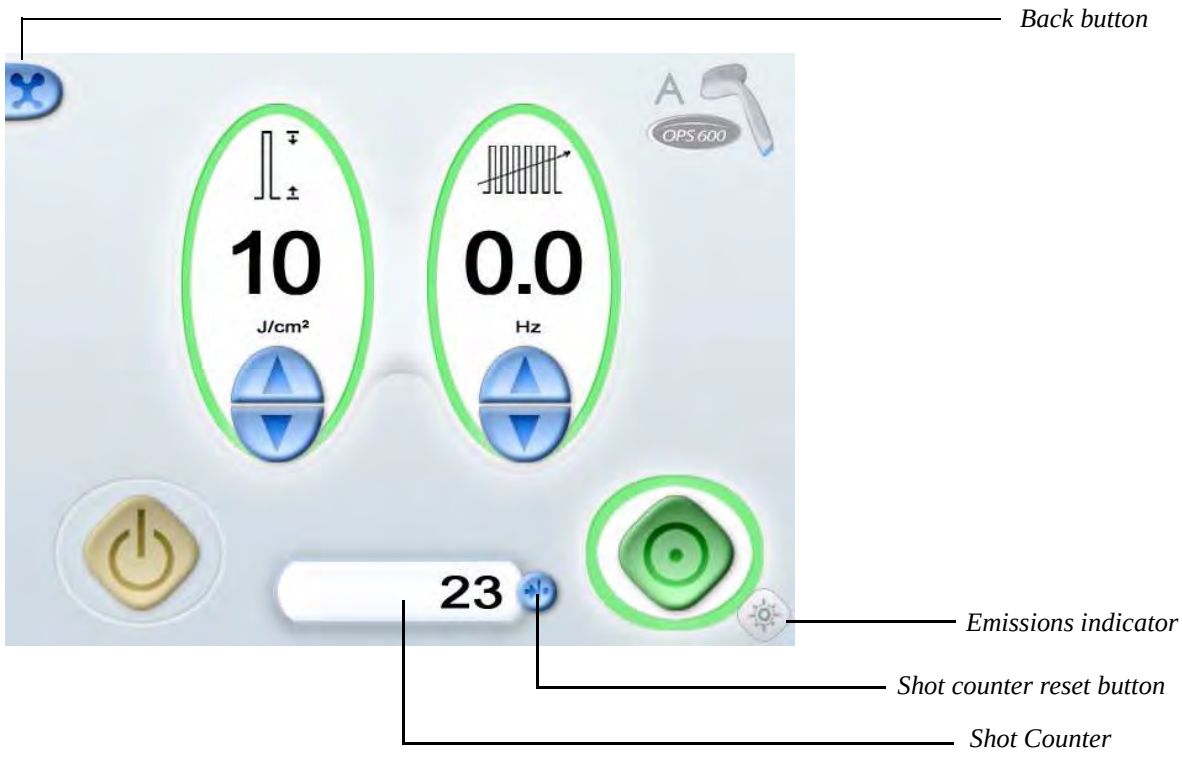
- An emissions indicator. The emissions indicator will illuminate when the system is set to READY and the footswitch is pressed.
- A BACK button, which returns the display to the Selection Display screen.



1064nm Nd:YAG Screen

(In OPS600 Mode)

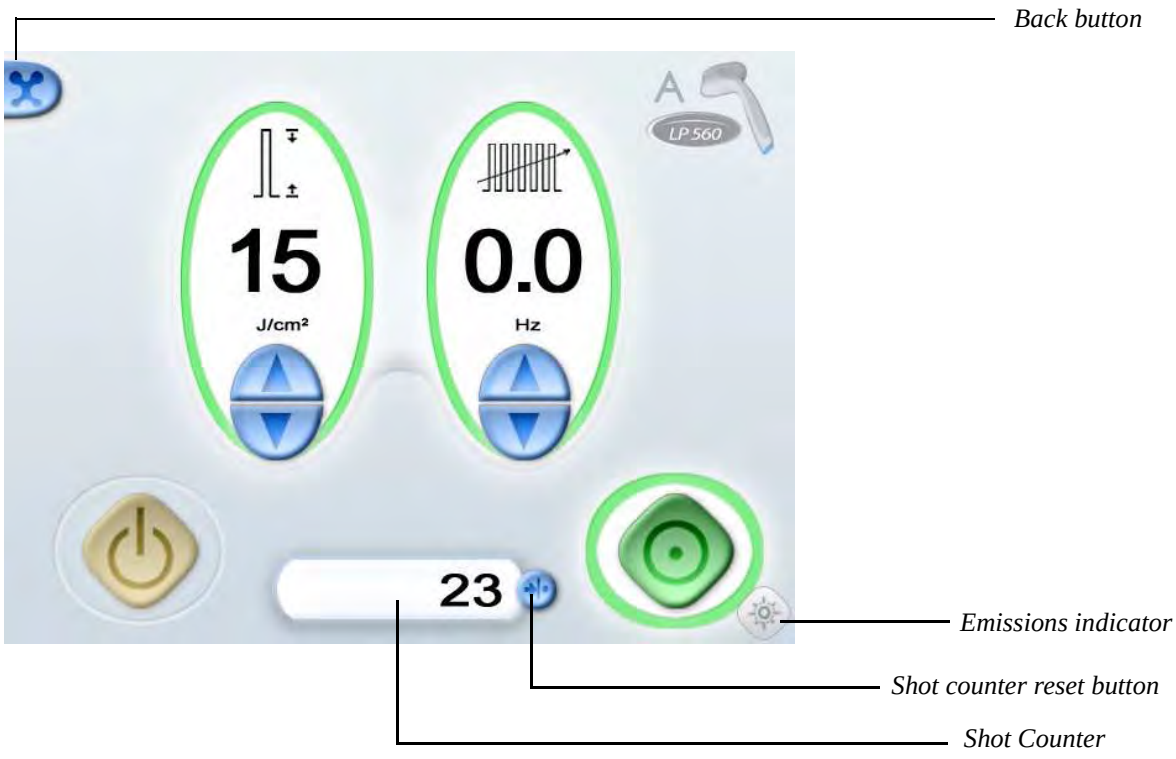
- A shot counter display including a shot counter reset button. The system will record the total number of OPS600 shots that the system fires since the last button reset.
- An emissions indicator. The emissions indicator will illuminate when the system is set to READY, and the footswitch is depressed.
- A Back button, which returns the display to the Selection Display screen.



OPS600 screen

(In LP560 Mode)

- A shot counter display including a shot counter reset button. The system will record the total number of LP560 shots that the system fires since the last button reset.
- An emissions indicator. The emissions indicator will illuminate when the system is set to READY, and the footswitch is depressed.
- A Back button, which returns the display to the Selection Display screen.



LP560 screen

User Selectable Parameters

Fluence

In the pulsed lasers and light sources available from Cutera, fluence affects the nature of the laser-tissue interaction. Fluence is defined as energy per unit area and is measured in Joules per square centimeter (J/cm^2).

Pulse Width

The CoolGlide Xeo and the Genesis *Plus* systems have sufficient laser peak power to allow for a wide range of pulse width and fluence combinations. This capability enables users to select optimal tissue interaction parameters. Even very small target tissues may be targeted with sufficient fluence, at appropriately small pulse widths, to achieve photoselective thermolysis effects. Pulse width information using the OPS600 and the LP560 handpieces are later addressed in the *Maintenance* and the *Clinical Application* sections of this manual.

Repetition Rate

The system repetition rate control allows you to specify the speed at which you work. Repetition rate refers to the number of fluence pulses delivered per second.

1064 nm Nd:YAG Mode

The 1064 nm Nd:YAG mode can be selected in the following ways:

- Select the ClearView Nd:YAG handpiece on the touchscreen display when prompted during the initial system turn-on or when the back button (at the top left-hand corner of the touchscreen display) is pressed.

The 1064 nm Nd:YAG mode settings are Fluence (J/cm^2), Pulse-Width (msec) and Repetition Rate (Hz). Each of these settings will be described later in this section.

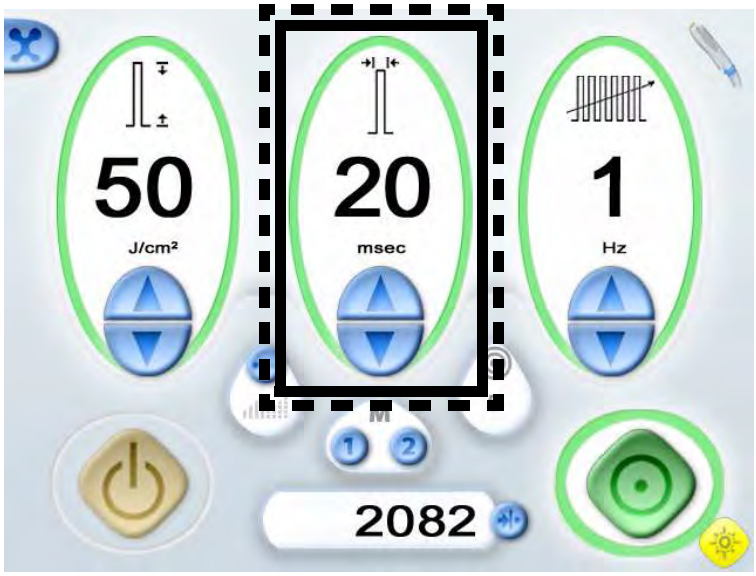
Set the Pulse Width

To set the pulse width:

1. Push the pulse width UP/DN buttons; the pulse width UP/DN buttons appear below the “msec” display.

2. Select the desired pulse width by pushing the UP/DN buttons

.



Pulse width UP/DN buttons

Set the Pulse Width

Set the Fluence

Push the fluence UP/DN buttons; Select the desired fluence buttons by pushing the UP/DN buttons below the J/cm^2 display.

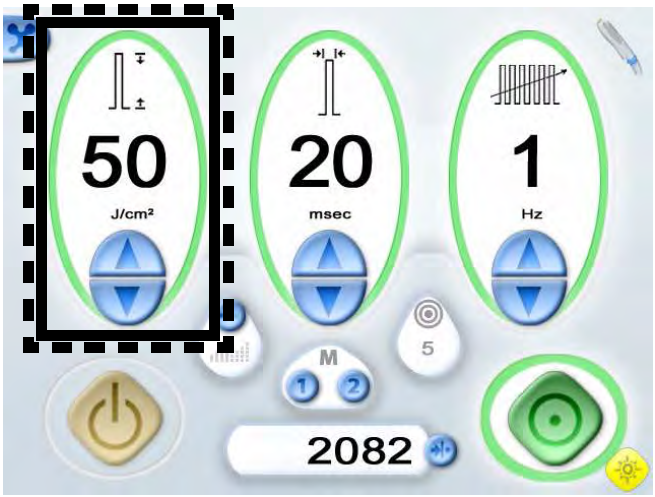
NOTE

Some fluence settings may not be available at higher repetition rate settings. If you attempt to select a fluence that is unavailable at the existing repetition rate setting, the system will emit an audible tone (distinct from the tone heard when treatment selections are made), indicating that the selection is not available. Reducing the repetition rate may increase the amount of available fluence.

CAUTION

The fluence shown on the fluence display indicates the fluence delivered to the tissue.

Fluence UP/DN buttons



Set the Fluence

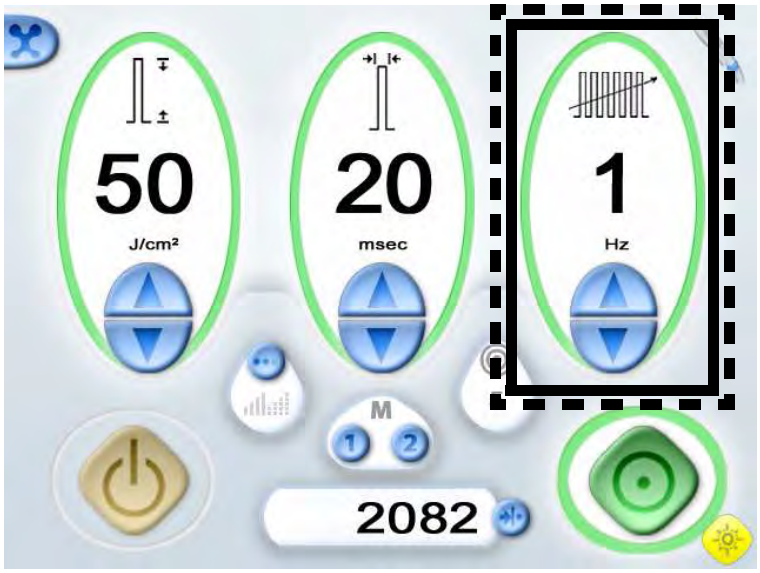
Set the Repetition Rate

To set the repetition rate:

1. Push the repetition rate UP/DN buttons. The repetition rate UP/DN buttons appear below the Hz display.

NOTE

Not all rates are available at all fluence levels. If a pulse rate is not available at a selected fluence level, the system will sound an audible tone to alert you that the value is not available. To achieve a higher rate, you will need to lower the fluence setting.



Set the Repetition Rate

Repetition rate UP/DN buttons

OPS600 Mode

The OPS600 mode can be entered in the following ways:

- Select the OPS600 handpiece on the touchscreen display when prompted after the initial turn-on and self-test of the system.
- Be sure the ClearView 1064 nm Nd:YAG handpiece is placed on the resting tree, removing the OPS600 handpiece from the resting tree and selecting the OPS600 handpiece icon on the touchscreen.
- Selecting the “X” icon at the top left-hand corner of the touchscreen display and selecting the OPS600 handpiece on the display. Be sure the ClearView 1064 nm Nd:YAG handpiece is parked in the proper position on the resting tree.

The OPS600 mode settings are Fluence (J/cm^2) and Rate (Hz), as described in the following topics.

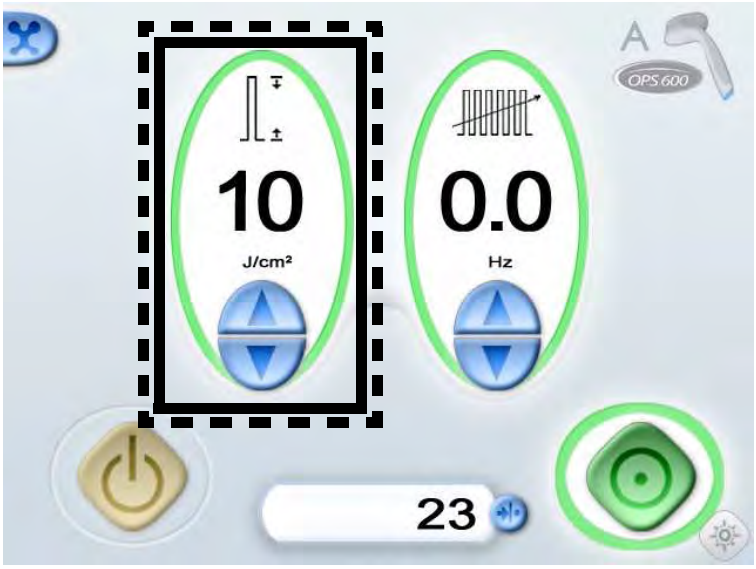
Set the Fluence

Select the desired fluence by pushing the UP/DN buttons located below the J/cm^2 display.

NOTE

Some fluence settings may not be available at higher repetition rate settings. If you attempt to select a fluence that is unavailable at the selected repetition rate setting, the system will emit an audible tone indicating that the selection is not available. Reducing the repetition rate may increase the amount of available fluence.

Fluence UP/DN Buttons



Set the Fluence in OPS600 Mode

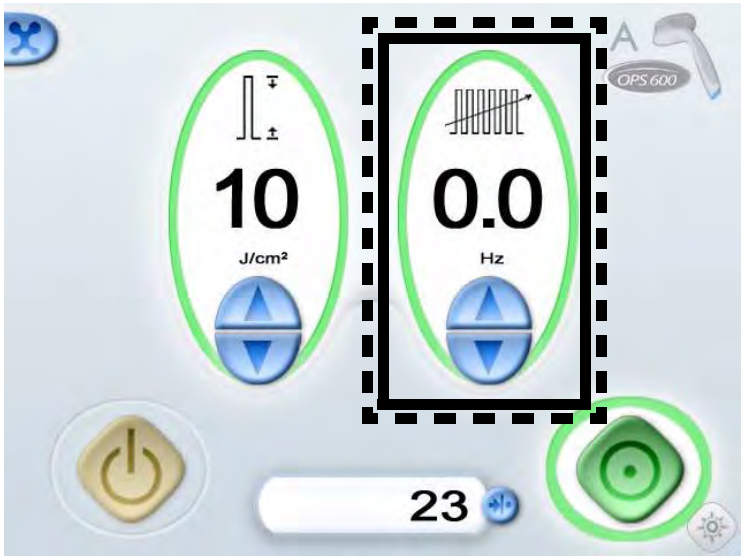
Set the Repetition Rate

NOTE

Not all rates are available at all fluence levels. If a pulse rate is not available at a selected fluence level, the system will sound an audible tone to alert you that the value is not available. To achieve a higher rate, you will need to reduce the fluence setting.

To set the repetition rate:

1. Push the repetition rate UP/DN buttons; the repetition rate UP/DN buttons appear below the Hz display.



OPS600 repetition rate UP/DN buttons

Set the OPS600 Repetition Rate

LP560 Mode

The LP560 mode can be entered in the following ways:

- Select the LP560 handpiece on the touchscreen display when prompted after the initial turn-on and self-test of the system.
- Be sure the ClearView 1064 nm Nd:YAG handpiece is placed on the resting tree, removing the LP560 handpiece from the resting tree and selecting the LP560 handpiece icon on the touchscreen.
- Selecting the “X” icon at the top left-hand corner of the touchscreen display and selecting the LP560 handpiece on the display. Be sure the ClearView 1064 nm Nd:YAG handpiece is parked in the proper position on the resting tree.

The LP560 mode settings are Fluence (J/cm^2) and Rate (Hz), as described in the following topics.

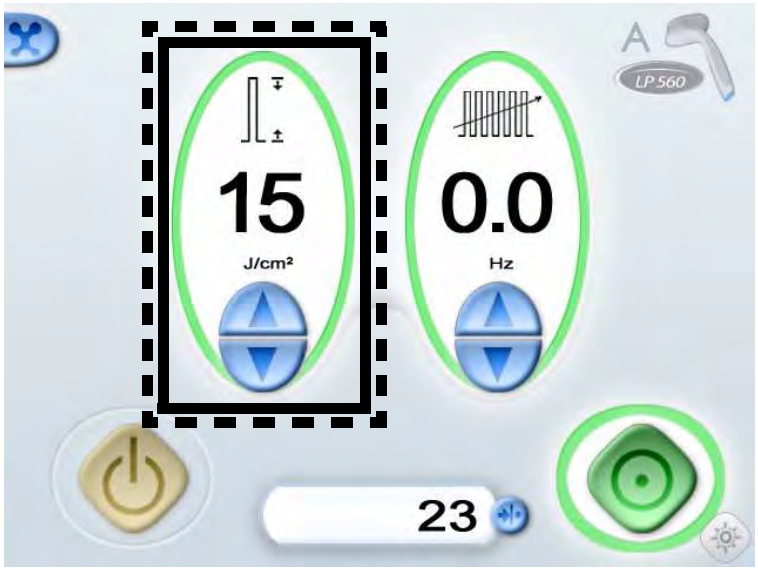
Set the Fluence

Select the desired fluence by pushing the UP/DN buttons located below the J/cm^2 display.

NOTE

Some fluence settings may not be available at higher repetition rate settings. If you attempt to select a fluence that is unavailable at the selected repetition rate setting, the system will emit an audible tone indicating that the selection is not available. Reducing the repetition rate may increase the amount of available fluence.

Fluence UP/DN buttons



Set the Fluence in LP560 Mode

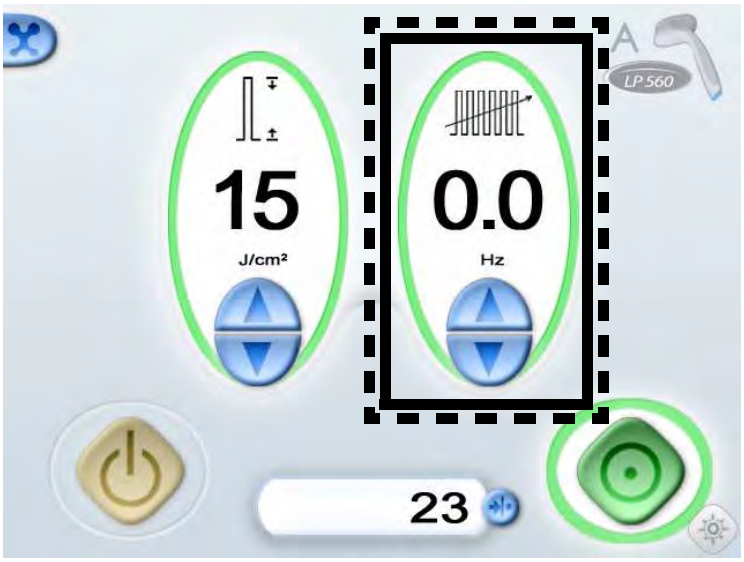
Set the Repetition Rate

NOTE

Not all rates are available at all fluence levels. If a pulse rate is not available at a selected fluence level, the system will sound an audible tone to alert you that the value is not available. To achieve a higher rate, you will need to reduce the fluence setting.

To set the repetition rate:

1. Push the repetition rate UP/DN buttons; the repetition rate UP/DN buttons appear below the Hz display.



LP560 repetition rate UP/DN buttons

Set the LP560 Repetition Rate

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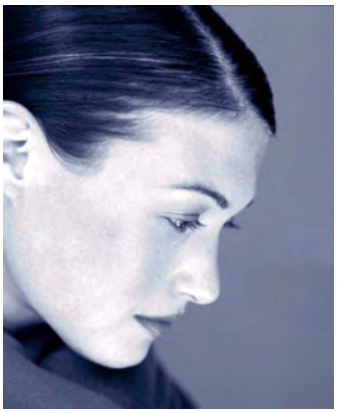


Maintenance

Troubleshooting Guide

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

1. Electrical power source...verify that the electrical disconnect switch (the circuit breaker) is turned on (in the UP position).

2. System console electrical...verify that the system is on and properly connected to an electrical service outlet.

3. OPS600 or LP560 handpiece connection...verify that the handpiece is properly connected and seated properly on the leftside of the Handpiece Resting Tree. If unsure, turn off the system, disconnect and reconnect the handpiece umbilical, listening for two clicks.

NOTE

When removing the OPS600 or the LP560 handpiece, It is important to turn the system OFF and let the system rest for approximately 30 seconds before removing the OPS600 or the LP560 handpiece, otherwise damage to the system will occur. When removing the handpiece be sure to press the two buttons before removing.

4. Remote Interlock...if the Remote Interlock plug is used in conjunction with a door switch, verify that the Remote Interlock plug is inserted in the Remote Interlock receptacle. Close the interlock door.

System does not turn on. The touchscreen does not illuminate.

Probable Cause: The system is not plugged in.
Suggestion: Place the system main power circuit breaker in the OFF (down)
position, insert the system electrical power cord plug into the appropriate outlet, and place the system main power circuit breaker in the ON (up) position. Turn the keyswitch to the START position.

Probable Cause: The building power (main electrical service) is turned off.
Suggestion: Turn on the building power or reset the room circuit breaker.

Probable Cause: The system main power circuit breaker is in the OFF (down) position.
Suggestion: Place the system main power circuit breaker in the ON (up) position.

Probable Cause: The electrical outlet is defective.
Suggestion: Use another outlet or have the outlet professionally tested and, if appropriate, repaired.

1064 nm Nd:YAG treatment beam is not present, although aiming beam operates properly.

Probable Cause: There is an internal laser system failure.
Suggestion: Contact your local Cutera service representative.

1064 nm Nd:YAG treatment and aiming beams are not present. Touchscreen displays and indicators are normal.

Probable Cause: The system is in STANDBY mode.
Suggestion: Place the system in READY mode.

Probable Cause: There is an internal laser system failure.
Suggestion: Contact your local Cutera service representative.

Inadequate or no aiming beam.

Probable Cause: The aiming beam is either set to “OFF” or at a low setting.

Suggestion: Go to READY mode and adjust the aiming beam intensity

on the 1064 nm Nd:YAG control screen. If adjusting the aiming beam does not resolve the problem, contact your local Cutera service representative.

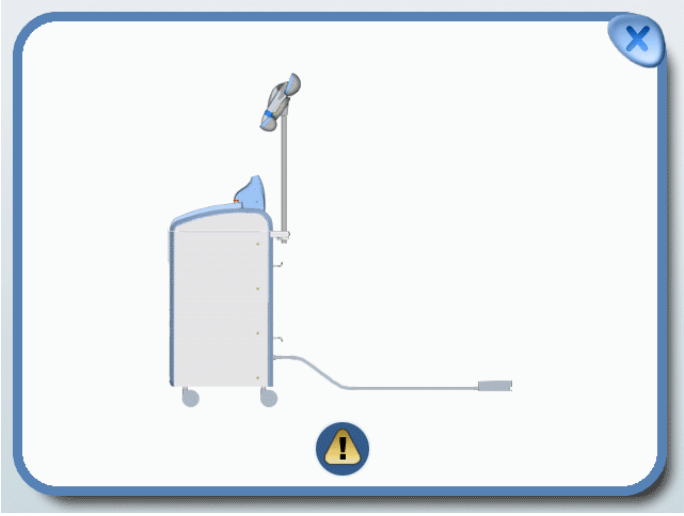
“Connect Footswitch” advisory pop-up screen appears on the touch screen with its corresponding error code(s).

Probable Cause: The footswitch is not properly connected to the console.

Suggestion: Ensure that the footswitch is properly connected to the console.

NOTE

Press the “X” in the upper right-hand corner of the pop-screen to clear the advisory message.



System displays E224 during the procedure in the 1064 nm Nd:YAG mode.

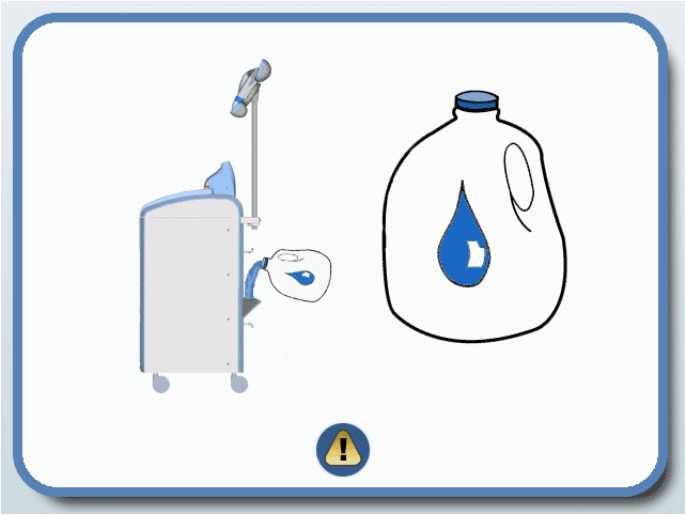
Probable Cause:	Handpiece cooling tip is above the preset temperature.
Suggestion:	Do not use a thick layer of gel as this increases the cooling requirement.
	Ensure that the heat exchanger on the bottom of the system is free of dust and debris. See the *Routine User Maintenance* topic.
	Ensure that the room temperature is below 27° C.

System shuts down during operation with no touchscreen display.

Probable Cause:	The building power (main electrical service) has been interrupted.
Suggestion:	Verify and/or turn on the building power.
Probable Cause:	The system main power circuit breaker has tripped.
Suggestion:	Place the system main power circuit breaker in the UP position.
Probable Cause:	Remote interlock is in use and the treatment room door has been opened.
Suggestion:	Close the treatment room door and restart the system.

"Water Low" advisory pop-up screen appears on the touch screen.

Probable Cause:	The system is low on water.
Suggestion:	Turn off the system, and add water as instructed in the *Routine User Maintenance* topic. Restart the system to continue with treatments.



A continuous audible tone is heard and the system cannot be placed into READY.

Probable Cause:	The spot size selection ring on the ClearView handpiece is between the selectable spot size positions.
Suggestion:	Move the spot size selection ring to the appropriate spot size position.

Low or no energy output (patient reports no sensation) for all handpieces.

Probable Cause:	Window is dirty or damaged on the ClearView 1064 nm Nd:YAG handpiece.
Suggestion:	Confirm that laser energy is not being emitted on the test area, such as on an arm. Check to see if the aiming beam is present. Clean or replace the window as described in this manual. If the problem is not resolved, call your local Cutera service representative.
Probable Cause:	Window may be damaged on the OPS600 or the LP560 handpiece.
Suggestion:	Detach and replace the OPS600 or the LP560 handpiece.

Error Code Guide

The Xeo series of systems utilize state-of-the-art, self-diagnostic software. In anticipation of or as a result of a system problem, an Error Code will appear in an advisory pop-up screen on the touchscreen display. Some of these codes serve as a warning and many are clearable by simply pressing the "***X***" in the advisory pop-up window, which is located at the top right hand corner of the touchscreen display. Some conditions require service by an authorized Cutera Service Representative.

Below is a brief explanation of some of the codes which may be seen in the advisory pop-up screen. If you have any questions about this information or the operation and service of your system, please contact your local Cutera representative *(refer to Appendix D)*.

Error Code Series/Description
Series 100 Codes - Series 100 Codes appear as a warning and typically will not hinder treatment(s). Most Series 100 Codes are clearable by resuming treatment or by pressing the "***X***" in the advisory pop-up screen on the touchscreen display. If after pressing the "***X***", the code does not clear, power off and re-start the system.
Series 200 Codes - Series 200 codes are "user clearable" faults and must be cleared in order to resume treatment(s). To clear, press the "***X***" in the advisory pop-up screen in the touchscreen display. If after pressing the "***X***", the code does not clear, power off and re-start the system.
Series 300 Codes - Series 300 codes indicate a "permanent fault" and the system must be powered off and re-started in order to clear the code. If this action fails to clear the code, contact your local Cutera representative to schedule an appointment.

* Contact your local Cutera representative if additional alert codes appear.

If any error codes or symptoms occur that are not addressed in the troubleshooting guide or if the suggested solutions do not resolve the problem, contact your local Cutera representative *(see Appendix D)*.

Annual System Maintenance

Preventive maintenance, safety, power, and calibration checks should be performed annually by a Cutera representative to ensure proper laser and pulsed-light performance.

System Repair

All CoolGlide Xeo, Xeo *SA* or Genesis *Plus* repairs should be performed by a Cutera-Certified service engineer. For training and information, contact your local Cutera representative.

Routine User Maintenance

Clean the external surfaces of the system console	Weekly, or as needed
Clean the system touchscreen display	Weekly, or as needed
Inspect and clean the heat exchanger intake	Inspect weekly; clean monthly, or as needed
Fill the coolant reservoir	On installation or if water evaporates
Clean the ClearView 1064 nm Nd:YAG handpiece	Between each patient use or every 100 shots
Clean the OPS600/LP560 handpiece	Between each patient use or every 100 shots

Clean the External Surfaces of the System Console

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

WARNING

Do not attempt to gain access to any internal components. Electrical shock and/or unintended laser exposure may result. Do not spray or pour cleaning agents directly on the system console.

Clean the System Touchscreen Display

Apply an alcohol-based cleaner to a soft cloth to clean the system touchscreen display.

CAUTION

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

Inspect and Clean the Heat Exchanger Intake

The heat exchanger intake, located on the bottom of the system console, should be kept free of dust and lint accumulation. If the heat exchanger intake becomes clogged, the system will overheat prematurely, resulting in a temperature-related error code (i.e., E221, E224, or E229).

Inspect and clean the heat exchanger regularly using a hand mirror and long-handled bath brush as described below.

1. Using a hand mirror, inspect the bottom of the system console for dust or lint accumulation.

2. Clean the heat exchanger intake by inserting a long-handled bath brush under either side of the system console, then pulling the brush toward your body to remove any dust or lint.

3. Repeat on the opposite side of the console to ensure that the entire heat exchanger intake is clean.

Fill the Coolant Reservoir

The system requires clean de-ionized or distilled water. Systems are delivered without any water in them and must be filled with distilled water upon installation. Occasionally, distilled water may need to be added to “top off” the system reservoir.

CAUTION

Permanent damage to internal components will occur *if improper coolant is used.* One gallon of distilled water is shipped with every system. Under no circumstances should ethylene glycol, tap water or any liquid other than de-ionized or distilled water be used.

To completely fill the coolant reservoir in the system:

1. Turn off the system.
2. Remove the reservoir fill cap at the rear of the system.
3. Add water to the reservoir. Use only clean, unused distilled/de-ionized water provided. Carefully fill the reservoir. Do not overfill.
4. After the reservoir is full, turn the system keyswitch to the START position and release to the ON position.

   This engages the water pump, allowing the coolant to be drawn into the cooling system. Allow the system to run for 5 to 10 seconds.
5. Turn the keyswitch to the OFF position.
6. Top off the reservoir carefully.
7. Repeat steps 4 thru 6 until the reservoir is full.

NOTE

The coolant capacity of the system is approximately one half gallon.

8. Replace the fill cap.

CAUTION

Ensure that the fill cap has a small hole to vent the system. A similar fill cap without a vent hole is used to transport the system.

Clean the ClearView 1064 nm Nd:YAG Handpiece

Clean the Handpiece Window

The recessed handpiece window is located at the distal end of the handpiece. Inspect the window for debris prior to each treatment as well as periodically during treatment. In both cases, ensure that the system is OFF or in the STANDBY mode prior to inspection.

WARNING

The system must be turned OFF or in the STANDBY mode prior to inspecting the window. Do not inspect the window while the system is in READY mode. Always wear proper eyewear while the system is ON. Severe eye damage can occur in the event of unintended laser emission.

CAUTION

If the window is not properly maintained, debris can build up on the window surface, which will lead to permanent damage to the window and ultimately permanent damage to the handpiece optical system.

NOTE

Debris and ejected hair from patients can accumulate on the window. It may be necessary to clean the window periodically during treatment.

Clean the handpiece window using a clean wood stick cotton swab and lens cleaning grade acetone, as described below.

NOTE

For optimal results, use acetone with 0.5% or lower water content, which is available at most camera shops. If unable to obtain acetone with 0.5% or lower water content, contact your local Cutera representative *(see Appendix D)*.

NOTE

Use only wood stick cotton swabs. Do not use products such as Q-Tips as they contain an adhesive that dissolves when it comes in contact with acetone.

1. Ensure that the system is turned OFF or is in STANDBY mode.

2. Place a small amount of acetone on a wood stick cotton swab; if necessary, shake the excess acetone off of the tip prior to cleaning the handpiece window.

3. Gently wipe the surface of the window. Refer to the picture below.

Use a small amount of acetone and a wood stick cotton swab to clean the window.

4. Inspect the window. If necessary, clean the window again with a new cotton swab.

NOTE

The window must be clean before treating a patient. A cloudy appearance is acceptable. Chips, pits, cracks or burned spots on the window are not acceptable, and a window with these types of defects must be replaced. If debris cannot be cleaned off the window, the window must be replaced.

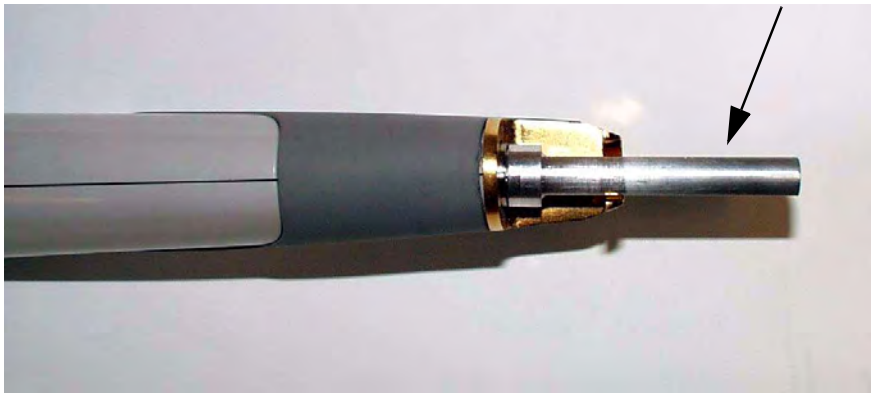
Replace the Handpiece Window

If the handpiece window is damaged or if debris cannot be cleaned off the window, replace the window as described below.

1. Ensure that the system keyswitch is in the OFF position.

2. Point the handpiece down towards the floor, and insert the window removal tool into the handpiece aperture. Refer to the picture below.

Window Removal Tool



3. Gently unscrew the old window and replace with a new window. Ensure that the handpiece is pointed down towards the floor while inserting the new window.

CAUTION

Do not attempt to sterilize the handpiece. Damage will occur if the handpiece is autoclaved, immersed or otherwise handled improperly.

Disinfect the Handpiece Tip

Disinfect the handpiece tip (i.e., cooling surface and treatment guide) between patient use with a germicidal disposable wipe, such as Sani-Cloth® Plus or Sani-Cloth® HB from Professional Disposables International, Inc.[1]

WARNING

Before disinfecting the handpiece tip, ensure that the system is either turned OFF or in the STANDBY mode. Always wear proper protective eyewear while the system is ON. Severe eye damage can occur in the event of unintended laser emission.

Clean the External Surfaces of the Handpiece

Clean the umbilical cable and handpiece housing as needed, using a soft cloth dampened with mild detergent and water.

CAUTION

Do not allow liquid or cleaning solution to enter the handpiece housing as damage may occur.

1. Sani-Cloth Plus and Sani-Cloth HB are registered trademarks of Professional Disposables International, Inc.

Clean the OPS600/LP560 Handpiece

WARNING

Never look into the OPS600 or LP560 handpiece while the system is in READY mode.

CAUTION

Do not attempt to sterilize the handpiece. Damage will occur if the OPS600 or LP560 handpiece is autoclaved, immersed, or otherwise handled improperly.

NOTE

The sapphire window is maintained at 25º C; it will not have the same cold “feel” as the ClearView 1064 nm Nd:YAG handpiece tip.

1. Inspect the sapphire window for debris prior to each treatment, as well as periodically during treatment.

2. Disinfect the sapphire window using a germicidal disposable wipe, such as Sani-Cloth® Plus or Sani-Cloth® HB from Professional Disposables, Inc.

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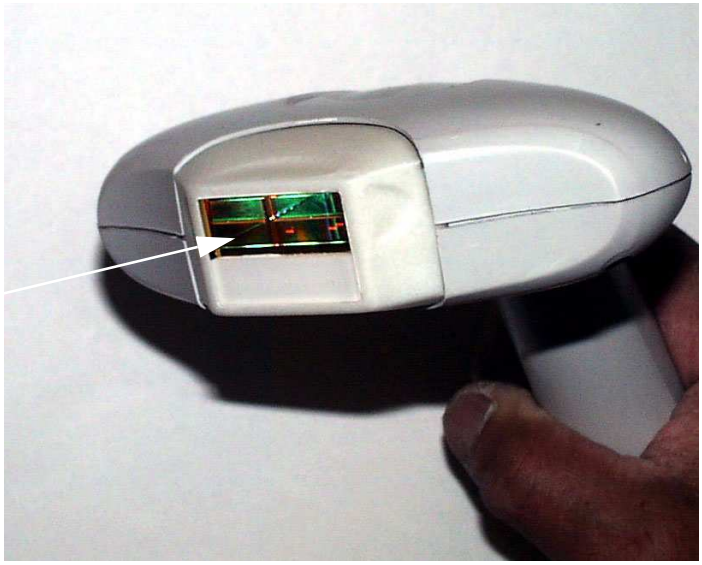
Inspect the sapphire window for debris. Disinfect the window between patient use.



WARNING

Before disinfecting the OPS600 or LP560 handpiece window, ensure that the system is either turned OFF or in the STANDBY mode. Always wear proper protective eye wear while the system is ON. Severe eye damage can occur in the event of unintended pulsed-light emission.

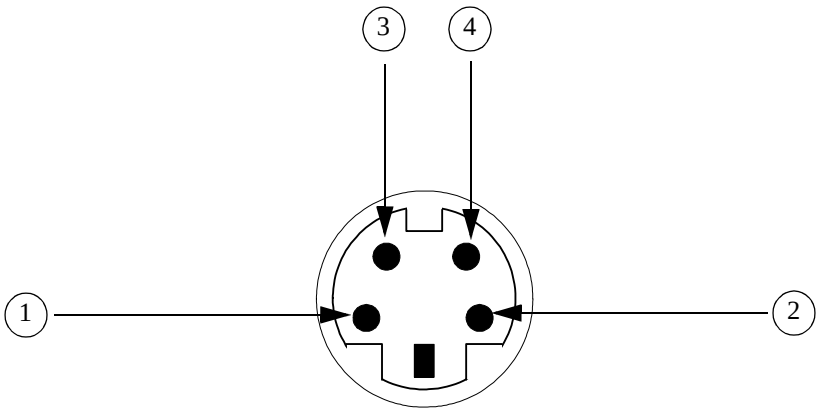
NOTE

If debris cannot be removed after repeated cleaning, disconnect/replace the OPS600 or LP560 handpiece and contact your local Cutera representative.

Remote Interlock Pin Assignments

In order to connect an external door switch to the Remote Interlock plug, the user must purchase a replacement four pin Mini DIN Plug and an external door switch. Connect the external door switch to the pin assignment found in the table below.

Pin	Signal Name	Signal Description
1	Return	Connect to switch common
2	Remote Interlock	Connect to Switch, Normally Open
3	None	No Connection
4	None	No Connection



Remote Interlock pin assignments (mating face shown)

Electrical Utilities

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

Systems Designed for Use Outside of Europe

The 120 VAC configurations must be supplied from a dedicated 120±10% VAC, single-phase, 50/60 Hertz source. The wiring should be rated for 20 amps (as per local codes) “Hospital Grade” (NEMA L-20P or NEMA L-30P). The system can be installed with a removable or lockable wall plug. The 120 VAC configuration may be changed to a 220 VAC configuration. This internal change must be made by a Cutera-certified service representative. Call your Cutera representative for information.

The 220 VAC configuration must be supplied from a dedicated 220±10% VAC, single-phase, 50/60 Hertz source. The wiring should be rated for 16/20 Amps (as per local codes) “Hospital Grade” (NEMA L6-20P or NEMA L6-30P). The system can be installed with a lockable wall plug. Such a connection will ensure compliance with allowable leakage current levels per UL2601 for this device. Leakage current for these systems does not exceed 500 µA.

Systems Designed for Use in European Communities Under MDD

In order to comply with the European Communities Medical Devices Directive 93/42/EEC and harmonized standard EN 60601-2-22, the 220 VAC configured Xeo series of systems must be either permanently connected to a 16A, 220 VAC 50 Hz supply mains in accordance with national wiring regulations, or connected by means of a dedicated single phase, 16A, 220V wall socket and lockable plug combination designed to ensure that the connection is “mechanically secured against accidental loosening”. Such a connection will ensure compliance with allowable leakage current levels per IEC 601 for this device. Leakage current for these systems does not exceed 500 µA.

Removable or Lockable Wall Socket and Plug Configurations

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

Systems Designed for Use in European Communities Under MDD

To comply with the European Communities Medical Devices Directive 93/94/EEC, the 16A, 250V wall socket and lockable plug combination must comply with EN 60309 (=IEC 309).

The wall socket and plug combination must meet the following specifications:

Plug:	MK LN 9024, 16A 220V, IP67, IEC 309
Wall Socket:	MK LN 9324, 16A 220V, IP67, IEC 309

System Specifications

Specifications subject to change without notice.

Treatment Beam

	Laser	***Pulsed-Light***
Type	High Power, Long Pulse Nd:YAG	Pulsed-Light Flashlamp
Wavelength	1064 nm (Nd:YAG)	600 - 850 nm (OPS600) 560 - 1200 nm (LP560)
Output	≤150 J Max.	≤150 J Max.
Fluence	1064 nm Nd:YAG: 3 to 300 J/cm^2	OPS600: 3 to 20 J/cm^2 LPS560: 10 to 40 J/cm^2
Pulse Duration	CoolGlide Xeo: 0.1 to 300 ms Genesis *Plus*: 0.1 to 30 ms	OPS600: Automatic LP560: Automatic
Repetition Rate	CoolGlide Xeo: Single shot to 10 Hz Genesis Plus: Single shot to 10 Hz	OPS600: Single shot to 1.0 Hz LP560: Single shot to 1.0 Hz
Delivery System	Permanently attached umbilical and handpiece	OPS600: User detachable umbilical cable and handpiece LP560: User detachable umbilical cable and handpiece
Treatment Spot	3.25, 5, 7, 10 mm circular spot	OPS600: 10 mm x 30 mm rectangle LP560: 10 mm x 30 mm rectangle
Epidermal Cooling	Contact pre-cooling and/or post cooling provided by chilled contact surface.	OPS600: Sapphire window is maintained at temperature to prevent window overheating LP560: Sapphire window is maintained at temperature to prevent window overheating
System Cooling	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger
Aiming Beam	615 nm	OPS600: None LP560: None

Physical Parameters

Size (W X D X H):	13 in. X. 18 in. X. 38 in. (.33 m x .46 m x .96 m)	
Weight:	140 lbs. (63.5 kg.) CoolGlide Xeo, Genesis *Plus* 110 lbs. (49.9 kg.) Xeo *SA*	
Operating length of umbilical:	6.5 ft. (2 m)	
Minimum bend radius of umbilical:	Storage Momentary	5 in. (126 mm) 2 in (50 mm)

Electrical Requirements

Voltage, Current	*(U.S.)*	100 - 120 VAC/20A 200 - 240 VAC/20A
	(International)	100 - 120 VAC/20A 200 - 240 VAC/16A
Frequency	50/60 Hz	

Environmental Requirements

Temperature	Operating Storage	5º C to 30º C -10º C to 50º C, coolant drained
Humidity	0 to 90%, non-condensing	
Max. Heat Dissipation	CoolGlide Xeo: 4,000 Watts Genesis *Plus*: 1200 Watts Xeo *SA*: 1200 Watts	
Max. Altitude	Operating Non-operating	15,000 ft. 50,000 ft.

Classifications

FDA Classification	Class II Medical Device
CDRH Classification	Class IV Laser Product
European MDD 93/42/EEC Laser Classification	Class 4 Laser to IEC 60825:2007

Eye Safety

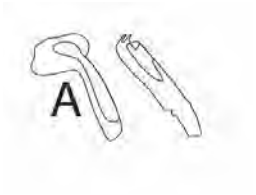
Nd:YAG Laser

Nominal Ocular Hazard Distance	81 m at 1064 nm
Minimum Optical Density for Protective Eyewear	≥6.1 at 1064 nm
Maximum Permissible Exposure	$2.69* 10^{-4}$ W/cm^2 at 1064 nm

OPS600/LP560

Recommended broadband protection Filter Factor* of 3 or greater.

For the OPS600 and LP560 Handpiece, Cutera safety glasses marked with the following icons should be used.



NOTE

One pair of goggles will satisfy both the laser and pulsed-light applications.

* Filter Factor defined for luminous transmittance in ANSI Z87.1-1989 (R-1998), Table 1.

The CoolGlide Xeo, Xeo *SA* and Genesis *Plus* systems are designed to comply with the following:

- US Federal Performance Standards 21 CFR 1040.10 and 1040.11 for Class IV Laser Products and IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-22, IEC 60825.
- European Communities Medical Devices Directive 93/42/EEC.

Calibration Procedure

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

Calibration of the laser output and the OPS600/LP560 light output should be checked periodically. With proper care under normal operating conditions, Cutera recommends calibration every twelve (12) months to ensure that the energy output delivered from the handpiece(s) corresponds accurately to the user-selected settings. The following procedure should also be performed after any service or repair work. Excessive vibration may necessitate more frequent calibration.

DISCLAIMER WARNING

Calibration is a service procedure to be performed only by a Cutera-certified Service Engineer or customers who have taken and passed a Cutera Service Certification Training course. Adjustments by anyone other than a trained Cutera Service Engineer or a certified customer voids any existing manufacturer's warranty on the instrument. A service manual for the CoolGlide Xeo, Xeo *SA* and Genesis *Plus* may be purchased from the Cutera Service Department, however, possession of service instructions or service tooling does not authorize repair or modification of a Cutera system by uncertified personnel.

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

Equipment Required

- Laser safety eyewear for all persons in the room (with appropriate optical densities at the wavelengths being generated).
- Laser energy meter (Ophir Nova display unit model with L40-150A-SH sensor). The meter used must have received a NIST-traceable calibration within the past 12 months (in the US) or a calibration conforming to the applicable standard (internationally).

Calibration Instructions

(Calibrate the 1064 nm Nd:YAG using ClearView Handpiece)

1. Set up the laser energy meter in a convenient location so that the sensor head can be easily reached with the ClearView handpiece. Set the meter display unit to the ENERGY mode.

2. Ensure that all personnel in the room are wearing the appropriate eyewear.

3. Connect the service computer to the serial port.

4. Start the system in service mode and using the Cutera Service software, place the system in CALIBRATION mode.

5. Follow the prompts on the calibration screen.

6. Place the system in User mode and verify the calibration using an external meter.

(Calibrate the OPS600 Handpiece)

1. Set up the laser energy meter at a convenient location so that the sensor head can be easily reached with the OPS600 handpiece.

2. Set the meter display unit to the Energy Mode.

3. Place the OPS600 handpiece tip in front of the energy meter sensor head.

NOTE

The distance must be no further than 2mm from the energy meter sensor to the sapphire window. The surface of the sapphire window must be oriented in parallel to the meter sensor surface.

CAUTION

Ensure all personnel in the room are wearing the appropriate protective eyewear.

4. Start the system in service mode and, using the Cutera service software, place the system in the Calibration mode.

5. Follow the prompts on the calibration screen.

6. Place the system in User mode and verify the calibration using the external meter.

CAUTION

Any work performed by unauthorized personnel will void all warranties.

(Calibrate the LP560 Handpiece)

1. Set up the laser energy meter at a convenient location so that the sensor head can be easily reached with the LP560 handpiece.

2. Set the meter display unit to the Energy Mode.

3. Place the LP560 handpiece tip in front of the energy meter sensor head.

NOTE

The distance must be no further than 2mm from the energy meter sensor to the sapphire window. The surface of the sapphire window must be oriented in parallel to the meter sensor surface.

CAUTION

Ensure all personnel in the room are wearing the appropriate protective eyewear.

4. Start the system in service mode and, using the Cutera service software, place the system in the Calibration mode.

5. Follow the prompts on the calibration screen.

6. Place the system in User mode and verify the calibration using the external meter.

CAUTION

Any work performed by unauthorized personnel will void all warranties.

Warranty Information

For specific and detailed warranty information for the CoolGlide Xeo, Xeo *SA*, or Genesis *Plus* system, please refer to the first page of your purchase "Agreement" and the last page of the "Terms and Conditions of Sale".

End of Life Disposal - Environmental Information

The Xeo series of systems must be disposed of according to local laws and hospital practices. This product is considered electronic equipment and must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

Proper disposal of electronic equipment is required according to EU Directive 2002/96/EC Waste Electrical and Electronic Equipment (WEEE).

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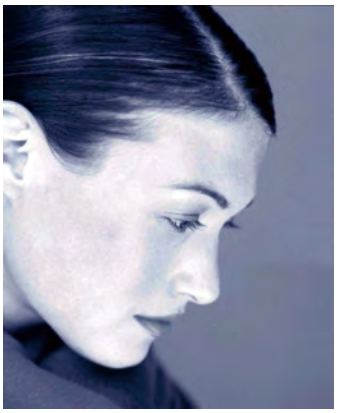

Safety and Regulatory

Introduction

Cutera's Xeo series of systems, when properly used by trained personnel, are safe and effective instruments for indicated clinical treatments. Keep in mind that safe operation requires a thorough understanding of the system and safety features as described in this Operator Manual.

Users must take precautions to prevent exposure of Nd:YAG, OPS600 or LP560 light energy to the eyes and skin from either direct or diffusely reflected light, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Cutera does not make recommendations regarding the practice of medicine. 1064 nm Nd:YAG, OPS600 and/or LP560 treatment parameters are provided as a guide. Individual treatments should be based on clinical training, clinical observation of laser tissue and/or pulsed-light interaction, and appropriate clinical endpoints.

Optical Hazard

1064 nm Nd:YAG, OPS600 and/or LP560 safety eyewear is routinely required with most lasers and/or pulsed-light systems. Personnel responsible for laser safety should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser or pulsed-light emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.3-2005, ANSI Z136.1-2007, or European Standard EN 60825:2007, Appendix A.

The Xeo series of systems are Class IV Laser Products as defined by the U.S. Code of Federal Regulations and Class 4 Laser Products as defined by the European Communities Medical Devices Directive.

WARNING

The laser light produced by these systems are an invisible infrared (1064nm) light that can cause permanent eye damage. The pulsed-light produced by these systems contain visible and invisible (600 - 850 nm and 560 - 1200 nm) light that can also cause permanent eye damage. Never look directly into the handpiece(s) even when wearing protective eyewear. Never look directly into the laser beam or at the pulsed-light or at scattered light from metallic or other reflective surfaces. Both direct and reflected laser or pulsed-light may contain sufficient energy to cause permanent eye damage.

All personnel operating the CoolGlide Xeo, Xeo *SA* or the Genesis *Plus* system or in the vicinity of the system, including the patient, staff personnel and observers, should wear protective eyewear with sufficient protection (optical density or shade factor specified or greater in *System Specifications*) for the appropriate wavelength range for each handpiece. The eyewear should have guards on both sides to protect the eyes from lateral exposure.

Guidelines and information on the safe use of lasers, and the safe use of lasers/laser systems in diagnostic and therapeutic areas, can be found in the following:

- *The American National Standard for the Safe Use of lasers in Health Care Facilities (ANSI Z136.3-2005).*
- *The American National Standard for Safe Use of Lasers (ANSI Z136.1-2007).*
- *European Standard EN 60825:2007, Appendix A.*

The ANSI and the European standards describe the following terms in the description of laser hazards:

- **Maximum Permissible Exposure (MPE)** - The highest level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin.
- **Nominal Ocular Hazard Distance (NOHD)** - The distance along the axis of the unobstructed beam beyond which exposure during normal operation is not expected to exceed the appropriate MPE. This distance is measured from the laser aperture.
- **Nominal Hazard Zone (NHZ)** - The space within which the exposure level during normal operation exceeds the applicable MPE. The outer limit of the NHZ is the NOHD.

For specific values, see **Eye Safety** in the *System Specifications* section of this manual.

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

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

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

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

NOTE

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

Depending on the procedure, the physician must protect the patient's eyes with either laser safety eyewear or with diffuse metal eye shields.

Additional Ocular Protection

WARNING

Never substitute non-laser prescription eyewear for the appropriate laser safety eyewear, as severe damage could occur.

WARNING

Use caution when performing procedures around the eyes. Severe and irreversible eye damage may occur from direct or indirect exposure to treatment beams.

WARNING

Never look directly into any optical lens, optical fiber, handpiece or laser system aperture while the system is energized. Severe eye damage could occur. Turn off the system before inspecting any delivery system or laser component.

Additional Safety Considerations

WARNING

Do not use this system in the presence of flammables or explosives such as anesthetics, alcohol, surgical preparation solutions, and similar substances. An explosion and/or fire could occur.

CAUTION

The Cutera Xeo series, and additional delivery systems are intended solely for licensed practitioners trained in their proper use.

CAUTION

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

Protecting Non-Target Tissues

WARNING

Except during actual treatment, the system must always be in the STANDBY mode. Maintaining the system in the STANDBY mode prevents accidental Nd:YAG, OPS600 or LP560 light exposure if the footswitch is inadvertently pressed.

WARNING

Never place hands or other objects in the path of the laser beam, OPS600 or LP560 beam.

CAUTION

To prevent accidental light energy discharge, always turn off the system before connecting or disconnecting the OPS600 or LP560 handpiece.

Electrical Hazard

- High Voltages are present inside the system. Do not remove the exterior housing.
- Only an authorized Cutera Service Representative should perform the service on the system.
- Do not attempt to perform maintenance other than that which is outlined in this manual.
- Maintenance should only be performed with the system turned off and disconnected from the power source.
- The system is grounded through the grounding conductor in the power cord. Grounding is essential for safe operation.

Fire Hazard

WARNING

Do not use this system in the presence of flammable materials, solutions, or gases or in an oxygen-enriched environment. An explosion and/or fire could occur.

WARNING

The high temperatures produced in normal use of the system may ignite endogenous gases, as well as some materials (e.g., cotton wool when saturated with oxygen). The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the system is used.

Regulatory Compliance

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

CE-Labeled devices comply with all appropriate performance standards as required in Annex II of the European Medical Device Directive MDD 93/42/EEC.

Location of Controls

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

Key Lock Switch

To prevent unauthorized use, the system can only be turned on with the proper key. The key cannot be removed while in the ON (or START) position and the system will only operate with the key in place. When treatments are complete or the system is not is use, always remove and store the key.

Emergency Off Push-Button

The system can be immediately shut down, terminating laser or light energy emission by pushing the red, mushroom-shaped Emergency-Off button that is located in the upper right hand corner of the control panel. Following emergency shutoff, the key-switch must be used to restart the system.

Laser Emission Indicator

When the system is turned on, controls and indicators appear on the touchscreen after a self-test. When the self-test is complete, the system defaults to STANDBY mode and the two handpiece icons appear in the display. The treatment beam can only be delivered when the system is in READY mode and the READY icon is highlighted on the touchscreen display. When the footswitch is pressed and the treatment beam is being delivered, the system will emit an audible tone and the laser emission icon will turn yellow.

Remote Interlock

A Remote Interlock connector on the back panel, when used in conjunction with an external switch connected to the treatment room door, will shut the system down if the treatment room door is opened.

Protective Housing

The Xeo series of systems have a protective housings that prevent unintended human access to laser radiation above Class I limits. The housing must be opened by only Cutera-Certified representative.

NOTE

No section of the protective system housing can be opened without special tools.

Laser Safety Shutter

The laser system contains a “normally closed” safety shutter that prevents laser emission when in the closed position. The shutter is opened only when the system is in the READY mode.

Audible Emission Indicator

Each Nd:YAG laser or pulsed light delivered is accompanied by an audible tone. In addition, when the CoolGlide Xeo, Xeo *SA* or the Genesis *Plus* system is operated at a repetition rate of 4 Hz or greater, a distinctive “water drop” sound is emitted each time the pulse counter reaches a count that ends in “00” in order to indicate the delivery of 100 shot increments.

Manual Reset

If the system shuts down during operation (due to electrical power loss, depression of the EMERGENCY OFF button, or opening of the Door Interlock switch), the system must be manually restarted using the key switch to resume operation. The system internal memory will recall the most recent operating parameters upon restart.

Electronic Fault Detection Circuitry

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

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

Electromagnetic Compatibility

Like other electrical medical equipment, the Xeo series of systems requires special precautions to ensure electromagnetic compatibility (EMC) with other electrical medical devices. To ensure electromagnetic compatibility, the Xeo series of systems must be installed and operated according to the EMC information provided in this manual.

WARNING

Do not use cables or accessories other than those provided with your Xeo system or compatible handpieces, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

WARNING

If the Xeo system is used adjacent to or stacked with other equipment, observe and verify normal operation of the system in the configuration in which it will be used prior to using it in a surgical procedure. Consult the tables below for guidance in placing the Xeo system.

CAUTION

Portable and mobile RF communications equipment may affect the normal function of the Xeo system.

NOTE

The Xeo series of systems complies with IEC 60601-1-2 (Edition 3) requirements for EMC with other devices.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The Xeo series of systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Xeo system should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment: Guidance**
RF emissions CISPR 11	Group 1	Xeo systems use RF energy only for internal function; therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Xeo systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The Xeo series of systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Xeo system 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	Floor 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 ±kV 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 the Xeo system requires continued operation during power mains interruptions, it is recommended that the Xeo system be powered from an uninterruptible 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 characteristics of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic immunity			
The Xeo series of systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Xeo system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 3V/m 80MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Xeo system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = 1.17 P d = 1.17 P 80MHz to 800MHz d = 2.33 P 800MHz to 2.5GHz 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 mobiles 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 Xeo system is used exceeds the applicable RF compliance level above, the Xeo system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Xeo system. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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

The Xeo series of systems is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Xeo system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Xeo 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 = 1.17 P	**80 MHz to 800 MHz** d = 1.17 P	**800 MHz to 2.5 GHz** d= 2.33 P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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

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

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

Operational Training

WARNING

Do not allow untrained or unqualified personnel to use the system at any time.

CAUTION

Federal law restricts the sale of this device to or by the order of a licensed practitioner licensed by the law of the state in which he practices to use or order the use of the device; and the method of its application or use.

Do not attempt to use this system until you have been properly trained on system operation by certified personnel and have read this manual thoroughly.

In addition to laser safety training of personnel, the user should consider adopting a training and safety program as outlined by the latest ANSI Standard Z-136.3, the *American National Standard for the Safe Use of Lasers in Health Care Facilities* or an equivalent European Union standard. The practitioner should also keep current with all relevant medical literature.

Operational Safety

WARNING

Laser plume obscures the operative field and is noxious to those who come in contact with it. The plume presents a possible pollution hazard and should be effectively evacuated.

CAUTION

Prior to each use of the system, inspect all protective eyewear, cables and handpieces for any damage, excessive wear, or crimping that could affect system performance or safe operation.

CAUTION

Do not place any unnecessary stress on the umbilical cable (i.e., by pulling on it, tightly bending it or twisting the handpiece). See *System Specifications* topic for additional information on minimum bend radius.

NOTE

On the ClearView 1064 nm Nd:YAG handpiece, the recessed laser aperture window and pre-cooling tip should be kept clean during and prior to each treatment procedure. See the *Maintenance* section for recommended cleaning and disinfecting procedures.

WARNING

The ClearView 1064 nm Nd:YAG, OPS600 and LP560 handpieces are fragile instruments and are not to be dropped. If it is dropped, you must carefully examine the handpiece(s) for any physical damage(s) prior to use.

CAUTION

Always verify that the treatment parameters are correct before activating the system.

CAUTION

Before placing the system in READY mode, confirm that the laser, OPS600 and/or the LP560 handpiece aperture is safely positioned to prevent unintended treatment exposure.

CAUTION

The system should always be in the STANDBY mode until the handpiece is safely positioned at the area to be treated.

WARNING

Never point the handpiece(s) at reflective objects, such as jewelry or smooth metal surfaces.

WARNING

Never activate the laser or the other light producing handpieces while pointing the handpiece into free space.

WARNING

Do not leave the system in READY mode when not in use. Always place the system in the STANDBY mode or turn the system OFF and remove the key when not performing treatments.

WARNING

Do not leave the system unattended with the key in place.

Location of Regulatory Compliance Labels

As required by national and international regulatory agencies, appropriate regulatory compliance labels have been mounted in specified locations. All treatment room staff should be familiar with the location and meaning of these labels.

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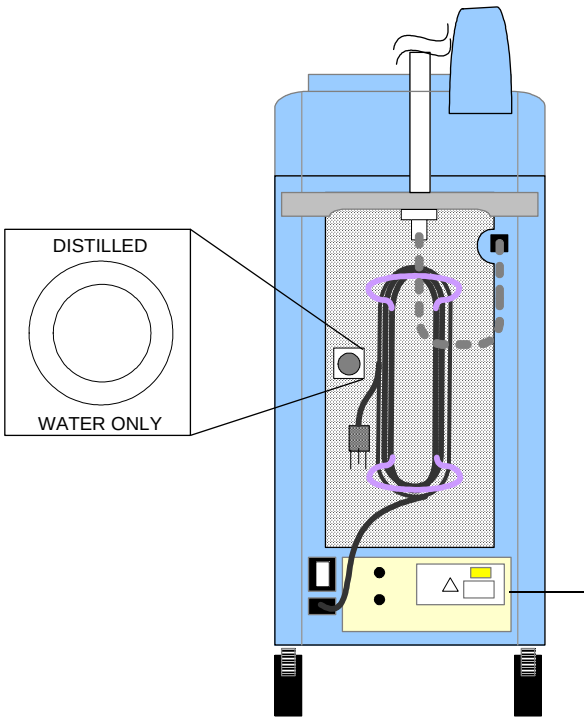
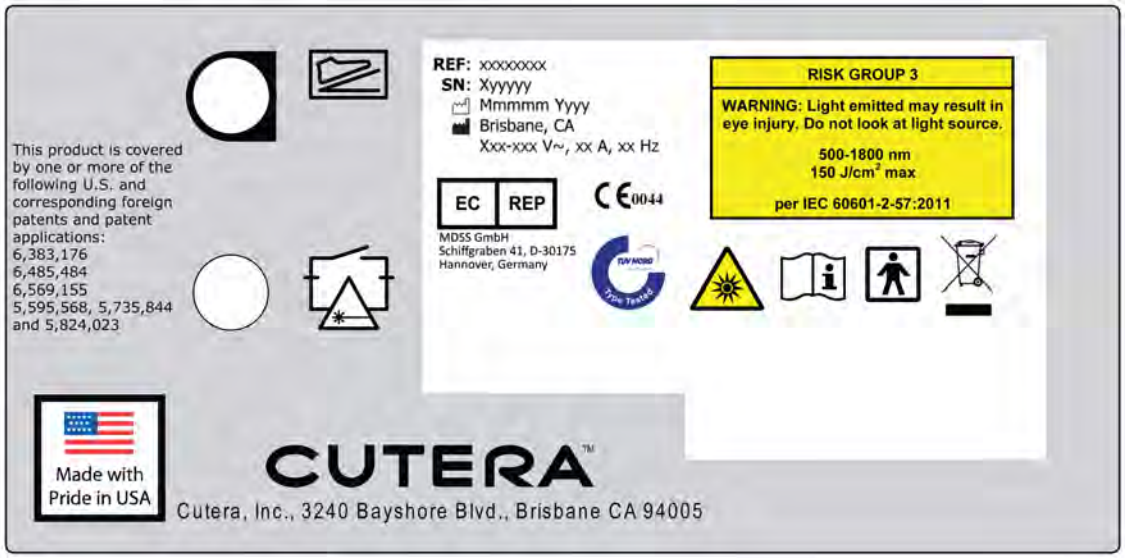


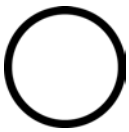
Regulatory compliance labels (Refer to the following page for label illustrations for all models. Refer to Appendix B for symbol descriptions.)

CoolGlide Xeo and Genesis Plus Identification Label



Xeo SA Identification Label

Emergency Stop Button
Located on top of console (next to red button)



System OFF
Located next to keyswitch

Momentary Start
Located next to keyswitch

System ON
Located next to keyswitch

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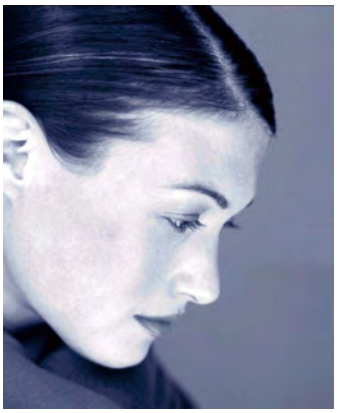

Clinical Applications

General Indications for Use

The Xeo series of systems are intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialties of general and plastic surgery, and dermatology.

1064 nm Nd:YAG Indications

- For removal of unwanted hair.
- For stable long-term, or permanent hair reduction through selective targeting of melanin in hair follicles.
- For treatment of pseudofolliculitis barbae (PFB).
- For use on all skin types (Fitzpatrick I-VI), including tanned skin.
- For coagulation and hemostasis of benign vascular lesions such as, but not limited to, hemangiomas, port wine stains, telangiectasias, rosacea, venous lakes, leg veins, spider veins and poikiloderma of Civatte.
- For treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

- For reduction of red pigmentation in hypertrophic scars where vascularity is an integral part of the scar.
- For treatment of warts.

Pulsed-Light Indications

- For treatment of benign pigmented lesions.

Contraindications for Use

Contraindications for use:

- Pregnant patients
- Patients undergoing treatment for skin cancer

Precautions

- Photosensitizing drugs (Tetracyclines, etc.)

  Be aware that you may have to adjust the treatment parameters according to clinical response from test area(s).

- Anticoagulants

  May increase risk of purpura or bruising

- History of coagulopathies
- History of keloids or hypertrophic scarring
- Diabetes

  May impede wound healing

- History of herpes

  Pre-treatment with an antiviral may be indicated.

- Isotretinoin (Accutane/Roaccutan) use
- History of vitiligo

Expected Transient Events and Possible Adverse Effects

- Erythema, edema and purpura may occur following treatment and typically resolve within one month.
- Hyperpigmentation, hypopigmentation, burns, erosion or blistering may occur, some of which may result in scarring. These complications are usually due to the use of excessive energy levels or lack of proper pre-cooling and/or post-cooling of the treatment area.
- Deep tissue injury and prolonged wound healing may occur when treating warts.

The Xeo series of systems should only be operated by qualified personnel who have received appropriate training. In addition to the information provided in the *Safety and Regulatory* section, the following safety precautions are recommended during use of the CoolGlide Xeo, Xeo *SA* or the Genesis *Plus* systems:

- Guard against accidental exposure to laser or other light energies.
- Instruct all staff members to carefully aim the treatment beam *only* at the targeted treatment areas.
- Ensure that the patient and all staff personnel in the treatment room wear appropriate protective eyewear. If the patient can not wear protective eyewear, be sure to fit the patient with opaque eye protection that will completely block light to the eyes. The eyewear must provide adequate protection from laser radiation of the wavelength being used, the 600 - 850 nm and the 560 - 1200 nm wavelength being used. See *Safety and Regulatory* section for protective eyewear requirements.
- Instruct all staff members and patients to never look directly at the laser light, pulsed-light or reflective surfaces, even when wearing proper protective eyewear.

WARNING

Never allow anyone near the system while the system is in use without proper protective eyewear. Unprotected laser or pulsed-light exposure could cause permanent eye damage.

Treatments

The Xeo series of systems can be used to treat vascular lesions, pigmented lesions, remove hair and perform non-ablative skin therapy by the process of selective photothermolysis.

When treating vascular lesions, the blood temperature at the targeted area is elevated to a level that causes coagulation without damage to the epidermis or surrounding tissue. Since 1064 nm laser energy is absorbed by melanin in the epidermis, as well as the desired target of hemoglobin, the epidermal-cooling feature integrated in the handpiece is used to reduce the temperature rise in the epidermis. Multiple treatments may be necessary to obtain a satisfactory response.

When treating pigmented lesions, the Xeo series of systems specifically targets the superficial pigment in the epidermis. In choosing the wavelength spectrum with strong melanin absorption and low hemoglobin absorption, lower fluences are needed for effective treatment.

When used for hair removal, 1064 nm laser energy is selectively absorbed by melanin in the hair follicle and shaft, resulting in selective destruction of the hair structure without damaging the epidermis or surrounding tissue. Because the laser energy is absorbed by melanin in the epidermis, as well as by the desired target structures, the epidermal-cooling feature integrated in the handpiece is used to reduce the temperature rise in the epidermis.

When used for non-ablative skin therapy, parameters are used that provide dermal heating with preferential heating of very fine vasculature. With the appropriate parameters, this procedure can be performed without epidermal cooling.

The Xeo series of systems give the user the flexibility to adjust key parameters. Pulse width and fluence parameters can be adjusted based on target size, skin type and tan, if present.

The results from prospective, controlled, clinical studies sponsored by Cutera indicate that the 1064 nm treatment parameters of 50 J/cm^2 at 15 ms and 60 J/cm^2 at 30 ms proved safe and effective in achieving stable long-term, or permanent hair reduction through selective targeting of melanin in hair follicles when percent of hair reduction was determined at 6, 9 and 12 months following the second of two treatments performed three months apart. A summary of those results are shown on the following page.

Median Hair Count Reductions After 2 Treatments with 1064nm Laser Energy

Fluence	50 J/cm^2	60 J/cm^2
Pulse Width	15 ms	30 ms
6 Months after 2nd Treatment	54%	47%
9 Months after 2nd Treatment	52%	49%
12 Months after 2nd Treatment	44%	60%

Statistical significance was demonstrated for each of these results. (p-values were computed using the Student's t-test comparing the population of treatment group results to the population of control group results to test if they are significantly different than one another.)

Previous clinical trial results from prospective, controlled, clinical studies sponsored by Cutera have demonstrated that the treatment parameters of 50 J/cm^2 at 15 ms proved safe and effective in achieving hair removal in patients with Fitzpatrick skin types I-V when percent hair reduction was determined at 3 months post treatment. A summary of those results is shown below.

Median Hair Count Reduction after 1 and 2 Treatments with 50 J/cm^2 Fluence and 15 ms Pulse Width

	Hair Count Reduction	Sample Size	p-value*
3 Months after 1st Treatment	24%	41	0.05
3 Months after 2nd Treatment	50%	21	0.0003

*p-values were computed using the Student's t-test comparing the population of treatment group results to the population of control group results to test if they are significantly different than one another.

Multiple treatments may be necessary to achieve the desired level of hair removal. Another fluence and pulse width combination has been tested and showed equivalent safety; however, data from this particular combination did not conclusively demonstrate effectiveness.

It is recommended that the clinical user begin with a low fluence and observe the epidermal response before increasing the fluence. Increasing the fluence may provide increased efficacy, however factors such as skin type and tanning may limit the maximum usable fluence without unwanted epidermal damage.

Treatment Information

1064 nm Laser Treatments

The CoolGlide Xeo and the Genesis *Plus* systems provide a wide range of available pulse durations at the wavelengths of the 1064 nm. This allows the operator to choose the appropriate pulse duration for each treatment consistent with the theory of selective photothermolysis. The following information identifies indications based on the major pulse duration ranges used in treatments.

0.1 millisecond to 1 millisecond

Targeting very small chromophores, such as the papillary dermal plexus and enlarged capillaries.

- Wrinkles
- Diffuse erythema, including erythema from rosacea
- Poikiloderma of Civatte
- Scars

5 milliseconds to 60 milliseconds

Targeting moderate size chromophores, such as hair and discretely visible veins.

- Hair removal, including the treatment of pseudofolliculitis barbae
- Facial telangiectasias and fine leg telangiectasis
- Spider leg veins
- Reticular leg veins
- Venous lakes
- Hemangiomas

OPS600 Treatments

The OPS600 handpiece is indicated for the treatment of benign pigmented lesions. The appropriate fluence is that which results in darkening of the pigmented lesion without affecting the surrounding skin. This is determined and based on test-spot treatments. The pulse duration does not need to be adjusted for these treatments.

LP560 Treatments

The LP560 handpiece is indicated for the treatment of benign pigmented lesions. The appropriate fluence is that which results in darkening of the pigmented lesion without affecting the surrounding skin. This is determined and based on test-spot treatments. The pulse duration does not need to be adjusted for these treatments.

Patient Information

Prior to treatment, the user should conduct a patient consultation. The consultation should include a complete medical history and exam. At that time, the user should also discuss all potential benefits, complications, options and risks of treatment.

Treatment Information for Vascular Lesions, Hair Removal, Non-Ablative and Solar Lentigines Procedures

- For information on operating the Xeo series systems, refer to the *Operation* section.
- For treatment specific guidelines, refer to the Hair Removal Treatment Guidelines, the Vascular Treatment Guidelines, the Non-Ablative Treatment Guidelines and the Solar Lentigines Treatment Guidelines accompanying this manual. These guidelines can also be obtained from your local Cutera representative.

WARNING

Extreme caution should be used when treating near the eyes, taking care to avoid ocular damage from the laser or light energy from the OPS600 or the LP560 handpiece. Patient eye protection appropriate for the treatment should be used. The laser, OPS600, or the LP560 light beam should always be directed away from the eye and only applied to the skin outside of the orbital rim.

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Laser Warning Sign

Nd:YAG Laser Warning Sign for the Xeo Series

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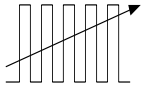
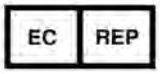
Symbols

This appendix describes the laser system symbols and their meanings.

Symbol	Standard Reference	Description	Location
CUTERA		Cutera logo	Control panel
	417-5007	Mains ON	Rear panel (at circuit breaker) and control panel (next to keyswitch)
	417-5008	Mains OFF	Rear panel (at circuit breaker) and control panel (next to keyswitch)
	417-5104	Momentary start	Control panel (next to keyswitch)
	DIN 18734	Emergency OFF	Control panel (next to red button)
	417-5266	Standby	Touchscreen display
	417-5264	Ready	Touchscreen display
	DIN 18734	Fluence (J/cm^2)	Touchscreen display
	DIN 18734	Exposure duration (ms)	Touchscreen display

Symbol	Standard Reference	Description	Location
	DIN 18734	Repetition rate (Hz)	Touchscreen display
	DIN 18734	Pulse counter reset	Touchscreen display
	Cutera-defined	Laser emission indicator	Touchscreen display
	Cutera-defined	Aiming beam adjustment	Touchscreen display
	Cutera-defined	Footswitch receptacle	Rear panel label
	IEC 60825-1	Remote interlock connector (as defined in 3.67 of IEC 825-1)	Rear panel label
REF	ISO 980	Model number	Rear panel label
SN	ISO 980	Serial number	Rear panel label
	ISO 980	Date of manufacture	Rear panel label
	ISO 980	Manufacturer	Rear panel label

Symbol	Standard Reference	Description	Location
	ISO 980	Authorized representative in the European Community	Rear panel label
	MDD 93/42/EEC	CE Mark	Rear panel label
		TUV Mark	Rear panel label
	ISO 980	Consult accompanying documents	Rear panel label
	WEEE Directive	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.	Rear panel label
	IEC 60601	Type BF equipment	Rear panel label
	IEC 60825-1	Laser radiation warning	Rear panel label (CoolGlide Xeo and Genesis *Plus*)
	IEC 60601-2-57	Optical radiation warning	Rear panel label (Xeo *SA*)

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