



Operator Manual

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©June 2014 Cutera, Inc.

Published in USA

D1313

Revision B



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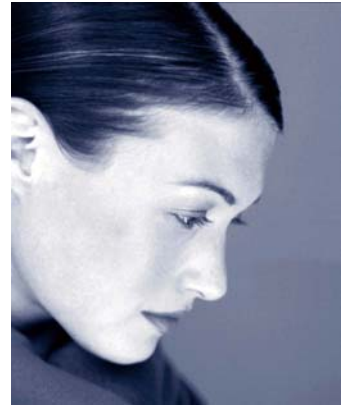
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Operation



Introduction

The Cutera VariLite™ is the most advanced and versatile semiconductor laser system in the market. The VariLite is cleared for a wide variety of indications including the treatment of vascular lesions, leg veins, benign pigmented lesions, cutaneous lesions, hair removal, and moderate inflammatory acne vulgaris.

The VariLite uses semiconductor diode lasers to produce high-energy pulses of 940 nm infrared laser light and to optically pump a solid-state laser, the fundamental wavelength of which is then converted to 532 nm light. The system is truly pulsed, with the diodes only energized during laser delivery. The combination of true-pulsed operation and the high efficiency of laser diodes make the VariLite extremely electrically efficient, allowing it to be operated from any standard electrical outlet.

The VariLite is a precision medical instrument. It has undergone extensive testing and with proper handling is a useful and reliable clinical instrument. If you have any questions regarding your system, contact your local Cutera representative.



WARNING

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

VariLite System Components

The VariLite consists of a system console, handpieces, and a footswitch. Other components necessary for operation, such as keys and electrical cables, are also included.

System Console

The system console houses the control panel, main power keyswitch, emergency off switch, handpiece fiber port, control electronics, laser source with associated optics, and power supply. The control panel allows you to select treatment settings.

Delivery Devices

Laser energy is delivered from the system console to the treatment site through a compatible handpiece or scanner. The VariLite console can be used with VariLite handpieces and with ScanLite scanners. VariLite handpieces are all dual wavelength compatible, allowing convenient switching between wavelengths during a treatment session. ScanLite scanners can only be used at 532 nm.

Laser energy is delivered to the handpiece via an optical fiber. The treatment handpiece focuses laser energy from the fiber onto the patient into a treatment spot of fixed diameter. The VariLite handpieces can be used either with removable distance gauges intended to be lightly in contact with the patient's skin, or with conical non-contact tips that give visual guides to the appropriate working distance.

Footswitch

The footswitch activates the laser treatment beam. The VariLite console can be operated with either a wired or wireless footswitch. The wireless device is designed to operate within 5 m (16.4 ft) of the console. It is comprised of two parts: a battery-powered footswitch and a console-powered receiver.

The wireless footswitch has LEDs to assist in troubleshooting and to indicate battery conditions. Refer to the Maintenance chapter for additional information.

NOTE

Each footswitch/receiver pair is uniquely linked to prevent any other footswitch from activating the laser console.

Remote Interlock

The Remote Interlock receptacle on the rear panel of the system console enables you to incorporate an external interlock switch or safety circuit (e.g., a switch that will disable the laser whenever the treatment room door opens).

When the external switch circuit opens, all laser circuits within the laser console automatically shut down, and “No Remote Interlock” displays in the Status Display on the front of the system console. Electrical continuity must be reestablished in the interlock circuit before treatment can resume.

After the interlock circuit is closed, the system will reinitialize to Standby mode and reset the Energy Density to zero. The Pulse Duration, Repetition Rate and the Counter will return to the most recent settings. To resume treatment, simply reset the Energy Density to the desired value and press the Standby/Treat button to select Treat mode.

Connecting the System Components

Before connecting the VariLite 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. Verify that the handpiece optical fiber is not twisted or kinked.



WARNING

Always turn off the system before inspecting the handpieces. Never look directly into any handpiece even when wearing protective eyewear. Never look directly into the laser beam or at scattered light from metallic or other reflective surfaces. The 532 nm and 940 nm laser beams can cause permanent eye damage.

Connecting the Main Power Cable

Insert the main power cable into the Appliance Inlet receptacle on the rear of the system console, and then insert the power plug into a standard electrical outlet.

Connecting the Footswitch

Insert the footswitch cable or wireless receiver cable into the Footswitch IN receptacle on the rear of the system console. If the footswitch or wireless receiver is not properly connected when the system is turned on, “Connect Footswitch” displays in the Status Display on the front of the system console.

Connecting an External Interlock

The VariLite will not operate unless the two pins in the Remote Interlock receptacle on the rear of the system console are electrically connected. The two pins are connected with a shorting wire at the factory. If you do not wish to incorporate an external interlock, no modifications are necessary. If you do wish to incorporate an external interlock, simply remove the factory-installed wire, and, in its place, connect the wires leading to your own switch.

Connecting an External Warning Device

The connection to the Auxiliary Indicator Contact is on the terminal block located on the rear of the system console. This contact is intended to support low voltage electrical signaling circuits of up to 5 Amps and 24 Volts AC or DC. All external wiring should be in accordance with local electrical code requirements.

Connecting a VariLite Handpiece

Before connecting the handpiece to the system console, uncoil and remove any residual twists from the optical fiber by holding the midpoint of the fiber at shoulder level, lowering the connector and handpiece until they are suspended, and allowing the optical fiber to untwist completely.

CAUTION

If you do not fully untwist the optical fiber, the fiber may form a twisted loop when not under tension. If a twisted fiber is pulled, the fiber may kink and break.

After uncoiling the optical fiber, connect the desired handpiece to the system console, as follows:

1. Remove the protective cap that covers the Fiber Port on the front of the system console, and store the cap so that it can be replaced when the handpiece is removed.

NOTE

Many customers find it convenient to store the cap on the Remote Interlock shorting wire on the rear of the console.

2. Remove the protective lanyard cap from the handpiece optical fiber.
3. Insert the fiber connector into the Fiber Port until it is fully seated.
4. While maintaining light pressure, finger-tighten the connector by turning clockwise. Do not overtighten!

CAUTION

Each VariLite handpiece has a proprietary connection. Substitution of a non-VariLite handpiece may result in no operation or inaccurate laser delivery. Any attempt to use fiber-optic devices manufactured by another company will void the warranty covering the VariLite laser console.

Connecting a ScanLite or ScanLite XP Scanner

Connect the ScanLite or ScanLite XP scanner to the system console, as follows:

1. Ensure that the console is turned off.

CAUTION

The scanner electrical cable should only be connected to or disconnected from the Scanner Port when the console power is off. Connecting or disconnecting the electrical cable while the console is turned on may damage the scanner.

2. Insert the electrical cable connector into the Scanner Port on the front of the system console.
3. Rotate the connector body until the indexed features align and the connector engages without undue force. The locking ring on the connector will click forward when the connection is complete.
4. Insert the scanner fiber connector into the Fiber Port on the front of the system console until it is fully seated.
5. While maintaining light pressure, finger-tighten the connector by turning clockwise. Do not overtighten!

NOTE

The electrical cable of the ScanLite can be left attached to the VariLite console while the ScanLite's optical fiber is detached from the console and a fixed spot size manual handpiece is used.

System Basics

Turning On the System

1. Insert the key into the keyswitch on the front of the VariLite console, and turn it to the ON position.

The system will conduct a self-diagnostic routine that lasts for about three seconds. During this self-diagnostic routine, the Status Display reads “Self Test.”

2. After a successful self-diagnostic routine, the Status Display momentarily reads “Self Test Complete” and then prompts you to “Connect Fiber”.
3. Attach the desired delivery device as described in the previous section.
4. The yellow Standby light will illuminate, and the Status Display will identify the wavelength selected and the delivery device or spot size in use.

NOTE

The VariLite verifies that the internal system temperatures are at optimal values at all times. If the internal temperatures are adjusting, the console may briefly display a message indicating “Cooling”, “Heating”, or “Optimizing”. If the console has been stored or transported in either a cold or hot environment, turn on the keyswitch a few minutes prior to use so that the console has adequate time to optimize its internal temperature.

Restarting the System

To restart the system:

1. Turn the keyswitch to the OFF position.
2. Wait five seconds before turning the keyswitch to the ON position.

The system will go through its normal start-up sequence.

Turning Off the System

Under normal operating conditions, turn the keyswitch to the OFF position, and store the key according to safety procedures established at your facility. You can remove the key only when the keyswitch is in the 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 button labeled “STOP” on the front panel near the keyswitch. The laser and all related circuits are immediately disabled, and “Emergency Stop! Turn Key Off Then On.” displays in the Status Display. Before you can reactivate the laser, you must turn off the keyswitch for a few seconds.

Disconnecting the System

1. Turn the keyswitch to the OFF position.
2. Remove the handpiece fiber connector from the Fiber Port, and replace the protective caps over the fiber connector and the Fiber Port.

CAUTION

Any dirt or fingerprints on the fiber face will interfere with transmission of light and may damage the fiber.

3. If using a scanner, pull back on the locking ring of the electrical cable to release the connector from the Scanner Port.
4. Remove the power plug from the electrical outlet, and remove the main power cable from the Appliance Inlet receptacle.
5. Remove the footswitch cable or wireless receiver cable from the Footswitch IN receptacle.
6. Disconnect the external interlock and/or external warning device, if used.

Moving the System

1. Disconnect the system as described above.
2. Move the system console to the desired site.



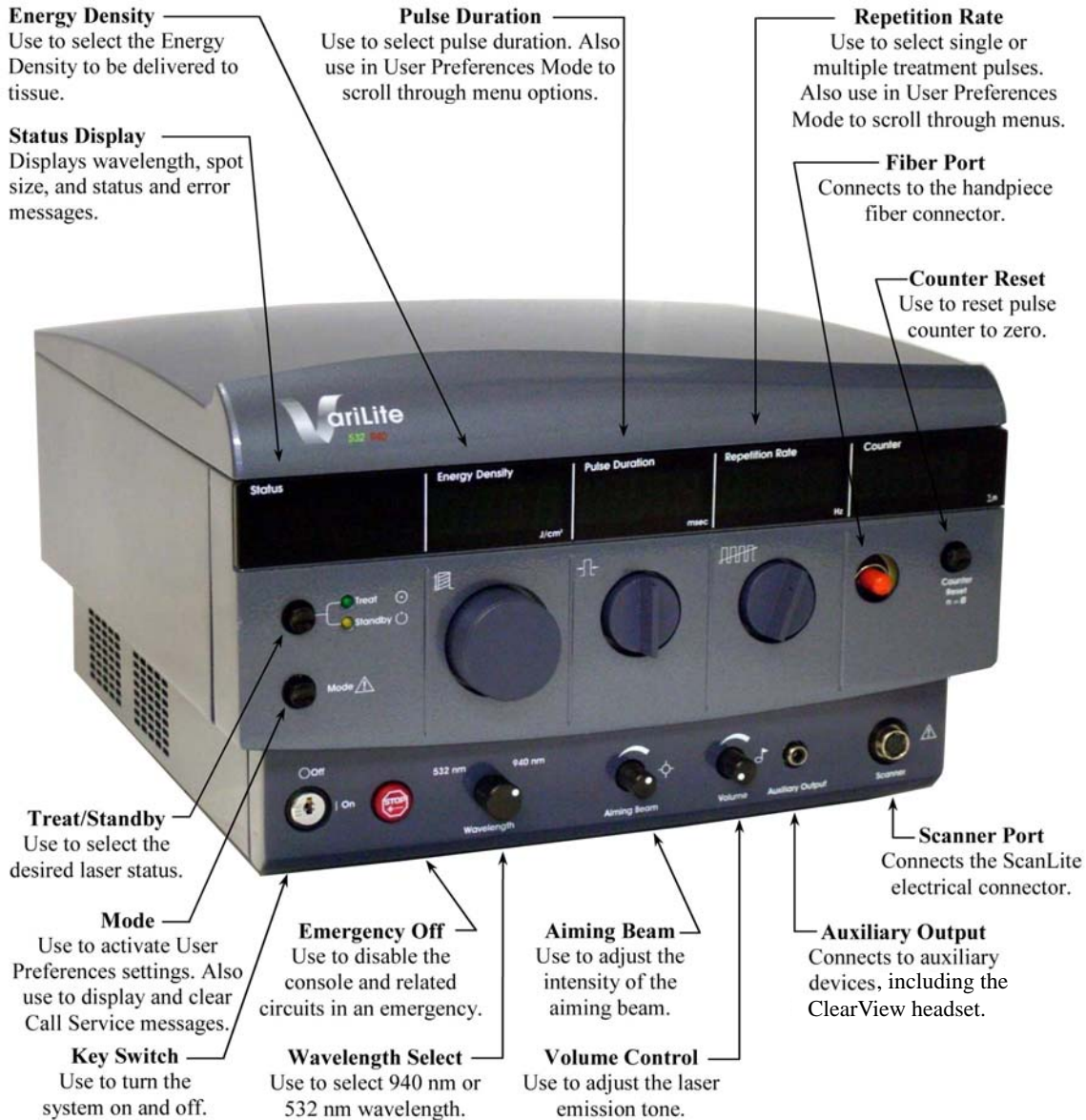
WARNING

The VariLite console weighs about 20 pounds (9 kg). Lift properly to avoid physical injury.

NOTE

Choose a well-ventilated location with ambient temperature ranging from 59° F to 83° F (15°C to 28°C) and relative humidity ranging from 10% to 70% percent non-condensing. Do not place the VariLite with side vent holes or back panel flush with walls or other equipment. Allow at least 2-inch clearance on all sides.

VariLite Console Displays and Controls



Status Display

The wavelength, spot size, and status and error messages display in the Status Display. Refer to the “Status Display Messages” section of this manual for a list of common messages and their meanings.

Energy Density Control and Display

The treatment Energy Density is selected with the Energy Density control and is displayed (in J/cm^2). At each startup and whenever the handpiece is exchanged, the Vari-Lite automatically resets the Energy Density value for both wavelengths to zero. To increase the Energy Density, rotate the Energy Density control clockwise. The first step will be to the last selected/used value. From this value the Energy Density can be adjusted up or down. The Energy Density can be adjusted in Standby and Treat modes, but not while the footswitch is depressed.

The last selected Energy Density for each delivery device and wavelength combination is recorded to allow more convenient parameter selection following delivery device or wavelength exchange. If the Energy Density has been set for a given handpiece at both wavelengths during a treatment session, then switching between wavelengths toggles to the last set Energy Density for that wavelength. The maximum Energy Density that can be selected is dependent on the delivery device, wavelength, and spot size selected.

Pulse Duration Control and Display

The treatment Pulse Duration is selected with the Pulse Duration control and is displayed in milliseconds. The Pulse Duration can be adjusted in Standby and Treat modes, but not while the footswitch is depressed. Each time the system is turned on or the wavelength or handpiece is changed, the Pulse Duration reverts to the last used/selected value for that handpiece/wavelength combination. The Pulse Duration can be adjusted from this value using the Pulse Duration control.

To make it easier to adjust parameters and maintain the shortest allowed Pulse Duration for each Energy Density, the Pulse Duration and Energy Density have been linked so that the Pulse Duration will adjust with the Energy Density. If a Pulse Duration longer than the minimum allowed for the selected Energy Density is desired, the Pulse Duration can be increased using the Pulse Duration control, and the link will be broken. The Pulse Duration can then be adjusted in 5 ms steps. The link will be reestablished if the Pulse Duration is decreased to the minimum allowed, or if an increase in the Energy Density requires a Pulse Duration longer than the selected value.

Repetition Rate Control and Display

The Repetition Rate control allows you to select the number of treatment pulses per second that are delivered while the footswitch is depressed. The delivery rate can be adjusted from a single pulse for each actuation of the footswitch to fifteen per second (15 Hz) in 1 Hz increments for the manual handpieces, to 25 Hz for the ScanLite, and to 50 Hz for the ScanLite XP.

To select single treatment pulses, rotate the Repetition Rate control counterclockwise until the display indicates 0.0 Hz. The system will then deliver only a single pulse each time the footswitch is depressed. To select Repeat mode, adjust the Repetition Rate control until the desired rate displays. In Repeat mode, the VariLite will deliver pulses as long as the footswitch is depressed. The display shows the number of pulses that will be delivered each second.



WARNING

The VariLite is a high-energy laser system. Correct positioning of successive exposures is important to achieving optimal clinical outcome. Bulk heating of tissue associated with excessive overlap may result in adverse effects. Low repetition rate delivery is recommended until the user is fully experienced both in technique and evaluation of intra-operative clinical endpoints.

The maximum Repetition Rate allowed is reduced as the Pulse Duration is increased to keep the duty cycle of the system below 33% for 532 nm and 940 nm operation with a manual handpiece, and below 47% for 532 nm operation with the ScanLite.

When using the ScanLite, the VariLite will by default lock the Repetition Rate to the maximum allowed for the Pulse Duration selected. In locked mode, the Repetition Rate will adjust with the Pulse Duration. Reducing the Repetition Rate below the maximum allowed will break the lock. When unlocked, the Repetition Rate will remain fixed as the Pulse Duration is adjusted. Lock is reestablished by adjusting the Repetition Rate or Pulse Duration to the maximum allowed.

Counter Display and Reset Button

The VariLite automatically counts and displays the number of pulses delivered for each wavelength during a treatment session. To reset the Counter display for each wavelength to zero, press the Counter Reset button directly below the display when that wavelength is selected. The system will not allow you to reset the Counter while the footswitch is depressed. When you restart the VariLite, the Counter displays the number of pulses counted when the system was last shut down.

Laser Status Button (Treat/Standby)

The Laser Status button toggles the system between Standby and Treat modes. In Standby mode, the aiming beam is normally OFF and the footswitch is disabled. In Treat mode, the aiming beam is ON and the footswitch is operational.

Status lights immediately to the right of the Laser Status button indicate Treat (green) or Standby (yellow) mode. Pressing the Laser Status button while the VariLite is in Treat mode overrides all other commands and returns the VariLite immediately to Standby mode.



WARNING

Except during actual treatment, the system must always be in 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 Treat mode.

Mode Button

The Mode button enables you to access the Extended Control Menu to select or set user preferences. Refer to the “Extended Control Menu (User Mode)” section of this chapter for detailed information.

Wavelength Control

The treatment wavelength is selected using the Wavelength control. The wavelength selection is indicated by the control position and is displayed in the Status Display. Treatment parameters appropriate for the wavelength selected and spot size are displayed in the console displays. Wavelength selection changes will not be registered while the footswitch is depressed in Treat mode (delivering treatment). If a change is made while the footswitch is depressed in Treat mode, the change will be recorded after the footswitch is released.

Aiming Beam Control

The Aiming Beam control adjusts the intensity of the aiming beam. To increase the intensity, rotate the control clockwise. To turn off the aiming beam, rotate the control fully counterclockwise. The aiming beam can be set from the Extended Control Menu to either remain at constant intensity during pulse delivery or to pulse to either increased or decreased intensity to give a visual indication that a pulse has been delivered.

Volume Control

The Volume control adjusts the volume of the tone heard during delivery of each treatment laser pulse. You can increase the volume by rotating the control clockwise and reduce it by rotating the control counterclockwise. For safety, the system will not allow you to completely turn off the tone.

Fiber Port

The handpiece optical fiber connects to the system console at the Fiber Port.

Scanner Port

The ScanLite electrical cable connects to system console at the Scanner Port.

Auxiliary Output Port

The Auxiliary Output Port is a +12V 4Amp BNC power port from which accessory devices for the VariLite, such as the ClearView headset, can be powered.

Extended Control Menu (User Mode)

The Extended Control Menu enables you to:

- Change the language used by the Status Display. Available languages are English, Spanish, French, German, Italian, and Portuguese (default setting is English).
- Set the conditions under which the Auxiliary Indicator Contact is closed (default setting is “On in Treat”).
- Set the VariLite so that the red aiming beam is either ON or OFF when the system in Standby mode (the default setting is OFF).
- Set the intensity to which the red aiming beam is pulsed during 532 nm laser delivery (default is constant intensity).
- Set the intensity to which the red aiming beam is pulsed during 940 nm laser delivery (default is 0++, 66% intensity increase during pulse delivery).
- Set the repeat delay between successive scans when using the ScanLite.

When in the Extended Control Menu, the Repetition Rate control is used to proceed to the next menu to be modified. The Pulse Duration control is used to cycle between available selections, and the Mode button is used to exit the Extended Control Menu. The new settings are automatically saved on exit, and the system will return to Standby mode.

To access the Extended Control Menu:

1. From Standby mode, press the Mode button for 3 seconds to enter the Extended Control Menu. The Status Display will display the message “User Mode”.
2. Rotate the Repetition Rate control to cycle to the desired menu. The state currently selected for each menu is shown in the second line of the Status Display or in the Pulse Duration display for each menu.
3. When the desired menu is reached, rotate the Pulse Duration control to cycle through the available selections. Flashing underscored text indicates the current setting.
4. Exit to Standby mode by pressing the Mode button when finished. All changes will be automatically saved.

ScanLite Instructions for Use

General Information

The ScanLite and ScanLite XP scanners (ScanLite) are handheld computer pattern generators with integrated controls designed to enhance the capabilities of the VariLite laser system. The scanners uniformly and rapidly distribute 0.7 mm spot size, 532 nm laser exposures over large area lesions. The ScanLite allows selection of a variety of pattern shapes, sizes and densities to ensure target matching and minimization of collateral thermal damage.

The ScanLite essentially duplicates the physician's hand moving the 0.7 mm handpiece in a controlled way back and forth uniformly covering large area lesions. Each individual exposure within the pattern is similar to an individual exposure from the 0.7 mm handpiece; however, some additive effects require the selection of parameters that may be different from those appropriate for treatments with the 0.7 mm handpiece. It is strongly recommended that operator read and fully understand this section before commencing treatments with the ScanLite.

The ScanLite kit includes the ScanLite, a 10' (3m) optical fiber/electrical interface cable, and a removable treatment guide. The removable treatment guide and cables will normally be attached to the ScanLite when delivered.

ScanLite Controls

All pattern controls for the ScanLite are located on the handpiece. Laser and treatment parameter controls remain on the VariLite console. The ScanLite allows selection of Pattern Shape, Pattern Size and Pattern Density. The LED's located on the handpiece indicate the selected pattern. The selected pattern is changed using the two arrow buttons located on either side of the ScanLite. The pattern selected can be changed anytime except while the laser footswitch is depressed.

Square, Circle or Rectangle patterns can be selected in either 14 mm (XP only), 10 mm, 7 mm or 5 mm (ScanLite only) sizes. Within each pattern, the spacing of treatment exposures for the ScanLite can be set for close packing, medium packing or open packing, to leave controlled spaces between treatment spots. Center to center distances for the ScanLite XP patterns are 0.875, 1.0 and 1.17 mm leaving 20%, 30%, and 40% spacing between treatment spots respectively. Center to center distances for the ScanLite patterns are 0.75, 0.875, and 1.0 leaving 10%, 20%, and 30% spacing between treatment spots respectively.

To change the selected pattern press either of the arrow buttons on the ScanLite. The lit LED on the last altered row will begin to flash indicating the settings can be changed. The active LED indicating the selection on this row can be cycled among the available settings by pressing the horizontal arrow button. When the desired setting is achieved, the active LED can be moved to the next row using the vertical arrow button. This process is repeated until each row has been set to the desired setting. If the console is in Treat mode, the aiming beam perimeter scan will change to indicate the new pattern as soon as any change is made.

The ScanLite will remain in change pattern mode and the LED will continue to flash for a few seconds after the last change is made. If scanning is initiated (footswitch depressed) while a LED is flashing, the system will immediately exit adjustment mode and scanning will commence with the selected pattern.

VariLite Controls

The VariLite controls are largely unchanged when the system is operated with the ScanLite. The differences are listed below.

Repetition Rate: The maximum Repetition Rate of the system in scanner mode is 50 Hz. The Repetition Rate can be adjusted in 1 Hz increments using the Repetition Rate adjustment control. The maximum Repetition Rate is limited by the Pulse Duration to keep the maximum duty cycle less than 47%.

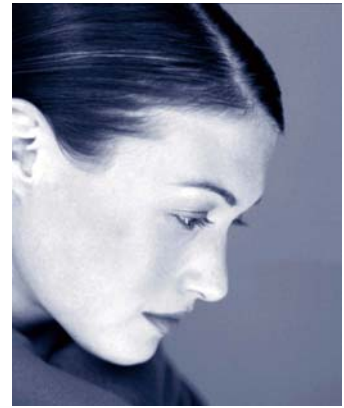
Repeat Delay: The Repeat Delay is the time delay between successive scans while the footswitch remains depressed. The Repeat Delay is indicated in the lower line of the alphanumeric display when the console is in Treat mode. The Repeat Delay can be set to 1, 2, 3, 4, or 5 seconds, or set to No Repeat. If No Repeat is selected the footswitch must be released after the completion of each scan before a new scan can be initiated. The Repeat Delay time can be adjusted in Treat mode by pressing the Mode button. The Repeat Delay will be indicated in the Repetition Rate display and can be adjusted with the Repetition Rate control. The system will return to Treat mode automatically 3 seconds after the last change. The Repeat Delay can also be adjusted in Standby mode from the Extended Control Menu.

NOTE

If the ScanLite is operated in a warm environment (73-83°F/23-28°C) with continuous footswitch depression for long periods at maximum Energy Density and Repetition Rate with the Repeat Delay set to minimum (1 second), the console may force brief cool-down periods by entering Optimizing mode. If this occurs the laser will be ready to resume treatment within 90 seconds. This can be avoided by, in warm environments, setting the repeat delay to 2 or more seconds between scans, or by taking brief (30 second) breaks every 3 to 4 minutes.

Aiming Beam Brightness and Perimeter Scan: When the console is in Treat mode with the ScanLite attached, the ScanLite will scan the aiming beam around the perimeter of the area to be treated. The brightness of the aiming beam should be adjusted towards maximum to aid visualization of the Perimeter Scan. The area to be scanned will include the perimeter outline. Successive scan areas should be aligned with the Perimeter Scan adjacent to the previously scanned area without overlap.

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. Remote interlock...Verify that the two pins in the Remote Interlock receptacle on the rear of the system console are electrically connected. If you have incorporated an external door switch, verify that the treatment room door is closed.

System does not turn on. The display is blank.

Probable Cause:	The system is not plugged in.
Suggestion:	Insert the main power cable into the Appliance Inlet receptacle on the rear of the system console, and then insert the power plug into a standard electrical outlet. Turn the keyswitch to the ON 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 electrical outlet is defective.
Suggestion:	Use another outlet or have the outlet professionally tested and, if appropriate, repaired.
Probable Cause:	The line fuses are blown.
Suggestion:	Check and, if necessary, change the line fuses as instructed later in this chapter.

Treatment beam is not present, although aiming beam operates properly.

Probable Cause:	There is an internal laser system failure.
Suggestion:	Test a second handpiece. If the treatment beam is still not visible, contact Cutera Service (<i>refer to Appendix C</i>).

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 Treat mode.
Probable Cause:	Energy Density is set to zero.
Suggestion:	Set the Energy Density to the desired value.
Probable Cause:	There is an internal laser system failure.
Suggestion:	Test a second handpiece. If the treatment and aiming beams are still not visible, contact Cutera Service (<i>refer to Appendix C</i>).

Inadequate or no aiming beam.

Probable Cause:	The aiming beam is set to OFF or at a low setting.
Suggestion:	Adjust the aiming beam intensity using the aiming beam knob on the front of the console. If adjusting the aiming beam does not resolve the problem, contact Cutera Service (<i>refer to Appendix C</i>).
Probable Cause:	The system is in Standby mode.
Suggestion:	Place the system in Treat mode.
Probable Cause:	There is an internal laser system failure.
Suggestion:	Test a second handpiece. If the aiming beam is still not visible, contact Cutera Service (<i>refer to Appendix C</i>).

The Standby light does not illuminate.

Probable Cause:	There is a system error.
Suggestion:	Refer to the Status Display for an error message and/or instructions.
Probable Cause:	No delivery device is connected to the Fiber Port on the front of the system console, or the delivery device is improperly connected.
Suggestion:	Verify that the delivery device is properly connected to the console.
Probable Cause:	The console is heating, cooling, or optimizing.
Suggestion:	Wait until the console reaches its optimum operating temperature.

The footswitch is inoperative.

Probable Cause:	The system is in Standby mode.
Suggestion:	Place the system in Treat mode.
Probable Cause:	No wired footswitch or wireless receiver is connected to the Footswitch IN receptacle on the rear of the system console, or the footswitch or receiver is improperly connected.
Suggestion:	Verify that the wired footswitch or wireless receiver is properly connected to the console.

Probable Cause:	The batteries in the wireless footswitch need to be replaced.
Suggestion:	Test the batteries, as described later in this chapter. If the batteries need to be replaced, contact your local Cutera representative for battery replacement.

Status Display Messages

The Status Display, located directly above the Standby/Treat button on the front of the system console, displays machine status messages, operator prompts, and diagnostic messages. This section lists some of the more common diagnostic messages and their meanings:

Connect Fiber	The system does not detect a valid optical fiber attached to the Fiber Port.
Unknown Fiber	The delivery device connected to the Fiber Port cannot be identified. Verify correct fiber connection.
940 nm Laser X.X mm Spot	The system has detected a valid X.X mm spot size handpiece attached to the Fiber Port, and the 940 nm wavelength is selected.
532 nm Laser X.X mm Spot	The system has detected a valid X.X mm spot size handpiece attached to the Fiber Port, and the 532 nm wavelength is selected.
532 nm only Device	The system has detected a 532 nm only device attached to the Fiber Port when the 940 nm wavelength is selected.
Connect Scanner	This message indicates that a ScanLite fiber is connected to the Fiber Port, and that the console is unable to communicate with the ScanLite via the electrical cable. Verify that the cable is connected to the Scanner Port.
532 nm Laser ScanLite (XP)	The system has detected a ScanLite (or ScanLiteXP) attached to the console. The console is in Standby mode.
ScanLite (XP) Repeat x sec	The system has detected a ScanLite (or ScanLiteXP) correctly attached to the console. The console is in Treat mode and repeat delay between successive scan patterns is x sec.

ScanLite (XP) No Repeat	The system has detected a ScanLite (or ScanLiteXP) correctly attached to the console. The console is in Treat mode and the footswitch must be released between successive scans.
Optimizing	This message is briefly displayed to indicate that the system is modifying internal temperatures. This may occur in response to parameter selections, or if the system is operated continuously for long periods at high repetition rates in warm environments.
Heating Delta: x.x C	If the system is cold when you initially turn on the keyswitch, the system will automatically enter Heating mode and will display the number of degrees Celsius (C) remaining between the system's current temperature and its optimum operating temperature. It will take about 45 seconds/degree C to heat the system. The system will automatically enter Standby mode when operating temperature has been reached.
Cooling Delta: x.x C	If the system is hot when you initially turn on the keyswitch, the system will automatically enter Cooling mode and will display the number of degrees Celsius (C) remaining between the system's current temperature and its optimum operating temperature. It will take about one minute/degree C to cool the system. The system will automatically enter Standby mode when operating temperature has been reached.
No Remote Interlock	The Interlock circuit is open. Insert a wire into the Remote Interlock connection, or close any door switches or other circuits you may have attached. The system cannot be used until the Interlock is closed.
Connect Footswitch	This message indicates that the footswitch cable or wireless receiver is not connected correctly to the rear panel. The system will not enter Treat mode unless a valid footswitch is correctly connected.

Release Footswitch	This message indicates that the footswitch was depressed when attempting to enter Treat Mode. The system will not enter Treat mode unless a valid footswitch is correctly connected and in the released state.
Call Service Error XX	When the system detects an apparent malfunction of any safety-related system or an inability to meet performance standards, it displays the Call Service message and a code number indicating the nature of the malfunction. In this mode, the system disables all controls except the keyswitch and the Mode button. When this occurs, push the Mode button; a description of the fault will briefly display in the Status Display. The system will then initiate the start sequence, perform self-diagnostics, and, if no faults are detected, enter Standby mode. Often this sequence will be sufficient to clear the Call Service message. Sometimes turning off the keyswitch for several seconds to several minutes is required.

If an error cannot be cleared, or if an error persists or reappears, note the Status Display message and/or code and contact Cutera Service (*refer to Appendix C*).

Annual System Maintenance

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

System Repair

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

Routine User Maintenance

The VariLite requires no internal maintenance by the user. However, you should periodically inspect and clean the console, footswitch, and handpieces as described below.

Cleaning the External Surfaces of the System Console

Periodically inspect the console for dirt, debris, and damage. 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. Avoid abrasive or ammonia-based cleaners.



WARNING

Do not attempt to gain access to any internal components. Electrical shock and/or unintended laser exposure may result.

CAUTION

Do not spray or pour cleaning agents directly on the system console.

Cleaning and Disinfecting the Footswitch

The VariLite wired and wireless footswitches are submersible (IPX8 IEC529). The wireless receiver is NOT submersible.

To decontaminate and disinfect the footswitch:

1. Disconnect the footswitch from the console (wired version).
2. Using water, isopropyl alcohol, or enzymatic detergents with mild pH (e.g., ENZOL), remove all traces of blood and other body fluids from all exposed surfaces of the footswitch assembly and footswitch cable (wired version).
3. Immerse the footswitch in a CIDEX (2.4% glutaraldehyde) solution to achieve the desired level of disinfection:
 - a minimum of 45 minutes at 25°C to achieve a high level of disinfection
 - a minimum of 10 minutes at 20°C to 25°C to achieve an intermediate level of disinfection.
4. Remove the footswitch from the CIDEX solution.
5. Stand the footswitch on end (opposite the cord for the wired version) to drain all fluids.
6. Immerse the footswitch in a large amount of water for a minimum of 1 minute. Repeat this step two or more times using clean water for each rinse.
7. Stand the footswitch on end (opposite the cord for the wired version).
8. Allow the footswitch to air-dry completely before reusing.
9. Reconnect the footswitch to the console (for the wired version).

Cleaning and Disinfecting the VariLite Handpieces

The VariLite handpieces are non-sterile reusable delivery devices. The external surfaces can be cleaned using a soft cloth moistened with either a mild detergent or alcohol. Aloe or other water-based gels may cause staining. To prevent staining, carefully remove all traces of gel after each use. A nickel polishing cloth or liquid may be used to remove stains.

The VariLite handpieces can be used with either non-contact conical tips or with a removable contact distance guide. The removable distance guide is the only portion of the handpiece intended to come into patient contact. The distance guide should be detached, cleaned, and disinfected between patient use.

CAUTION

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

Cleaning and Disinfecting the ScanLite

The ScanLite is a non-sterile reusable delivery device. The external surfaces can be cleaned using a soft cloth moistened with either a mild detergent or alcohol. The distance guide should be detached, cleaned, and disinfected between patient use.

The ScanLite has an optic at the output aperture. Before use, inspect the optic for dirt, debris, or damage, and clean if necessary using a cotton swab lightly dampened with alcohol. Gently wipe the optic in a single movement across the surface. Use each cotton swab only once and repeat if necessary until all visible contamination is removed.

CAUTION

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

Testing the Wireless Footswitch Batteries

Footswitch battery status can be tested at any time. To test battery condition, first ensure a safe console status (e.g., Standby mode or turned off), then depress the footswitch. The color of the initial flash from the footswitch LEDs indicates battery status, as follows:

- green flash following pedal depression = footswitch OK, batteries OK
- amber flash following pedal depression = footswitch OK, batteries low
- blink red LED for 10 seconds = no RF communication

The footswitch uses long-life lithium ion batteries and has an operational life in excess of five years. When the batteries need to be replaced, contact your local Cutera representative for battery replacement.

Changing the AC Line Fuses

Both legs of the AC line contain fuses. The fuse holder is integral to the power inlet on the rear panel of the VariLite console. To check or change fuses, remove the power cord from the inlet receptacle by pulling straight back. Remove the fuse carrier with the blade of a small screwdriver (Note: there are latches on both sides of the fuse carrier), then remove and inspect both fuses. If they are blown, replace them with F6H-250V (5 x 20 mm) fuses. The proper fuse types are also indicated on the rear panel.

If newly replaced fuses also blow, contact your local Cutera representative.

Remote Interlock Pin Assignments

A terminal block connection labeled “Remote Interlock” on the rear panel of the VariLite allows you to incorporate your own external interlock, or safety circuit. The VariLite will operate only when two pins (#1 & #2) inside the Remote Interlock connector are electrically shorted. At the factory, we connect those two pins with a short wire.

Electrical Utilities

The VariLite system is available in several electrical configurations. Electrical power should be set up according to the model ordered and the location of installation, as defined below.

North American Installation

The VariLite is provided with a hospital-grade (green dot) three-wire grounding plug, which fits a standard grounding type 120 volt AC receptacle. This equipment must be connected to an electrical supply source in the US at 120V or 240V with a center tap. A grounding type AC receptacle is essential for safe operation. The reliability of the ground connection can only be assured when this device is connected to an approved mating receptacle and installed in accordance with the appropriate Electrical Codes for medical occupancy.

Installation in Other Locations

The VariLite is provided with a power cord appropriate for your geographic area. You can obtain replacement cords locally to match the IEC320 standard appliance inlet on the back panel. Always use a three-wire grounding cord set. Do not alter the appliance inlet, as it contains protective fusing. Follow local electrical codes for installation to ensure proper grounding (earth connection).



WARNING

Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.

System Specifications

Specifications subject to change without notice.

Treatment Beam

Type	Diode-pumped solid-state (DPSS)	Laser diode array
Wavelength	532 nm	940 nm
Energy Density	950 J/cm ²	900 J/cm ²
Pulse Duration	5 to 100 ms	
Treatment Spot Size	Standard: 0.7 and 1.0 mm Optional: 1.4 and 2.0 mm	
Divergence	1.9° to 12.6°	5.4° to 22°
Repetition Rate	Manual handpieces - single pulse to 15 Hz ScanLite scanners - single pulse to 50 Hz	
Aiming Beam	Red diode laser (630-650 nm), user-adjustable from 0 to 0.95 mW	
Delivery System	Optical fiber with handpiece	

Physical Parameters

Dimensions (W x D x H): 12 in x 12 in x 7.5 in (30 cm x 30 cm x 19 cm)

Weight: 20 lb (9 kg)

Electrical Requirements

Input Power 90-240 VAC, 50/60 Hz, 5 A Max

Ground Leakage Current <300 μ A, 120V, 50/60 Hz
<500 μ A, 264V, 50/60 Hz

Environmental Requirements

Temperature Operating: 15°C to 28°C (59° F to 83° F)
Storage: -20°C to +60°C (-40° F to 140° F)

Relative Humidity Operating: 10%-90%, 15°C to 26°C
10%-70%, 15°C to 28°C
Storage: 10%-95%

Classifications

FDA Classification	Class II Medical Device
CDRH Classification	Class IV Laser Product
IEC 60825-1 Classification	Class 4 Laser
IEC 60601-1 Classification	Class I, Type BF, Ordinary Equipment suitable for continuous operation

Eye Safety

Nominal Ocular Hazard Distance	≤ 69 feet (21 m) at 532 nm ≤ 58 feet (17.5 m) at 940 nm
Minimum Optical Density for Protective Eyewear	<input type="checkbox"/> 3.5 at 532 nm <input type="checkbox"/> 4.5 at 940 nm

ScanLite Specifications

Specifications subject to change without notice.

<i>Patterns</i>	Square, circle and rectangle
<i>Pattern Sizes</i>	ScanLite: 5, 7 and 10 mm ScanLite XP: 7, 10 and 14 mm
<i>Repetition Rate</i>	ScanLite: 25 Hz maximum ScanLite XP: 50 Hz maximum
<i>Repeat Mode</i>	Single scan or variable delay
<i>Spot Size</i>	700 μm (532 nm only)
<i>Pattern Density</i>	ScanLite: nominally adjacent, 20% or 40% separation (center to center spacing of 750, 875 and 1000 μm respectively) ScanLite XP: nominally 20%, 40% or 60% separation (center to center spacing of 875, 1000 and 1170 μm respectively)
<i>Pattern Outline</i>	Perimeter scanned aiming beam
<i>Fiber Length</i>	10 ft (3 m)
<i>Controls</i>	Integrated
<i>Dimensions (H x D x W)</i>	4.7 in x 4.7 in x 1 in (12 cm x 12 cm x 2.5 cm)
<i>Weight</i>	10 oz (290 g) (excludes cable and fiber)

Calibration Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and IEC 60825-1 Class 3 and 4 medical lasers supply their customers with power calibration instructions.

Calibration of the laser 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 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.



WARNING

Failure to perform the annual calibration may contribute to device malfunction and to potential patient injury.

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 VariLite system 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 Cutera Service (*refer to Appendix C*).

CAUTION

Any work performed to the VariLite console or handpieces by unauthorized personnel will void all warranties.

Equipment Required

- Laser energy meter (Ophir Optronics Model AN/2 or Coherent Model Field-Max-TO). 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).

Console/Handpiece Power Calibration Verification

Perform the following procedure at least annually for all handpieces and both wavelengths.

NOTE

Copy the Calibration Sheets on the following page for recording data.

1. Ensure that all personnel in the room are wearing the appropriate laser safety eye-wear.
2. Connect the handpiece to the console, and select the wavelength.
3. Set the Pulse Duration to locked mode and the Repetition Rate to 5 Hz.
4. Refer to the Calibration Sheet for the selected wavelength, and set the Energy Density to the designated value for the spot size/handpiece in use for each of the three Energy Density ranges on the sheet (circle the spot size tested).
5. Enter Treat mode.
6. Aim the output from the handpiece onto the power meter, making sure the aiming beam is fully contained within the active sensor area of the power meter.
7. Depress the footswitch, and record the meter readings on the Calibration Sheet.
8. Place signed copies of the completed Calibration Sheets in your device records.

If any readings fall outside the minimum/maximum levels, recheck the test setup (i.e., the power meter, accurate beam placement on the power meter, and optical fiber attachment to console), and test with additional handpieces and both wavelengths. If the system is out of calibration for all handpieces tested, the console is likely to be the cause. The console cannot be returned into calibration by simple field adjustment; it must be repaired. If the system is in calibration for one or more handpieces, then only the handpieces not in calibration need to be repaired. Contact your local Cutera representative for instructions on returning the system and/or handpieces for repair.

Power Calibration Verification Sheet for 532 nm

Spot Size	Energy Density	Meter Reading	Min/Nominal/Max Value		
<i>Low Power Range</i>	<i>(J/cm²)</i>	<i>(Watts)</i>	<i>(Watts)</i>		
0.7 mm	8		0.123	0.154	0.185
1.0 mm	6	_____	0.188	0.236	0.283
1.4 mm	4		0.246	0.308	0.369
2.0 mm	2		0.251	0.314	0.377
<i>Medium Power Range</i>					
0.7 mm	16		0.246	0.308	0.369
1.0 mm	12	_____	0.377	0.471	0.565
1.4 mm	8		0.493	0.616	0.739
2.0 mm	4		0.503	0.628	0.754
<i>High Power Range</i>					
0.7 mm	24		0.369	0.462	0.554
1.0 mm	18	_____	0.565	0.707	0.848
1.4 mm	12		0.739	0.924	1.108
2.0 mm	6		0.754	0.942	1.131

Date: _____ Calibration verified by: _____ Serial No.: _____

Power Calibration Verification Sheet for 940 nm

Spot Size	Energy Density	Meter Reading	Min/Nominal/Max Value		
<i>Low Power Range</i>	<i>(J/cm²)</i>	<i>(Watts)</i>	<i>(Watts)</i>		
0.7 mm	160		2.4	3.1	3.7
1.0 mm	90	_____	2.8	3.5	4.2
1.4 mm	50		3.1	3.8	4.6
2.0 mm	30		3.8	4.7	5.7
<i>Medium Power Range</i>					
0.7 mm	300		4.6	5.8	6.9
1.0 mm	180	_____	5.7	7.1	8.5
1.4 mm	100		6.2	7.7	9.2
2.0 mm	60		7.5	9.4	11.3
<i>High Power Range</i>					
0.7 mm	460		7.0	8.8	10.6
1.0 mm	270	_____	8.5	10.6	12.7
1.4 mm	150		9.2	11.5	13.9
2.0 mm	90		11.3	14.1	17.0

Date: _____ Calibration verified by: _____ Serial No.: _____

ScanLite Power Calibration Verification (532 nm only)

Perform the following procedure at least annually.

NOTE

Copy the Calibration Sheet on the following page for recording data.

1. Ensure that all personnel in the room are wearing the appropriate laser safety eye-wear.
2. Connect the ScanLite to the console, and select 532 nm.
3. Set the Pulse Duration to locked mode.
4. Set the pattern to the 10 mm circle with close packing.
5. Refer to the Calibration Sheet, and set the Energy Density and Repetition Rate to the designated values for each of the three Energy Density ranges on the sheet.
6. Enter Treat mode.
7. Aim the output from the handpiece onto the power meter, making sure the aiming beam is fully contained within the active sensor area of the power meter.
8. Depress the footswitch, and record the meter readings on the Calibration Sheet.
9. Place a signed copy of the completed Calibration Sheet in your device records.

If any readings fall outside the minimum/maximum levels, recheck the test setup (i.e., the power meter, scan placement on the power meter, optical fiber attachment to console, and cleanliness of output lens on the ScanLite). If the system is in calibration for manual handpieces and out of calibration for the ScanLite, the ScanLite cannot be returned into calibration by simple field adjustment; it must be repaired. Contact your local Cutera representative for instructions on returning the ScanLite for repair.

ScanLite Power Calibration Verification Sheet						
	Energy Density <i>(J/cm²)</i>	Rep. Rate <i>(Hz)</i>	Meter Reading <i>(Watts)</i>	Min/Nominal/Max Value <i>(Watts)</i>		
Low Power Range	10	25	_____	0.77	0.96	1.15
Medium Power Range	15	23	_____	1.06	1.33	1.59
High Power Range	20	17	_____	1.05	1.31	1.57
Date: _____ Calibration verified by: _____ Serial No.: _____						

End of Life Disposal - Environmental Information

The VariLite system 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.

Warranty Information

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

Safety and Regulatory



Introduction

The VariLite system, when properly used by trained personnel, is a safe and effective instrument 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 laser 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. Treatment parameters are provided as a guide. Individual treatments should be based on clinical training, clinical observation of laser-tissue interaction and appropriate clinical endpoints.

NOTE

The treating practitioner bears sole responsibility for determining the applicability of the VariLite for any patient or condition and bears sole responsibility for the clinical effects of any treatment delivered.

Optical Hazard

Laser safety eyewear is routinely required with most laser 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 the 532 nm and 940 nm wavelengths 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 IEC 60825-1:2007, Annex A.

The VariLite system is a Class IV Laser Product as defined by the U.S. Code of Federal Regulations and a Class 4 Laser as defined by the IEC 60825-1.



WARNING

The VariLite produces visible green (532 nm) light, as well as invisible (940 nm) light, both of which can cause permanent eye damage. Never look directly into the hand-piece even when wearing protective eyewear. Never look directly into the laser beam or at scattered light from metallic or other reflective surfaces. Both direct and reflected laser beams may contain sufficient energy to cause permanent eye damage.

All personnel operating VariLite or in the vicinity of the system, including the patient, staff personnel and observers, should wear protective eyewear with sufficient dual wavelength protection for the 532 nm and 940 nm wavelengths. Protective eyewear must have an optical density (OD) of 3.5 or greater at 532 nm and 4.5 or greater at 930 - 950 nm. The eyewear should have guards on both sides to protect the eyes from lateral exposure.



WARNING

Never allow anyone without proper protective eyewear near the laser while the system is in use.

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).*
- *IEC 60825-1:2007, Annex A.*

The ANSI 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 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 an ANSI-approved laser 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 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.

**WARNING**

The 940 nm wavelength is capable of causing retinal injury when applied to or near the surface of a patient's eye. Do not use the 940 nm wavelength on or near the surface of a patient's eye without providing additional protection for the patient. The 532 nm output penetrates tissue less deeply but will penetrate the eyelid when lesions on or near the eyelid are treated. Do not use the 532 nm output to treat lesions on or near the eyelid without providing additional protection for the patient.

Additional Ocular Protection**WARNING**

When set to the maximum intensity, the aiming beam generates Class II intensity levels. The beam can damage your retina if you stare into it for longer than 5 seconds. Diffuse light from the aiming beam reflected from the patient's skin is well below the Class I limits and presents no danger.

**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**

Verify that laser safety eyewear has sufficient protection for the 532 nm and 940 nm wavelengths.

**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.

**WARNING**

Severe eye injury can be caused by radiation backscattered from the skin during treatment. The 940 nm output from the VariLite is completely invisible, but it is absorbed by melanin in the retina. Since the output is invisible, there is no visual indicator of failure to wear eye protection. Before treatment, always verify all personnel, including the operator and patient, are wearing laser safety eyewear specifically indicated for 940 nm.

Additional Safety Considerations

CAUTION

The VariLite system is intended solely for licensed practitioners trained in its proper use.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser 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 laser exposure if the footswitch is inadvertently pressed.



WARNING

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

Electrical Hazard



WARNING

Do not remove any protective covers. Doing so may expose you and others to dangerous optical radiation and lethal electrical voltages. There are no user-serviceable parts or functions inside the protective housing, and no section of the housing can be opened without special tools. Only an authorized Cutera service representative should have access to the interior of the VariLite or perform service on the system.

**WARNING**

Do not attempt to perform maintenance other than that which is outlined in this manual.

**WARNING**

Maintenance should only be performed with the system turned off and disconnected from the power source.

**WARNING**

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.

**WARNING**

If the aiming beam is absent, diffuse, uneven or out of focus, the handpiece may be damaged. Use of damaged handpiece may result in fire. If you suspect the cable or handpiece is damaged, call Cutera Customer Service for a replacement.

Regulatory Compliance

All Cutera aesthetic platforms are designed to comply with the following:

- US Federal Performing Standards 21 CFR 1040.10 and 1040.11, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6, IEC 60601-2-22 and IEC 60825-1
- 21 CFR Chapter I, Subchapter J, as administered by the Center for Device and Radiological Health of the US Food and Drug Administration (FDA)

Location of Controls

Operation and adjustment controls are located so that the user need not be exposed to laser radiation 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 position and the system will only operate with the key in place. When treatments are complete or the system is not in use, always remove and store the key.

Emergency Off Push-Button

The laser diodes and all related circuits can be immediately disabled by pressing the red button labeled “STOP” on the bottom left front panel. Following emergency shut-off, the keyswitch must be used to restart the system.

Laser Emission Indicator

The treatment beam can only be delivered when the system is in Treat mode and the green Treat light is illuminated. When the footswitch is pressed and the treatment beam is being delivered, the green Treat light flashes.

Remote Interlock Connector

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

Safety Interlocks

Electronic interlocks at the fiber port prevent the console from emitting laser energy if a VariLite handpiece is absent or incorrectly connected.

Protective Housing

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

Laser Beam Attenuation

The treatment laser diodes do not emit continuously. Lasing only occurs during delivery of laser energy to the patient. The laser diodes are only energized in Treat mode and lasing is prevented by a fail-safe combination of electronic elements until all requirements for emission are met and the footswitch is depressed. The aiming beam intensity is controlled by rotating the aiming beam knob. You can turn off the aiming beam by rotating the knob fully counterclockwise, by selecting the Standby mode, by opening the Remote Interlock circuit, by pressing the Emergency Off button, or by turning off the keyswitch.

Audible Emission Indicator

An audible tone is generated during treatment beam delivery. The volume can be adjusted but not turned off.

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 keyswitch to resume operation. VariLite will reinitialize and enter Standby mode with the Energy Density set to zero. To begin operation of the laser, reset the Energy Density and select Treat mode.

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.

Additional Safety Features

Laser Turn-on Sequence

Each time you start or restart with the keyswitch, the VariLite conducts a diagnostic sequence and initializes the control and safety circuitry. Each time the system enters Treat mode, the system checks footswitch integrity and executes a diagnostic sequence verifying power supply functionality and safety features. All diagnostic tests must successfully complete and all connection requirements must be satisfied before the system can emit laser energy.

Footswitch

The VariLite console can be operated with either a wired or wireless footswitch. When the system is in Treat mode, the user activates the laser with the footswitch. Both footswitch types are submersible (in compliance with IEC529) and shrouded for safety (in compliance with ANSI Standard Z136.3).

The VariLite incorporates several additional safety features to prevent accidental emission of laser energy:

- Redundant hardware and firmware prevent the VariLite from delivering laser energy unless a wireless footswitch receiver or wired footswitch is correctly installed, the footswitch depressed, and the system is in Treat mode.
- The VariLite always tests for a properly connected wireless receiver or wired footswitch in the released state before entering Treat mode. If the footswitch or receiver is damaged or improperly connected, the “Connect Footswitch.” appears in the Status Display. You must then connect or, if necessary, repair or replace the footswitch or receiver before the system will enter Treat mode. If the footswitch is depressed, “Release Footswitch” appears in the Status Display.
- The VariLite will not allow adjustment of the treatment settings while the footswitch is depressed when in Treat mode.
- Each wireless footswitch and receiver pair is uniquely linked to prevent any other wireless footswitch from activating the laser console.

Auxiliary Indicator Contact

As an additional safety measure, a relay contact is provided inside the VariLite console to allow connection of external warning devices that indicate laser status, such as a warning light or a small rotating beacon.

The Auxiliary Indicator Contact can be user-programmed to close when one of three operational modes is entered: (1) when the keyswitch is turned on; (2) when Treat mode is selected; or (3) when the footswitch is actuated in Treat mode. The VariLite is shipped from the factory programmed to close the relay contacts when entering Treat mode.

The connection to the Auxiliary Indicator Contact is located on the terminal block located on the rear of the VariLite console. This contact is intended to support low voltage electrical signaling circuits of up to 5 Amps and 24 Volts AC or DC. All external wiring should be in accordance with local electrical code requirements.

Operational Training



WARNING

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

CAUTION

US 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.

CAUTION

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.

Refer to the VariLite Treatment Guidelines accompanying this operator manual and to the Cutera VIP website for available training options and resources. The Treatment Guidelines can also be obtained from your local Cutera representative or on the VIP website.

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*. The practitioner should also keep current with all relevant medical literature.

Operational Safety



WARNING

The handpiece is a fragile instrument and must not be dropped. If it is dropped, you must carefully examine the handpiece for any physical damage prior to use.



WARNING

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



WARNING

Never activate the treatment beam while pointing the handpiece into free space.



WARNING

Do not leave the system in Treat mode when not in use. Always place the system in Standby mode or turn off the system and remove the key when not performing treatments.



WARNING

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

CAUTION

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

CAUTION

Uncoil and remove any residual twists from the handpiece optical fiber cable before attaching it to the front of the console. If you do not fully untwist the optical fiber, the fiber may form a twisted loop when not under tension. If a twisted fiber is pulled, it may kink and break.

CAUTION

Do not place any unnecessary stress on the handpiece fiber optic cable (i.e., by pulling on it, tightly bending it or twisting the handpiece). Do not bend the optical fiber into loops smaller than eight inches in diameter.

CAUTION

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

CAUTION

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

CAUTION

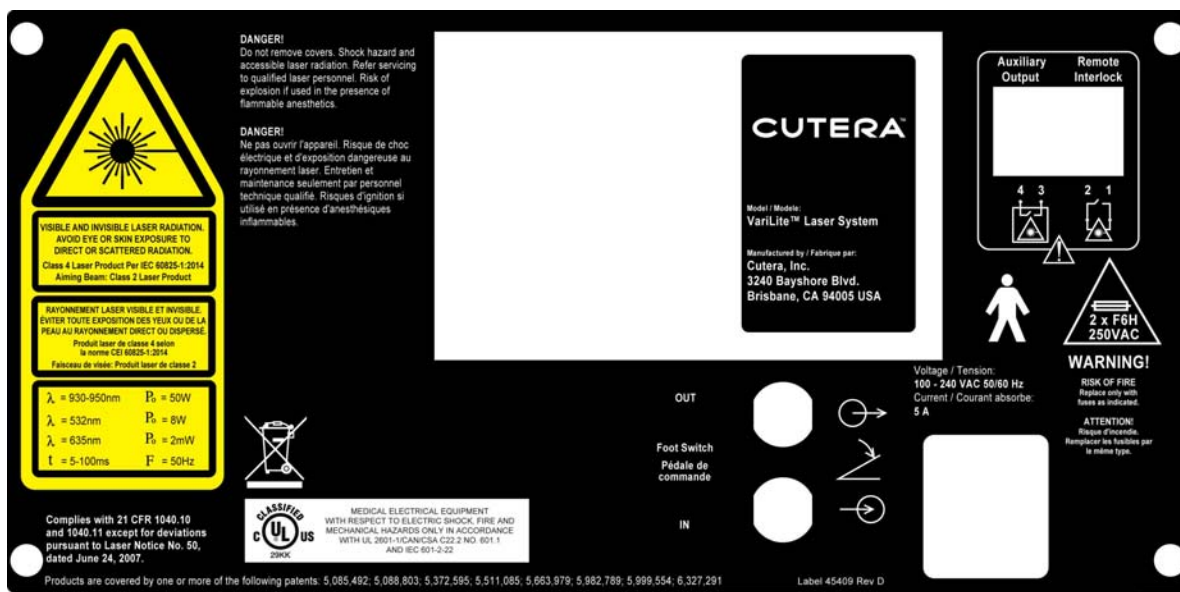
Before placing the system in Treat mode, confirm that the laser aperture on the handpiece is safely positioned to prevent unintended treatment exposure.

NOTE

The VariLite does not vaporize tissue and does not produce a plume of smoke or steam that may contain viral fragments. Use of a smoke evacuation system is generally not required. However, a malodorous gas, hydrogen sulfide, may be produced when the laser beam interacts with surface hair. While not medically necessary, if this odor is sufficiently unpleasant or irritating to warrant removal, a conventional smoke evacuator may be used.

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.




VariLite Identification Label
Located on rear panel of console

The reliability of the ground connection can only be assured when this device is connected to an approved mating receptacle marked for hospital use and installed in accordance with the appropriate Electrical Codes for medical occupancy.

Reliability of Ground Connection Label

Located on bottom of console

Serial Number	SN _____
Date of Manufacture 	_____
PN 10384b	

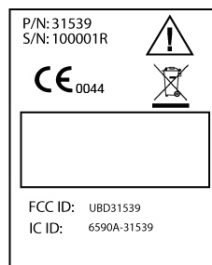
Serial Number and Date of Manufacture Label

Located on bottom of console



Wireless Footswitch Label

Located on top of wireless footswitch



Wireless Receiver Label

Located on bottom of wireless receiver

Electromagnetic Compatibility

The design of the VariLite console and accessories, including the wireless footswitch, complies with IEC 60601-1-2 (3rd edition) requirements for electromagnetic compatibility (EMC) with other devices. Like other electrical medical equipment, the VariLite console and accessories require special precautions to ensure EMC with other electrical medical devices and must be installed and operated according to the EMC information provided in this manual.

CAUTION

Portable and mobile RF communications equipment may affect the normal function of the VariLite console and accessories.



WARNING

Do not use cables or accessories other than those provided with the VariLite console and accessories, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.



WARNING


If the VariLite console and accessories are used adjacent to or stacked with other equipment, observe and verify normal operation in the configuration in which they will be used prior to use in a surgical procedure. Consult the tables below for guidance in placing the VariLite console and accessories.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The VariLite console and accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the VariLite console and accessories should ensure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment: Guidance
RF emissions CISPR 11	Group 1	The VariLite console and accessories 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	The VariLite console and accessories 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 B	
Voltage Fluctuations/flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The VariLite console and accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the VariLite console and accessories should ensure that they are used in such environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±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 Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±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 VariLite console and accessories requires continued operation during power mains interruptions, it is recommended that the VariLite console and accessories be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The VariLite console and accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the VariLite console and accessories should ensure that they are 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 Vrms 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the VariLite console and accessories, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance $d = [3.5/\sqrt{V1}]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

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

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

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

(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 VariLite Console and Accessories

The VariLite console and accessories are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the VariLite console and accessories can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VariLite console and accessories 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 $d = [3.5/\sqrt{P}]$	80 MHz to 800 MHz $d = [3.5/\sqrt{P}]$	800 MHz to 2.5 GHz $d = [7/\sqrt{P}]$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

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.

Wireless Footswitch Safety Information

The VariLite console and wireless footswitch have been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The laser console and accessories generate, use and can radiate radio-frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If the wireless footswitch does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the VariLite console into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Cutera Customer Service for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

NOTE

Portable and mobile RF communications equipment can affect medical electrical equipment.

NOTE

The frequency range RF transmission is 2.41GHz to 2.46GHz.

NOTE

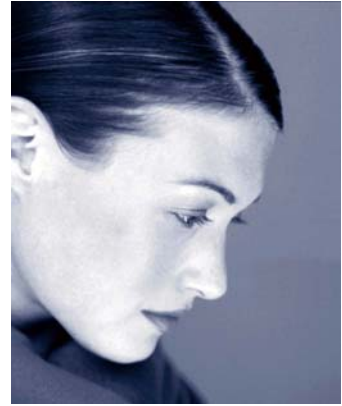
The measured power (field strength) as determined by FCC testing is 39.8 $\mu\text{V/m}$.

NOTE

The system does not utilize spread-spectrum or frequency hopping modalities. Transmissions are continuous transmissions at discrete frequencies within the transmission frequency range.

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Clinical



Applications

Indications for Use

The VariLite laser system is intended for use in dermatological applications.

The 532 nm wavelength delivered with VariLite handpieces and the ScanLite Scanner is indicated for:

- the treatment of vascular lesions including:
 - Telangiectasia
 - Cherry Angiomas
 - Leg Veins
 - Neovascularization
 - Spider Angiomas
 - Port Wine Stains
 - Rosacea
 - Venous Lakes

- the treatment of benign pigmented lesions including:
 - Lentigines
 - Freckles

- Dermatitis Papulosis Nigra
- Poikiloderma of Civatte
- Café-au-lait Stains
- Melasma
- the treatment of cutaneous lesions including:
 - Verruca
 - Keratoses
 - Skin Tags
- the treatment of moderate Inflammatory Acne Vulgaris

The 940 nm wavelength delivered with VariLite handpieces is indicated for:

- the treatment of vascular lesions including:
 - Telangiectasia
 - Cherry Angiomas
 - Leg Veins
 - Neovascularization
 - Spider Angiomas
 - Port Wine Stains
 - Rosacea
 - Venous Lakes
- the treatment of benign pigmented lesions including:
 - Lentigines
 - Freckles
 - Dermatitis Papulosis Nigra
 - Poikiloderma of Civatte
 - Café-au-lait Stains
 - Melasma
- Hair Removal

Contraindications

Contraindications for use:

- Pregnant patients
- Patients undergoing treatment for skin cancer

Precautions

Caution is advised in treating patients with any of the following:

- history of keloid scarring
- active infection or history of herpes simplex in the treatment area
- use of anticoagulants within the preceding 6 months
- presence of refluxing veins
- history of bleeding disorders
- use of Accutane[®] (isotretinoin) within the preceding 6 months

Complications and Adverse Effects

Complications and adverse effects during and following treatment with the wavelengths of VariLite have been reported. These complications and adverse effects are generally minor and include the following:

- Pain during treatment: Use of topical gel, anesthetic creams, and/or skin-cooling devices may be helpful.
- Erythema and edema immediately following treatment: These will generally resolve within several hours.
- Fine linear epidermal crusting: Pigmented lesions will crust as part of the anticipated healing process. Linear crusting, while less common, may develop over linear vascular lesions that are treated. If crusting occurs, it is important that the patient not disturb the crusts. A topical antibiotic should be applied if the area develops sensitivity or redness. Crusts will typically slough 5 to 10 days after treatment.
- Hypopigmentation or hyperpigmentation during healing: Both are infrequent and are normally transient and minor and typically resolve spontaneously over several months.
- Undesirable Hair Removal: Hair removal at treatment sites may occur following 940 nm treatments of vascular lesions and leg veins.

- **Purpura:** Purpura developing during treatment has not been reported. However, delayed onset (1 - 3 days) localized bruising has been reported following leg vein treatment. If bruising occurs it may persist up to 14 days.
- **Blistering or scarring:** Blistering or scarring can result from dermal or epidermal injury associated with excessive overlap. Avoid high repetition rate delivery when using high treatment doses. Excessive overlap should be avoided.

Training

The VariLite 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 the system:

- Guard against accidental exposure to laser energy.
- 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 cannot 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 532 nm and 940 nm laser radiation. See the *Eye Safety* section of the Maintenance chapter for protective eyewear requirements.
- Instruct all staff members and patients to never look directly at the laser 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 exposure could cause permanent eye damage.

General Discussion

The primary absorbing chromophores in skin are oxyhemoglobin and melanin. Both oxyhemoglobin and melanin absorb 532 nm and 940 nm light. The clinical effect of treatment is dependent both on the wavelength selected and the amount of absorbing chromophore present. In general, the more chromophore present, the less applied energy is required to achieve a clinical effect. Similarly, the more strongly a wavelength is absorbed, the less energy is required to achieve a clinical effect. Since 532 nm light is more strongly absorbed by both chromophores than 940 nm light, 532 nm treatments will generally be performed at lower applied fluences than 940 nm treatments. However, the high absorption at 532 nm can also limit both depth of penetration through tissue and uniformity of heating of larger target structures. Thus, 940 nm treatments at higher fluence may be preferred for deeper or larger structures, while 532 nm treatments may be preferred for more superficial and smaller structures.

For a given laser wavelength and lesion, tissue response to pulsed laser light is primarily determined by the Energy Density used during treatment. The Energy Density (joules/cm²) is calculated as the product of the laser Power in watts and the Pulse Duration in seconds, divided by the area (cm²) of the illuminated spot. In general, higher Energy Density levels will result in greater clinical effect and also higher inflammatory response and increased likelihood of epidermal damage.

After selecting the wavelength, the treatment spot size should be selected appropriate for the indication and area to be treated. Larger structures and larger areas are often more appropriately and more quickly treated with a large diameter spot, while smaller diameter spots allow the selection of higher Energy Density settings, shorter Pulse Durations, and allow better radial cooling of the treatment spot.

The Energy Density should be selected to give a treatment endpoint appropriate for the indication and patient's pigmentation. If you are uncertain of expected clinical response, always start with a conservative Energy Density setting and increase the setting until you observe satisfactory clinical endpoints.

The Pulse Duration should be selected either at the minimum allowed for the selected Energy Density (default), or adjusted longer if appropriate for the indication.

**WARNING**

The maximum tolerated Energy Density is generally inversely proportional to the patient's skin pigmentation and to the level of absorbing chromophore in the target structure.

**WARNING**

The VariLite is a high-energy laser system. Correct positioning of successive exposures is important to achieving optimal clinical outcome. Bulk heating of tissue associated with excessive overlap may result in adverse effects. Low repetition rate delivery is recommended until the user is fully experienced both in technique and evaluation of intra-operative clinical endpoints.

The red aiming beam and the treatment beams of the VariLite are collinear and come to focus at the same distance. Ensure that the aiming beam is always in sharp focus during laser delivery. An out-of-focus treatment beam may not produce clinically satisfactory or consistent results.

If treatments at high Energy Density levels are anticipated, or if epidermal heating is a concern due to the patient's skin type, passive or active epidermal cooling should be considered. Coating the area to be treated with a thin (0.5 mm) layer of clear water based gel is often adequate to provide significant epidermal protection. Third-party cold air and contact skin cooling devices can also be used with the VariLite when additional skin cooling is appropriate. These devices may also be used to improve treatment comfort.

Discussion of Indications

Vascular Lesions: Both 532 nm and 940 nm wavelengths are used in the treatment of vascular lesions. Generally, smaller vessel diameter lesions are more amenable to treatment with 532 nm and larger vessel diameter and deeper lesions are more amenable to treatment with 940 nm. Fine diameter vessels generally respond quickly and easily to 532 nm treatment. As the vessel diameter increases, higher Energy Density with 532 nm is often required to achieve the desired endpoint. In contrast, and somewhat counter intuitively, larger diameter vessels respond more quickly and easily to 940 nm treatment than do smaller vessels. A 940 nm treatment Energy Density appropriate for medium or small diameter vessels may be excessive for large diameter vessels. The Pulse Duration is normally left at minimum and increased only when treating larger vessels on patients with darker skin types.



WARNING

The maximum tolerated Energy Density is generally inversely proportional to the patient's skin pigmentation and to the level of absorbing chromophore in the target structure. When using 940 nm output in particular, larger vascular structures will respond more aggressively than smaller structures, often requiring the selection of lower energy settings.

Facial Telangiectasia: Facial Telangiectasia is commonly treated with the 0.7 and 1.0 mm handpieces with both the 532 nm and 940 nm wavelengths, and vessels of all diameters can be effectively treated with both wavelengths. However, fine vessels (< 200 microns diameter) generally respond more readily to 532 nm. While large vessels (> 350 microns) generally respond more readily to 940 nm. Small and medium vessels (200 to 350 microns) respond well to both wavelengths, and the choice of wavelength is often based on vessel depth, patient discomfort, epidermal pigmentation, epidermal cooling, and vessel response considerations. The endpoint for treatment with both wavelengths is immediate vessel disappearance without epidermal blanching. It is important to minimize overlap and to use appropriate energy to close the vessel with a single pulse at each point along the vessel.

Spider Angiomas: The peripheral vessels of spider angiomas are normally treated first, using either 532 nm or 940 nm, at a moderate Energy Density similar to that used for telangiectasia treatments. The core or feeder is treated last. Higher Energy Density and/or 940 nm is normally used on the core and several pulses are often delivered to ensure closure.

Leg Vessels: Laser treatment of leg vessels is indicated for small vessels that blanch with compression and refill slowly or at a moderate rate. The 940 nm wavelength is preferred for leg vessel treatments, but 532 nm can be used for the treatment of superficial small red vessels. All leg vein patients should be screened for reflux, and a comprehensive treatment plan should be formed to address all aspects of the patient's conditions. Options including sclerotherapy, endovascular, ambulatory phlebectomy, laser treatment, and combination therapies should be considered. Third-party skin cooling systems (Cryo 5™, Zimmer Elektromedizin; Slim Pack™ or Cool Wand™, Cool Laser Optics, Inc.) should be considered for leg vessel treatment, as high Energy Density treatments are generally required. At a minimum, the treatment area should be covered with a thin (½ to 1 mm) layer of clear water-based gel if treatments at high energy are planned. The gel provides an additional volume into which heat absorbed by epidermal melanin can conduct, thus limiting the temperature to which the epidermis is raised. The Pulse Duration is normally left at minimum and increased only when treating larger vessels and patients of darker skin types.

Cherry Angiomas: Cherry angiomas are treated with similar parameters to telangiectasia, using either 532 nm or 940 nm at a moderate Energy Density. The treatment spot should be moved over the full surface of the lesion. Unlike telangiectasia, cherry angiomas do not disappear during treatment. The endpoint is graying/darkening. "No red remaining" is the intended treatment endpoint.

Pigmented Lesions: Benign pigmented lesions are amenable to treatment using the 532 nm and 940 nm wavelengths. 532 nm is generally preferred as the high absorption of 532 nm by melanin allows treatment with lower incident fluence. Smaller-diameter highly pigmented lesions including freckles, lentigines, and dermatosis papulosa nigra (DPN) are more amenable to treatment than larger area or low pigmentation lesions. The endpoint for treatment is a slight darkening or graying of the lesion. A subtle color change is sufficient. It is important to achieve a color change over the full diameter of the lesion. For this reason, on larger lesions, it is often better to circumscribe the lesion, ensuring the lesion perimeter is fully treated, before filling the area of the lesion. Try to "paint" the untreated center area of the lesion moving steadily back and forth at a rate to give 10 to 20% spot overlap. Following treatment, the lesion will continue to darken for a few days forming a scaly dry crust that will slough between day 5 and day 10. Patients should be instructed not to disturb the crust. Darker lesions absorb more of the incident laser light than do fainter lesions and, as a result, require less energy to reach the clinical endpoint. Darker lesions are more easily treated than fainter lesions. The more color contrast there is between the lesion and normal skin, the easier it is to select an Energy Density where the lesion responds and the normally pigmented surrounding skin does not. The 0.7 mm, 1.0 mm, and 1.4 mm handpieces are commonly used to treat pigmented lesions. The Pulse Duration is normally left at minimum and increased only for thicker epidermal pigmented lesions.

Cutaneous Lesions: Cutaneous lesions including skin tags, keratoses, and warts are amenable to 532 nm treatment. Current literature suggests that the treatment beam is heating melanin at the D/E junction and oxyhemoglobin in the upper papillary dermis. The endpoint for treatment is a subtle frosting or graying of the lesion. Cutaneous lesions are treated similarly to pigmented lesions using parameters appropriate for low pigmentation lesions. Cutaneous lesions will dry forming crusts that will slough 5 to 10 days after treatment.

Hair Removal: Unwanted hair is amenable to treatment with the 940 nm output of the VariLite. Prior to treatment, the treatment area should be closely shaved since surface hair will absorb treatment energy, which will add to epidermal heating. The area should be cleaned and covered with a thin layer of clear colorless water-based gel. If treatments at high Energy Density settings are planned, third-party skin cooling systems (Cryo 5, Zimmer Elektromedizin; Slim Pack or Cool Wand, Cool Laser Optics, Inc.) should be considered. The treatment spot is used to target individual hairs. In high hair density areas, take care to avoid bulk heating of skin by making sure untreated skin is left between each directed exposure.

Darkly pigmented and larger diameter hair is more responsive than less pigmented or finer diameter hair. The desired treatment endpoint is the delayed onset of perifollicular edema or erythema 2 to 5 minutes after the exposure. Early onset of edema, edema extending between follicles, and epidermal blanching are indications of excessive response and should be avoided. Following treatment, the hair will extrude over 5 to 7 days. Current literature suggests the efficacy of hair removal treatment is dependent on the growth cycle of the hair (anagen, catagen, or telogen) at the time of treatment; thus, multiple treatments are usually required to achieve the desired treatment outcome.

Inflammatory Acne Vulgaris: Moderate inflammatory acne vulgaris is amenable to 532 nm treatment. Current literature suggests that primary method of action is photo-activation of endogenous porphyrins produced by P-acne (*Propionibacterium acne*) bacteria. The activated porphyrins reduce the bacteria count diminishing acne severity. It has also been suggested that thermal effects suppress sebaceous gland activity reducing sebum production. Lesions are typically treated weekly or biweekly for 3 to 5 weeks using low Energy Density settings from the vascular lesion table. Lesions are typically painted using relatively high Repetition Rate delivery. There should be no immediate change to the lesion during treatment. Mild erythema may develop in the area several minutes after treatment. If blanching or edema is seen, reduce the Energy Density setting.

Treatment Information

For information on operating the VariLite system, refer to the *Operation* section of this manual. For treatment-specific guidelines, refer to the VariLite 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 treatment beam. Patient eye protection appropriate for the treatment should be used. The treatment beam should always be directed away from the eye and only applied to the skin outside of the orbital rim.

NOTE














It is advisable to take pre-treatment photographs prior to initial treatment for before/after comparisons.







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.

Symbols

This appendix describes the laser system symbols and their meanings.

Symbol	Description
	Laser Hazard - Avoid Exposure
	Energy Density Adjustment
	Pulse Duration Adjustment
	Repetition Rate Adjustment
$\Sigma_n = 0$	Counter Reset
	Treat Mode
	Standby Mode
On	Power On
○ Off	Power Off
	Aiming Beam Intensity Adjustment
	Volume Adjustment
	Attention, See Instructions For Use
	Auxiliary Output
	Remote Interlock
	Input
	Output

Symbol	Description
	Footswitch
	Type BF Applied Part
	Fuse Specification
SN	Serial Number
	Date of Manufacture
	Manufacturer
	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

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